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Application Proof of

Broncus Holding Corporation

堃博醫療控股有限公司

(the “**Company**”)

(A company incorporated in the Cayman Islands with limited liability)

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Broncus Holding Corporation

堃博醫療控股有限公司

(Incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under : [REDACTED] (subject to the
the [REDACTED] [REDACTED])
Number of [REDACTED] : [REDACTED] (subject to adjustment)
Number of [REDACTED] : [REDACTED] (subject to adjustment
and the [REDACTED])
[REDACTED] : HK\$[REDACTED] per [REDACTED],
plus brokerage fee of 1.0%, SFC
transaction levy
of 0.0027% and Hong Kong Stock
Exchange trading fee of 0.005%
(payable in full on application in
Hong Kong dollars, subject to refund)
Nominal value : US\$[0.000025] per [REDACTED]
[REDACTED] : [REDACTED]

Joint Sponsors, [REDACTED]

Goldman
Sachs



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Prior to making an [REDACTED] decision, prospective [REDACTED] should consider carefully all of the information set out in this document and the related [REDACTED], including the risk factors set out in the section headed “Risk Factors” in this document. The obligations of the [REDACTED] under the [REDACTED] to subscribe for, and to procure subscribers for, the [REDACTED], are subject to termination by the [REDACTED] (on behalf of the [REDACTED]) if certain events shall occur prior to 8:00 a.m. on the [REDACTED]. Such grounds are set out in the section headed “[REDACTED]” in this document. It is important that you refer to that section for further details.

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[REDACTED]

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SUMMARY

This summary aims to give you an overview of the information contained in this document. As it is a summary, it does not contain all the information that may be important to you. You should read the whole document before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Hong Kong Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours. In addition, we have incurred net losses since our inception and we may incur net losses for the foreseeable future. We had negative net cash flow from operating activities during the Track Record Period. We did not declare or pay any dividends during the Track Record Period and may not pay any dividends in the near future. Your [REDACTED] decision should be made in light of these considerations.

There are risks associated with any investment. Some of the particular risks in [REDACTED] 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 [REDACTED] in the [REDACTED].

OUR VISION

Our vision is to be a global leader in the transformation of lung disease treatment.

OUR MISSION

Our mission is to establish our interventional diagnosis and therapeutic solutions as the gold standard for the treatment of lung diseases.

OVERVIEW

We are a pioneer in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Leveraging our whole lung access navigation technology and encompassing navigation, diagnosis and treatment, our integrated interventional pulmonology platform addresses the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases.

Led by our experienced management team with an average of over 20 years of experience in designing, developing and commercializing medical devices, we believe that by leveraging on their expertise, we are well positioned to capture the significant commercial opportunities in the large and fast-growing market for the lung disease treatment with a focus on chronic obstructive pulmonary disease (“COPD”) and lung cancer in China and globally. We also benefit from our stable and dedicated senior management personnel with complimentary background and expertise. Members of our board and management team have experience in commercializing medical devices such as peripheral vascular intervention products, and our transcatheter aortic valve replacement systems in China, the U.S. and Europe.

SUMMARY

We are backed by a number of large institutional investors focused on the healthcare sector, such as Qiming Venture Capital, DiNovA Capital, LAKE Bleu Capital and FountainVest, and strategic investors including Intuitive Surgical, a global technology leader in robotic-assisted, minimally invasive surgical platforms and diagnostic tools listed on the Nasdaq Stock Market (NASDAQ: ISRG).

Under the leadership of our management team and with the support of our investors, we have successfully developed the world’s first and only real-time image whole lung access augmented reality navigation system, which enabled us to build an integrated product portfolio for lung disease diagnosis and treatment supported by the navigation system. Our whole lung access navigation system enables access to any part of the entire lung, both inside and outside of the airways, based on which we are able to develop revolutionary medical devices and solutions to transform the diagnosis and treatment paradigms of lung diseases. Our LungPoint ATV System, also known as LungPro in the mainland of China or the Archimedes System outside the mainland of China (the “**Archimedes System**”)¹ is the world’s only navigation system capable of whole lung access augmented reality real-time image navigation, according to Frost & Sullivan. Our proprietary Bronchoscopic Trans-Parenchymal Nodule Access (“**BTPNA**”) technology supporting the Archimedes System is able to precisely access any part of the entire lung and lead directly to lesions away from or adjacent to an airway by establishing a standard 2mm working channel through pulmonary parenchyma, creating a direct path to further diagnosis and treatment. Fully integrated with our lung navigation system, we offer a comprehensive portfolio of industry-leading interventional diagnostic and therapeutic products. Our InterVapor system (the “**InterVapor**”) is the world’s first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer, according to Frost & Sullivan. We are also developing RF Generator + RF Ablation Catheter (“**RF-II**”), a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer. We have also developed a pulmonary surgery marker, H-Marker, to mark the location of the lung nodule to achieve precise positioning during surgical pneumonectomy. We also offer a variety of diagnostic medical consumables. Our diagnostic solutions facilitate the early diagnosis and treatment of lung diseases, which could in turn help increase survival rates for patients. We believe that our three-in-one pulmonology platform which delivers the features of navigation, diagnostics and treatment with high accuracy, minimal side effects and lower costs has created high entry barriers to market followers and resulted in high switch cost for doctors or patients, thereby strengthening our market position in the interventional pulmonology medical device space in China and globally.

¹ LungPro and the Archimedes System are used interchangeably in this document.

SUMMARY

The following chart summarizes the development status of our products and product candidates on our three-in-one pulmonology platform as of the Latest Practicable Date. For details, please refer to “Business – Our Products and Product Pipeline.”

	Indication	Portfolio	Region	Preclinical	Clinical Trial	Registration	
Treatment	COPD	InterVapor® for COPD ⁽²⁾	China	Clinical trial and expert review completed, technical review in process			
			US	FDA 510(K); registration application in preparation			
			EU	Launch for sale (2018)			
			Others	Launch for sale			
	Lung Cancer / Lung Nodules	InterVapor® for Lung Cancer ⁽³⁾	China	In design stage			
			US/EU	In design stage			
		RF Generator + RF Ablation Catheter (RF - II)*	China ⁽⁴⁾	Clinical trial in process			
			US/EU ⁽⁵⁾	FDA 510(K)/CE			
		EMPOWER RF Ablation Catheter (RF-I)	US	Launch for sale (2019)			
			EU	Launch for sale (2019)			
Navigation	Navigation Platform ⁽¹⁾	LungPoint	China	Launch for sale (2014)			
			US	Launch for sale (2009)			
			EU	Launch for sale (2010)			
		LungPoint Plus / Archimedes Lite	China	Launch for sale (2020)			
			US/EU	Launch for sale (2021)			
		LungPro / Archimedes System	China	Launch for sale (2017)			
			US	Launch for sale (2014)			
			EU	Launch for sale (2014)			
	Diagnosis	lung Cancer / Lung Nodules	FlexXNeedle	China	Launch for sale (2014)		
				US	Launch for sale (2009)		
EU				Launch for sale (2013)			
ATV FlexXNeedleCN ⁽⁷⁾			China	Launch for sale (2019)			
			BioStarNeedle	China	Launch for sale (2020)		
			China	Launch for sale (2018)			
ATV Sheath			US	Launch for sale (2013)			
			EU	Launch for sale (2014)			
			China	Launch for sale (2018)			
ATV Balloon			US	Launch for sale (2013)			
	EU		Launch for sale (2014)				
	China		Launch for sale (2020)				

Notes:

* Our Core Products

1. Our navigation systems have been approved for marketing in the U.S., EU and PRC. Post-market study (EAST 2 Trial) for the Archimedes System has been completed.
2. The expert review by NMPA has been completed and technical review is currently in process.
3. R&D clinical trial (VAPORIZE trial) is currently in process.
4. The first-in-man clinical trial has been completed with a registration clinical trial currently in process.
5. Expect to leverage clinical data collected in China to apply for registrations in the U.S. and EU.
6. The clinical trial has been completed and the registration in the PRC is expected to be approved in the second quarter of 2021.
7. The version of FlexNeedle manufactured in China.

We are a fully-integrated interventional pulmonology platform with an efficient R&D model, global commercialization capabilities and strong production capacity.

Efficient R&D model. We believe we will continue to strengthen our competitive advantages through our R&D model combining international technologies with local R&D cost advantages and operational efficiencies to support a strong intellectual property portfolio and rapid product iterations to meet real-time clinical demands. On the one hand, we leverage our software and hardware expertise, mature interventional pulmonology technology and proven medical device development experience in the U.S., and our global network with KOLs to promote our products; and on the other hand, we leverage the cost advantages of the R&D environment and clinical research capabilities in China. Our innovation capabilities and patent

SUMMARY

portfolio have been endorsed by international industry giants, such as Intuitive Surgical, the manufacturer of the globally-renowned da Vinci surgical robots, who strategically invested in us in 2018. As of the Latest Practicable Date, we owned an aggregate 476 patents and patent applications which consisted of 87 issued patents (including pending announcements) and 248 patent applications in China and 95 issued patents and 46 patent applications overseas including key markets such as the U.S. and the EU.

Global commercialization capabilities. We believe the significant clinical data generated under our R&D model provides a solid clinical foundation for our global commercialization. Our ability to commercialize our technologies is further strengthened by the promotion of our brand through early market education efforts and extensive training, hospital cooperation, local clinical trials and tailored commercialization strategies. To achieve the most effective commercialization outcome, we employ different sales models in different countries and regions. We have a dedicated in-house sales team which conducts academic marketing and clinical training driven by our extensive expertise and clinical resources. In particular, as the provider of the world’s only real-time image whole lung access augmented reality navigation system, our products have contributed to the clinical experience of leading experts in China in setting up the guidelines for doctors conducting endoscopy procedures.

Strong production capacity. Our production centers are based in China and the U.S. with an approximately 3,122 sq.m. facility in Hangzhou, China and an approximately 863 sq.m. leased facility in San Jose, the U.S. We currently manufacture LungPoint, LungPoint Plus, the Archimedes System and InterVapor in the U.S. and most of the consumables in China. Over the years, we have been gradually localizing the manufacturing process by moving it to China while maintaining quality production in manufacturing pulmonology diagnostic and therapeutic products, which we believe forms a solid basis for our long-term growth.

To accomplish our mission, we plan to strengthen our presence in the interventional pulmonology market in China and globally by growing sales in hospitals that already use our products and penetrating into new hospitals with doctor education and patient engagement. We plan to continue to expand our international R&D team based in China and the U.S. and leverage our R&D model to stay abreast with technological developments and medical device development experience in the U.S. and Europe while leveraging the cost advantages of clinical research capabilities based in China. To enhance our understanding of patient needs for technology and product innovation, we plan to increase investment in artificial intelligence and machine learning.

SUMMARY

OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors.

- China’s first and only three-in-one in-house pulmonology platform supported by real-time image whole lung access navigation technology
- Pioneer in a large untapped and fast-growing interventional pulmonology market with huge unmet medical needs
- At the forefront of transforming the diagnosis and treatment paradigms of lung diseases
- Efficient R&D capabilities creating strategically designed IP portfolio endorsed by global industry pioneers
- Strong branding and commercialization capability with a focus on clinical training and early market education
- Experienced board and management backed by renowned shareholders

OUR STRATEGIES

We plan to execute the following strategies to achieve our vision and mission.

- Continue to enhance global commercialization of our products by cultivating market needs, raising patient awareness and taking education initiatives
- Expand our international R&D team to enrich our intellectual property pipeline and achieve rapid product iterations to facilitate our vertical and horizontal expansions
- Increase spending on artificial intelligence and machine learning to upgrade and optimize solutions for patients with lung diseases
- Selectively partner with and invest in key players along the healthcare supply chain

OUR BUSINESS MODEL

We focus on our proprietary whole lung access virtual navigation technology, with our therapeutic ablation devices and diagnostic medical consumables built from this core navigation technology to provide comprehensive lung solution offerings from navigation and diagnostics to therapeutic treatment. Our three-in-one pulmonology platform is built upon a self-developed portfolio of interventional pulmonology products and product candidates with 33 in-licensed patents as of the Latest Practicable Date.

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INTERVAPOR – OUR CORE PRODUCT

Through strategic expansion, we have established the world’s first thermal vapor energy ablation system, InterVapor, targeting treatment of COPD and lung cancer. It is a therapeutic device that delivers thermal vapor bronchoscopically to the lung to achieve targeted ablation. In 2018, an EC certificate (CE 678945) was issued by the BSI Group, The Netherlands B.V. (“BSI”), a notified body designated by the competent authorities to conduct conformity assessment of medical devices under the EU regulations. BSI confirmed that the quality assurance system for InterVapor meets the requirements under relevant EU regulations. InterVapor is classified as a Class II medical device in the European Economic Area (“EEA”). Based on the InterVapor system, the world’s first thermal vapor energy ablation system, we have developed InterVapor for COPD and InterVapor for lung cancer targeting COPD treatment and lung cancer treatment respectively. For InterVapor for COPD, the expert review by NMPA has been completed and registration is currently in process. We expect NMPA to complete the technical review of InterVapor for COPD by the end of May 2021. We are also in the process of preparing the FDA 510k clearance of InterVapor for COPD and registration of the product in South Korea and Hong Kong. The results of one of the core clinical trials related to InterVapor for COPD, the STEP-UP trial, was published in the world’s authoritative medical journal *The Lancet*. As the only lung volume reduction therapy that has been reported to be successfully performed at the segmental rather than lobar level, the InterVapor treatment was recommended by the GOLD Guidelines for the treatment of patients with emphysema for three consecutive years from 2019 to 2021. InterVapor for COPD was also granted designation as a Breakthrough Device by the FDA in 2019 due to technology innovation and medical value to patients in need.

InterVapor for COPD is designed for COPD treatment through thermal vapor energy ablation. It delivers thermal vapor to the airway and lung parenchyma of the targeted location of the lung, which requires precise catheter placement and enhanced imaging. The transmission of energy is achieved through air convection, which overcomes the obstacle to energy transmission due to the high air volume in the lung. InterVapor for COPD has the following features, which makes it a highly desirable therapeutic solution for COPD treatment.

- *Accuracy.* It performs targeted lung ablation and thus provides effective treatment with high accuracy.
- *Multi-time treatment opportunities.* It can be applied to multi-focus or recurrent disease and can be used for multi-time treatment without damaging the entire lung lobe at once.
- *Safety.* It treats COPD through non-surgical operation, thus causing minimal damage to patients which reduces the risk of incurrence of pneumothorax. There is also no permanent implant associated with its operation.

SUMMARY

- *Efficiency.* It only asks for a few extra seconds of treatment time after the routine endoscopy examination is completed.
- *Broad patient coverage.* Due to the fact that it does not require the intactness of interlobular fissure for the patient, it can be applied to a much broader base of patients.

InterVapor for lung cancer is designed for lung cancer treatment through continuous release of thermal vapor energy into the lung. It is designed to ablate lung lesions with a surrounding margin by the application of heated water vapor to the bronchus of the lung region targeted for treatment and can sufficiently cover the lesion area with low dose of energy. This application of thermal energy causes an acute injury to the tissues, destroying lung lesions in a quick and minimally invasive manner with injury limited to target airways and adjacent parenchyma. Thermal vapor passes through the airway and delivers heat energy during the process of condensation. Ablation is achieved through energy transmission from the outside to the inside via the small airway and destroying the surrounding tissues.

There is no assurance that we will be able to ultimately develop and market InterVapor in China or U.S.

RF-II – OUR CORE PRODUCT

RF-II is a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter, which acts on lung tumors via a bronchoscope to perform ablation to the lung tumors. It is currently the only RFA system that specifically focuses on lung cancer treatment globally, according to Frost & Sullivan. According to Frost & Sullivan, radiofrequency ablation is the most widely used ablative technique globally for the treatment of lung malignancies. Radiofrequency ablation has the advantage of being the first commercially viable ablation device with the benefits of cost-effectiveness, safety and compatibility.

We have completed the first-in-man clinical trial with a registration clinical trial currently in process in China, and are preparing the application for the FDA 510k clearance of RF-II.

There is no assurance that we will be able to ultimately develop and market RF-II in China or the U.S.

SUMMARY

RESEARCH AND DEVELOPMENT

We focus on developing innovative technologies and products for navigation, diagnosis and treatment of pulmonary diseases. We believe that the success of our operations has depended and will continue to depend to a large extent on our ability to develop new or improved medical devices. We have a proven track record of developing and commercializing interventional pulmonology medical devices. To strengthen our R&D capabilities, we adopt a highly efficient R&D model that combines international technologies with local R&D cost advantage to support our strong intellectual property portfolio and fast product iterations. We believe our R&D model allows us to stay abreast with global-leading technologies and medical device development experience in the U.S. and Europe while taking advantage of the cost-effective and highly efficient clinical research capabilities in China.

We are engaged in ongoing R&D activities to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, reliability, and to expand the applications of our products as appropriate. As of the Latest Practicable Date, we had 12 product candidates in various stages of development.

Our R&D capabilities in China are reflected by our strong intellectual property portfolio. As of the Latest Practicable Date, we owned an aggregate of 476 patents and patent applications comprising 87 issued patents (including pending announcements) and 248 patent applications in China and 95 issued patents and 46 patents applications overseas. See “Business – Intellectual Property Rights.

CUSTOMERS

We sell a significant portion of our products to distributors, and all of our five largest customers in December 31, 2019 were distributors. For the years ended December 31, 2019 and 2020, the aggregate sales to our five largest customers were US\$3.8 million and US\$1.8 million, representing 47.1% and 54.9% of our revenue, respectively. Sales to our largest customer for the same periods were US\$2.0 million and US\$0.6 million, representing 25.3% and 17.3% of our revenue, respectively. For more information, see “Business – Customers”.

SUPPLIERS

For the years ended December 31, 2019 and 2020, purchases from our five largest suppliers in aggregate accounted for 28.5% and 26.4% of our total purchases (excluding value added tax), respectively, and purchases from our largest supplier accounted for 8.9% and 13.8% of our total purchases for the same periods (excluding value added tax), respectively. During the Track Record Period, our purchases mainly included raw materials, machines and equipment and services from third parties such as CROs and global manufacturers. For more information, see “Business – Raw Materials and Suppliers – Suppliers”.

SUMMARY

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we owned an aggregate 476 patents and patent applications, including more than 190 invention patents and patent applications, 185 utility models, 13 PCT applications and 49 industry designs. We own 87 issued patents (including pending announcements) and 248 patent applications in China, and 95 issued patents and 46 patent applications overseas. Among the overseas patents, there are 58 issued patents and 20 patent applications in the U.S., 31 issued patents and seven patent applications in Europe, three issued patents and one patent applications in Japan and three issued patents and five patent applications in other overseas countries and regions, and 13 valid applications under the Patent Cooperation Treaty, or PCT, relating to certain of our products, product candidates and technologies.

We obtain patents through primarily self-development or, in limited circumstances, from third parties through patent or asset purchase. Among the 476 patents and patent applications, a majority of them were self-developed, 21 were acquired through purchasing, and 24 patents were related to InterVapor, which were formerly owned by Uptake Medical Corp., which we acquired through the asset purchase agreement signed in July 2016, and the legal titles for such patents were transferred to our subsidiary. Besides the patents and patent applications we owned, as of the Latest Practicable Date, we also in-licensed a total of 33 issued patents.

The term of an individual patent may vary based on the countries/regions in which it is granted. In most countries and regions in which we file patent applications, including China and the U.S., the term of an issued patent generally ranges from 10 to 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. For more information, see “Business – Intellectual Property Rights.”

There are certain risks related to our intellectual property rights. For example, we may not be able to obtain, maintain and enforce patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates. We also cannot ascertain that we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successful defend against any claims by third parties.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent. The Joint Sponsors have discussed with our management and our intellectual property counsel on whether there are any instances of infringement of third parties intellectual property rights by us, and have also reviewed the due diligence report on our intellectual property rights prepared by our intellectual property counsel. As far as our Directors are aware, there had not been any instances of infringement of third parties’ intellectual property rights by us as of the Latest Practicable Date. However, there are risks if we fail to protect our intellectual property rights in the future. For more details, see “Risk Factors – Risks Relating to Our Intellectual Property Rights.”

SUMMARY

COMPETITION

We focus on the interventional pulmonology market which is characterized by rapid changes resulting from technological advances and scientific discoveries and subject to changes in the overall healthcare industry in China and globally.

Interventional Pulmonology Treatment

Interventional pulmonology therapy with minimally invasive methods has been increasingly used in the treatment of pulmonary diseases such as COPD and lung cancer. According to Frost & Sullivan, in 2019, the number of bronchoscopy examination procedures conducted globally reached 7.6 million units at a CAGR of 6.1% from 2015 to 2019. Such number is expected to reach 9.5 million units by 2024 and 11.7 million units by 2030. In 2019, the number of bronchoscopy examination procedures conducted in China reached 4.1 million units at a CAGR of 6.4% from 2015 to 2019 and such number is expected to reach 5.3 million units by 2024 and 6.7 million units by 2030.

Lung Navigation and Diagnosis

According to Frost & Sullivan, in 2019, the interventional pulmonology navigation device market in China reached US\$14.7 million with a high CAGR of 130.6% from 2015 to 2019, and is expected to reach US\$142.3 million by 2024. In 2019, the sales of interventional pulmonology navigation platform in China reached 55 devices at a CAGR of 130.0% during the period from 2015 to 2019, and is expected to reach 821 devices by 2024 at a CAGR of 71.1%. Based on Frost & Sullivan’s analysis, in 2019, the number of bronchoscopy examination procedures performed under navigation platform guidance in China reached 1,538 units at a CAGR of 130.0% from 2015 to 2019, and is expected to reach 56,843 by 2024 at a CAGR of 105.9% from 2019 to 2024, accounting for 1.1% of total bronchoscopy procedures in China. The market penetration of bronchoscopy examination procedures performed under navigation platform guidance is expected to ultimately reach almost 50% of total bronchoscopy procedures in China by 2030, presenting a significant market potential for the growth of lung navigation system sales. Furthermore, in 2019, the market size of interventional pulmonology diagnostic consumables in China reached US\$23.6 million at a CAGR of 37.7% from 2015 to 2019, and is expected to reach US\$43.1 million by 2024.

SUMMARY

Competitive Landscape

There are three major players in China’s interventional pulmonology navigation device market, including Broncus, which share the entire market of interventional pulmonology navigation platform sales. Broncus is the largest market player in China’s interventional pulmonology navigation device market with a market share of 54.1% measured by sales revenue and 62.1% measured by sales volume respectively in 2019, with the other two market players sharing a market share of 31.0% and 6.9% measured by sales volume, respectively.

The table below lists out the commercialized interventional pulmonary navigation platforms globally. The Archimedes System developed by Broncus, also known as LungPro in the mainland of China, is the world’s only navigation system capable of whole lung access augmented reality real-time image navigation, according to Frost & Sullivan.

Product Name	LungPro /Archimedes	superDimension™ Navigation System (Newest Generation)	Auris Robotic Endoscopy System	LungVision	SPiN Thoracic Navigation System	Monarch	Ion	ILLUMISITE	LungCare
Manufacturer	Broncus	Medtronic, USA	AURIS, USA	Body Vision Medical	Veran Medical Technologies	Johnson & Johnson AURIS, USA	Intuitive Surgical, USA	Medtronic, USA	LungCare Medicals, China
Classification	Optical Navigation	Electromagnetic Navigation	Electromagnetic Navigation	Optical Navigation	Electromagnetic Navigation	Electromagnetic and Optical Navigation	Fiber Optic RealShape Navigation	Electromagnetic Navigation	Electromagnetic Navigation
Key Technology	VBN Whole Lung Access with BTPNA	Real-time continuous guidance	Robotic-assisted bronchoscopy	Fluoroscopic navigation	Stereotactic accessories	Robotic-assisted navigation	Robotic-assisted Lung Biopsy	Real-time continuous guidance	Combination of ENB and VBN
Whether Whole Lung Access	Yes by BTPNA	Yes by CrossCountry™ *No blood vessel reconstruction	No	No	Yes by TTNA	No	No	Yes by CrossCountry™ *No blood vessel reconstruction	No
FDA Approval Time	2014.02	2015.01	2016.05	2017.04	2017.05	2018.03	2019.02	2019.08	N/A
NMPA Approval Time	2017	2017	N/A	N/A	2017	N/A	N/A	N/A	2016

Source: Frost & Sullivan Analysis

SUMMARY

SUMMARY OF KEY FINANCIAL INFORMATION

This summary historical data of financial information set forth below have been derived from, and should be read in conjunction with, our consolidated financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in “Financial Information” of this document. Our financial information was prepared in accordance with IFRS.

Consolidated Statements of Profit or Loss

The table below sets forth our consolidated statements of profit or loss with line items in amounts and as percentages of our revenue for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	% of Revenue	US\$'000	% of Revenue
Revenue	8,072	100.0	3,259	100.0
Cost of sales	(2,094)	(25.9)	(753)	(23.1)
Gross profits	5,978	74.1	2,506	76.9
Other income and gains	304	3.8	1,074	33.0
Selling and distribution expenses	(8,609)	(106.7)	(6,352)	(194.9)
Administrative expenses	(8,855)	(109.7)	(7,722)	(236.9)
Impairment losses on financial assets, net	(20)	(0.2)	(214)	(6.6)
Research and development expenses	(11,376)	(140.9)	(9,353)	(287.0)
Finance costs	(517)	(6.4)	(647)	(19.9)
Other expenses	(6)	(0.1)	(456)	(14.0)
Changes in fair value of convertible redeemable preferred shares	(9,448)	(117.0)	(27,620)	(847.5)
Loss before tax	(32,549)	(403.2)	(48,784)	(1,496.9)
Income tax expense	(2)	(0.0)	(2)	(0.1)
Loss for the year	(32,551)	(403.3)	(48,786)	(1,497.0)
<i>Add:</i>				
Changes in fair value of convertible redeemable preferred shares	9,448	117.0	27,620	847.5
Share awards ⁽¹⁾	5,597	69.3	509	15.6
[REDACTED] expenses	—	—	1,599	49.1
Non-IFRS Measure (unaudited)				
Adjusted net loss for the year (unaudited)⁽²⁾	(17,506)	(216.9)	(19,058)	(584.8)

SUMMARY

Notes:

- (1) Represent the total expenses associated with the shares we granted to our sales and marketing employees, administrative employees and research and development employees.
- (2) We consider changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses provides useful information to investors in facilitating a comparison of our operating performance from year to year.

Non-IFRS Measures

To supplement our consolidated statements of profit or loss which are presented in accordance with IFRS, we also use adjusted net loss as non-IFRS measures, which are not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measures when shown in conjunction with the corresponding IFRS measures provides useful information to investors and management in facilitating a comparison of our operating performance from year to year by eliminating potential impacts of certain non-operational or one-off expenses that do not affect our ongoing operating performance, including changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses. Such non-IFRS measures allow investors to consider metrics used by our management in evaluating our performance. Changes in fair value of convertible redeemable preferred shares represent the changes in fair value of various rights associated with the Preferred Shares, which is non-recurring and non-operational in nature. Share awards expenses are non-operational expenses arising from granting shares to selected executives, employees and R&D consultants, the amount of which may not directly correlate with the underlying performance of our business operations, and is also affected by non-operating performance related factors that are not closely or directly related to our business activities. With respect to share awards, determining its fair value involves a high-degree of judgment. Historical occurrence of share awards is not indicative of any future occurrence. [REDACTED] expenses are one-off expenses in relation to the [REDACTED] and the [REDACTED]. Therefore, we do not consider changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses to be indicative of our ongoing core operating performance and exclude them in reviewing our financial results. From time to time in the future, there may be other items that we may exclude in reviewing our financial results. The use of the non-IFRS 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 condition as reported under IFRS. In addition, the non-IFRS financial measures may be defined differently from similar terms used by other companies and therefore may not be comparable to similar measures presented by other companies.

SUMMARY

The following table shows reconciliation of net loss for the year to our adjusted net loss for the year indicated:

	For the year ended/as of	
	December 31,	
	2019	2020
	US\$'000	US\$'000
Loss for the year	(32,551)	(48,786)
Add:		
Changes in fair value of convertible		
redeemable preferred shares	9,448	27,620
Share awards ⁽¹⁾	5,597	509
[REDACTED] expenses	–	1,599
Adjusted net loss for the year (unaudited) ⁽²⁾	(17,506)	(19,058)

Notes:

- (1) Represent the total expenses associated with the shares we granted to our sales and marketing employees, administrative employees and research and development employees.
- (2) We consider changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses provides useful information to investors in facilitating a comparison of our operating performance from year to year.

Our net loss increased from US\$32.6 million for the year ended December 31, 2019 to US\$48.8 million for the year ended December 31, 2020, primarily because our revenue decreased from US\$8.1 million to US\$3.3 million and changes in fair value of convertible redeemable preferred shares increased from US\$9.4 million to US\$27.6 million.

Selected Items of Consolidated Statements of Financial Position

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Total non-current assets	12,947	13,195
Total current assets	9,056	26,682
Total assets	22,003	39,877

SUMMARY

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Total current liabilities	14,144	14,227
Net current (liabilities)/assets	(5,088)	12,455
Total non-current liabilities	81,739	148,091
Total liabilities	95,883	162,318
Net liabilities	(73,880)	(122,441)
Share capital	6	6
Reserves	(72,370)	(120,519)
Non-controlling interests	(1,516)	(1,928)
Total equity	(73,880)	(122,441)

We had net current assets of US\$46.5 million as of March 31, 2021, being the latest practicable date for the purpose of liquidity disclosure in this document, compared to net current assets of US\$12.5 million as of December 31, 2020. The change was primarily due to an increase in cash and cash equivalents of US\$30.3 million, which was primarily due to the completion of the series D funding.

We had net current assets of US\$12.5 million as of December 31, 2020, compared to net current liabilities of US\$5.1 million as of December 31, 2019. The change was primarily due to (i) an increase in inventories of US\$1.2 million, (ii) an increase in cash and cash equivalents of US\$15.7 million and (iii) a decrease in interest-bearing bank and other borrowings of US\$2.0 million. Among the above, the increase in cash and cash equivalents was primarily due to the completion of Series C financing. For changes in other key line items, see “Financial Information – Inventories,” “Financial Information – Trade Receivables,” “Financial Information – Prepayments, Other Receivables and Other Assets” and “Financial Information – Related-Party Transactions.”

Cash Flows

During the Track Record Period, we relied on capital contributions by our shareholders and bank loans as the major sources of liquidity. We also generate cash from our sales revenue of medical devices and consumables, including the LungPoint and the Archimedes System. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue of the existing commercialized products and by launching new products, as a result of the broader market acceptance of our existing products and our continued efforts in marketing and expansion, improving cost control and operating efficiency and accelerating the turnover of trade receivables by tightening our credit policy.

SUMMARY

Our cash and cash equivalent increased from US\$3.1 million as of December 31, 2019 to US\$18.8 million as of December 31, 2020. Our Directors are of the opinion that, taking into account of the following financial resources available to us described below, we have sufficient working capital to cover at least 125% of our costs, including R&D costs, selling and distribution expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document. For details, see “Financial Information – Working Capital.” The following table sets forth our cash flows for the periods indicated:

	For the year ended	
	December 31,	
	2019	2020
	US\$'000	US\$'000
Cash flows from operating activities before movements in working capital	(15,173)	(17,411)
Net cash flows used in operating activities	(15,815)	(15,588)
Net cash flows used in investing activities	(268)	(1,089)
Net cash flows from financing activities	16,341	32,225
Net increase in cash and cash equivalents	258	15,548
Cash and cash equivalents at beginning of year	2,778	3,085
Effect of foreign exchange rate changes, net	49	155
Cash and cash equivalents at end of year	3,085	18,788

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, which includes research and development expenses, and (ii) capital expenditures. We had bank balance and cash of US\$49.1 million as of March 31, 2021. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and 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. Assuming an average cash burn rate going forward of two times the level in 2020, we estimate that our cash and cash equivalents as of March 31, 2021 will be able to maintain our financial viability for [17.6] months or, if we take into account 10% of the estimated net [REDACTED] from the [REDACTED] (namely, the portion allocated for our working capital and other general corporate purposes), [29.2] months or, if we also take into account the estimated net [REDACTED] from the [REDACTED], [134.3] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

SUMMARY

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs, selling and distribution expenses and administrative expenses.

Key Financial Ratios

The table below sets forth the key financial ratios of our Group for the periods indicated.

	For the year ended/As of December 31,	
	2019	2020
Gross margin ⁽¹⁾	74.1%	76.9%
Current ratio ⁽²⁾	64.0%	187.5%

Notes:

- (1) Gross margin equals gross profit divided by revenue for the year.
- (2) Current ratio equals current assets divided by current liabilities as of the end of the year.

Our gross margin remained stable for the year ended December 31, 2020 compared to that for the year ended December 31, 2019.

Our current ratio increased significantly from 64.0% for the year ended December 31, 2019 to 187.5% for the year ended December 31, 2020, mainly due to an increase in total current assets of US\$17.6 million as a result of increases in both inventories and cash and cash equivalents.

[REDACTED]

SUMMARY

[REDACTED]

SUMMARY

OUR CONTROLLING SHAREHOLDERS

Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), QM12 and BBL, acting in concert, together with Mr. Zi and the other Shareholders set out in the section headed “Relationship with our Controlling Shareholders” in this document, will be collectively interested in [REDACTED]% of our total issued share capital. Accordingly, they will be our Controlling Shareholders immediately following the completion of the [REDACTED]. See the section headed “Relationship with Our Controlling Shareholders” in this document for more information about our Controlling Shareholders.

OUR [REDACTED] INVESTORS

Since the establishment of our Company, we have entered into several rounds of financing agreements with our [REDACTED] Investors, including QM12, BBL, Dinova Healthcare (Hong Kong) Co., Limited, Intuitive Surgical Operations, Inc., Elegant Holding Limited (FountainVest) and LBC Sunshine Healthcare Fund L.P. Our broad and diverse base of [REDACTED] Investors consist of investors focusing on the biotech and/or healthcare industry. For further details of the identity and background of the [REDACTED] Investors, see the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document.

DIVIDEND

No dividend has been paid or declared by us for the years ended December 31, 2019 and 2020, respectively. You should note that historical dividend distributions are not indicative of our future dividend distribution policy.

We are a holding company incorporated in the Cayman Islands. We may need dividends and other distributions on equity from our PRC subsidiary to satisfy our liquidity requirements. Current PRC regulations permit our PRC subsidiary to pay dividends to us only out of their accumulated profits, if any, determined in accordance with our Articles of Association and accounting standards and regulations in PRC. In addition, our PRC subsidiary is required to set aside at least 10% of their respective accumulated profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiary may also allocate a portion of its after-tax profits based on PRC accounting standards to employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiary incurs debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us. In addition, the PRC tax authorities may require us to adjust our taxable income under the contractual arrangements we currently have in place in a manner that would materially and adversely affect our PRC subsidiary’s ability to pay dividends and other distributions to us.

SUMMARY

We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Cayman Companies Act a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

FUTURE PLANS AND USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and 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]% of net [REDACTED], or approximately HK\$[REDACTED] allocated to our Core Products as follows:
 - (i) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D and commercial launches of InterVapor including:
 - (a). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on clinical trials, including approximately HK\$[REDACTED] and HK\$ [REDACTED] on clinical trials of InterVapor on lung cancer in China and U.S./EU, respectively, and approximately HK\$[REDACTED] on construction of research, development and testing facilities;
 - (b). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on post-market studies, including approximately HK\$[REDACTED], [REDACTED], HK\$[REDACTED] and HK\$[REDACTED] on the post-market studies in China, U.S., EU and other countries, respectively; and

SUMMARY

- (c). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on registration, including approximately HK\$[REDACTED], HK\$ [REDACTED] and HK\$[REDACTED] on the registration in China, U.S. and other countries, respectively;
 - (ii) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D and commercial launches of RF-II, including:
 - (a). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on clinical trials, including approximately HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED] on clinical trials of RF-II in China, EU and U.S., respectively;
 - (b). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on commercialization in various jurisdictions, including approximately HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED] of the commercial launch of RF-II in China, EU and other countries, respectively, after receiving relevant marketing approval or CE Marking certification;
 - (c). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on product update; and
 - (d). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on registration, including approximately HK\$[REDACTED] and HK\$[REDACTED] on the registration in China and EU, respectively;
- [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] allocated to our other products and product candidates as follows:
 - (i) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund the research and development of our navigation products, including the development of next-generation navigation systems;
 - (ii) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D, registration and commercialization of H-Marker;
 - (iii) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D of other product candidates;

SUMMARY

- [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund our continued product line expansion of our manufacturing facilities;
- [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund our continued expansion of product portfolio through potential acquisition; and
- [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for working capital and other general corporate purposes.

For further details, see “Future Plans and Use of [REDACTED].”

RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. These risks are set out in “Risk Factors” in this document. Some of the major risks we face include:

- Clinical product development involves a lengthy and expensive process with an uncertain outcome, and unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We have incurred net losses since our inception and may incur net losses for the foreseeable future, and you may lose substantially all your [REDACTED] us given the high risks involved in the medical device business.
- Our future growth depends substantially on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval or CE Marking certification and commercialize our product candidates, or further promote our approved or CE Marked product candidates, or experience significant delays in doing so, our business will be materially harmed.
- All material aspects of the research, development and commercialization of our products are heavily regulated.

SUMMARY

- If we are not able to obtain, or experience delays in obtaining, required regulatory approvals or CE Marking certification, we will not be able to commercialize our product candidates in a timely manner or at all, and our ability to generate revenue will be materially impaired.
- Undesirable adverse events caused by our products and product candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval or CE Marking certification, limit the commercial profile of an approved or CE Marked label, or result in significant negative consequences following any regulatory approval or CE Marking certification.
- Our products and any future 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 fail to comply with regulatory requirements or experience unanticipated problems with our products and/or product candidates.
- If our current and new 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 operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks, in particular the COVID-19 outbreak.

[REDACTED] EXPENSE INCURRED AND TO BE INCURRED

The total [REDACTED] expenses (including [REDACTED]) payable by our Company are estimated to be approximately HK\$[REDACTED] (or approximately RMB[REDACTED]) assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, [REDACTED] payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

As of December 31, 2020, the [REDACTED] expenses (excluding [REDACTED] and incentive fees) incurred by our Company in relation to the [REDACTED] were US\$[REDACTED]. No such expenses were recognized or charged to our consolidated statements of profit or loss for the year ended December 31, 2019. In the year ended December 31, 2020, the [REDACTED] expenses charged to profit or loss were US\$[REDACTED] (approximately HK\$[REDACTED]) and the [REDACTED] expenses capitalized to deferred [REDACTED] expenses were US\$[REDACTED] (approximately HK\$[REDACTED]). We estimate that additional [REDACTED] expenses of approximately HK\$[REDACTED] (including [REDACTED]) will be incurred by our Company, approximately HK\$[REDACTED] of which is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] of which is expected to be capitalized.

SUMMARY

IMPACT OF THE COVID-19 PANDEMIC

Since the end of December 2019, the outbreak of a novel strain of coronavirus named COVID-19 has materially and adversely affected the global economy. In response, countries across the world, including both China and the United States, have imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. As of the Latest Practicable Date, substantially all of the Chinese cities had eased or lifted domestic travel restrictions and resumed normal social activities, work and production.

The government lockdown and other restrictive measures had resulted in significantly reduced mobility of our employees, causing most of the employees to work remotely during early phases of COVID-19 outbreak. As a result, we had implemented various precautionary measures and adjusted our employee’s work arrangements according to the relevant regulations and policies, which had allowed us to maintain a sufficient number of personnel on-site who managed to work under flexible schedule to continue our research and development activities.

In line with government guidelines, we have been closely tracking the health and wellness status of our employees and we routinely check their body temperature before they enter our offices or facilities. As of the Latest Practicable Date, all of our employees had resumed normal operations. We have maintained operations by taking measures that the management deemed necessary to ensure the high standards of workplace safety. Such measures include leveraging virtual meetings for work, requiring employees who work on site to wear masks and obey social distancing policies, informing employees with governmental guidelines, and preparing guidance materials on COVID-19 for employees.

During the COVID-19 outbreak, we experienced some delays in the patient enrollment process and data entry for certain of our clinical trials, particularly at the beginning of the COVID-19 pandemic. Nonetheless, there has not been any material disruption of our ongoing clinical trials. The COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in the clinical trials. To manage the risks associated with the COVID-19 pandemic, we adopted various measures, such as cooperating with clinical trial sites to offer personal protection equipment such as masks to our enrolled patients, engaging in frequent communications with our principal investigators to identify and address any issues that may arise, suggesting the investigators to communicate with the enrolled patients on visiting local qualified hospitals for follow-up evaluations if necessary. To minimize the temporary impacts of the COVID-19 impact, we have mobilized internal and external resources and leveraged our strong research and development capabilities to accelerate the temporarily delayed development programs and strive to remediate the temporary disruption caused by the COVID-19 outbreak. As normal business operations, including the medical system operations in China started to recover in the second quarter of 2020, our clinical activities has fully resumed. We have not experienced and currently do not expect any material delays in regulatory affairs with respect to our clinical trials or any long-term impact

SUMMARY

on our operation or deviation from our overall development plans due to the COVID-19 pandemic. Since we conduct business and engage in preclinical studies and clinical trials in China, our clinical trial progress in the first quarter of 2021 has exceeded that of the corresponding period last year.

To some extent, reduced transportations and disruption to manufacturing and logistics networks in China due to the COVID-19 outbreak affected our suppliers’ abilities to manufacture and transport consumables, equipment and other supplies necessary for our operations. We have imported sufficient volume of raw materials from our overseas suppliers in advance to support our current manufacturing activities, after taking into account the potential delay in delivery. We are also actively seeking domestic suppliers for certain materials that are currently sourced from overseas suppliers. Nevertheless, as of the Latest Practicable Date, most of our suppliers had resumed normal operations and we had not experienced any material disruption or shortage of supplies since the outbreak of COVID-19.

As of the Latest Practicable Date, we had no suspected or confirmed COVID-19 cases on our premises or among our employees. To prevent any spread of COVID-19 in our offices and production facilities, we have implemented preventive measures such as regularly sterilizing and ventilating our offices and production facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees, and providing face masks and disinfectant to employees attending our offices and facilities. During the year ended December 31, 2020, our equipment sales and marketing activities had been adversely affected globally due to the pandemic, and only a limited number of new orders were generated and delivered for our LungPoint and Archimedes System. However, we believe the impact of the COVID-19 pandemic on our sales performance is temporary. Purchases from hospitals have resumed in China and we expect a gradual recovery in the overseas market as the pandemic gets more controlled.

It is uncertain when and whether COVID-19 will be contained globally. We plan to continue implementing our remedial measures and may implement additional measures as necessary to ease the impact of the COVID-19 outbreak on our operations. However, we cannot guarantee you that the COVID-19 outbreak will not further escalate or have a material adverse effect on our results of operations, financial position or prospects. For details, please refer to “Risk Factors – Risks Relating to Our Operations – Our operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks, in particular the COVID-19 outbreak.”

RECENT DEVELOPMENT AND NO MATERIAL ADVERSE CHANGE

Our Directors confirm that up to the date of this document, there had been no material adverse change in our financial, operational or trading positions or prospects since December 31, 2020, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this document.

DEFINITIONS

In this document, unless the context otherwise requires, the following expressions shall have the following meanings. Certain other terms are defined in the section headed “Glossary of Technical Terms” in this document.

“A\$”	Australian dollar, the lawful currency of Australia
“ACL”	Aether Corporate Limited, a company duly incorporated and validly existing under the laws of Hong Kong. Please see the section headed “History, Reorganization and Corporate Structure – Reorganization” in this document for details
“affiliate”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Articles” or “Articles of Association”	the amended and restated articles of association of our Company adopted by special resolution on [●], 2021 with effect from [REDACTED], as amended from time to time, a summary of which is set out in Appendix III headed “Summary of the Constitution of our Company and Cayman Islands Companies Law” to this document
“associate”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of the Board
“BBL”	Broncus Biomedical Limited, a company incorporated under the laws of the Cayman Islands, which is a party in the group of our Controlling Shareholders. For the background of BBL, please refer to the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document
“Board of Directors”, “Board” or “our Board”	our board of Directors
“Broncus Australia”	Broncus Medical (Australia) Pty Ltd, a corporation established in accordance with the laws of Australia and one of our Company’s subsidiaries

DEFINITIONS

“Broncus China Holding”	Broncus China Holding Corporation, an exempted company established in accordance with the laws of the Cayman Islands and one of our Company’s subsidiaries
“Broncus Hangzhou”	Hangzhou Broncus Medical Co., Ltd. (for identification only) (杭州堃博生物科技有限公司), a corporation established in accordance with the laws of the PRC and one of our Company’s subsidiaries
“Broncus Medical”	Broncus Medical Inc., a corporation established in accordance with the laws of the State of California, the United States and one of our Company’s subsidiaries
“Broncus Medical GmbH”	Broncus Medical GmbH, a corporation established in accordance with the laws of Germany and one of our Company’s subsidiaries
“Broncus Medical (Hong Kong)”	Broncus Medical (Hong Kong) Co., Limited, a corporation established in accordance with the laws of Hong Kong and one of our Company’s subsidiaries
“Broncus Shanghai”	Broncus Medical (China) Co., Ltd. (for identification only) (堃博生物科技(上海)有限公司), a corporation established in accordance with the laws of the PRC and one of our Company’s subsidiaries
“Business Day”	any day (other than a Saturday, Sunday or public holiday) in Hong Kong on which banks in Hong Kong are open generally for normal banking business
“BVI”	the British Virgin Islands
“CAGR”	compound annual growth rate
“Cayman Companies Act”	the Companies Act, Cap. 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“CCASS Broker Participant”	a person admitted to participate in CCASS as a broker participant

DEFINITIONS

“CCASS Clearing Participant”	a person admitted to participate in CCASS as a direct clearing participant or a general clearing participant
“CCASS Custodian Participant”	a person admitted to participate in CCASS as a custodian participant
“CCASS Investor Participant”	a person admitted to participate in CCASS as an investor participant, who may be an individual or joint individuals or a corporation
“CCASS Participant”	a CCASS Broker Participant, a CCASS Custodian Participant or a CCASS Investor Participant
“CEO”	chief executive officer
“CTO”	chief technical officer
“China” or “PRC”	the People’s Republic of China, which for the purpose of this document and for geographical reference only, excludes Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“Code”	The Corporate Governance Code and Corporate Governance Report set out in Appendix 14 to 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”, “our Company” or “the Company”	Broncus Holding Corporation (堃博醫療控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on April 30, 2012
“Compliance Adviser”	Red Solar Capital Limited

DEFINITIONS

“Concert Party Agreement”	a concert party agreement dated December 17, 2020 entered into by and between QM12 and BBL, as set out in more detail in the section headed “History, Reorganization and Corporate Structure – Reorganization – 3. Concert Party Agreements” in this document
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules
“Controlling Shareholder(s)”	has the meaning ascribed thereto under the Listing Rules and unless the context require otherwise, as at the date of this document, refers to QM12 and BBL, acting in concert, together with Mr. Zi and other Shareholders set out in the section headed “Relationship with our Controlling Shareholders” in this document
“core connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Core Product”	each of InterVapor and RF-II, our Company’s designated “core product” as defined under Chapter 18A of the Listing Rules
“Corporate Governance Code”	the Corporate Governance Code and Corporate Governance Report set out in Appendix 14 to the Listing Rules
“DNA”	DNA 06 Limited, a business company duly incorporated and validly existing under the laws of the BVI
“Director(s)” or “our Director(s)”	the director(s) of our Company
“Equity Incentive Plans”	the equity incentive plans adopted by our Company on [●], 2021, including the Share Option Plan and the RSU Scheme, the principal terms of which are set out in the section headed “Statutory and General Information – D. Equity Incentive Plans” in Appendix IV to this document
“EU”	the European Union

DEFINITIONS

“Extreme Condition(s)”	extreme condition(s) including but not limited to serious disruption of public transportservices, extensive flooding, major landslides and large-scale power outage caused by a super typhoon according tothe revised “Code of Practice in Times of Typhoons and Rainstorms” issued by the Labour Department of thegovernment of Hong Kong in June 2019, as announced by the government of Hong Kong
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[REDACTED]

“Group”, “our Group”, “we”, “us” or “our”	our Company and its subsidiaries
“HK\$” or “Hong Kong dollars” or “HK dollars” and “HK cents”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“HKSCC”	Hong Kong Securities Clearing Company Limited
“HKSCC Nominees”	HKSCC Nominees Limited, a wholly-owned subsidiary of HKSCC
“Hong Kong”, “Hong Kong SAR” or “HK”	the Hong Kong Special Administrative Region of the PRC

[REDACTED]

DEFINITIONS

[REDACTED]

“IFRS”	International Financial Reporting Standards
“Independent Third Party(ies)”	person(s) or company(ies) who/which, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is/are not connected person(s) of our Company
“Industry Consultant” or “Frost & Sullivan”	Frost & Sullivan International Limited
“INED(s)”	independent non-executive Director(s)

[REDACTED]

DEFINITIONS

[REDACTED]

“Joint Sponsors”	Goldman Sachs (Asia) L.L.C. and Haitong International Capital Limited
“Kunpeng Hangzhou”	Hangzhou Kunpeng Medical Co., Ltd. (for identification only) (杭州堃鹏生物科技有限公司), a corporation established in accordance with the laws of China and one of our Company’s subsidiaries
“Latest Practicable Date”	April 30, 2021, being the latest practicable date for the purpose of ascertaining certain information contained in this document before its publication

[REDACTED]

“Listing Committee”	the listing sub-committee of the board of directors of the Stock Exchange
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[REDACTED]

DEFINITIONS

“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
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange
“Memorandum” or “Memorandum of Association”	the amended and restated memorandum of association of our Company adopted by special resolution on [●], 2021 with effect from Listing, as amended from time to time, a summary of which is set out in the section headed “Summary of the Constitution of our Company and Cayman Islands Companies Law” in Appendix III to this document
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“Mr. Zhan”	Guowei Zhan (湛國威), our executive Director and CEO
“Mr. Zhao”	Michael Yi Wei Zhao, our non-executive Director and the chairman of our Board
“Mr. Zi”	Zhenjun Zi (訾振軍), our non-executive Director and one of our Controlling Shareholders
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NMPA”	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“Nomination Committee”	the nomination committee of the Board

[REDACTED]

DEFINITIONS

[REDACTED]

“PRC Legal Adviser”	King & Wood Mallesons
“Preferred Share(s)”	preferred share(s) in the share capital of our Company, including Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares and Series D Preferred Shares
“[REDACTED] Investments”	the [REDACTED] investments in the Company undertaken by the [REDACTED] investors pursuant to the relevant investment agreements, details of which are set forth in the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this document
“[REDACTED] Investors”	the Series A Preferred Shareholders or their respective affiliates, the Series B Preferred Shareholders, the Series C Preferred Shareholders and the Series D Preferred Shareholders

[REDACTED]

[REDACTED]

[REDACTED]

DEFINITIONS

“QIB”	a qualified institutional buyer within the meaning of Rule 144A
“QM12”	QM12 Limited, a company incorporated in accordance with the laws of Hong Kong, a party in the group of our Controlling Shareholders. For the background of QM12, please refer to the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration Committee”	the remuneration committee of our Board
“Reorganization”	the reorganization arrangements undertaken by our Group in preparation for the [REDACTED], the details of which are set out in the section headed “History, Reorganization and Corporate Structure – Reorganization” in this document
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“RSU Scheme”	the restricted share unit scheme of the Company as adopted on [●], 2021, a summary of the principal terms of which is set forth in “Statutory and General Information – D. Equity Incentive Plans” in Appendix IV to this document
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAIC”	the State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局), which has been merged into the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理局)
“Series A Preferred Share(s)”	the series A preferred share(s) of our Company with a par value of US\$0.0001 per share
“Series A Preferred Shareholder(s)”	holder(s) of Series A Preferred Shares of our Company

DEFINITIONS

“Series A Share Purchase Agreement”	the preferred share purchase agreement entered into between, among others, our Company and the Series A Preferred Shareholders or their respective affiliates dated March 2, 2018
“Series B Preferred Share(s)”	the series B preferred share(s) of our Company with a par value of US\$0.0001 per share
“Series B Preferred Shareholder(s)”	holder(s) of Series B Preferred Shares of our Company
“Series B Share Purchase Agreement”	the Series B preferred share purchase agreement entered into between, among others, our Company and the Series B Preferred Shareholders dated April 17, 2018
“Series C Preferred Share(s)”	the series C preferred shares of our Company with a par value of US\$0.0001 per share
“Series C Preferred Shareholder(s)”	holder(s) of Series C Preferred Shares of our Company
“Series C Share Purchase Agreement”	the Series C preferred share purchase agreement entered into between, among others, our Company and the Series C Preferred Shareholders dated August 17, 2020
“Series D Preferred Share(s)”	the series D preferred shares of our Company with a par value of US\$0.0001 per share
“Series D Preferred Shareholder(s)”	holder(s) of Series D Preferred Shares of our Company
“Series D Share Purchase Agreement”	the Series D preferred share purchase agreement entered into between, among others, our Company and the Series D Preferred Shareholders dated January 25, 2021
“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 share capital of our Company

DEFINITIONS

“Share Option Plan”	the share incentive plan of the Company as adopted on [●], 2021, a summary of the principal terms of which is set forth in “Statutory and General Information – D. Equity Incentive Plans” in Appendix IV to this document
“Share Subdivision”	the subdivision of issued and unissued authorized Shares of our Company with nominal value of US\$0.0001 each into 4 Shares of the corresponding class with nominal value of US\$0.000025, the details of which are set out in the section headed “History, Reorganization and Corporate Structure – Reorganization – 5. Share Subdivision” in this document
“Shareholder(s)”	holder(s) of Shares
“Shareholders Agreement”	the third amended and restated shareholders agreement entered into between, among others, our Company and the Series A Preferred Shareholders dated March 2, 2018, the fourth amended and restated shareholders agreement entered into between, among others, our Company and the Series B Preferred Shareholders dated April 19, 2018, the fifth amended and restated shareholders agreement entered into between, among others, our Company and the Series C Preferred Shareholders dated August 27, 2020, and the sixth amended and restated shareholders agreement entered into between, among others, our Company and the Series D Preferred Shareholders dated January 25, 2021.
“Sophisticated Investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL-92-18 issued by the Stock Exchange, and unless the context otherwise requires, refers to [REDACTED] Investors such as QM12, Intuitive Surgical Operations, Inc., Elegant Holding Limited (FountainVest), Velocity Zero Limited (DCP Capital) and LBC Sunshine Healthcare Fund L.P. (Lake Bleu Capital). Please see the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” for details.
	[REDACTED]
“subsidiary(ies)”	has the meaning ascribed to it under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed to it under the Listing Rules

DEFINITIONS

“Takeovers Code”	the Hong Kong Code on Takeovers and Mergers
“Third Schedule”	the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance
“Track Record Period”	the financial years ended December 31, 2019 and December 31, 2020
“Trustee”	[name of trustee], the trustee appointed by our Company to hold Shares on trust for grantees under the RSU Scheme pursuant to a trust deed between the Trustee and our Company on [●], 2021
[REDACTED]	
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Uptake Medical B.V.”	Uptake Medical B.V., a company established in accordance with the laws of Netherlands and one of our Company’s subsidiaries
“Uptake Medical”	Uptake Medical Technology Inc., a corporation established in accordance with the laws of the state of Delaware, the United States and one of our Company’s subsidiaries
“US\$” or “U.S. dollars”	United States dollars, the lawful currency of the United States
“U.S. FDA”	U.S. Food and Drug Administration
“U.S. Securities Act”	the United States Securities Act of 1933, as amended

DEFINITIONS

[REDACTED]

“Zhejiang Dinova”

Zhejiang Dinova Ruiying Venture Investment L.P. (浙江德諾瑞盈創業投資合夥企業(有限合夥)), a limited partnership and a venture capital fund holding various portfolios established in the PRC on August 19, 2015. Zhejiang Dinova Capital Management L.P. (浙江德諾資本管理合夥企業(有限合夥)) is the general partner of Zhejiang Dinova Ruiying Venture Investment L.P.. Hangzhou Dinova Commercial Information Consulting Ltd. (杭州德諾商務信息諮詢有限公司) is the general partner of Zhejiang Dinova Capital Management L.P.. Hangzhou Dinova Commercial Information Consulting Ltd. is 40% controlled by Mr. Zi, our non-executive Director and one of our Controlling Shareholders.

“%”

per cent

In this document:

- *Unless otherwise expressly stated or the context otherwise requires, all data in this document is as of the date of this document.*
- *Unless otherwise specified, all references to any shareholdings in our Company assume that the [REDACTED] has not been exercised.*
- *The English names of the PRC entities, PRC laws or regulations, and the PRC governmental authorities referred to in this document are translations from their Chinese names and are for identification purposes only. If there is any inconsistency, the Chinese names shall prevail.*

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain terms used in this document in connection with our Company and our business. Some of these may not correspond to standard industry definitions.

“AEs”	adverse events
“CAGR”	compound annual growth rate, the rate of return that would be required for an investment to grow from its beginning balance to its ending balance, assuming the profits were reinvested at the end of each year of the investment’s lifespan
“CBCT”	cone-beam computed tomography
“CE Mark”	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
“COPD”	chronic obstructive pulmonary disease
“COVID-19”	coronavirus disease 2019, a disease caused by a novel virus designated as severe acute respiratory syndrome coronavirus 2
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CT”	computed tomography
“CV”	collateral ventilation, ventilation of alveolar structures through passages or channels that bypass the normal airways
“cytology”	the exam of a single cell type, as often found in fluid specimens
“DLCO”	diffusing capacity of the lung for carbon monoxide
“EMA”	the European Medicines Agency

GLOSSARY OF TECHNICAL TERMS

“endoscopy”	a procedure in which a doctor uses an endoscope – a flexible tube with a camera – to observe an internal organ or tissue in detail
“FDA”	The United States Food and Drug Administration, a federal agency of the Department of Health and Human Services
“FEV1”	forced expiratory volume in 1 second
“FEV1/FVC ratio”	a calculated ratio in diagnosing COPD, which represents the proportion of a person’s vital capacity that they are able to expire in the first second of forced expiration (FEV1) to the full, forced vital capacity (FVC)
“FRC”	functional residual capacity
“FVC”	forced vital capacity
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“GOLD”	The Global Initiative for Chronic Obstructive Lung Disease
“H&E”	hematoxylin and eosin
“high-value medical consumables”	medical consumables that are directly used for human bodies and have strict requirements for safety. All of our products and product candidates are high-value medical consumables
“HRCT”	high-resolution computed tomography
“ICH-GCP”	International Conference on Harmonisation-Good Clinical Practice
“IFU”	Instructions for Use
“incidence”	the number of new cases occurring in a specified population per year

GLOSSARY OF TECHNICAL TERMS

“invention patents”	patents for new technical solutions proposed for products, methods or improvements thereof
“KOLs”	acronym for Key Opinion Leaders who are doctors that influence their peers’ medical practice, including but not limited to prescribing behavior
“LABA”	long-acting β 2-agonist, a typical COPD drug treatment
“LAMA”	long-acting muscarinic antagonist, a typical COPD drug treatment
“MDD”	Medical Device Directive of the European Union
“MDR”	Medical Device Regulation of the European Union
“Medtronic”	a medical device company committing to medical technology, services and solutions, incorporated under the laws of Ireland
“mortality rate”	a measure of the number of deaths in a particular population, scaled to the size of that population, per unit of time
“MRI”	magnetic resonance imaging, a procedure that uses magnetism, radio waves, and a computer to create images of areas inside the body
“Notified Body/Notified Bodies”	an accredited notified body designated by a EU Member State to conduct conformity assessment of medical devices in accordance with the Directive 93/42 on Medical Devices or the Regulation (EU) 2017/745 on Medical Devices and relevant member state laws, as applicable
“NSCLC”	non-small-cell lung carcinoma
“prevalence”	the number of disease cases present in a particular population at a given time
“PTNB”	percutaneous transthoracic needle biopsy
“RFA”	radiofrequency ablation

GLOSSARY OF TECHNICAL TERMS

“SCLC”	small-cell lung carcinoma
“sensitivity”	the ability of a test to correctly identify those with the disease (true positive rate)
“SGRQ-C”	St. George’s Respiratory Questionnaire for COPD
“specificity”	the ability of the test to correctly identify those without the disease (true negative rate)
“SPN”	solitary pulmonary nodule
“sq.m.”	square meter, a unit of area
“standard of care”	a diagnostic and treatment process that a clinician should follow with respect to a certain type of patients, illnesses, or clinical circumstances
“survival rate”	the percentage of people in a study or treatment group still alive for a given period of time after diagnosis
“TBLB”	transbronchial lung biopsy, the most basic form of bronchoscopy
“TBNA”	transbronchial needle aspirations
“TLC”	total lung capacity
“treatment rate”	the percentage of patients diagnosed with the diseases that are actively under treatments
“TTNA/B”	transthoracic needle aspiration/biopsy, the most basic form of percutaneous interventional pulmonology diagnostic methods
“VATS”	video-assisted thoracic surgery
“VBN”	virtual bronchoscopic navigation
“6MWT”	6-minute walk test

FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements that relate to our current expectations and views of future events. These forward-looking statements are contained principally in the sections entitled “Summary,” “Risk Factors,” “Future Plans and Use of [REDACTED],” “Financial Information,” “Industry Overview” and “Business.” These statements relate to events that involve known and unknown risks, uncertainties and other factors, including those listed in the section headed “Risk Factors” in this document, which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, these forward-looking statements can be identified by words or phrases such as “may,” “will,” “expect,” “anticipate,” “aim,” “estimate,” “intend,” “plan,” “believe,” “potential,” “continue,” “is/are likely to” or other similar expressions. These forward-looking statements include, among other things, statements relating to:

- our operations and business prospects;
- our financial conditions and our operating results and performance;
- industry trends and competition;
- our services and products under development or planning;
- our strategies and initiatives, business plans, objectives and goals;
- our ability to attract users and further enhance our brand recognition;
- our dividend distribution plans;
- the amount and nature of, and potential for, future development of our business;
- general political and economic conditions; and
- changes to regulatory and operating conditions in the markets in which we operate.

These forward-looking statements are subject to risks, uncertainties and assumptions, some of which are beyond our control. In addition, these forward-looking statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual outcomes may differ materially from the information contained in the forward-looking statements as a result of a number of factors, including, without limitation, the risk factors set forth in the section entitled “Risk Factors” in this document.

FORWARD-LOOKING STATEMENTS

The forward-looking statements made in this document relate only to events or information as of the date on which the statements are made in this document. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this document completely and with the understanding that our actual future results or performance may be materially different from what we expect.

In this document, statements of, or references to, our intentions or those of any of our Directors are made as of the date of this document. Any of these intentions may change in light of future development.

RISK FACTORS

An [REDACTED] 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 [REDACTED] 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 [REDACTED]. 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 BUSINESS

Risks Relating to the Development of Our Product Candidates

Clinical product development involves a lengthy and expensive process with an uncertain outcome, and unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.

Clinical testing is expensive and can take multiple years to complete, and its outcome is inherently uncertain. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Failure to successfully complete these trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results.

Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including differences in physical conditions, and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials.

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Our future clinical trial results may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. For our certain interventional pulmonology therapeutic products like InterVapor, it is likely that they may not suit the conditions of a number of patients, and severe adverse events and complications may incur for some patients after the procedure.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities 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 patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol.

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

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

Before obtaining regulatory approval or CE Marking certification for the sale of our product candidates, unless waived or exempted by the regulatory authorities, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. 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 CE Marking certification or commercialize our product candidates, including but not limited to:

- regulatory authorities, institutional review boards, or IRBs, 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;

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- our inability to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and hospitals as trial centers;
- manufacturing issues, including problems with manufacturing, supply quality, or obtaining sufficient quantities of a product candidate for use in a clinical trial;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;
- regulatory authorities, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates, companion diagnostics or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

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

- be delayed in obtaining regulatory approval or CE Marking certification for our product candidates;
- not obtain regulatory approval or CE Marking certification at all;
- obtain approval or CE Marking certification for indications that are not as broad as intended;
- have the product removed from the market after obtaining regulatory approval or CE Marking certification;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- be unable to obtain reimbursement for use of the product.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates, the commercial prospects of that product candidate will be harmed, and our ability to generate product sales revenues from any of those product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval or CE Marking certification process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

We have incurred net losses since our inception and may incur net losses for the foreseeable future, and you may lose substantially all your [REDACTED] in us given the high risks involved in the medical device business.

Investment in medical device development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or CE Marking certification or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we incurred losses during the Track Record Period. We incurred net loss of US\$32.6 million and US\$48.8 million for the years ended December 31, 2019 and 2020, respectively. Substantially all of our operating losses were resulted from costs incurred in connection with our R&D programs and from selling, general and administrative expenses associated with our operations.

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We may continue to incur losses for the foreseeable future, and the losses may increase as we expand our development of, and seek regulatory approval or CE Marking certification for, our product candidates, and commercialize our products. Typically, it takes many years to develop one new product from the time it is designed to when it is available for commercial sales. In addition, we will start incurring costs associated with being a public company in Hong Kong after the [REDACTED]. We will also incur costs in support of our growth. The size of our future net losses will depend, in part, on the number and scope of our product development programs and the associated costs of those programs, the cost of commercializing any approved or CE Marked products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with arrangements with third parties. If any of our product candidates fails in clinical trials or does not gain regulatory approval or CE Marking certification, or if approved or CE Marked, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations.

Our future growth depends substantially on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval or CE Marking certification and commercialize our product candidates, or further promote our approved or CE Marked product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business substantially depends on the successful development, regulatory approval or CE Marking certification and commercialization of our product candidates for the treatment of patients with pulmonary diseases, which are under registration or still in clinical development or design stage, and other product candidates we may develop in the future. We have invested a significant portion of our efforts and financial resources in the development of our existing product candidates. We incurred net losses for the years ended December 31, 2019 and 2020, because the expenses we incurred exceeded the gross profit generated from the sales of our current products, primarily the LungPoint and the Archimedes System and consumables, with R&D costs alone amounted to 140.9% and 287.0% of our total revenue for the same periods. Whether we can generate profit from our operating activities largely depends on the successful commercialization of our product candidates.

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For example, we have recently completed the patient enrollment and all follow-up visits for a pre-market clinical study of our H-Marker. We have received the designation of H-Marker as a Class II “innovative medical device”, which is eligible for expedited approval, by Zhejiang MPA (浙江省藥品監督管理局) in October 2020 and expect to obtain the Zhejiang MPA approval in the second quarter of 2021. We have completed the first-in-man clinical trial with a registration clinical trial currently in process in China, and are preparing the application for the FDA 510k clearance of RF-II. The success of our product candidates will depend on several factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals or CE Marking certification;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by any third parties we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- successfully launching our product candidates, if and when approved or CE Marked;
- obtaining favorable governmental and private medical reimbursement for our products, if and when approved or CE Marked;
- competition with other interventional pulmonology products; and
- continued acceptable safety profile following regulatory approval or CE Marking certification.

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

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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 and commercialization activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of China, the U.S. and the EU. These geopolitical areas all have strict regulation on medical devices, and in doing so they employ broadly similar regulatory strategies, including regulation of product development, approval or CE Marking certification, manufacturing, sales and marketing and distribution of medical devices. However, there are differences in the regulatory regimes in different regions, which makes regulatory compliance more complex and costly for companies like us that plan to operate in each of these regions.

The process of obtaining regulatory approvals or CE Marking certification and compliance with appropriate laws and regulations require substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval or CE Marking certification process, or after approval or CE Marking certification, may subject an applicant to administrative or judicial sanctions. These sanctions could include a refusal to approve pending applications, withdrawal of an approval, license or CE Marking certification 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, financial condition and prospects.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals or CE Marking certification, we will not be able to commercialize our product candidates in a timely manner or at all, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals or CE Marking certification for the commercial sale of any product candidate for a target indication, unless waived or exempted by the authorities, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in China, to the satisfaction of the NMPA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Obtaining regulatory approvals or CE Marking certification is a lengthy, expensive and uncertain process, and approvals or CE Marking certification may not be obtained. When we submit a filing application to the NMPA, the NMPA will decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the NMPA. NMPA may also slow down, suspend or cease review of our applications and any of these could prolong the registration process of our products.

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Our product candidates could fail to receive regulatory approval or CE Marking certification for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a product candidate is safe and effective;
- failure of clinical trial results to meet the level of statistical significance required for approval or CE Marking certification;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval or CE Marking certification policies or regulations that render our preclinical and clinical data insufficient for approval or CE Marking certification or require us to amend our clinical trial protocols;
- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; and/or
- rejection by the relevant authorities to approve or CE mark pending applications or supplements to approved or CE Marking certification applications filed by us or suspension, revocation or withdrawal of approvals or CE Marking certification.

Regulatory authorities outside of China, such as the FDA, Notified Bodies and/or comparable regulatory authorities, also have requirements for approval or CE Marking certification of medical devices for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval or CE Marking certification in one country does not mean that regulatory approval or CE Marking certification will be obtained in any other country. Approval or CE Marking certification processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval or CE Marking certification could require additional nonclinical studies or clinical

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trials, which could be costly and time consuming. The foreign regulatory approval or CE Marking certification process may include all of the risks associated with obtaining the NMPA approval. For these reasons, we may not obtain foreign regulatory approvals or CE Marking certification on a timely basis, if at all.

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 IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The process to develop, obtain regulatory approval or CE Marking certification for and commercialize medical device product candidates is long, complex and costly both inside and outside China. Even if our product candidates were to successfully obtain approval or CE Marking certification from the regulatory authorities, any approval or CE Marking certification might significantly limit the approved indications for use, 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 or CE Marking certification. Following an approval or CE Marking certification for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval or CE Marking certification by the NMPA, FDA, Notified Bodies and/or comparable regulatory authorities. Regulatory approvals or CE Marking certification for any of our product candidates may also be withdrawn. If we are unable to obtain regulatory approval or CE Marking certification for our product candidates in one or more jurisdictions, or any approval or CE Marking certification contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates 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 any other product candidate in the future.

Undesirable adverse events caused by our products and product candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval or CE Marking certification, limit the commercial profile of an approved or CE Marked label, or result in significant negative consequences following any regulatory approval or CE Marking certification.

Undesirable adverse events caused by our products or product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or CE Marking certification by the NMPA, FDA, Notified Bodies or other comparable regulatory authorities, or could result in limitations or withdrawal following approvals or CE Marking certification.

All manufacturers placing medical devices on the market in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or Competent Authority, in whose jurisdiction the incident occurred. Under the MDD an incident is defined

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as any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health; any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in above, leading to systematic recall of devices of the same type by the manufacturer.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

If results of our trials reveal a high and unacceptable severity or prevalence of adverse events, our trials could be suspended or terminated and the NMPA, FDA, Competent Authorities of EEA Member States, Notified Bodies or other comparable regulatory authorities could order us to cease further development of, or deny approval or CE Marking certification of, our product candidates.

Adverse events have been reported in our clinical trials which could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In this document and from time to time, we disclose clinical results for our product candidates, including the occurrence of adverse events and serious adverse events. Each such document speaks only as of the date of the data cutoff used in such document, and we undertake no duty to update such information unless required by applicable law.

Our products and any future 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 fail to comply with regulatory requirements or experience unanticipated problems with our products and/or product candidates.

Our products and any additional product candidates that are approved by the regulatory authorities or CE marked are and 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 in China, the U.S., the EEA, and/or other countries.

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Manufacturers and manufacturers' facilities are required to comply with extensive regulatory requirements from the NMPA, FDA, Competent Authorities of EEA Member States, Notified Bodies and/or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulatory authorities in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other regulatory authorities. Accordingly, we must continue to devote time, money and effort in all areas of regulatory compliance.

The regulatory approvals or CE Marking certification for our products and any approvals or CE Marking certification that we receive for our product candidates are and may be subject to limitations on the indicated uses for which our product may be marketed. The approvals or CE Marking certification we obtain may also be subject to other conditions which may require potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of our products or product candidates. Such limitations and conditions could adversely affect the commercial potential of our products.

The NMPA or comparable authorities and Notified Bodies may seek to impose a consent decree or withdraw marketing approval or CE Marking certification if we fail to maintain compliance with these ongoing regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products or product candidates or with our manufacturing processes may result in revisions to the approved or CE Marked 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, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities and Notified Bodies to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or CE Marking certification or withdrawal of approvals or CE Marking certification;
- product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or
- injunctions or the imposition of civil or criminal penalties.

The NMPA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products placed on the market. Products may be promoted only for their approved or CE Marked indications and for use in accordance with the provisions of the approved or CE Marked label. The NMPA, FDA, Competent Authorities of EEA Member States, and other regulatory authorities actively enforce the laws and regulations prohibiting

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the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the NMPA, FDA, Competent Authorities of EEA Member States and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval or CE Marking certification of our product candidates. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, 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, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval or CE Marking certification that we have obtained and we may not achieve or sustain profitability.

If our current and new 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. We have established a quality management system and adopted standardized operating procedures in order to prevent quality issues with respect to our products and operation processes. For further details of our quality management system, please refer to “Business – Quality Management.” Despite our quality management system and procedures, 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;
- tampering by third parties; and/or
- quality issues with the raw materials we produce or purchase.

In addition, failure to detect quality defects in our 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.

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Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval or CE Marking certification of and commercialize our product candidates and affect the prices we may obtain.

In China, the U.S. and some other jurisdictions, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval or CE Marking certification of our product candidates, restrict or regulate post-approval or post-CE Marking certification activities and affect our ability to profitably sell our products and any product candidates for which we obtain regulatory approval or CE Marking certification. 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 or CE Marked 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 commercialize our 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 regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. On June 25, 2018, a revised draft amendment to the Regulations on the Supervision and Administration of Medical Devices was published by the Ministry of Justice (the “**Draft Amendment**”) for public comments. As a medical device company, if the Draft Amendment is passed, the requirements of clinical trial, sales and regulation would be changed. The impact of these more specific requirements and whether it will adversely affect the registration of our products with NMPA is yet to be observed.

In furtherance of the healthcare reform, the Chinese government announced a pilot program to implement a “two-invoice” system which generally limits the distribution to a single level of distributors for the sale of pharmaceutical products from manufacturers to public hospitals. According to the Notice on Opinions on the Implementation of the “Two Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)的通知), the Notice on Consolidating the Achievements of Cancelling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (關於鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知) and the Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables (關於印發治理高值醫用耗材改革方案的通知), as of the Latest Practicable Date, a few provinces have implemented the “Two Invoice System” in the field of medical consumables. As the implementation of the “two-invoice system” is still at an early stage, and the interpretation and enforcement of such system in the medical device industry are evolving and subject to uncertainty, we cannot predict how the implementation and enforcement will evolve in different provinces in China, or whether and how that will affect our business and results of operations in the future.

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Recent changes to the regulatory framework in the EU may increase the difficulty and cost for us to carry out business in the EEA.

The EU legislative institutions have enacted a regulation on medical devices (“MDR”) which was published in the Official Journal of the European Union on May 5, 2017 and entered into force on May 25, 2017. The MDR is directly applicable in all EU Member States and will replace the current Medical Devices Directive as of May 26, 2021. The revision will affect all kinds of medical devices. For details regarding MDR, see “Regulatory Environment – Europe Union and EEA Regulatory Overview – Changes to the Regulatory Framework.” In general, medical devices will be subject to more stringent requirements under the MDR, such as the strengthening of clinical data requirements related to medical devices and an extension of transparency requirements through the establishment of a comprehensive EU database on medical devices and a device traceability system allowing to trace the device from its manufacturer through the supply chain to the final user. In addition, Notified Bodies will need to be accredited by the EU Member States’ accreditation bodies to conduct assessment procedures for medical devices in accordance with the MDR. There are currently a relatively small number of notified bodies that have been accredited to conduct these assessments. This may delay conformity assessment procedures in the future in the EU. This may impact our activities in the EEA, the renewal of our existing CE Certificates of Conformity and conformity assessment related to future bodies. Once applicable, the MDR may impose increased compliance obligations for us to access the EU market. These requirements may be challenging to fulfill for medical device manufacturers like us, and, may in general increase our costs of doing business in the EEA. Our failure to continue to comply with regulatory requirements administered by Competent Authorities of the EEA Member States, could result in enforcement actions against us, including refusal, suspension, variation, or withdrawal of our CE Certificates of Conformity by our EU Notified Body, which could impair our ability to market products in the EEA in the future.

Changes to the membership of the EU may increase the difficulty and costs for us to carry out business in the EEA.

Any changes to the membership of the EU, such as the recent departure of the United Kingdom (Brexit), may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

The UK’s withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. On 24 December 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods. The Agreement does not however, specifically address medical devices. The Agreement seeks to ensure that the parties ensure “regulatory cooperation”. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. In light of the fact that the CE Marking certification process is set out in EU

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law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE mark. Northern Ireland will, however, continue to be covered by the regulations governing CE marks. As part of the Agreement, the EU and the UK have agreed to continue to recognize declarations of conformity based on a self-assessment in the other territory. Given the lack of comparable precedent to Brexit, it is unclear what the financial, regulatory, and legal implications of Brexit will be and how it will affect us. However, potentially changing regulatory schemes engendered by Brexit may add additional complexity, cost and delays in marketing or selling our products in the United Kingdom. Our revenue and profit, supply and demand for our products, and customer retention and acquisition in both the long term and short term could be adversely affected.

Risks Relating to Commercialization and Distribution of Our Products

We are subject to the risk of product concentration.

We derived the majority of our revenue from the sales of certain Core Products during the Track Record Period. In the years ended December 31, 2019 and 2020, our revenue from sales of medical devices and consumables accounted for 94.2% and 85.5% of our total revenue, respectively. Such medical devices and consumables primarily include our navigation equipment, i.e., LungPoint and Archimedes System. We expect to continue to generate most of our revenue from sales of medical devices and consumables in the near future.

The profitability of our business in the mid and long run depends substantially on the sales of our navigation equipment and consumables and our Group is subject to the risk of product concentration. Continued and increasing market acceptance of LungPoint and the Archimedes System and our other products is critical to our future success. If there is any adverse change in the demand of our products, our financial position, results of operation and long-term development could be materially and adversely affected.

In line with our strategy to develop more innovative technologies and expand into new areas for product development, we intend to expand our interventional pulmonology treatment product portfolio to cover all kinds of available energy ablation therapeutic methods. However, there can be no assurance that we will be successful in reducing our dependence on current products.

We consider that successful product development and market acceptance of our existing and future products will depend on a number of factors, including:

- accurate prediction of market requirements;
- reputation, quality and price of our products and the products of our competitors;
- successful maintenance and development of our relationships with existing and potential customers; and

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- changes in industry standards or end-user preferences.

There can be no assurance that any products we develop and introduce will achieve market acceptance and any such failure to achieve market acceptance may materially and adversely affect our business, financial condition, results of operations and prospects.

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 management 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 regulatory authorities, such as the NMPA, FDA, Competent Authorities of EEA Member States and/or Notified Bodies, 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 or CE Marking certification for the relevant products or the relevant production facilities;
- damage to the brand name of our products and the reputation of our Company;
- removal of relevant products from 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 prospects could be materially and adversely affected.

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Failure to achieve broad market acceptance or maintain good reputation necessary for our interventional pulmonary products and any future products would have a material adverse impact on our results of operations and profitability.

The commercial success of our current and future products depends upon the degree of market acceptance they achieve, particularly among hospitals and doctors. As a pioneer in the interventional pulmonology medical device market, our success is highly dependent on our continuous clinical training and early market education efforts to promote market awareness and cultivate market needs of interventional pulmonary procedures. As a novel treatment recently developed and introduced to the market, interventional pulmonary procedures such as radiofrequency ablation procedures navigated by navigation systems may fail to receive broad acceptance from patients or doctors as anticipated. As an alternative, video-assisted thoracic surgery (“VATS”) may have a competitive advantage over radiofrequency ablation procedures navigated by navigation systems, given its established market acceptance, comparatively lower price and coverage by governmental and private medical insurance. If our radiofrequency ablation products and any future approved or CE Marked product candidates fail to gain sufficient market acceptance by doctors, patients, third-party payors and others in the industry, the sales of our products will be adversely affected. For example, the VATS developed by some of our competitors are well established in the global surgical industry, and doctors may continue to rely on these treatments to the exclusion of our products and product candidates. In addition, doctors, patients and third-party payors may prefer other novel products to ours. If our products and product candidates 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 product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our products and product candidates are approved or CE Marked;
- doctors, hospitals, pulmonary diseases treatment centers and patients considering our products and product candidates as a safe and effective treatment;
- the potential and perceived advantages of our products and product candidates over alternative products;
- the prevalence and severity of any adverse effects or complications;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved or CE Marked by regulatory authorities;
- the timing of market introduction of our products and product candidates as well as competitive products;

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- the cost of treatment 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.

If any products that we commercialize fail to achieve market acceptance among doctors, patients, hospitals, pulmonary diseases treatment centers or others in the industry or if we fail to maintain good relationships with them, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

We primarily rely on our in-house marketing force to promote our products.

Under our strategic marketing model, our marketing force actively works with doctors and hospitals by providing professional education throughout the entire navigation procedures from candidate screening, operation assistance to follow-up visit post operations. We conduct post-market clinical studies which are initiated and supervised by our sales team to monitor the efficacy of our products. Our sales team also assists in providing training to doctors on navigation procedures. We incurred selling and distribution expenses of US\$8.6 million and US\$6.4 million for the years ended December 31, 2019 and 2020, respectively. The success of our marketing model depends on our ability to attract, motivate and retain qualified and professional employees in our marketing, promotion and sales teams who have, among other things, the sufficient expertise in the interventional pulmonology areas and are able to communicate effectively with medical professionals. Competition for experienced marketing, promotion and sales personnel is intense. If we are unable to attract, motivate and retain a sufficient number of qualified sales personnel to support our marketing model, sales volumes or margin of our existing and future products may be adversely affected and we may be unable to extend our hospital coverage and deepen our market penetration as contemplated.

There is no guarantee that we will succeed in expanding our sales network to cover new hospitals or new indications.

Despite the current leading position of sales of our navigation systems in China, we plan to expand our sales network to cover more hospitals to increase our market share and penetration in the China market to drive future growth. During the years ended December 31, 2019 and 2020, we sold 37 units and 7 units of our navigation systems, including LungPoint and Archimedes System, respectively. We may seek to expand our sales network to cover additional hospitals which are not able to independently conduct navigation procedures and hospitals in emerging markets where we have limited experience or resources. This marketing

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strategy could require us to strengthen our sales and marketing efforts, and we may not be able to do so. If we are unable to expand our sales network effectively, our sales volumes and business prospects could be materially and adversely affected.

If we fail to maintain an effective distribution channel for our products, our business and sales of the relevant products could be adversely affected.

While we market our LungPoint/Archimedes System and InterVapor system directly to hospitals, we rely mostly on third-party distributors to distribute our products in China. Our ability to maintain and grow our business will depend on our ability to maintain effective distribution channels that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we have relatively limited control over our distributors, who may fail to distribute our products in the manner we contemplate. We usually enter into one-year agreements with our distributors, with whom we may terminate such sales arrangements in case of distributors’ failure to meet their sales target or change of business. If PRC price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our products to hospitals and medical institutions, our distributors may terminate their relationships with us.

As of December 31, 2019 and December 31, 2020, we had a total of 11 and 28 distributors, respectively. For the years ended December 31, 2019 and 2020, the aggregate sales to our five largest distributors were US\$3.8 million and US\$0.8 million, representing 47.2% and 25.4% of our revenue, respectively. Sales to our largest distributor for the same periods were US\$2.0 million and US\$0.2 million, representing 25.3% and 7.3% of our revenue, respectively. While we believe alternative distributors are readily available in China, if the distribution of our products is interrupted, our sales volumes and business prospects could be adversely affected.

If we experience delays in collecting payments from our distributors, our cash flows and operations could be adversely affected.

Under the distributorship arrangement, we generally provide credit term for up to 120 days to our distributors for the sales of navigation system based on their credit profile and credit history. We conduct annual review of our distributors, based on their financial and business performance. We retain the discretion to adjust their credit terms based on the review results. We generally do not provide credit terms to hospitals for our navigation and ablation systems. We generally provide credit term to hospitals for medical consumables only according to their standard credit term, which is usually ranged from three to six months. For details, see “Business – Sales and Marketing – Our Sales Arrangements.” As of December 31, 2019 and December 31, 2020, our trade receivables were US\$4.1 million and US\$2.9 million, respectively. The average turnover days of our trade receivables for the same periods were 185 days and 390 days, respectively. For the formula of average turnover days of our trade receivables, see “Financial Information – Net Current Assets/Liabilities – Trade Receivables.” For our sales to distributors, our distributors receive payments from hospitals for our products they sold to the hospitals and will make payments to

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us accordingly. If our distributors’ cash flows, working capital, financial condition or results of operations deteriorate or they experience delays in payments from the hospitals, they may be unable, or they may otherwise be unwilling, to make payments owed to us promptly or at all. 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.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new products is highly competitive. We face competition from interventional pulmonary medical device companies worldwide. A number of companies in the global market currently market and sell pulmonology navigation and interventional energy ablation systems or are pursuing the development of such products for the treatment of pulmonary diseases for which we are commercializing our products or developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunities could be reduced or eliminated if we do not upgrade our products in a timely manner and our competitors develop and commercialize products that are safer, more effective, have fewer severe adverse events, are more convenient or are less expensive than any products that we commercialize or may develop. Our competitors may also be applying for marketing approvals in China or other countries for medical device products with the same intended use as our products and product candidates. The ability of the relevant authorities, such as NMPA, to concurrently review multiple marketing applications for the same type of innovative medical device may be limited. When our product and its competing products are subject to the NMPA’s concurrent review, the NMPA’s schedule may be affected, and the registration process of our product may be prolonged. Moreover, our competitors may obtain approval or CE Marking certification from the NMPA, FDA, Notified Bodies or other comparable regulatory authorities for their products more rapidly than we obtain approval or CE Marking certification for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our regulatory approval or CE Marking certification.

Many of the companies against which we are competing have significantly greater financial resources and expertise in R&D, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals or CE Marking certification and marketing approved or CE Marked products than we do. Mergers and acquisitions in the medical device industries may result in even more resources being concentrated among a small number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific

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and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our business and results of operations will suffer if we fail to compete effectively.

Downward change in pricing of our products may have a material adverse effect on our business and results of operations.

In line with market practice, we sell a significant portion of our products to distributors who resell our products to hospitals. In addition, we also sell a portion of our products directly to the hospitals. Our distributors, or we in our direct sales to the hospitals, negotiate and set retail prices directly with hospitals. Also, we sell certain of our products to distributors at the contract price. For details, see “Business – Sales and Marketing – Pricing.” Hospitals may gain more bargaining power depending on the availability of alternative products, demands of patients and the preference of doctors. If hospitals lower retail prices of our products and therefore reduce the profitability of our distributors, our distributors may have less incentive to purchase and promote our products, and we may need to lower the order price we set for our distributors.

As of the Latest Practicable Date, there was generally no tender or bidding process or price guidance set on our navigation equipment and interventional pulmonology therapeutic products by the PRC government. The absence of a tender process and price guidance is primarily because bronchoscopic navigation and ablation procedures and related navigation equipment and interventional pulmonology therapeutic products have only been introduced to the Chinese market in recent years, and there are only a few navigation system products approved for marketing in China and the application of bronchoscopic navigation procedures is still limited to top-tier hospitals in tier 1 and tier 2 cities. Along with our increasing efforts to promote bronchoscopic navigation and ablation procedures and our navigation and interventional pulmonology therapeutic products in the market, awareness of bronchoscopic navigation and ablation procedures and our navigation and interventional pulmonology therapeutic products is expected to increase. More competing interventional pulmonology products may become available, which will offer alternatives for hospitals and patients to choose for bronchoscopic navigation or ablation procedure. If the PRC government issues price guidance or introduces tender process for our navigation equipment and interventional pulmonology therapeutic products, it may negatively affect the price of our products and therefore have a material adverse effect on our business and results of operations. We may also face downward pricing pressure if our products are included in the medical insurance reimbursement list.

Our sales may be affected by the level of medical insurance reimbursement patients receive for lung disease diagnosis and treatment using our products.

Our ability to sell our products is related to the availability of governmental and private health insurance in China for treatments using our products. China has a complex medical insurance system that is undergoing reform. The governmental insurance coverage or reimbursement level in China for new procedures such as BTPNA and/or navigation-guided

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bronchoscopy procedures and the medical device used in such procedures is subject to significant uncertainty and varies from region to region, as local government approvals for such coverage must be obtained in each geographic region in China. Currently, whether BTPNA and/or navigation-guided bronchoscopy is reimbursable varies in each province and may vary among hospitals in the same province, depending on if BTPNA and/or navigation-guided bronchoscopy procedures can be categorized as BTPNA and/or navigation-guided bronchoscopy procedure. Because BTPNA and/or navigation-guided bronchoscopy procedures have been introduced to China only in recent years, for such procedures and the medical devices used in BTPNA and/or navigation-guided bronchoscopy procedure to be covered by medical insurance, BTPNA and/or navigation guided bronchoscopy procedure needs to be categorized by the hospital under the bronchoscopy procedure or another procedure that is reimbursable. Without reimbursement for BTPNA and/or navigation-guided bronchoscopy procedures and related consumables products, market demand for such products including biopsy tools may drop and our results of operations may be adversely affected.

In addition, insurance companies in China tend to reimburse patients for a higher percentage of the product cost if they use a medical device manufactured by a Chinese domestic company as opposed to an imported device. We cannot be certain that insurers will continue to adopt this favorable policy in the future.

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, financial condition and results of operation.

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 Manufacture and Supply of Our Products

Delays in completing and receiving applicable regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

Our principal manufacturing facilities are located at our headquarters in Hangzhou, Zhejiang province, China and San Jose, California, the U.S. As of the Latest Practicable Date, we rented an aggregate area of approximately 863 sq.m. for manufacturing facilities in San Jose, California, the U.S. Our facilities have been expanded by another 3,121 sq.m. in Hangzhou, which we plan to mainly use for the R&D, manufacture and commercialization of our medical products manufactured in China. We need to apply for a change of our manufacture permit to include our new facilities, which requires regulatory approval including our compliance with CGMP and ISO 13485 requirements. The facilities may encounter

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unanticipated expenses due to a number of factors, including regulatory requirements. Our manufacturing facilities will be subject to ongoing, periodic inspection by the NMPA, FDA, Notified Bodies or other comparable regulatory agencies to ensure compliance with CGMP. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval or CE Marking certification of our product candidates, delays, suspension or withdrawal of approvals or CE Marking certification, supply disruptions, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

Our facilities may be harmed or rendered inoperable by physical damage from fire, floods, earthquakes, typhoons, tornadoes, power loss, telecommunications failures, break-ins, and similar events. If our manufacturing facilities or the equipment are damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval or CE Marking certification before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our products or product candidates in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our products and product candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

If we fail to increase our production capacity to meet customer demand, our business prospects could be materially and adversely affected.

To produce our products in the quantities that we believe will be required to meet anticipated market demand for our products, we may need to increase, or scale up, the production capacity and the utilization rate. Our utilization rate for our major product, Archimedes systems, in 2019 and 2020 was 66% and 18%, respectively. 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, the production of our consumable products is highly labor-intensive as our workers need to manually assemble the parts by glue, crimping, laser welding or heat sealing, which requires experience and technique. To enhance our production capacity, we also need to employ more workers. If we are unable to do so, or if the

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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.

We are expanding our production output by adding a phase III manufacturing facility with a total floor area of 3,121 sq.m. located at our headquarters in Hangzhou, Zhejiang province, China. Phase III manufacturing facility is intended to be used for the production of our existing products and our other pipeline products to be commercialized. 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 or CE Marking certification 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 by physical and chemical methods, which are costly and time consuming. Regulatory authorities may also require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

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, as well as our ability to timely recruit sufficient qualified staff to support the increase in production capacity. Consequently, we may not capture the expected growth in demand for our products, which could adversely affect our business prospects.

There can be no assurance that our existing and future production 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.

The manufacture of our products is highly complex and subject to strict quality controls. If we or any of our suppliers or logistics partners encounters manufacturing, logistics, or quality problems, including as a result of natural disasters, our business could suffer.

The manufacture of many of our products is highly complex and subject to strict quality controls, due in part to rigorous regulatory requirements. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, or human error. Furthermore, if contaminants are discovered in our supply of our products or product candidates or in the manufacturing facilities, such manufacturing facilities may need

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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 product candidates could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. 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 or other applicable regulatory bodies, which include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals or CE Marking certification could be delayed, and our business could otherwise be adversely affected.

In addition, our manufacturing and warehousing facilities, as well as those of our suppliers and logistics partners, could be materially damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances, which could have a material adverse effect on our business.

Fluctuations in prices of our raw materials may have a material adverse effect on us.

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. One of our principal raw materials is pet heat shrink tube that we procure from third-party suppliers. During the Track Record Period, the pet heat shrink tube was generally available and sufficient for our demands, and the price of the pet heat shrink tube from our suppliers was not affected by the international environment. However, we cannot assure you that this will continue to be the case in the future. The prices of pet heat shrink tube or other raw materials may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as the outbreak of the COVID-19 pandemic, the PRC and 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, financial conditions, results of operation and prospects.

We may experience supply interruptions that could harm our ability to manufacture products.

We purchase certain of the materials and components used in the manufacture of our products from external suppliers, and we purchase certain supplies from fixed sources or single sources for reasons of quality assurance, cost effectiveness, availability, or constraints resulting from regulatory requirements. Our principal raw materials are computer workstations, medical optical trackers, metal fabrication assemblies (cart), laptops and catheters and other raw materials. General economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. While we work closely with suppliers to monitor their financial viability, assure continuity of supply, and maintain high quality and reliability, these efforts

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may not be successful. In addition, due to the rigorous regulations and requirements of the NMPA and/or foreign regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources in a timely manner or at all if the need arises. Certain suppliers may also elect to no longer service medical device companies due to the high amount of requirements and regulation. Although we consider alternative supplier options, we typically do not pursue regulatory qualifications of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with our internal validation process. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us. A reduction in, or lack of availability of, raw materials or interruptions in the supply chain may also impact our profitability to the extent that we are required to pay higher prices for, or are unable to secure adequate supplies of, the necessary raw materials.

We rely on supply from limited suppliers, which may severely harm our operations if the supplier loses its qualification or eligibility because of its failure to comply with regulatory requirements or stops our supply due to contractual disputes.

During the Track Record Period, all of our five largest suppliers including suppliers of raw materials and others are primarily located either in the U.S. or China. Our suppliers are subject to various regulations and are required to obtain and maintain various qualifications, government licenses and approval or CE Marking certification. If any of these suppliers loses its qualification or eligibility because of its failure to comply with regulatory requirements, we may not be able to find alternative suppliers in a timely manner or at all, which may cause delay in supply of our raw materials and interruption in our manufacturing. If any of these happens, our results of operations may be materially and adversely affected. Some of our suppliers are located outside China. As a result, trade or regulatory embargoes imposed by foreign countries or China could also result in delays or shortages that could harm our business.

Failure to maintain and predict inventory levels in line with the level of demand for our products could cause us to lose sales or face excess inventory risks and holding costs, either of which could have a material adverse effect on our business, financial condition and results of operations.

To operate our business successfully and meet our customers’ demands and expectations, we must maintain a certain level of inventory for our products to ensure immediate delivery when required. Furthermore, we are required to maintain an appropriate level of inventory of our raw materials, including pet heat shrink tube and PEBAX tube, for our commercial production. For the years ended December 31, 2019 and 2020, our average inventory turnover days were 245 days and 546 days, respectively. For the formula of our average inventory turnover days, see “Financial Information – Net Current Assets/Liabilities – Inventories.” However, we maintain our inventory levels based on our internal forecasts which are inherently uncertain. If our forecast demand is lower than actual demand, we may not be able to maintain an adequate inventory level of our products or produce our products in a timely manner, and

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may lose sales and market share to our competitors. On the other hand, we may be exposed to increased inventory risks due to accumulated excess inventory of our products or raw materials (for example, our consumable medical devices made in our Hangzhou facility typically have a shelf life of three years and are subject to expiration). Excess inventory levels may increase our inventory holding costs, risk of inventory obsolescence or write-offs.

In addition, we actively monitor our inventory level and track the flow of our products through an online distribution platform. However, there is no guarantee that the inventory information we collect is complete and accurate or that such information would allow us to effectively manage our inventory level. If we fail to maintain and predict inventory levels in line with the level of demand for our products, our business, financial condition and results of operations will be materially and adversely affected.

Risks Relating to Our Intellectual Property Rights

We depend on intellectual property licensed from third parties, and termination of any of these licenses or disruption to our business relationship with our licensors could result in monetary damages or the loss of significant rights, which would harm our business.

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We are currently party to and may in the future enter into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents and patent applications. In particular, we have in-licensed significant intellectual property rights from The Penn State Research Foundation (“**PSRF**”). For further details regarding our license agreements with PSRF, please refer to “Business – Collaboration and License Agreements – Collaboration with PSRF”. Any termination of these licenses could result in the loss of significant rights and could adversely affect our ability to commercialize our product candidates. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under any of our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or product candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business.

Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In addition, such an event may cause us to experience significant delays in development and commercialization of our product candidates or incur liability for damages. If any such license is terminated, we may be required to cease our development and commercialization of certain of our product candidates, and if our competitors or other third parties obtain such license, they would be able to seek regulatory

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approval or CE Marking certification of, and to market such products and technologies. Additionally, we may be required to out-license part of our improvements in an agreed manner in our licensed territory to a third party with which our licensor has such obligations.

We may need to obtain additional licenses to advance our research or allow commercialization of product candidates we may develop. Our current license from PSRF with respect to navigation systems is for lung navigation in connection with the related licensed product. If, in the future, we develop our navigation systems for additional uses, we may need to obtain additional licenses. In connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors’ obligation to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- whether and the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patents and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates;
- the amount and timing of payments owed under license agreements;
- the priority of invention of patented technology patents; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

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In addition, the agreements under which we license intellectual property or technology from third parties are, and such future license agreements are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

Our success depends in large part on our ability to protect our proprietary technology, products and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technology, products and product candidates that we consider commercially important by filing patent applications in the PRC, the U.S. and other countries, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file 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 R&D 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 R&D output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements or include such provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our R&D output, such as our employees, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. Patent applications in China and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all.

Under the Patent Law of the PRC (中華人民共和國專利法) promulgated by the Standing Committee of the NPC, as amended, invention patent applications are maintained in confidence until their publication at the end of 18 months from the filing date. The publication of

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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 U.S. 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 (for example, in the U.S.). In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, 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 U.S. and other countries. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA, USPTO or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or inter parts 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 product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products and product candidates without infringing,

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misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the CNIPA, 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 product candidates. 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 product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

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

Filing, prosecuting, maintaining and defending patents on products and product candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength from

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those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing medical products made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other countries. These products may compete with our products and product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

As of the Latest Practicable Date, we owned 476 patents and patent applications, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights.

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.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our products and product candidates could be found invalid or unenforceable if being challenged in court or before the CNIPA or courts or related intellectual property agencies in other jurisdictions.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims

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against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

Defendant counterclaims alleging invalidity or unenforceability are commonplace, a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiner could be unaware of invalidating prior art during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as we expect.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our product candidates. We may also be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. There are a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the medical device industry generally. As the medical device industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from

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their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would substantially divert diversion of employee resources from our business. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the market price of our Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance fees on any issued patent are due to be paid to the CNIPA, USPTO and other patent agencies in several stages over the lifetime of the patent. The CNIPA, USPTO and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar 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, non-compliance can result in abandonment or

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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.

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

Depending on decisions by the NPC and the CNIPA, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The U.S. has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

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

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our products and product candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into employment agreement or consulting agreement with our employees and consultants that includes undertakings regarding assignment of inventions and discoveries. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management,

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executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail 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, while we typically require our employees, consultants and contractors involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party 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.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we or any future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;
- we or any future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

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- patents that may be issued from our pending patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Relating to Our Reliance on Third Parties

If the third parties with which we contract for pre-clinical research and clinical trials do not perform in an acceptable manner, or if we suffer setbacks in these pre-clinical studies or clinical trials, we may be unable to develop and commercialize our product candidates as anticipated.

We rely on third parties, including leading academic institutions, public hospitals and CROs, to assist us in designing, implementing and monitoring our pre-clinical research and conducting clinical trials. As of the Latest Practicable Date, we worked with a number of CROs and hospitals. If any of these parties terminates its agreements with us, the development of the product candidates covered by those agreements could be substantially delayed. In addition, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical, laboratory and manufacturing guidelines. Our reliance on these third parties may result in delays in completing, or in failing to complete, these studies if they fail to perform in accordance with the contractual arrangements. Furthermore, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA, FDA, Notified Bodies and/or other comparable regulatory authorities may not accept the data generated by those studies, which would increase the cost of and the development time for the relevant product candidate. If any of the pre-clinical studies or clinical trials of our product candidates is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

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We rely upon strong relationships with certain key doctors and leading hospitals in the clinical development and marketing of our products.

The clinical development, marketing and sale of our products require us to maintain close relationships with doctors upon whom we rely to provide considerable knowledge and experience. These doctors may assist us as researchers, marketing consultants, trainers for interventional pulmonology procedures, inventors, and as public speakers. Since inception and up to the Latest Practicable Date, we had arranged doctor trainings at various hospitals. Only a limited number of hospitals and doctors have the expertise and are eligible to routinely perform complex procedures such as BTPNA. If we fail to develop or maintain strong relationships with these professionals or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

We may establish or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances 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 product candidates and any future product candidates that we may develop. For example, in March 2018, our major subsidiary, Broncus Medical, entered into a collaboration agreement with Intuitive Surgical Operations Inc. and Intuitive Surgical Sarl (collectively, “**Intuitive**”) to co-develop therapeutic products compatible with our navigation systems and Intuitive’s robot-assisted systems. For details, see “Business – Collaboration and Licensing Agreements – Collaboration between BMI and Intuitive.”

We face significant competition in seeking appropriate strategic partners and the negotiation process for the collaboration, alliances 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 product candidates because they may be deemed to be at too early of a development stage for collaborative effort and third parties may not view our product candidates 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 product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For any products or product candidates 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.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to 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 may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new design of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- 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 product candidates, 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 product candidates; 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.

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,

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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 product candidate, 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 product candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

Our cross-border transfer of data may be limited or restricted.

The clinical trials, registration and post-marketing surveillance of our products and product candidates in different jurisdictions involve the obtainment and storage of personal health information for scientific purposes, and it may require cross-border transfer of personal or scientific data, which subjects us to relevant laws and regulations. As of the Latest Practicable Date, we had not been restricted from transferring data across jurisdictions for the purposes of medical device registration, however, our transfer of data may be limited or even restricted if the information is considered of national security interest in certain jurisdictions or if we fail to continue to comply with the requirement on data protection, in which case, our business may be harmed as a result.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our R&D of medical device product candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of product candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

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Cross-border data transfer from other jurisdictions may also be limited if we fail to comply with relevant requirements, such as obtaining authorization from patients regarding the use, transfer and retrieval of their personal information or data and adopting measures to ensure the safety of personal information or data in the transfer. For example, cross-border data transfer from the EU to abroad is governed by the General Data Protection Regulation. Also, cross-border transfer of personal data by its nature is subject to general data privacy regulations in various jurisdictions, and thus any failure to comply with data privacy protection may lead to a restriction of transferring our data across different jurisdictions.

Our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. For example, in July 2020, the Court of Justice of the European Union, or the Court of Justice, declared the Privacy Shield Decision (Decision 2018/1250) invalid, which could adversely impact our ability to transfer personal data from the EU to the U.S. The Court of Justice further ruled that in order to transfer data outside of the EU, under the existing mechanism known as the Standard Contractual Clauses, or SCCs, the importing country’s level of protection must be adequate.

On September 8, 2020, the Federal Data Protection and Information Commissioner, or FDPIC, of Switzerland issued an opinion concluding that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. The FDPIC also found that SCCs may still be legally adequate at an individual level provided that they can pass a risk assessment conducted by the FDPIC. If the level of protection in the U.S. or any other importing country is called into question under the SCCs, this could further impact our ability to transfer data outside of the EU or Switzerland.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had net current liabilities during the Track Record Period, which may expose us to liquidity risk.

While we had net current assets of US\$12.5 million as of December 31, 2020, we had net current liabilities of US\$5.1 million as of December 31, 2019. For details, see “Financial Information.” A net current liabilities position may expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources including the [REDACTED], and/or other sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed may have a material adverse effect on our business, financial condition, results of operations and prospects.

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If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.

As of December 31, 2020, we had intangible assets of US\$8.3 million which comprised of US\$8.2 million related to intellectual property and US\$78 thousand related to software. Our intangible assets are primarily related to the intellectual property rights we previously acquired from the acquisition of Broncus Technologies Inc. and Uptake Medical Corp. and our proprietary intellectual property rights developed by Hangzhou Broncus Medical Co., Ltd. For more information, see “History, Reorganization and Corporate Structure – Major Acquisitions, Disposals and Mergers.”

The value of intangible assets is based on a number of assumptions made by the management. For a detailed discussion on the intangible assets, see Note 15 to the Accountants’ Report in Appendix I to this document. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant decrease in the value of our intangible assets and record a significant impairment loss. Furthermore, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset. If the carrying amount exceeds its recoverable amount, our other intangible assets may be impaired. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information regarding our impairment policy in relation to intangible assets, see Note 2.3 “Summary of Significant Accounting Policies – Intangible assets” and Note 3 “Significant Accounting Judgments and Estimates – Useful lives of intangible assets” to the Accountants’ Report in Appendix I to this document.

We will need to obtain additional financing to fund our operations and we had net cash outflows from our operating activities during the Track Record Period. If we are unable to obtain that financing, we may be unable to complete the development and commercialization of our product candidates.

Our product candidates will require completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. Our operating activities used US\$15.8 million of net cash in 2019 and US\$15.6 million of net cash in 2020. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise finance by issuing further equity securities, your interest in our Company may be diluted. If we continue to have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

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We expect to continue to spend substantial amounts on R&D, advancing the clinical development of our product candidates, commercializing our products and launching and commercializing any product candidates for which we receive regulatory approval or CE Marking certification, including building our own commercial organization to address China and other markets. Our existing cash and cash equivalents may not be sufficient to enable us to complete all global development or commercially launch all of our current product candidates for the anticipated indications and to invest in additional programs. Accordingly, we will require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. We cannot assure you that our financial resources will be adequate to support our operations. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approval or CE Marking certification of our product candidates;
- the number and characteristics of product candidates that we may develop;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our products and any existing or future product candidates that may be approved or CE Marked, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the cost and timing of development and completion of commercial-scale internal or outsourced, if any, manufacturing activities; and/or
- our headcount growth and associated costs.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our R&D programs or future commercialization efforts.

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

We have historically received government grants in the form of subsidies for certain of our product development projects. For the years ended December 31, 2019 and 2020, we recognized government grants as other income of US\$25 thousand and US\$352 thousand, respectively. For further details of our government grants, see “Financial Information.” 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 R&D 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.

Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Share-based payment may cause shareholding dilution to our existing Shareholders and have a material and adverse effect on our financial performance.

We adopted Employee Incentive Scheme for the benefit of our employees (including directors) and non-employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For details, see “Appendix IV – Statutory and General Information – E. Equity Incentive Plans.” During 2019 and 2020, we incurred share-based compensation of US\$5.6 million and US\$0.5 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of

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additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

There is valuation uncertainty with respect to the fair value of our convertible redeemable preferred shares and fair value changes of our convertible redeemable preferred shares may materially affect our financial positions and results of operations.

Fair value loss of our convertible redeemable preferred shares represents the changes in fair value of the various rights associated with our convertible redeemable preferred shares. And the fluctuations of the fair value of our convertible redeemable preferred shares affect our financial positions. We recorded fair value loss from changes in fair value of our convertible redeemable preferred shares of US\$9.4 million and US\$27.6 million for the years ended December 31, 2019 and 2020, respectively, primarily due to the increase in fair value of our convertible redeemable preferred shares. The valuation of our convertible redeemable preferred shares is subject to uncertainty due to the various assumptions made as outlined in Note 26 to the Accountants’ Report as set out in Appendix I to this document. Although our preferred shares will be automatically converted to Shares upon the closing of the [REDACTED], to the extent we need to revalue the preferred shares prior to the closing of the [REDACTED], any change in fair value of these preferred shares could materially affect our financial positions and performance.

RISKS RELATING TO OUR OPERATIONS

Our operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks, in particular the COVID-19 outbreak.

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand globally. In March 2020, the World Health Organization characterized the COVID-19 outbreak as a global pandemic. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. The COVID-19 outbreak is expected to have an unprecedented impact on the global economy as it has significantly reduced market liquidity and depressed economic activities.

The COVID-19 outbreak has caused and may continue to cause a long-term adverse impact on the economy and social conditions in China and other affected countries, which may have an indirect impact on our industry and cause temporary suspension of projects and shortage of labor and raw materials, which would severely disrupt our operations and have a material adverse effect on our business, financial condition and results of operations. For example, our revenue in the year ended December 31, 2020 decreased by 59.6% from the year ended December 31, 2019, primarily due to the COVID-19 outbreak. We are uncertain as to when the COVID-19 outbreak will be contained globally, and we also cannot predict whether

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COVID-19 will have long-term impact on our business operations. Our operations and clinical trials could also be disrupted if any of our employees or employees of our distributors, suppliers and other business partners were suspected of contracting or contracted COVID-19, since this could require us and our distributors, suppliers and other business partners to quarantine some or all of these employees and disinfect facilities used for operations. In addition, the commencement of new clinical trials for other product candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. Our commercialization plan for commercial-ready or near commercial-ready assets could also be disrupted. If we are not able to effectively and efficiently develop and commercialize our product candidates as planned, we may not be able to grow our business and generate revenue from sales of our product candidates as anticipated, our business operations, financial condition and prospects may subsequently be materially and adversely affected.

In addition, any future occurrence of force majeure events, natural disasters or outbreaks of other epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. Moreover, the PRC has experienced natural disasters such as earthquakes, floods and droughts in the past few years. Any future occurrence of severe natural disasters in China may materially and adversely affect its economy and our business. We cannot assure you that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken by the Chinese government or other countries in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and results of operations.

Our future success depends on our ability to retain key personnel in our R&D team, sales and marketing team and executives and to attract, train, retain and motivate qualified and highly skilled personnel.

Our business and growth depend on the continued service of our senior management and personnel in our R&D team to develop product candidates and our sales and marketing team to promote our products. Although we have formal employment agreements with each of our employees, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided share awards 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. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

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In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval or CE Marking certification of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous medical device companies for similar personnel.

We also experience competition for the hiring of R&D and clinical personnel from universities and research institutions. 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 have a limited operating history and our historical sales relied on limited products, which may make it difficult to evaluate our future business prospects.

We have a limited operating history compared to some of our competitors. Our operations to date have focused on business planning, raising capital, establishing our intellectual property portfolio, conducting preclinical studies and clinical trials of our product candidates and the commercialization of our products. During the Track Record Period, a substantial amount of our revenue was derived from the sales of our navigation systems (mainly the Archimedes System and LungPoint), which accounted for 76.7% and 58.5% of our total revenue for the years ended December 31, 2019 and 2020, respectively, and will continue to account for a significant portion of our total sales in the near future. There is also no assurance that we will be able to maintain and further improve our sales and profit margin for such products, which may be adversely affected by many factors out of our control, including business disruption due to the recent COVID-19 pandemic, expiration of patent protection, and disputes over intellectual property or other matters with third parties.

Moreover, there is no guarantee that we may be able to successfully develop or commercialize new products that would diversify our product portfolio. We have not yet obtained regulatory approval or CE Marking certification for our therapeutic products such as InterVapor for COPD, RF-II and some other product candidates. Accordingly, our limited operating history and past commercialization of limited products, particularly in light of the rapidly evolving interventional pulmonology field, may not be a reliable indicator of our future

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performance or serve as an adequate basis for reliably predicting our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

We have significantly increased the size and capabilities of our organization, and we may experience difficulties in managing our growth.

As our development and commercialization plans and strategies evolve, we need to recruit a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our products and product candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- 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 product candidates and regulatory approval or CE Marking certification; 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.

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.

Product liability claims or lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the commercialization of our products in China and the clinical testing and any future commercialization of our product candidates globally. For example, we may be sued if our products or product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the medical device product, negligence, strict liability or a breach of warranties. Claims could also be

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asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

If we are unable to obtain sufficient product liability insurance at an acceptable cost, potential product liability claims could prevent or inhibit the commercialization of our products and product candidates. We currently do not hold any product liability insurance coverage, and we may be unable to acquire such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. The insurance policies which we are able to obtain at a reasonable cost may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including but not limited to various disputes with or claims from our suppliers, customers, contractors, business partners and other third parties that we engage for our business operations. On-going or threatened litigation, legal or contractual disputes, investigations or administrative proceedings 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, investigations or administrative proceedings which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. If 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, financial condition and results of operations may be materially and adversely affected.

We may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval or CE Marking certification. Our operations are subject to various applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, including, without limitation, criminal law of the PRC, Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Administrative Measures for the Registration of Medical Devices (《醫療器械註冊管理辦法》). These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

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Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, we are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

If any of the doctors or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the anti-bribery laws of various jurisdictions, particularly in China. As our business expands, the applicability of the applicable anti-bribery laws to our operations has increased. Our 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. If we fail to comply with the applicable anti-bribery laws due to either our own deliberate or inadvertent acts or those of others, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our internal computer systems may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including R&D information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or 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

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of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment 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 a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

Because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal information, including health data.

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We may also need to collect more extensive health-related information from our employees to manage our workforce. If we or our third party partners fail to comply or are alleged to have failed to comply with applicable data protection and privacy laws and regulations, and related employment rules, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits.

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

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Third parties, such as research institutions, distributors and suppliers on whom we may rely to develop, produce, promote, sell and distribute our products, may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the third parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, could be subject to natural or man-made disasters or business interruptions. In addition, we partially rely on our third-party research institution collaborators for conducting R&D of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We partially rely on third-party manufacturers to produce and process our products and product candidates. Our ability to obtain supplies of our products and product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease

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or delay development or commercialization of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

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

We plan to broaden our sales and expand our presence globally especially in the U.S. and EU by commercializing our pipeline products, such as InterVapor to benefit from higher medical expense levels in these developed regions. We are in the process of various clinical trials and registration applications in EU, and we have also been expanding our business in emerging markets, such as India. However, our limited experience in overseas markets may expose us to risks and uncertainties, including the risks associated with the following:

- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;
- substantial time which may be required for us to obtain approval or CE Marking certification for registering and selling our products in additional countries, especially in developed countries;
- commercializing our products in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- higher costs for new product development and reliance on overseas partners for the development, commercialization and marketing of our products;
- product liability litigation and regulatory scrutiny arising from the marketing and sale of products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness and inflation;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;

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- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

Our insurance coverage may not completely cover the risks related to our business and 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, including social insurance for all of our employees, property insurance and personal accident insurance. For details, please refer to “Business – Insurance.” However, there is no assurance that our insurance policies will be adequate to cover all losses incurred. Losses incurred and associated liabilities may have a material adverse effect on our results of operation if such losses or liabilities are not covered by our insurance policies.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and, as a result, our business, financial condition and results of operations may be negatively affected.

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees and business partners were noncompliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

RISKS RELATED TO DOING BUSINESS IN CHINA

The medical device industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our product candidates.

We conduct the majority of our operations in China. The medical device industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new devices. In recent years, the regulatory framework in China regarding the medical device industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our

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business or cause delays in or prevent the successful development or commercialization of our product candidates in China and reduce the benefits we believe are available to us from developing and manufacturing interventional pulmonology products and their delivery systems in China.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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

The majority of our operations are conducted in China, and are governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the non-binding nature of such decisions, the

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interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, 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. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Additionally, the reform of the medical device approval system in 2017 may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our product candidates in a timely manner. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with our Articles of Association and accounting standards and regulations in PRC. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

In response to the persistent capital outflow in China and RMB's depreciation against the U.S. dollar, People's Bank of China, or PBOC, and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and

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substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate.

The Enterprise Income Tax Law and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement.

Pursuant to the Arrangement Between the Mainland of China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income, or the “Hong Kong Tax Treaty” (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排), the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income, and our Hong Kong subsidiary directly holds 25% or more interests in our PRC subsidiary. On February 3, 2018, the State Administration of Taxation issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (關於稅收協定中“受益所有人”有關問題的公告), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by

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complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Our business benefits from certain tax preferences, financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives, tax preferences or policies would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Governments authorities may decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations. In addition, according to relevant PRC tax laws and regulations, enterprises in the PRC are entitled to tax preferences when certain requirements and qualifications are satisfied. Our relevant PRC subsidiaries may not continue to be entitled to relevant tax preferences if relevant tax preferences expire or the relevant PRC subsidiaries fail to continue to satisfy certain requirements and qualifications. For example, small and micro enterprises in the PRC are entitled to preferential rate of 20%. All our subsidiaries which operate in the mainland of China except Hangzhou Broncus Medical Co., Ltd. are currently entitled to such preferential income tax rate. If any of these PRC subsidiaries fails to continue to qualify in a subsequent year, tax expenses would increase, which may have a material adverse effect on our results of operations.

We are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to

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accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. Such adjustments or changes, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations.

It may be difficult to effect service of process upon us or our management that reside in China or to enforce against them or us in China any judgments obtained from foreign courts.

A significant portion of our operating subsidiaries are incorporated in China. A majority of our management reside in China from time to time. A significant portion of our assets are located in China. Therefore, it may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions. On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排) (the “Arrangement”), pursuant to which a party with an enforceable 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 China. Similarly, a party with an enforceable final judgment rendered by a Chinese 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 court or a Chinese court is expressly designated as the court having sole jurisdiction for the dispute.

On January 18, 2019, the Supreme People’s Court and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排) (the “New Arrangement”), which seeks to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and the China. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in the Hong Kong Special Administrative Region. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the

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dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

Furthermore, China does not have treaties or other forms of written agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

Any failure by the Shareholders or beneficial owners of our Shares to comply with PRC foreign exchange or other regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The State Administration of Foreign Exchange (SAFE) has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by domestic Residents in China via Special-Purpose Companies (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), or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

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According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (國家外匯管理局關於發佈境內機構境外直接投資外匯管理規定的通知) (SAFE Circular 30) and other regulations, if our shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our shareholders may be required to suspend or stop the investment and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知), or SAFE Circular 13, which came into effect on June 1, 2015, pursuant to which local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and other regulations; however, due to the inherent uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not be always practically available in all circumstances as prescribed in those regulations. As of the Latest Practicable Date, to the best knowledge of our Company, two of our ultimate Shareholders, each of whom is a PRC citizen and beneficially owns less than 1% of the equity interest in us, did not conduct the registration with the SAFE. There is uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. Due to the uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not be always be practically available in all circumstances as prescribed in those regulations. In addition, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC nationals or entities, and may not be able to compel them to comply with SAFE Circular 37, SAFE Circular 30 or other regulations. We cannot assure you that all of our Shareholders or beneficiaries will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by SAFE rules or other regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

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We face uncertainty relating to PRC laws and regulations relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.

On February 3, 2015, the PRC State Administration of Taxation issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (關於非居民企業間接轉讓財產企業所得稅若干問題的公 告), or Circular 7, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on non-Resident Enterprises (關於加強非居民企業股 權轉讓企業所得稅管理的通知), or Circular 698, which was previously issued by the State Administration of Taxation on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and heightened the PRC tax authorities' scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or PRC Taxable Assets.

For example, Circular 7 specifies that when a non-resident enterprise transfers PRC Taxable Assets indirectly by disposing of equity interests in an overseas holding company which directly or indirectly holds such PRC Taxable Assets, the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of PRC Taxable Assets by disregarding the existence of such overseas holding company and considering the transaction to be a direct transfer of PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding PRC enterprise income taxes and without any other reasonable commercial purpose.

Except as provided in Circular 7, transfers of PRC Taxable Assets under the following circumstances shall be automatically deemed as having no reasonable commercial purpose, and are subject to PRC enterprise income tax: (i) more than 75% of the value of the equity interest of the overseas enterprise is directly or indirectly attributable to the PRC Taxable Assets; (ii) more than 90% of the total assets (cash excluded) of the overseas enterprise are directly or indirectly composed of investment in China at any time during the year prior to the indirect transfer of PRC Taxable Assets, or more than 90% of the income of the overseas enterprise is directly or indirectly from China during the year prior to the indirect transfer of PRC Taxable Assets; (iii) the overseas enterprise and its subsidiaries directly or indirectly hold PRC Taxable Assets and have registered with the relevant authorities in the host countries (regions) in order to meet the local legal requirements in relation to organization forms, yet prove to be inadequate in their ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of PRC Taxable Assets payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

Circular 7 contains certain exemptions, including (i) the Public Market Safe Harbor described below; and (ii) where there is an indirect transfer of PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement. However, it remains unclear whether any exemptions

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under Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will reclassify such transactions by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about this Document and the [REDACTED]” in this document, potential [REDACTED] should consult their professional advisors if they are in any doubt as to the tax implications of subscribing for, purchasing, holding, disposing of and dealing in the Shares.

Under China’s Enterprise Income Tax Law, we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under China’s Enterprise Income Tax Law, or the “EIT Law,” an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. A tax circular issued by the PRC State Administration of Taxation (SAT) on April 22, 2009, or Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions paid by such resident enterprises which are considered to be PRC source income will be subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011,

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the PRC State Administration of Taxation issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Currently, most of the members of our management team as well as the management team of some of our offshore holding companies are located in China. However, Circular 82 and Bulletin 45 only apply to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreign corporations like us. In the absence of detailed implementing regulations or other guidance determining that offshore companies controlled by PRC individuals or foreign corporations like us are PRC resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a PRC resident enterprise.

Despite the foregoing, the SAT may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises.

Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, under the EIT Law and its implementing rules issued by PRC tax authorities dividends paid by us to our non-PRC shareholders may be subject to a withholding tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, and gains recognized by our non-PRC shareholders may be subject to PRC tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders.

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Any PRC tax liability on dividends or gain described above may be reduced under applicable tax treaties. However, it is unclear whether, if our Cayman Islands holding company is considered a PRC resident enterprise, non-PRC shareholders might be able to claim the benefit of income tax treaties entered into between PRC and their countries. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

Government control of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional contributions to our PRC subsidiaries, which could restrict our ability to utilize the [REDACTED] from the [REDACTED] effectively and affect our ability to fund and expand our business.

The PRC government imposes controls on the convertibility of foreign currencies into Renminbi. Under China’s existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the MOFCOM or its local counterparts.

In August 2008, SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign Invested Enterprises (國家外匯管理局綜合司關於完善外商投資企業外匯資本金支付結匯管理有關業務操作問題的通知), or SAFE Circular 142, providing that the Renminbi capital converted from foreign-currency-registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC.

On March 30, 2015, SAFE released the Notice on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知), or SAFE Circular 19, which came into force and superseded SAFE Circular 142 from June 1, 2015. On June 9, 2016, SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (關於改革和規範資本項目結匯管理政策的通知), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises, and some foreign exchange restrictions under SAFE Circular 142 are expected to be lifted. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. Considering that SAFE Circular 19 and SAFE Circular 16 are relatively new, it is unclear how they will be

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implemented, and there exist high uncertainties with respect to its interpretation and implementation by authorities. For example, under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign-currency-registered capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital to provide loans to a its non-affiliated company.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

Any failure to comply with PRC regulations regarding the mandatory social insurance and housing provident fund may subject us to fines and other legal or administrative sanctions.

Pursuant to the relevant PRC laws and regulations, employers in the PRC are required to make social insurance contributions and housing provident fund contributions for their employees, and entities failing to make contributions may be ordered to settle the outstanding contributions within a prescribed time limit and subject to penalties or fines. During the Track Record Period and up to the Latest Practicable Date, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees. While we have not received any order or notice from the local authorities nor any claims or complaints from our current and former employees as of the Latest Practicable Date regarding the shortfall in payments and contributions, we cannot assure you that we will not be subject to penalties or fines imposed by the relevant PRC governmental authorities as a result of such non-compliance incidents or be ordered to rectify such non-compliance incidents. Although the likelihood that we are subject to centralized collection of historical arrears and any material penalties due to our failure to provide full social insurance and housing provident funds contributions for our employees is remote, as advised by our PRC Legal Advisor, any such penalties, fines, orders or complaints may harm our corporate image and may have an adverse effect on our financial condition and results of operations.

The political relationships between China and other countries or regions may affect our business operations.

During the Track Record Period, we formed partnerships with entities in foreign countries and regions, in particular Asia, the U.S. and EU, and establishing new collaboration partnerships is key to our future growth. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China’s political relationships

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with those foreign countries and regions may affect the prospects of maintaining existing or establishing new collaboration partnerships. Since mid-2018, political tension has increased between China and the U.S. and has escalated into a tariff war. Currently, it remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, or if tariffs continue to be raised on foreign-sourced goods imported to the U.S., our business, financial condition and results of operations could be negatively impacted. There can be no assurance that potential collaboration partners will not alter their perception of us or their preferences as a result of such adverse changes between China and relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects.

RISKS RELATED TO THE [REDACTED]

No public market currently exists for our Shares, and an active trading market for our Shares may not develop and the market price for our Shares may decline or become volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and [REDACTED] (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. We have applied to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares. A [REDACTED] on the Hong Kong Stock Exchange, however, does not guarantee that an active and liquid trading market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will rise following the [REDACTED].

The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval or CE Marking certification of our product candidates, regulatory developments affecting our industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Hong Kong Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and our Shares may be subject to changes in price not directly related to our performance.

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There will be a gap of several days between pricing and trading of our Shares, and the price of our Shares when trading begins could be lower than the [REDACTED].

The initial price to the public of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence trading on the Hong Kong Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when trading begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

Future sales or perceived sales of a substantial number of our Shares in the public market following the [REDACTED] could materially and adversely affect 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 public market 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 new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the public market 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 offerings. 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].

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future, including pursuant to the share incentive schemes.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net

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tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time. Furthermore, we may issue Shares pursuant to the share incentive schemes, which would further dilute Shareholders’ interests in our Company.

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

Immediately following the [REDACTED], our Controlling Shareholders will hold in aggregate approximately [REDACTED]% of our Shares, assuming the [REDACTED] is not exercised. Our Controlling Shareholders will, through their voting power at the Shareholders’ meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our Shares for a return on your investment.

We intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline product candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] 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 declares and pays dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [REDACTED] 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 purchased the Shares. You may not realize a return on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

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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. We plan to use the net [REDACTED] from the [REDACTED] to fund:

- ongoing and planned R&D and commercialization of our most promising product candidates,
- the expansion of our product portfolio through internal research and/or potential acquisitions, and
- general working capital.

For details, see “Future Plans and Use of [REDACTED] – Use of [REDACTED].”

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].

We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Companies Law and common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, 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 established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law” in this document.

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Controlling Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

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Facts, forecasts and statistics in this document relating to the interventional pulmonology medical device industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the interventional pulmonology medical device industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED], the Joint Sponsors, the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the interventional pulmonology medical device industry in and outside China may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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 [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information.

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your [REDACTED] 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 [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] 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].

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In preparation for the [REDACTED], we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemptions from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the Company must appoint a company secretary who possesses the necessary academic or professional qualifications or relevant experience is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. Note 1 to Rule 3.28 of the Listing Rules provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Institute of Chartered Secretaries;
- (b) a solicitor or a barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

Note 2 to Rule 3.28 of the Listing Rules further sets out the factors that the Stock Exchange will consider in assessing an individual’s “relevant experience”:

- (a) length of employment with the issuer and other issuers and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

We have principal business activities primarily outside Hong Kong. Our Company is established under the laws of the Cayman Islands and a significant part of our business operations are conducted in the PRC and the United States. All Directors and members of the senior management of the Company who are familiar with its activities and have extensive experience in board and corporate management matters presently do not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules.

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We have therefore appointed Mr. Wen Hao Wang and Mr. Leong Yin Lee as our joint company secretaries. Although Mr. Wen Hao Wang does not possess the qualifications set out in Rule 3.28 of the Listing Rules, we would like to appoint him as a joint company secretary due to his past management experience and work experience in the United States. See the section headed “Directors and Senior Management” in this document for further information regarding the qualifications and experience of Mr. Wen Hao Wang and Mr. Leong Yin Lee.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules in relation to the appointment of Mr. Wen Hao Wang as our joint company secretary. Pursuant to the Guidance Letter HKEX-GL108-20, the waiver will be for a period of three years (“**Waiver Period**”) and on the following conditions: (i) the proposed company secretary must be assisted by a person who possesses the qualifications or experience as required under Rule 3.28 of the Listing Rules (“**Qualified Person**”) and is appointed as a joint company secretary throughout the Waiver Period; and (ii) the waiver can be revoked if there are material breaches of the Listing Rules by the issuer. In order to provide support to Mr. Wen Hao Wang, we have appointed Mr. Leong Yin Lee, an associate member of the Hong Kong Institute of Chartered Secretaries and The Chartered Governance Institute, who is a Qualified Person, as a joint company secretary to provide assistance to Mr. Wen Hao Wang, for a three-year period from the [REDACTED] so as to enable him to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge his duties. If and when Mr. Leong Yin Lee ceases to be a joint company secretary before the end of the three-year period, the Company will appoint another Qualified Person as a replacement.

Such waiver will be revoked immediately if and when Mr. Leong Yin Lee ceases to be a joint company secretary or ceases to provide such assistance, and can also be revoked if there are material breaches of the Listing Rules by our Company. We will liaise with the Stock Exchange before the end of the three-year period to enable it to assess whether Mr. Wen Hao Wang, having had the benefit of Mr. Leong Yin Lee’s and, if applicable, another Qualified Person’s assistance for three years, will have acquired relevant experience within the meaning of Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

WAIVER IN RELATION TO MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 of the Listing Rules, an issuer must have sufficient management presence in Hong Kong. This normally means that at least two of its executive directors must be ordinarily resident in Hong Kong.

We do not have sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules. Our Group’s management, business operations and assets are primarily based outside Hong Kong. The headquarters and business operations of our Group are primarily based, managed and conducted in the PRC and the U.S., respectively. Currently, the executive Directors of our Company ordinarily reside in

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the PRC. The senior management team of our Company is primarily based in the PRC and the U.S. and they manage our Group’s business operations from the PRC and the U.S.. Historically, the Directors of our Company typically met in the PRC. As the executive Directors and the senior management team play very important roles in our Company’s business operations, our Company considers that it is in the best interests of our Company for the executive Directors and the senior management team to be based in the places where the Group has significant operations. As such, our Company does not, and will not for the foreseeable future, have a sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. We will ensure that there is an effective channel of communication between us and the Stock Exchange by way of the following arrangements:

- (a) pursuant to Rule 3.05 of the Listing Rules, we have appointed and will continue to maintain two authorized representatives, namely Mr. Michael Yi Wei Zhao, our non-executive Director and chairman of our Board and Mr. Leong Yin Lee (李亮賢), our joint company secretary, to be the principal communication channel at all times between the Stock Exchange and our Company. Each of our authorized representatives will be readily contactable by the Stock Exchange based on information provided to the Stock Exchange for the contact details of the authorized representatives. Both of our authorized representatives are authorized to communicate on our behalf with the Stock Exchange;
- (b) we will implement a policy to provide the contact details of each Director (such as mobile phone numbers, office phone numbers and email addresses) to each of the authorized representatives, to their alternate representative and to the Stock Exchange. This will ensure that each of the authorized representatives, the alternate representative and the Stock Exchange will have the means to contact all the Directors (including the independent non-executive Directors) promptly as and when required, including means to communicate with the Directors when they are travelling;
- (c) we will ensure that all Directors who are not ordinarily resident in Hong Kong have valid travel documents to visit Hong Kong and will be able to come to Hong Kong to meet with the Stock Exchange within a reasonable period of time when required;
- (d) we have retained the services of the Compliance Adviser, in accordance with Rule 3A.19 of the Listing Rules. The Compliance Adviser, among other things, will serve as an additional channel of communication in addition to the authorized representatives of our Company. The Compliance Adviser will provide our Company with professional advice on ongoing compliance with the Listing Rules and will be available to respond to enquiries from the Stock Exchange. We will ensure that the Compliance Adviser has prompt access to our Company’s authorized representatives

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and Directors who will provide to the Compliance Adviser such information and assistance as the Compliance Adviser may need or may reasonably request in connection with the performance of the Compliance Adviser’s duties. The Compliance Adviser will also provide advice in compliance with Rule 3A.23 of the Listing Rules; and

- (e) meetings between the Stock Exchange and the Directors could be arranged through the authorized representatives or the Compliance Adviser, or directly with the Directors within a reasonable time frame. Our Company will inform the Stock Exchange as soon as practicable in respect of any change in the authorized representatives and/or the Compliance Adviser in accordance with the Listing Rules.

EXEMPTION IN RELATION TO FINANCIAL STATEMENTS IN THIS DOCUMENT

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all documents to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance (the “**Third Schedule**”), and set out the reports specified in Part II of the Third Schedule.

Paragraph 27 of Part I of the Third Schedule requires a company to include in its document a statement as to the gross trading income or sales turnover (as the case may be) of the company during each of the three financial years immediately preceding the issue of the document, including an explanation of the method used for the computation of such income or turnover and a reasonable breakdown between the more important trading activities.

Paragraph 31 of Part II of the Third Schedule further requires a company to include in its document a report by the auditors of the company with respect to (i) the profits and losses of the company for each of three financial years immediately preceding the issue of the document and (ii) the assets and liabilities of the company of each of the three financial years immediately preceding the issue of the document.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or would otherwise be unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the listing document be included in the Accountants’ Report to this document.

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According to Rule 18A.06 of the Listing Rules, an eligible biotech company shall comply with Rule 4.04 modified so that references to “three financial years” or “three years” in that rule shall instead reference to “two financial years” or “two years”, as the case may be. Our Company is a Biotech Company as defined under Chapter 18A of the Listing Rules and is seeking a [REDACTED] under Chapter 18A. Rule 18A.03(3) of the Listing Rules requires that a Biotech Company must have been in operation in its current line of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules requires that a Biotech Company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 shall instead be references to “two financial years” or “two years”, as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the [REDACTED] document.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants’ Report of our Company set out in Appendix I to this document is currently prepared to cover the financial years ended December 31, 2019 and 2020.

As such, the Joint Sponsors have applied, on behalf of our Company, to the SFC for a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule regarding the inclusion of the accountants’ report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) our Company is primarily engaged in the research and development, manufacturing and commercialization of medical devices, and falls within the scope of Biotech Company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;
- (b) as of the Latest Practicable Date, we have commercialized one of our Core Products, InterVapor. Major financing activities conducted by us since our incorporation include our [REDACTED] Investments, the details of which have been fully disclosed in the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this document;
- (c) the Accountants’ Report for each of the financial years ended December 31, 2019 and 2020 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;

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- (d) notwithstanding that the financial results set out in this document are only for the financial years ended December 31, 2019 and 2020 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements. Therefore, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule would be unduly burdensome as this would require additional work to be performed by our Company and the reporting accountant; and
- (e) the Accountants' Report covering the financial years ended December 31, 2019 and 2020 (as set out in Appendix I to this document), together with other disclosures in this document, have already provided adequate and reasonable up-to-date information in the circumstances for the potential [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects and to form a view on the track record of our Company. Therefore, the exemption would not prejudice the interest of the [REDACTED] public.

The SFC [has granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting the Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule on the condition [that particulars of the exemption are set out in this document and that this document will be issued on or before [●], 2021].

[REDACTED]

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

[REDACTED]

WAIVER AND EXEMPTION IN RELATION TO THE SHARE OPTION PLAN

Rule 17.02(1)(b) of the Listing Rules requires a listing applicant to, inter alia, disclose in the document full details of all outstanding options and their potential dilution effect on the shareholdings upon [REDACTED] as well as the impact on the earnings per share arising from the exercise of such outstanding options.

Paragraph 27 of Appendix 1A to the Listing Rules requires a listing applicant to disclose, inter alia, 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 grantee, or an appropriate negative statement, provided that where options have been granted or agreed to be granted to all the members or debenture holders or to any class thereof, or to employees under a share option scheme, it shall be sufficient, so far as the names and addresses are concerned, to record that fact without giving the names and addresses of the grantees.

Under section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the document must state the matters specified in Part I of the Third Schedule.

Under paragraph 10 of Part I of the Third Schedule, the number, description and amount of any shares in or debentures of the company which any person has, or is entitled to be given, an option to subscribe for, together with the particulars of the option, that is to say, (a) the period during which it is exercisable; (b) the price to be paid for shares or debentures subscribed for under it; (c) the consideration (if any) given or to be given for it or for the right to it; and (d) the names and addresses of the persons to whom it or the right to it was given or, if given to existing shareholders or debenture holders as such, the relevant shares or debentures must be specified in the document.

As of the Latest Practicable Date, the Company plans to grant share options to 31 grantees, including a member of the senior management and 30 other employees (including former employees) of our Group (who were granted options to subscribe for [●] Shares and [●] Shares respectively), to subscribe for an aggregate of 3,170,566 Shares.

We have applied to (i) the Stock Exchange for a waiver from strict compliance with the requirements under Rule 17.02(1)(b) of the Listing Rules and paragraph 27 of Appendix 1A to the Listing Rules and (ii) the SFC for an exemption from strict compliance with paragraph

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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10(d) of Part I of the Third Schedule pursuant to section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in connection with the disclosure of certain details relating to the share options and certain grantees in this document on the ground that the waiver and the exemption will not prejudice the interest of the [REDACTED] public and strict compliance with the above requirements would be unduly burdensome for our Company for the following reasons:

- (a) our Directors consider that it would be unduly burdensome to disclose in the document full details of all the share options granted by the Company to each of the grantees, who are all based in the United States, which would significantly increase the cost and time required for information compilation and document preparation and create additional legal and compliance implications for strict compliance with such disclosure requirements;
- (b) material information on the share options has been disclosed in the document to provide prospective [REDACTED] with sufficient information to make an informed assessment of the potential dilutive effect and impact on earnings per Share of the share options in making their [REDACTED] decision, and such information includes:
 - (i) a summary of the terms of the Share Option Plan;
 - (ii) the aggregate number of Shares subject to the share options and the percentage of the Shares of which such number represents;
 - (iii) the dilutive effect and the impact on earnings per Share upon full exercise of the share options immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised);
 - (iv) full details of the share options granted to the members of the senior management are disclosed in the document, and such details include all the particulars required under Rule 17.02(1)(b) of the Listing Rules, paragraph 27 of Appendix 1A to the Listing Rules and paragraph 10 of Part 1 of the Third Schedule;
 - (v) with respect to the share options granted by the Company under the Share Option Plan to employees, other than those referred to in subparagraph
 - (iv) above, details including the aggregate number of such grantees and the number of Shares subject to the share options, the consideration paid for the grant of the share options and the exercise period and the exercise price for the share options; and
 - (vi) should the Stock Exchange and the SFC grant a waiver and exemption, the particulars of the waiver and exemption, respectively;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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and the above disclosure is consistent with the conditions ordinarily expected by the Stock Exchange in similar circumstances as set out in Guidance Letter HKEx-GL11-09 issued in July 2009 and updated in March 2014 by the Stock Exchange;

- (c) with respect to the 30 other employees (including former employees) to whom the Company plans to grant share options under the Share Option Plan to acquire an aggregate of [●] Shares, such number of Shares (representing only approximately [REDACTED] of the total issued share capital of the Company immediately following the completion of the [REDACTED], assuming the [REDACTED] is not exercised) is not material in the circumstances of the Company, and the exercise in full of such share options will not cause any material adverse change in the financial position of the Company;
- (d) our Directors consider that non-compliance with the above disclosure requirements would not prevent the Company from providing potential [REDACTED] with sufficient information for an informed assessment of the activities, assets, liabilities, financial position, management and prospects of the Group; and
- (e) a full list of all the grantees containing all details (except for the addresses of the grantees) as required under Rule 17.02(1)(b) of the Listing Rules, paragraph 27 of Appendix 1A to the Listing Rules and paragraph 10 of Part I of the Third Schedule will be made available for public inspection in accordance with the section headed “Documents Delivered to the Registrar of Companies and Available for Inspection – Documents Available for Inspection” in Appendix V to this document.

The Stock Exchange [has granted] us a waiver from strict compliance with the relevant requirements under the Listing Rules subject to the conditions that disclosure in respect of the information referred to in paragraph (c) above has been made in this document.

The SFC has granted us a 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) of Part I of the Third Schedule, subject to the conditions that:

- (a) full details of the share options granted to the Directors (if any), members of the senior management and other connected persons of the Company be disclosed in the document, and such details include all the particulars required under paragraph 10 of Part 1 of the Third Schedule;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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- (b) with respect to the share options granted by the Company under the Share Option Plan to employees, other than those referred to in (a) above, the following details, including (i) the aggregate number of such grantees and the number of Shares subject to the share options; (ii) the consideration paid for the grant of the share options; and (iii) the exercise period and the exercise price for the share options be disclosed in this document;
- (c) a full list of all the grantees (including the persons referred to in sub-paragraph (a) above) who have been granted share options to acquire Shares under the Share Option Plan, containing all the details as required under paragraph 10 of Part 1 of the Third Schedule (except for the addresses of the grantees), be made available for public inspection in accordance with the section headed “Documents Delivered to the Registrar of Companies and Available for Inspection – Documents Available for Inspection” in Appendix V to this document; and
- (d) the particulars of the exemption be set forth in this document and that this document will be issued on or before [●], 2021.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
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Executive Directors

Guowei Zhan (湛國威)	Room T4-1403, 622 Tianhe Beilu, Tianhe District, Guangzhou, Guangdong, China	Chinese
Hong Xu (徐宏)	1-2-501, Ruili Dongfang Huacheng, 42 Bin'an Road, Binjiang District, Hangzhou, Zhejiang, China	Chinese

Non-executive Directors

Michael Yi Wei Zhao	Room 2412, World Trade Building, 2299 Yanan West Road, Changning District, Shanghai	Canadian
Zhenjun Zi (訾振軍)	19 Lingshan Road, Xukou, Wuzhong district, Suzhou, Jiangsu, 215164, China	Chinese
Ao Zhang (張奧)	Room 1504, Block A, Building No. 1, Furun Jiayuan, Xueyuan Road 6, Haidian District, Beijing, China	Chinese

Independent Non-executive Directors

Pok Man Kam (甘博文)	Flat B, 7/F, Tower 1, Marina South, 8 Ap Lei Chau Drive, Hong Kong	Chinese Hong Kong
Joseph Wan Yee Lau (劉允怡)	Flat LG201 (Master's Quarters), North Blk, Lee Woo Sing College, The Chinese University of Hong Kong, Hong Kong	Chinese Hong Kong
Jian Ji (計劍)	Room 401, Unit 1, Block 24, Gangwan Jiayuan, Xihu district, Hangzhou, China	Chinese

Please refer to the section headed “Directors and Senior Management” in this document for further information with respect to our Directors.

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Goldman Sachs (Asia) L.L.C.

68/F, Cheung Kong Center
2 Queen’s Road Central
Hong Kong

Haitong International Capital Limited

8/F, Li Po Chun Chambers
189 Des Voeux Rd Central
Hong Kong

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisers to our Company

As to Hong Kong law and United States law:

Davis Polk & Wardwell

18/F, The Hong Kong Club Building
3A Chater Road
Hong Kong

As to PRC law:

King & Wood Mallesons

28th Floor, China Resources
Tower, 2666 Keyuan South Road
Nanshan District
Shenzhen, Guangdong
PRC

As to Cayman Islands law:

Maples and Calder (Hong Kong) LLP

26th Floor, Central Plaza
18 Harbour Road
Wanchai
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

**Legal Advisers to the Joint Sponsors
and the [REDACTED]**

*As to Hong Kong law and United States
law:*

Sullivan & Cromwell (Hong Kong) LLP
20th Floor, Alexandra House
18 Chater Road, Central
Hong Kong

Dentons Hong Kong LLP
Suite 3201, Jardine House
1 Connaught Place
Hong Kong

As to PRC law:

Han Kun Law Offices
20/F, Kerry Plaza Tower 3
1-1 Zhongxinsi Road
Futian District
Shenzhen, Guangdong
PRC

Auditor and Reporting Accountant

Ernst & Young
Certified Public Accountants
Registered Public Interest Entity Auditor
22/F, CITIC Tower B
1 Tim Mei Avenue
Central
Hong Kong

Industry Consultant

Frost & Sullivan International Limited
1706, One Exchange Square
8 Connaught Place
Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Registered Office	PO Box 309, Ugland House Grand Cayman, KY1-1104 Cayman Islands
Head office and Principal Place of Business in China	Room 317, 3/F, Building 2 No. 88 Jiangling Road Xixing Street, Binjiang District Hangzhou China
Principal Place of Business in Hong Kong	40th Floor, Dah Sing Financial Centre No. 248 Queen’s Road East Wanchai Hong Kong
Company’s Website	<u>www.broncus.com</u> <i>(The information contained in this website does not form part of this document)</i>
Joint Company Secretaries	Mr. Wen Hao Wang (王文豪) Room 2403, 3/F, World Trend Mall No. 2299 West Yan’an Road Shanghai, China Mr. Leong Yin Lee (李亮賢) (ACS, ACG) 40th Floor, Dah Sing Financial Centre No. 248 Queen’s Road East Wanchai Hong Kong
Audit Committee	Dr. Pok Man Kam (<i>Chairman</i>) Professor Joseph Wan Yee Lau Dr. Jian Ji
Remuneration Committee	Mr. Michael Yi Wei Zhao (<i>Chairman</i>) Dr. Jian Ji Dr. Pok Man Kam
Nomination Committee	Mr. Michael Yi Wei Zhao (<i>Chairman</i>) Professor Joseph Wan Yee Lau Dr. Jian Ji

CORPORATE INFORMATION

Authorized Representatives

Mr. Michael Yi Wei Zhao
Room 2412, World Trade Building
2299 Yanan West Road
Changning District
Shanghai

Mr. Leong Yin Lee (李亮賢)
40th Floor, Dah Sing Financial Centre
No. 248 Queen’s Road East
Wanchai
Hong Kong

Compliance Adviser

Red Solar Capital Limited
Unit 402B, 4/F
China Insurance Group Building
No. 141 Des Voeux Road Central
Central
Hong Kong

[REDACTED]

Principal Banks

China Citic Bank
Hu Shu Road South Sub-Branch
Hang Zhou

Silicon Valley Bank
3003 Tasman Drive
Santa Clara, CA 95054
USA

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OVERVIEW

We are a pioneer in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Leveraging our whole lung access navigation technology and encompassing navigation, diagnosis and treatment, our integrated interventional pulmonology platform addresses the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases.

In preparation for the [REDACTED], we conducted the Reorganization, details of which are set out in the sub-section headed “Reorganization” in this section.

OUR BUSINESS MILESTONES

The following sets forth certain key business development milestones of our Group:

Year	Milestone
<i>April 2012</i>	Our Company was incorporated.
<i>May 2012</i>	Broncus Medical was established in the U.S. and acquired assets from Broncus Technology, Inc. pursuant to an asset purchase agreement.
<i>February 2014</i>	Archimedes was approved for marketing in the U.S.
<i>February 2016</i>	Broncus Hangzhou was established in the PRC to build a global R&D and operation center.
<i>July 2016</i>	Uptake Medical was established in the U.S.
<i>July 2016</i>	Our Company, through Uptake Medical, acquired certain assets from Uptake Medical Corporation including InterVapor.
<i>January 2018</i>	InterVapor for COPD received CE Marking Certification.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Year	Milestone
<i>March 2018</i>	Our series A financing was fully settled which in aggregate raised approximately US\$22,318,944, of which US\$15,000,000 was received in cash with the balance being the principal and interest of convertible bonds issued by our Company.
<i>January 2019</i>	Bronchoscopic Thermal Vapor Ablation (BTVA) treatment included in the Global Initiative for Chronic Obstructive Lung Disease (“GOLD”) 2019 Report.
<i>February 2019</i>	Empower RF Ablation catheter received FDA approval.
<i>March 2019</i>	Empower RF Ablation catheter received CE marking Certification.
<i>July 2019</i>	Our series B financing was fully settled which in aggregate raised approximately US\$29,125,003.
<i>February and May 2020</i>	InterVapor for COPD was approved by the NMPA to be eligible for expedited registration review.
<i>May 2020</i>	InterVapor for COPD completed the NMPA’s expert panel review.
<i>June 2020</i>	BioStarNeedle completed registration with the ZheJiang Medical Products Administration.
<i>July 2020</i>	Steerable sheath completed registration with the ZheJiang Medical Products Administration.
<i>October 2020</i>	Our series C financing was fully settled which in aggregate raised approximately US\$37,620,430.
<i>December 2020</i>	First-in-Man trial of RF-II was completed. The West China Hospital trial of InterVapor for COPD was completed.
<i>January 2021</i>	Our series D financing was fully settled which in aggregate raised approximately US\$39,999,986.
<i>January 2021</i>	Confirmatory clinical trial of RF-II was commenced.
<i>January 2021</i>	Clinical trial of H-marker was completed.
<i>March 2021</i>	Clinical data from VAPORIZE trial of BTVA for localized cancer lesions of the lung was published in Respiration.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OUR MAJOR SUBSIDIARIES AND OPERATING ENTITIES

The principal business activities and the dates of incorporation and commencement of business of our major subsidiaries most relevant to the core operations of our Group during the Track Record Period are shown below. Such major subsidiaries had accounted for 10% or more of either of our Group’s total assets or revenue during the Track Record Period:

<u>Name of major subsidiary</u>	<u>Place of incorporation</u>	<u>Date of incorporation and commencement of business</u>	<u>Principal business activities</u>
Broncus Medical	U.S.	May 7, 2012	Research, development and commercialisation of medical devices and consumables
Broncus Hangzhou	PRC	February 24, 2016	Research, development and commercialisation of medical devices and consumables
Uptake Medical	U.S.	July 19, 2016	Research, development and commercialisation of medical devices and consumables

MAJOR SHAREHOLDING CHANGES OF OUR COMPANY AND OUR MAJOR SUBSIDIARIES

Shareholding Changes of our Company

1. Establishment of Our Company

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on April 30, 2012 as the holding company of our Group. After incorporation, our Company underwent its first increase of share capital on May 8, 2012 and a series of share subscription such that as of June 19, 2012, our Company was owned by Dinova Broncus Limited as to 60% and by LifeTech Scientific (Hong Kong) Co., Ltd. as to 40%.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding structure of our Company immediately before the Series A financing in 2018 was as follows:

Shareholder	Number of Shares	Ownership percentage of our Company (%)
Shanghai Biomedical Enterprise Incubator Limited ⁽¹⁾	7,385,879	13.20
Tip-Broncus Limited ⁽¹⁾	3,692,939	6.60
ACL ⁽²⁾	34,475,372	61.62
DNA ⁽³⁾	10,390,480	18.57
Total	55,944,670	100.0

Notes:

1. Dinova Broncus Limited transferred the Shares of our Company to its shareholders, Shanghai Biomedical Enterprise Incubator Limited and TIP-Broncus Limited, respectively, in February 2014.
2. ACL became a Shareholder of our Company in May 2014 upon conversion of convertible bonds issued by Broncus Medical for Shares of our Company. Subsequently, LifeTech Scientific (Hong Kong) Co., Ltd. transferred Shares it held in our Company to ACL and ceased to be a Shareholder of our Company.
3. DNA became a Shareholder of our Company in October 2016 upon conversion of convertible bonds issued by our Company into Shares of our Company.

2. Major Shareholding Changes During the Track Record Period

For details of the major shareholding changes of our Company during the Track Record Period, please see the subsection headed “[REDACTED] Investments” and “Reorganization” in this section below.

Shareholding Changes of Our Major Subsidiaries

For details of the shareholding changes in our major subsidiaries, see the section headed “Statutory and General Information – A. Further Information about our Group – 3. Changes in the Share Capital of our Subsidiaries” in Appendix IV to this document.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

MAJOR ACQUISITIONS, DISPOSALS AND MERGERS

On July 20, 2016, Uptake Medical entered into an asset purchase agreement with Uptake Medical Corporation, an Independent Third Party, pursuant to which Uptake Medical agreed to purchase certain assets of Uptake Medical Corporation in connection with the treatment of emphysema and lung cancer for a total consideration of US\$9,000,000. These assets include all equipment, inventories and intellectual properties (including patents, trademarks and copyrights) in relation to InterVapor, one of our Core Products. The consideration was determined by arms’ length negotiations between the parties in good faith. Our Company has satisfied the consideration payable for the acquisition in cash, which was legally and properly settled on July 22, 2016.

Our Directors consider the terms of the asset purchase agreement are on normal commercial terms, and fair and reasonable, and the acquisition is in the interest of our Company and Shareholders as a whole. Our Directors confirm that the acquisition has been properly and legally completed and all applicable regulatory approval or CE Marking certification have been obtained. To the best knowledge, information and belief of our Directors after having made all reasonable enquiries, Uptake Medical Corporation and its ultimate beneficial owner(s) are Independent Third Parties.

We did not conduct any acquisitions, disposals or mergers during the Track Record Period.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

[REDACTED] INVESTMENTS

1. Series A Financing

On March 2, 2018, our Company entered into the Series A Share Subscription Agreement with the Series A Preferred Shareholders set out in the table below, pursuant to which, each Series A Preferred Shareholder agreed to subscribe for and purchase, and our Company agreed to issue and sell to such Series A Preferred Shareholder, the number of Series A Preferred Shares set forth in the below table for the aggregate purchase price as consideration set forth opposite such Series A Preferred Shareholder’s name:

<u>Name of Investor</u>	<u>Number of Series A Preferred Shares</u>	<u>Aggregate Purchase Price</u> (US\$)
Intuitive Surgical Operations, Inc. ⁽¹⁾	5,834,473	15,000,000.00
ACL ⁽²⁾	1,595,316	1,324,112.93
DNA ⁽²⁾	7,222,686	5,994,831.13
Total	14,652,475	22,318,944.06

Notes:

- Intuitive Surgical Operations, Inc. subscribed Series A Preferred Shares at the price of US\$2.57 per Series A Preferred Share.
- ACL and DNA received their respective Series A Preferred Shares pursuant to the conversion of convertible bonds issued by our Company at the conversion price of US\$0.83 per Series A Preferred Share.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

2. Series B Financing

On April 17, 2018, our Company entered into the Series B Share Purchase Agreement with the Series B Preferred Shareholders set out in the table below, pursuant to which, each Series B Preferred Shareholder agreed to subscribe for and purchase, and our Company agreed to issue and sell to such Series B Preferred Shareholder, the number of Series B Preferred Shares set forth in the table below for the aggregate purchase price as consideration set forth opposite such Series B Preferred Shareholder’s name:

Name of Investor	Number of Series B Preferred Shares	Aggregate Purchase Price (US\$)
Gain Yield Holdings Limited	1,641,794	5,000,001.54
Genius Life Investment I Limited	1,641,794	5,000,001.54
Hangzhou Hua Que Investment L.P. (杭州華鵲投資合夥企業(有限合夥)) ⁽¹⁾	1,970,152	5,999,999.41
Hangzhou Yun Zhong Zi Investment L.P. (杭州雲中子投資合夥企業(有限合夥)) ⁽¹⁾	1,641,794	5,000,001.54
Suzhou Bondshine Ying Xin Venture Investment LLP. (蘇州邦盛贏新創業投資企業(有限合夥))	985,076	2,999,999.70
Hangzhou Lu Shu Investment L.P. (杭州鹿蜀投資合夥企業(有限合夥)) ⁽¹⁾	656,717	1,999,998.79
Hangzhou Pu Hua Rui Kun Venture Investment L.P. (杭州普華銳昆創業投資合夥企業(有限合夥))	1,026,121	3,125,000.20
Total	9,563,448	29,125,002.72

Note:

- On May 17, 2019, Hangzhou Hua Que Investment L.P. (杭州華鵲投資合夥企業(有限合夥)), Hangzhou Yun Zhong Zi Investment L.P. (杭州雲中子投資合夥企業(有限合夥)) and Hangzhou Lu Shu Investment L.P. (杭州鹿蜀投資合夥企業(有限合夥)) each transferred all of their Series B Preferred Shares to their respective subsidiaries, Hongkong Chinamagpie Limited, Cloud Neutron (Hongkong) Limited and Lushu (Hong Kong) Limited. Upon completion of such share transfers, Hangzhou Hua Que Investment L.P. (杭州華鵲投資合夥企業(有限合夥)), Hangzhou Yun Zhong Zi Investment L.P. (杭州雲中子投資合夥企業(有限合夥)) and Hangzhou Lu Shu Investment L.P. (杭州鹿蜀投資合夥企業(有限合夥)) ceased to be Shareholders of our Company.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

3. Series C Financing

On August 17, 2020, our Company entered into the Series C Share Purchase Agreement with the Series C Preferred Shareholders set out in the table below, pursuant to which, each Series C Preferred Shareholder agreed to subscribe for and purchase, and our Company agreed to issue and sell to such Series C Preferred Shareholder, the number of Series C Preferred Shares set forth in the table below for the aggregate purchase price as consideration set forth opposite such Series C Preferred Shareholder’s name:

Name of Shareholder	Number of Series C Preferred Shares	Aggregate Purchase Price (US\$)
LBC Sunshine Healthcare Fund L.P.	4,684,706	18,000,000.00
ACM 01 Limited	1,301,307	5,000,000.00
BC Mars L.P.	2,342,353	9,000,000.00
Silver Pearl Limited	161,474	620,430.00
CNCB CAPITAL VALUE SPC ⁽¹⁾	1,301,307	5,000,000.00
Total	9,791,147	37,620,430.00

Note:

- The full name shown in the Company’s register of members is “CNCB CAPITAL VALUE SPC – CNCB Capital Energy Investment Fund SP” which is referred to as “CNCB CAPITAL VALUE SPC” for short in this section.

4. Series D Financing

On January 7, 2021, our Company entered into the Series D Share Purchase Agreement with the Series D Preferred Shareholders set out in the table below, pursuant to which, each Series D Preferred Shareholder agreed to subscribe for and purchase, and our Company agreed to issue and sell to such Series D Preferred Shareholder, the number of Series D Preferred Shares set forth in the below table for the aggregate purchase price as consideration set forth opposite such Series D Preferred Shareholder’s name:

Name of Shareholder	Number of Series D Preferred Shares	Aggregate Purchase Price (US\$)
Elegant Holding Limited	5,309,619	34,999,999.63
Strong Leap Holdings Limited	303,406	1,999,994.71
Valliance Emerging Opportunities Limited Partnership Fund	303,406	1,999,994.71
Emerging Markets Healthcare Partners LLC	151,703	999,997.36
Total	6,068,134	39,999,986.41

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

5. Capitalization of our Company

The below table is a summary of the capitalization of the Company:

Shareholder	As at the Latest Practicable Date ⁽¹⁾				As at the [REDACTED] ⁽²⁾	
	Ordinary Shares	Series A Preferred Shares		Series B Preferred Shares		Aggregate ownership percentage
		Preferred Shares	Shares	Preferred Shares	Shares	
BRS Biomedical Limited ⁽³⁾	3,660,897	–	–	–	–	[REDACTED] [REDACTED]%
Huzhou Zhebei Health Production Investment Partnership (Limited Partnership) (湖州浙貝健康產業投資合夥企業(有限合夥)) ⁽⁴⁾	2,122,839	–	–	–	–	[REDACTED] [REDACTED]%
BBL	10,935,494	–	–	–	–	[REDACTED] [REDACTED]%
QM12 ⁽⁵⁾	18,757,886	1,595,316	–	–	–	[REDACTED] [REDACTED]%
Adventure 01 Limited	2,655,169	–	–	–	–	[REDACTED] [REDACTED]%
Prime State Ventures Limited	780,900	–	–	–	–	[REDACTED] [REDACTED]%
NBL Holding Group Limited	473,969	–	–	–	–	[REDACTED] [REDACTED]%
Rocky Ventures Ltd	383,576	–	–	–	–	[REDACTED] [REDACTED]%
Xu Han	280,803	–	–	–	–	[REDACTED] [REDACTED]%
Velocity Zero Limited ⁽⁶⁾	1,602,143	–	–	–	–	[REDACTED] [REDACTED]%
Ideal Fund SPC	780,784	–	–	–	–	[REDACTED] [REDACTED]%
Proteligen Group Limited	351,353	–	–	–	–	[REDACTED] [REDACTED]%
Banyan Capital Investment Holdings Limited	390,392	–	–	–	–	[REDACTED] [REDACTED]%
Great Takley International Co., Limited	390,392	–	–	–	–	[REDACTED] [REDACTED]%
St. Christopher Investment Ltd. ⁽⁷⁾	1,017,219	782,162	–	–	–	[REDACTED] [REDACTED]%
Yuan Management Ltd.	241,227	3,701	–	–	–	[REDACTED] [REDACTED]%

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Shareholder	As at the Latest Practicable Date ⁽¹⁾					As at the [REDACTED] ⁽²⁾	
	Ordinary Shares	Series A Preferred Shares		Series B Preferred Shares		Series D Preferred Shares	Aggregate ownership percentage
		Preferred Shares	Shares	Preferred Shares	Shares		
Dinova Healthcare Delta Fund (USD) L.P.	2,309,619	905,762	–	–	–	–	[REDACTED] 3.35% [REDACTED]
Dinova Healthcare (Hong Kong) Co., Limited	6,239,960	2,038,228	–	–	–	–	[REDACTED] 8.62% [REDACTED]
Sloan Investment Company Limited	601,775	611,576	–	–	–	–	[REDACTED] 1.26% [REDACTED]
Xin Nuo Tong Investment Limited ⁽⁸⁾	565,629	744,193	–	–	–	–	[REDACTED] 1.36% [REDACTED]
Intuitive Surgical Operations, Inc.	–	5,834,473	–	–	–	–	[REDACTED] 6.08% [REDACTED]
Dinova Venture Partners GP III, L.P.	–	865,002	–	–	–	–	[REDACTED] 0.90% [REDACTED]
Dinova Venture Partners GP IV, L.P.	–	409,017	–	–	–	–	[REDACTED] 0.43% [REDACTED]
Wang Qi	–	616,461	–	–	–	–	[REDACTED] 0.64% [REDACTED]
Flourishing Forest Limited	–	246,584	–	–	–	–	[REDACTED] 0.26% [REDACTED]
Gain Yield Holdings Limited	–	–	1,641,794	–	–	–	[REDACTED] 1.71% [REDACTED]
Genius Life Investment I Limited	–	–	1,641,794	–	–	–	[REDACTED] 1.71% [REDACTED]
Hongkong Chinamagpie Limited	–	–	1,970,152	–	–	–	[REDACTED] 2.05% [REDACTED]
Cloud Neutron (Hongkong) Limited	–	–	1,641,794	–	–	–	[REDACTED] 1.71% [REDACTED]
Hangzhou Pu Hua Rui Kun Venture Investment L.P. (杭州普華銳昆創業投資合夥企業(有限合夥))	–	–	1,026,121	–	–	–	[REDACTED] 1.07% [REDACTED]
Suzhou Bondshine Ying Xin Venture Investment LLP (蘇州邦盛贏新創業投資企業(有限合夥))	–	–	985,076	–	–	–	[REDACTED] 1.03% [REDACTED]
Lushu (Hong Kong) Limited	–	–	656,717	–	–	–	[REDACTED] 0.68% [REDACTED]
LBC Sunshine Healthcare Fund L.P.	–	–	–	4,684,706	–	–	[REDACTED] 4.88% [REDACTED]
ACM 01 Limited	–	–	–	1,301,307	–	–	[REDACTED] 1.36% [REDACTED]

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Shareholder	As at the Latest Practicable Date ⁽¹⁾					As at the [REDACTED] ⁽²⁾	
	Ordinary Shares	Series A Preferred Shares	Series B Preferred Shares	Series C Preferred Shares	Series D Preferred Shares	Aggregate ownership percentage	Aggregate number of Shares Ownership percentage
Silver Pearl Limited	–	–	–	161,474	–	0.17%	[REDACTED] [REDACTED]%
BC Mars L.P.	–	–	–	2,342,353	–	2.44%	[REDACTED] [REDACTED]%
CNCB CAPITAL VALUE SPC	–	–	–	1,301,307	–	1.36%	[REDACTED] [REDACTED]%
Elegant Holding Limited	–	–	–	–	5,309,619	5.53%	[REDACTED] [REDACTED]%
Emerging Markets Healthcare Partners LLC	–	–	–	–	151,703	0.16%	[REDACTED] [REDACTED]%
Valliance Emerging Opportunities Limited Partnership Fund	–	–	–	–	303,406	0.32%	[REDACTED] [REDACTED]%
Strong Leap Holdings Limited ⁽⁵⁾	1,402,644	–	–	–	303,406	1.78%	[REDACTED] [REDACTED]%
Investors taking part in the [REDACTED]	–	–	–	–	–	–	[REDACTED] [REDACTED]%
Total	55,944,670	14,652,475	9,563,448	9,791,147	6,068,134	100.0	[REDACTED] 100.0

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Notes:

1. Based on the assumption that the conversion of the Preferred Shares into Shares of our Company becomes unconditional. All Preferred Shares will automatically be converted into Shares on a [one-to-one] basis on the [REDACTED].
2. Calculated after taking into account the Shares to be issued pursuant to the [REDACTED], assuming that the [REDACTED] is not exercised, that no Shares are issued under the Equity Incentive Plans and that the Share Subdivision is completed.
3. On May 24, 2019, Shanghai Biomedical Enterprise Incubator Limited transferred all of its Shares to BRS Biomedical Limited. Upon completion of such share transfer, Shanghai Biomedical Enterprise Incubator Limited ceased to be a Shareholder of our Company.
4. On July 28, 2020, pursuant to the resolutions of the Board dated July 6, 2020 and a share transfer agreement between BRS Biomedical Limited and Huzhou Zhebei Health Production Investment Partnership (Limited Partnership) (湖州浙嘢健康產業投資合夥企業(有限合伙)), BRS Biomedical Limited transferred 2,122,839 Shares to Huzhou Zhebei Health Production Investment Partnership (Limited Partnership) (湖州浙嘢健康產業投資合夥企業(有限合伙)).
5. On September 11, 2020, pursuant to a share purchase agreement dated August 1, 2020 between TIP-Broncus Limited and Strong Leap Holdings Limited, a share purchase agreement dated August 28, 2020 between Tip-Broncus Limited and QM12 and a supplemental agreement dated September 1, 2020 between Tip-Broncus Limited and Strong Leap Holdings Limited, TIP-Broncus Limited transferred 1,402,644 Shares to Strong Leap Holdings Limited and 2,290,295 Shares to QM12, respectively. Upon completion of such share transfer, TIP-Broncus Limited ceased to be a Shareholder of our Company.
6. On September 4, 2020, pursuant to the resolutions of the Board dated September 4, 2020 and a share transfer agreement between BRS Biomedical Limited and Velocity Zero Limited, BRS Biomedical Limited transferred 1,602,143 Shares to Velocity Zero Limited.
7. Prior to the [REDACTED], St. Christopher Investment Ltd. is expected to obtain an additional 971,635 Shares of our Company as part of the Reorganization as set out in more detail in the section headed “History, Reorganization and Corporate Structure – Reorganization – 4. Flip-up of ESOP and minority shares at subsidiaries” in this document.
8. Prior to the [REDACTED], Xin Nuo Tong Investment Limited is expected to obtain an additional 971,635 Shares of our Company as part of the Reorganization as set out in more detail in the section headed “History, Reorganization and Corporate Structure – Reorganization – 4. Flip-up of ESOP and minority shares at subsidiaries” in this document.
9. The following changes will take place after the Latest Practicable Date but prior to the [REDACTED]:
 - (a) Dinova Healthcare Holding Corporation will become a registered Shareholder of our Company as part of the Reorganization as set out in more detail in the section headed “History, Reorganization and Corporate Structure – Reorganization – 4. Flip-up of ESOP and minority shares at subsidiaries” in this document.
 - (b) Wise Seed Limited will become a registered Shareholder of our Company as part of the Reorganization as set out in more detail in the section headed “History, Reorganization and Corporate Structure – Reorganization – 4. Flip-up of ESOP and minority shares at subsidiaries” in this document.
 - (c) Our Company will adopt the Equity Incentive Plans under which we may allot and issue shares not exceeding (i) 3,170,566 Shares to holders of the [REDACTED] Share Options upon exercise of their respective share options under the Share Option Plan and (ii) 9,877,197 Shares to a special purpose vehicle managed by the Trustee which will hold Shares on trust for grantees under the RSU Scheme. For more details, see the section headed “Statutory and General Information – D. Equity Incentive Plans” in Appendix IV to this document.

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6. Principal Terms of the [REDACTED] Investments

The below table summarizes the principal terms of the [REDACTED] Investments:

	Series A	Series B	Series C	Series D
Cost per Preferred Share paid (US\$)	0.83 – 2.57 ⁽¹⁾	3.05	3.84	6.59
Date of the agreement	March 2, 2018	April 17, 2018	August 17, 2020	January 7, 2021
Funds raised by the Group (US\$)	22,318,944	29,125,003	37,620,430	39,999,986
Date on which the investment was fully settled	March 5, 2018	July 29, 2019	October 26, 2020	January 25, 2021
Number of Shares following conversion of the Preferred Shares	14,652,475	9,563,448	9,791,147	6,068,134
Corresponding post-money valuation of our Company (US\$)	181,434,663	244,489,808 ⁽²⁾	387,389,683 ⁽³⁾	739,796,572 ⁽⁴⁾
Discount to the [REDACTED] (approximation) ⁽⁵⁾	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Basis of determination of valuation and consideration	The valuation and consideration for each round of [REDACTED] Investments was determined based on arm’s length negotiation between the respective [REDACTED] Investors and our Group.			
Lock-up Period	The [REDACTED] Investors are not subject to any lock-up arrangement at the time of [REDACTED] pursuant to the relevant agreements in relation to the [REDACTED] Investments.			
Use of proceeds from the [REDACTED] Investments	We utilized the proceeds for the business expansion, capital expenditures and general working capital needs. As of the Latest Practicable Date, the Group has utilized approximately 62% of the net proceeds from the [REDACTED] Investments.			
Strategic benefit from the [REDACTED] Investments to our Group	At the time of the [REDACTED] Investments, our Directors were of the view that our Group could benefit from the additional capital that would be provided by the [REDACTED] Investors’ investments in our Group and the [REDACTED] Investors’ knowledge and experience.			
Conversion rights	Each Preferred Share shall be automatically converted into Shares on a [one-to-one] basis at the then effective applicable conversion price, upon the completion of the [REDACTED].			

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Notes:

1. The difference in the cost per Series A Preferred Share is that two of the Series A Preferred Shareholders received their Preferred Shares upon conversion of convertible bonds at a conversion price of US\$0.83 per Series A Preferred Share. For details, please refer to the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 1. Series A Financing” in this document.
2. The valuation of our Company increased significantly during the period between our Series A and Series B financing primarily due to the start of commercialization of LungPro in China in the first quarter of 2018. LungPro is our Company’s key product in China which is a strategic market of interventional pulmonology.
3. The valuation of our Company increased significantly during the period between our Series B and Series C financing primarily due to the FDA designated the InterVapor for COPD as a Breakthrough Device due to technology innovation and medical value to patients in need in 2019.
4. The valuation of our Company increased significantly during the period between our Series C and Series D financing primarily due to the clinical progress of RF-II, more pipelines of therapeutic consumables being in development stage and the better recognition of interventional pulmonology from authorities and businesses.
5. The discount to the [REDACTED] is calculated assuming that the Share Subdivision is completed and that the [REDACTED] is HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED], assuming the conversion of the Preferred Shares into Shares of our Company on a [one-to-one] basis.

With regard to the significant increase in our Company’s valuation upon [REDACTED] as compared to the [REDACTED] valuation at the time of the Series D financing, this was primarily due to (1) the confirmatory clinical trial of RF-II, one of our Core Products, for treatment early-stage lung cancer has been commenced since January 2021, (2) the license to import InterVapor, one of our Core Products, has been granted in India since March 2021, (3) development of ongoing pipelines of therapeutic consumables, (4) more demand for therapeutic consumables for lung diseases in the foreseeable period after COVID-19 inflicted recession, and (5) potential business cooperation opportunities.

7. Special Rights of the [REDACTED] Investors

Our Company and, among others, the [REDACTED] Investors entered into the Shareholders Agreement, pursuant to which certain shareholder rights were agreed among the parties. Pursuant to the Shareholders Agreement and the then memorandum and articles of association of our Company, certain [REDACTED] Investors have, among other rights, (i) information and inspection rights; (ii) right of first offer, right of first refusal and right of co-sale; (iii) the right to elect Directors; (iv) veto rights against certain corporate actions; and (v) redemption rights.

The relevant redemption rights ceased to be exercisable on the date immediately before the date of the first submission of a [REDACTED] form by our Company to the Stock Exchange for the purpose of the [REDACTED], and shall be restored automatically in all respects upon the earlier of (i) twelve (12) calendar months after the date our Company submits its first [REDACTED] when a qualified [REDACTED] as defined under the Shareholders Agreement has not been consummated on the Main Board and (ii) the date that the Company’s application for [REDACTED] on the Main Board is withdrawn, rejected, returned or otherwise

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lapsed. All other special rights of the [REDACTED] Investors granted under the foregoing documents will be terminated upon completion of the Company’s qualified [REDACTED]. No special rights granted to the [REDACTED] Investors will survive after the [REDACTED].

8. Information about our Shareholders

The background information of Shareholders of our Company and our [REDACTED] Investors is set out below.

Our [REDACTED] Investors include Sophisticated Investors, such as QM12 (Qiming Venture Partners), Intuitive Surgical Operations, Inc., Elegant Holding Limited (FountainVest), Velocity Zero Limited (DCP Capital), and LBC Sunshine Healthcare Fund L.P. (Lake Bleu Capital).

- (i) BRS Biomedical Limited is a limited liability company incorporated under the laws of the BVI and is wholly owned by Dinova Venture Partners LP II, L.P. whose general partner is Dinova Venture Partners GP II, L.P.. Dinova Venture Partners Limited, the general partner of Dinova Venture Partners GP II, L.P., is owned by Mr. Zi as to one third. BRS Biomedical Limited is a connected person of our Company.
- (ii) Huzhou Zhebei Health Production Investment Partnership (Limited Partnership) (湖州浙貝健康產業投資合夥企業(有限合夥)) is a company duly incorporated in China which focuses on equity investments in the healthcare industry, whose general partner is Dunhou Equity Investment Management (Hangzhou) Co., Ltd (敦厚股權投資管理(杭州)有限公司)). To the best knowledge of our Directors, Huzhou Zhebei Health Production Investment Partnership (Limited Partnership) (湖州浙貝健康產業投資合夥企業(有限合夥)) is an Independent Third Party.
- (iii) BBL is a company incorporated in Hong Kong. Its sole shareholder is Dinova Healthcare Gamma Fund (USD), L.P., a private fund holding various portfolios established in the Cayman Islands. Dinova Venture Partners GP III, L.P. is the general partner of Dinova Healthcare Gamma Fund (USD), L.P.. Dinova Capital Limited is the general partner of Dinova Venture Partners GP III, L.P.. Xin Nuo Tong Investment Limited is the sole shareholder of Dinova Capital Limited and Mr. Zi is the sole shareholder of Xin Nuo Tong Investment Limited. BBL is a connected person of our Company.
- (iv) Banyan Capital Investment Holdings Limited is a company incorporated in the BVI, 95% owned by Wang Zhe. To the best knowledge of our Directors, Banyan Capital Investment Holdings Limited is an Independent Third Party.

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- (v) Great Takley International Co., Limited is a company incorporated in Hong Kong and is wholly-owned by Known Well World Limited, a company incorporated in the British Virgin Islands, which is ultimately 50% owned by Ma Ren De and 50% owned by Wong Lai Wa. To the best knowledge of our Directors, Great Takley International Co., Limited is an Independent Third Party.
- (vi) IDEAL Fund SPC is a Segregated Portfolio Company incorporated in the Cayman Islands. It is advised by Zeta Capital (H.K.) Limited, a limited company incorporated in Hong Kong with Type 4 and Type 9 licenses issued by the Hong Kong Securities and Futures Commission, and RQFII license approved by China Securities Regulatory Commission. Zeta Capital (H.K.) Limited is indirectly wholly owned by Mr. Zhu Xuejun. Mr. Zhu Xuejun is responsible officer of Zeta Capital (H.K.) Limited, with more than 15 years of experience in asset management. Mr. Zhu has overall authority over, and responsibility for, the operation and management of IDEAL Fund SPC. He has established more than 20 umbrella funds with AUM more than US\$200 million. He has managed investment into a number of early-stage TMT and biotech companies, including Apollomics Inc. and Akeso, Inc.. To the best knowledge of our Directors, IDEAL Fund SPC is an Independent Third Party.
- (vii) Proteligen Group Limited is a company incorporated in Hong Kong. Proteligen Group Limited is controlled by Proteligen Holding Limited, a company registered in the BVI, which is ultimately owned by Zhong Jian (鐘劍). To the best knowledge of our Directors, Proteligen Group Limited is an Independent Third Party.
- (viii) QM12 is a Sophisticated Investor which has made meaningful investment in our Company for more than six months before the [REDACTED] for the purpose of paragraph 3.2(g) of Guidance Letter HKEX-GL 92-18 issued by the Stock Exchange. QM12 is a company duly incorporated and validly existing under the laws of Hong Kong, owned by Qiming Venture Partners IV, L.P. (96.94%) and Qiming Managing Directors Fund IV, L.P. (3.06%). Each of Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. is an exempted limited partnership registered in the Cayman Islands. The general partner of Qiming Venture Partners IV, L.P. is Qiming GP IV, L.P., an exempted limited partnership registered in the Cayman Islands whose general partner is Qiming Corporate GP IV, Ltd., an exempted company incorporated in the Cayman Islands with limited liability. The general partner of Qiming Managing Directors Fund IV, L.P. is Qiming Corporate GP IV, Ltd.. Voting and investment power of shares held by Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. is exercised by shareholders of Qiming Corporate GP IV, Ltd., which consists of Mr. Duane Ziping Kuang, Mr. Gary Rieschel, Mr. Robert Headley, Independent Third Parties, and Ms. Nisa Bernice Leung, a connected person of our Company, each of whom owns 25% of Qiming Corporate GP IV, Ltd. Qiming Venture Partners is a leading China venture capital firm with US\$5.9 billion of assets under management as of the Latest Practicable Date, and its portfolio companies include some of today’s most influential brands in their respective sectors, such as Xiaomi Corporation (stock

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code: 1810), Meituan (stock code: 3690), Beijing Roborock Technology Co., Ltd. (stock code: 688169), Bilibili Inc. (stock ticker: BILI), Gan & Lee Pharmaceuticals (stock code: 603087), Venus Medtech (Hangzhou) Inc. (stock code: 2500), Hangzhou Tigermed Consulting Co., Ltd. (stock code: 300347 (SZSE), 3347 (HKSE)), Zai Lab Limited (stock ticker/code: ZLAB (NASDAQ), 9688 (HKSE)), Shanghai Sanyou Medical Co., Ltd. (stock code: 688085) and Amoy Diagnostics Co., Ltd. (stock code: 300685). QM12 is a connected person of our Company.

- (ix) Adventure 01 Limited is a private company by shares incorporated in Hong Kong. Shares of Adventure 01 Limited are held by Shenzhen Futian Tongchuang Weiye Great Health Industry Investment Fund Partnership (Limited Partnership) (深圳福田同創偉業大健康產業投資基金合夥企業(有限合夥)), Hangzhou Qiaowen Equity Investment Partnership (Limited Partnership) (杭州叩問股權投資合夥企業(有限合夥)) and Hong Kong Langxes Limited, as to 30%, 60% and 10%, respectively. To the best knowledge of our Directors, Adventure 01 Limited is an Independent Third Party.
- (x) Prime State Ventures Limited is a company incorporated in the BVI and wholly owned by Kim Cheung. To the best knowledge of our Directors, Prime State Ventures Limited is an Independent Third Party.
- (xi) St. Christopher Investment Limited is a company incorporated in the BVI and wholly owned by Mr. Zhao, our non-executive Director and the chairman of our Board. St. Christopher Investment Limited is a connected person of our Company.
- (xii) NBL Holding Group is a company incorporated in the BVI, owned by Huili Zhu. To the best knowledge of our Directors, NBL Holding Group is an Independent Third Party.
- (xiii) Yuan Management Limited is a company incorporated in the BVI and controlled by Zhang Ling, an Independent Third Party.
- (xiv) Dinova Healthcare Delta Fund (USD) L.P. is a limited partnership established in the Cayman Islands and is a private fund holding various portfolios. Dinova Venture Partners GP IV, L.P. is the general partner of Dinova Healthcare Delta Fund (USD) L.P. Dinova Venture Capital Limited is the general partner of Dinova Venture Partners GP IV, L.P.. Dinova Venture Capital Limited is held as to 40% by Xin Nuo Tong Investment Limited and Mr. Zi, our non-executive Director and one of our Controlling Shareholders, is the sole shareholder of Xin Nuo Tong Investment Limited. Dinova Healthcare Delta Fund (USD) L.P. is a connected person of our Company.

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- (xv) Dinova Healthcare (Hong Kong) Co., Limited is a company incorporated in Hong Kong. Its sole shareholder is Zhejiang Dinova, a venture capital fund holding various portfolios established in the PRC. Zhejiang Denuo Capital Management L.P. (浙江德諾資本管理合夥企業(有限合夥)) is the general partner of Zhejiang Dinova. Hangzhou Denuo Commercial Information Consulting Co., Ltd. (杭州德諾商務資訊諮詢有限公司) is the general partner of Zhejiang Denuo Capital Management L.P. Mr. Zi, our non-executive Director and one of our Controlling Shareholders, is a limited partner holding 39.60% interest of Zhejiang Denuo Capital Management L.P. and is a 40% shareholder of Hangzhou Denuo Commercial Information Consulting Co., Ltd.. Dinova Healthcare (Hong Kong) Co., Limited is a connected person of our Company.
- (xvi) Sloan Investment Company Limited is a company incorporated in the BVI and wholly owned by Chi Keung Chan, an Independent Third Party.
- (xvii) Rocky Ventures Ltd is a company duly incorporated in Anguilla and owned by Min Frank Zeng and Yang Yuanxin, an Independent Third Party.
- (xviii) Xin Nuo Tong Investment Limited is an investment holding company incorporated in the BVI and wholly owned by Mr. Zi, our non-executive Director and one of our Controlling Shareholders. Xin Nuo Tong Investment Limited is a connected person of our Company.
- (xix) Xu Han is a Hong Kong resident, an Independent Third Party.
- (xx) Dinova Venture Partners GP III, L.P. is a limited partnership incorporated under the laws of the Cayman Islands. Dinova Capital Limited is the general partner of Dinova Venture Partners GP III, L.P.. Dinova Capital Limited is wholly owned by Xin Nuo Tong Investment Limited, which is in turn wholly owned by Mr. Zi, our non-executive Director and one of our Controlling Shareholders. Dinova Venture Partners GP III, L.P. is a connected person of our Company.
- (xxi) Dinova Venture Partners GP IV, L.P. is a limited partnership incorporated under the laws of the Cayman Islands. Dinova Venture Capital Limited, the general partner of Dinova Venture Partners GP IV, L.P., is held as to 30%, 30% and 40% by NBL Holding Group Limited, Sloan Investment Company Limited and Xin Nuo Tong Investment Limited respectively. Xin Nuo Tong Investment Limited is wholly owned by Mr. Zi, our non-executive Director and one of our Controlling Shareholders. In addition, Xin Nuo Tong Investment Limited is a shareholder holding 40% of Dinova Venture Capital Limited and a limited partner holding approximately 39.95% in Dinova Venture Partners GP IV, L.P.. Dinova Venture Partners GP IV, L.P. is a connected person of our Company.
- (xxii) Wang Qi is a Hong Kong resident, an Independent Third Party.

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- (xxiii) Flourishing Forest Limited is a company duly incorporated in the BVI and wholly owned by Xinxin Xie. To the best knowledge of our Directors, Flourishing Forest Limited is an Independent Third Party.
- (xxiv) Intuitive Surgical Operations, Inc. is a company duly incorporated in Delaware, United States and a wholly-owned subsidiary of Intuitive Surgical, Inc. which is a company incorporated in Delaware, United States and listed on the Nasdaq Stock Market (NASDAQ: ISRG). ISRG is a Sophisticated Investor which has made meaningful investment in our Company for more than six months before the [REDACTED]. It is a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery. To the best knowledge of our Directors, Intuitive Surgical Operations, Inc. is an Independent Third Party.
- (xxv) Gain Yield Holdings Limited is an investment holding company wholly owned by China Biotech Service Holdings Limited (中國生物科技服務控股有限公司), a public company listed on the Stock Exchange (stock code: 8037). To the best knowledge of our Directors, Gain Yield Holdings Limited is an Independent Third Party.
- (xxvi) Genius Life Investment I Limited is an investment holding company incorporated in Samoa and its ultimate shareholders are Anthony Wu Ting Yuk and Li Haifeng, Independent Third Parties.
- (xxvii) Hongkong Chinamagpie Limited is a private company limited by shares incorporated in Hong Kong. Hangzhou Hua Que Investment L.P. (杭州華鵲投資合夥企業 (有限合夥)) is its sole shareholder, an Independent Third Party.
- (xxviii) Cloud Neutron (Hong Kong) Limited is a private company limited by shares incorporated in Hong Kong. Hangzhou Simiao Equity Investment Co., Ltd (杭州思邈股權投資有限公司) is its general partner. To the best knowledge of our Directors, Cloud Neutron (Hong Kong) Limited is an Independent Third Party.
- (xxix) Hangzhou Puhua Rui Kun Venture Investment L.P. (杭州普華銳昆創業投資合夥企業(有限合夥)) is a company duly incorporated in China whose general partner is Hangzhou Puhua Ze Xi Venture Investment Fund Management Co., Ltd. (杭州普華澤翕股權投資基金管理有限公司) which is owned by Zhejiang Puhua Tianqin Equity Investment Management Co., Ltd. (浙江普華天勤股權投資管理有限公司) which is in turn controlled by Shen Qinhu (沈琴華). To the best knowledge of our Directors, Hangzhou Puhua Rui Kun Venture Investment L.P. (杭州普華銳昆創業投資合夥企業(有限合夥)) is an Independent Third Party.

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(xxx) Suzhou Bondshine Ying Xin Venture Investment LLP (蘇州邦盛贏新創業投資企業(有限合夥)) is a company duly incorporated in China whose general partner is Nanjing Bondshine Venture Investment Management (Limited Partnership) (南京邦盛投資管理合夥企業(有限合夥)) whose general partner is Gao Chong (郅翀). To the best knowledge of our Directors, Suzhou Bondshine Ying Xin Venture Investment LLP (蘇州邦盛贏新創業投資企業(有限合夥)) is an Independent Third Party.

(xxxi) Lushu (Hong Kong) limited is a limited company incorporated in Hong Kong and a wholly owned subsidiary of Hangzhou Lushu Investment Partnership (杭州鹿蜀投資合夥企業(有限合夥)), which is a limited partnership organized in the PRC. Hangzhou Jiuyouque Investment Management Co., Ltd. (杭州九幽雀投資管理有限公司) is its general partner. To the best knowledge of our Directors, Lushu (Hong Kong) limited is an Independent Third Party.

(xxxii) Velocity Zero Limited is a company incorporated in the Cayman Islands, which is ultimately owned by DCP Capital Partners, L.P., a limited partnership organized in the Cayman Islands. DCP General Partner, Ltd., a company incorporated in the Cayman Islands, is the general partner of DCP Capital Partners, L.P. DCP General Partner, Ltd. is a company managed by DCP Capital which is a leading international private equity firm founded by experienced private equity investors in Greater China. The DCP team previously led KKR and Morgan Stanley’s private equity businesses in Asia, with an outstanding long-term track record across multiple economic cycles. DCP is supported by a diverse group of world-class long-term institutional investors, including leading sovereign wealth funds, pension funds, endowments, family offices and funds of funds around the globe. Over the past 28 years, the DCP team has led a number of successful transactions and nurtured numerous industry leaders in China such as Venus Medtech (stock code: 2500), Dongbao Pharmaceutical (stock code: 600867), Ping An Insurance (stock code: 2318), Mengniu Dairy (stock code: 2319), Haier Electronics (stock code: 600690), China International Capital Corp (stock code: 3908), Oriental Yuhong (stock code: 002271), Far East Horizon (stock code: 3360), COFCO Meat (stock code: 1610), Hengan Intl. (stock code: 1044) and Modern Dairy (stock code: 1117). Velocity Zero Limited is a Sophisticated Investor which has made meaningful investment in our Company for more than six months before the [REDACTED]. To the best knowledge of our Directors, Velocity Zero Limited is an Independent Third Party.

(xxxiii) Strong Leap Holdings Limited is a company limited by shares with its registered office in the BVI. It is 51.2% held by Summer Master Fund Limited (formerly known as Chiyuan Master Fund Limited), an exempted company with limited liability incorporated in the Cayman Islands, and 48.8% held by Summer Healthcare Fund, L.P. (formerly known as Summer Global Healthcare Fund, L.P.), a limited partnership established under the laws of Cayman Islands. Summer Master Fund Limited and Summer Healthcare Fund, L.P. are both controlled by Summer Capital

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Limited, a multi-strategy investment management company, focusing on investing in the healthcare, fintech, consumer and education sectors. To the best knowledge of our Directors, Summer Capital Limited is an Independent Third Party.

(xxxiv) LBC Sunshine Healthcare Fund L.P. is managed by Lake Bleu Capital (Hong Kong) Limited. LBC Sunshine Healthcare Fund L.P., an exempted limited partnership registered in the Cayman Islands. It specializes in investing in late-stage healthcare companies in Asia/Greater China and is a Sophisticated Investor which has made meaningful investment in our Company for more than six months before the [REDACTED]. The investment scope includes pharmaceuticals, biotech, medical devices, and healthcare services. LBC GP II Limited, an exempted company incorporated in the Cayman Islands, acts as the general partner of the LBC Sunshine Healthcare Fund L.P. Lake Bleu Capital (Hong Kong) Limited invested in biotech and healthcare sectors include, among others, JD Health (stock code: 6618 (SEHK)), New Horizon Health (stock code: 6606 (SEHK)), MicroPort Cardioflow (stock code: 2160 (SEHK)), RemeGen (stock code: 9995 (SEHK)), Hygeia Healthcare (stock code: 6078 (SEHK)), Kangji Medical (stock code: 9997 (SEHK)), Hansoh Pharmaceutical (stock code: 3692 (SEHK)), Jinxin Fertility (stock code: 1951 (SEHK)), Akeso Biopharma (stock code: 9926 (SEHK)) and Pharmaron (stock code: 3759 (SEHK), 300759 (SZSE)). To the best knowledge of our Directors, LBC Sunshine Healthcare Fund L.P. is an Independent Third Party.

(xxxv) ACM 01 Limited is a company incorporated in the BVI and is wholly owned by Ascendum Healthcare Fund I, L.P., a Cayman Islands exempted limited partnership, which makes equity investments in companies operating in life science, healthcare and related industries. To the best knowledge of our Directors, Ascendum Healthcare Fund I, L.P. is an Independent Third Party.

(xxxvi) Silver Pearl Limited is an investment holding company registered under the laws of the Cayman Islands and owned by Mr. Zhenhua Li (李振華), who is a member of our senior management. For the biography and industry experience of Mr. Li Zhenhua (李振華), please refer to the section headed “Directors and Senior Management” in this document. To the best knowledge of our Directors, Silver Pearl Limited is an Independent Third Party.

(xxxvii) BC Mars L.P. is an exempted limited partnership registered under the laws of the Cayman Islands managed by Baidu Capital GP Limited as its general partner. Baidu Capital GP Limited, an Independent Third Party and an affiliate of Baidu Inc., whose shares are listed on the Nasdaq Stock Market (NASDAQ: BIDU) and on the Stock Exchange (HKSE: 9888), was incorporated in the Cayman Islands and focused on equity investments. To the best knowledge of our Directors, BC Mars L.P. is an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

(xxxviii) CNCB CAPITAL VALUE SPC is a segregated portfolio company incorporated in the Cayman Islands with limited liability and wholly owned by CNCB (Hong Kong) Capital Limited (“**CNCB Capital**”). CNCB Capital is a wholly-owned subsidiary of CNCB (Hong Kong) Investment Limited (“**CNCB HK**”). CNCB HK, formerly known as China Investment and Finance Limited, is a company incorporated and registered in Hong Kong, and is the overseas investment and financing platform of China CITIC Bank Corporation Limited. China CITIC Bank Corporation Limited is a commercial bank listed on the Hong Kong Stock Exchange (stock code: 998) and is in turn ultimately controlled by CITIC Group Corporation (中國中信集團有限公司), a PRC state-owned investment company. The business scope of CNCB HK covers lending (it holds a Hong Kong money lender license), investment, overseas licensed investment banking business and domestic equity investment fund management business via its own subsidiaries. As of the end of July 2020, the total assets of CNCB HK are about US\$3 billion. To the best knowledge of our Directors, CNCB CAPITAL VALUE SPC is an Independent Third Party.

(xxxix) Elegant Holding Limited (formerly known as Orca Holding Limited) is a limited liability company incorporated under the laws of the Cayman Islands. Elegant Holding Limited is an investment holding company wholly owned by FountainVest China Capital Partners Fund III, L.P. and its parallel funds, FountainVest China Capital Parallel Fund III, L.P. and FountainVest China Capital Parallel-A Fund III, L.P., whose sole general partner is FountainVest China Capital Partners GP3 Ltd (together, the “**FountainVest Partners**”). Founded in 2007, FountainVest Partners is one of the most established independent private equity firms in Asia and a Sophisticated Investor which has made meaningful investment in our Company for more than six months before the [REDACTED]. FountainVest Partners focuses on long-term oriented investments in industry leaders, partnering closely with management teams to drive growth and create value in diversified areas including in strategy, operations, finance, and industry consolidation. FountainVest Partners has completed a number of successful landmark investments in Asia, Europe, and the U.S. Sectors of focus include consumer, media & technology, healthcare, industrials, and financial services. FountainVest Partners is backed by some of the largest sovereign wealth funds and public pension plans around the world, with assets under management of close to approximately US\$6 billion. Selective biotech and healthcare portfolio companies that FountainVest Partners has invested in include Shanghai Kehua Bio-Engineering Co., Ltd. (a company listed on the Shenzhen Stock Exchange (stock code: 002022)) and LBX Pharmacy Chain Joint Stock Company (a company listed on the Shanghai Stock Exchange (stock code: 603883)). To the best knowledge of our Directors, Elegant Holding Limited is an Independent Third Party.

(xl) Emerging Markets Healthcare Partners LLC is a company incorporated under the Delaware, United States and owned by Samuel D. Isaly and Exome Asset Management LLC. Exome Asset Management LLC, incorporated in Delaware and based in New York, is the investment adviser. To the best knowledge of our Directors, Emerging Markets Healthcare Partners LLC is an Independent Third Party.

(xli) Valliance Emerging Opportunities Limited Partnership Fund is a limited partnership duly incorporated in Hong Kong. Valliance Asset Management Limited, an asset management firm licensed by the Securities and Futures Commission of Hong Kong, is the general partner of Valliance Emerging Opportunities Limited Partnership Fund and wholly owned by Mr. Lin Li, an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

- (xlii) Dinova Healthcare Holding Corporation is incorporated in the Cayman Islands and owned as to approximately 83.54% by St. Christopher Investment Limited which is in turn wholly owned by Mr. Zhao, our non-executive Director and the chairman of our Board, and as to 9% by Xin Nuo Tong Investment Limited which is in turn wholly owned by Mr. Zi, our non-executive Director. Dinova Healthcare Holding Corporation is a connected person of our Company.
- (xliii) Wise Seed Limited is an investment holding company incorporated in the BVI in which Mr. Zhan, our executive Director and CEO, holds 63.37% interest. Wise Seed Limited is a connected person of our Company.

9. Public Float

Upon completion of the Share Subdivision and the [REDACTED] (assuming the [REDACTED] is not exercised), the following Shareholders, (i) QM12, (ii) BRS Biomedical Limited, (iii) BBL, (iv) Dinova Healthcare Delta Fund (USD) L.P., (v) Dinova Healthcare (Hong Kong) Co., Limited, (vi) Dinova Venture Partners GP III, L.P., (vii) Dinova Venture Partners GP IV, L.P., (viii) Xin Nuo Tong Investment Limited, (ix) St. Christopher Investment Limited, (x) Dinova Healthcare Holding Corporation, and (xi) Wise Seed Limited will hold (directly or indirectly) approximately [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]% and [REDACTED]% of the total issued Shares, respectively, and such Shares will not be counted towards the public float.

Save as disclosed above in this section and the section headed “Substantial Shareholders” in this document, to the best of the Directors’ knowledge, all other [REDACTED] Investors and Shareholders of our Company are not connected persons of our Company. As a result, an aggregate of approximately [REDACTED]% of the total issued Shares (upon completion of the [REDACTED], assuming the [REDACTED] is not exercised with a market capitalization of approximately HK\$[REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED]) will count towards the public float; hence, over [REDACTED]% of our Company’s total issued Shares with a market capitalization of at least HK\$[REDACTED] will be held by the public upon completion of the [REDACTED] as required under Rule 8.08(1)(a) and Rule 18A.07 of the Listing Rules.

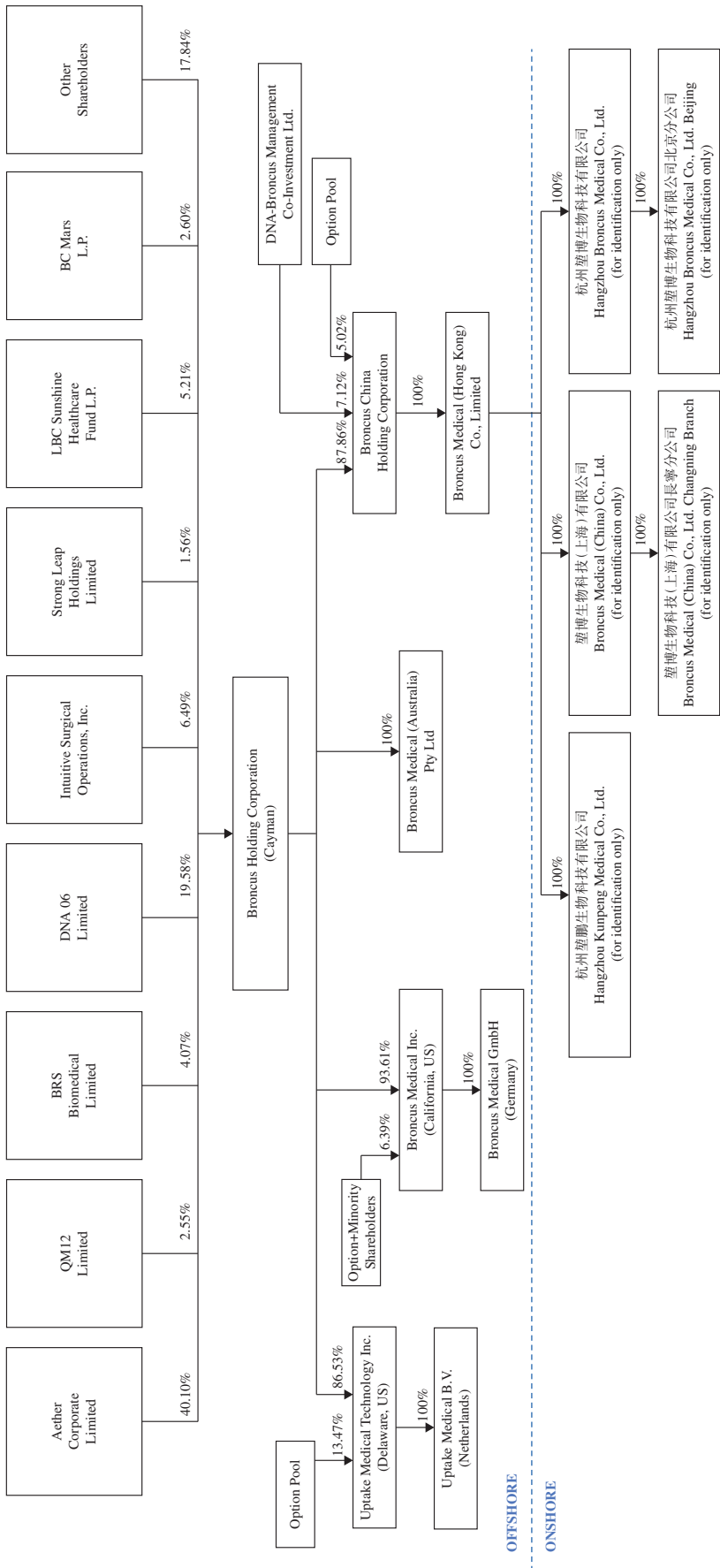
10. Compliance with Interim Guidance and Guidance Letters

The Joint Sponsors confirm that the [REDACTED] Investments are in compliance with the Guidance Letter HKEX-GL29-12 issued on 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 March 2017 by the Stock Exchange.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

REORGANIZATION

The following chart sets forth our Group’s corporate and shareholding structure immediately prior to the commencement of the Reorganization:



Note:

- Shareholders' shareholding percentages in this chart are based on the Company's register of members dated September 30, 2020.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

In preparation for the [REDACTED], we underwent the following Reorganization steps:

1. Distribution of Shares of Our Company by ACL

On December 16, 2020, ACL passed board resolutions to distribute Shares then held by ACL to the then shareholders of ACL, pursuant to which ACL distributed such Shares to the then shareholders of ACL or their nominees on December 17, 2020. Upon completion of such transfer, the following shareholders of ACL or their nominees as shown in the table below became registered Shareholders of our Company:

<u>Shareholders of ACL or their nominees</u>	<u>Number of Shares received</u>	<u>Number of Series A Preferred Shares received</u>
BBL ⁽²⁾	12,848,415	—
QM12 ⁽²⁾	16,467,591	1,595,316
Adventure 01 Limited ⁽²⁾	2,655,169	—
Xin Nuo Tong Investment Limited ⁽¹⁾⁽²⁾	431,120	—
NBL Holding Group Limited ⁽²⁾	473,969	—
Prime State Ventures Limited ⁽²⁾	780,900	—
Xu Han ⁽²⁾	280,803	—
St. Christopher Investment Limited ⁽²⁾	449,038	—
Yuan Management Ltd. ⁽²⁾	88,367	—
	<u>34,475,372</u>	<u>1,595,316</u>

Notes:

1. China Dragon One Limited, a then shareholder of ACL, nominated Xin Nuo Tong Investment Limited to accept 431,120 Shares and Xu Han to accept 280,803 Shares transferred from ACL.
2. For background of these parties, please see the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document.

Upon completion of the arrangement abovementioned, ACL was no longer a Shareholder of our Company.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

2. Distribution of Shares of Our Company by DNA

On December 16, 2020, DNA passed board resolutions to distribute Shares then held by DNA to its then shareholders, pursuant to which DNA transferred such Shares to the then shareholders of DNA or their nominees on December 17, 2020. Upon completion of such distribution, the following shareholders of DNA or their nominees as shown in the table below became direct Shareholders of our Company:

Shareholder of DNA or their nominee	Number of Shares received	Number of Series A Preferred Shares received
Dinova Healthcare Delta Fund (USD) L.P. ⁽¹⁾	2,309,619	905,762
Dinova Healthcare (Hong Kong) Co., Limited ⁽¹⁾	6,239,960	2,038,228
Rocky Ventures Ltd ⁽¹⁾	383,576	–
Xin Nuo Tong Investment Limited ⁽¹⁾	134,509	744,193
Sloan Investment Company Limited ⁽¹⁾	601,775	611,576
Yuan Management Limited ⁽¹⁾	152,860	3,701
St. Christopher Investment Limited ⁽¹⁾	568,181	782,162
Dinova Venture Partners GP III, L.P. ⁽¹⁾	–	865,002
Dinova Venture Partners GP IV, L.P. ⁽¹⁾	–	409,017
WANG Qi ⁽¹⁾	–	616,461
Flourishing Forest Limited ⁽¹⁾	–	246,584
	<u>10,390,480</u>	<u>7,222,686</u>

Notes:

- For details of these Shareholders, please see the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document.

Upon completion of share transfers abovementioned, DNA was no longer a Shareholder of our Company.

3. Concert Party Agreements

QM12 and BBL entered into an agreement to act in concert on May 27, 2014 pursuant to which they agreed and undertook to act in concert as shareholders of ACL, the Company’s controlling shareholder as of the date of the agreement. ACL was entitled to control approximately 45.00% of the total issued share capital of the Company before ACL transferred Shares of our Company to its then shareholders on December 17, 2020. Prior to December 17, 2020, ACL was owned as to 50.08% by QM12 and as to 35.62% by BBL. Therefore, QM12 and BBL, acting in concert, had control over our Company through ACL.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

On December 17, 2020, QM12 and BBL entered into the Concert Party Agreement, a new concert party agreement, pursuant to which they have agreed to act in concert as Shareholders of our Company in the event that our Company’s Shareholders’ approval is required until the Concert Party Agreement is otherwise terminated.

Therefore, QM12 and BBL have been parties acting in concert since May 27, 2014 and will continue to act in concert in accordance with the Concert Party Agreement upon and after [REDACTED].

4. Flip-up of ESOP and minority shares at subsidiaries

Uptake Medical, Broncus Medical and Broncus China Holding cancelled all the share options and/or RSUs in each of these subsidiaries in exchange for options and/or RSUs in the Company. On [date], 2021, our Company adopted the Equity Incentive Plans. For details of the award of options and/or RSUs by our Company, see the section headed “Statutory and General Information – D. Equity Incentive Plans” in Appendix IV to this document.

Our Company purchased shareholdings from the minority shareholders of Broncus Medical so that Broncus Medical became a wholly-owned subsidiary of our Company.

On March 11, 2021, Broncus China Holding passed written board resolutions to repurchase all of the shares held by DNA-Broncus Management Co-Investment Ltd. in Broncus China Holding. The Company has approved the allotment and issuance as fully paid and non-assessable of the following number of Shares to the shareholders of DNA-Broncus Management Co-Investment Ltd. or their respective designated affiliates as shown in the table below.

Name of Shareholder⁽¹⁾	Number of Shares⁽²⁾
St. Christopher Investment Ltd.	971,635
Xin Nuo Tong Investments Limited	971,635
Dinova Healthcare Holding Corporation	475,256
Wise Seed Limited	749,849
Total	3,168,375

Notes:

1. For details of these Shareholders, please see the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document.
2. As of the Latest Practicable Date, the relevant Shares have not been issued but will be issued in due course before [REDACTED].

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

5. Share Subdivision

On [date], 2021, our Shareholders resolved, among other things, that:

- (a) conditional upon each of (i) the Stock Exchange granting the [REDACTED] of, and permission to deal in, the Shares in issue and to be issued pursuant to the [REDACTED] (including upon the re-designation of the Preferred Shares) and such permission not subsequently having been revoked prior to the commencement of dealings in the Shares on the Stock Exchange with effect from 8:00 am on the [REDACTED], and (ii) the [REDACTED] being a “Qualified [REDACTED]” (as defined in the Shareholders Agreement), each of the issued Preferred Shares be converted into [one] Share by re-designation and re-classification of each Preferred Share in issue as an Share on a [one-for-one] basis and all the unissued and authorized Preferred Shares be re-designated and re-classified as Shares (the “**Re-designation and Re-classification**”), such that the authorized share capital of our Company is US\$50,000 divided into 500,000,000 Shares with a nominal value of US\$0.0001 each, each with effect prior to the completion of the [REDACTED] on the [REDACTED];
- (b) immediately after the Re-designation and Re-classification prior to the completion of the [REDACTED], each Share of US\$0.0001 in the then authorized and issued share capital of our Company be sub-divided into four Shares of US\$0.000025 each (the “**Share Subdivision**”) such that immediately following the Share Subdivision, (i) the authorized share capital of the Company is US\$50,000 divided into 2,000,000,000 Shares of US\$0.000025 each; and (ii) the issued share capital of the Company shall consist of [REDACTED] Shares of US\$0.000025 each.

REASONS FOR THE [REDACTED]

Our Board is of the view that the net [REDACTED] of approximately HK\$[REDACTED] from the [REDACTED], after deducting the [REDACTED] and other estimated [REDACTED] expenses payable by us, and assuming the initial [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] set forth on the cover page of this document, and assuming the [REDACTED] is not exercised, will provide us with the necessary funding for us to further develop, commercialize and increase market penetration of our pipeline products as disclosed in the section headed “Business – Our Strategies” in this document.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

PRC REGULATORY REQUIREMENTS

SAFE Circular 37

According to SAFE Circular 37 issued by the SAFE in 2014, before a domestic resident contributes its legally owned onshore or offshore assets or equity into a special purpose vehicle, the domestic resident shall conduct foreign exchange registration for offshore investment with the local branch of the SAFE. SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to, among others, the domestic individual resident shareholder, the operating period, capital and merger or division events of the special purpose vehicle. Pursuant to SAFE Circular 13 promulgated by SAFE, which became effective on June 1, 2015, SAFE registration was delegated from local SAFE branches to local banks.

As advised by our PRC Legal Advisor, our major ultimate Shareholders Mr. Zi, Mr. Zhan, Zhang Ling, Xie Xinxin and Kuang Yanhong, all of whom are PRC citizens, have completed the process of registration required under SAFE Circular 37.

M&A RULES

On August 8, 2006, six PRC ministries and commissions, including MOFCOM and CSRC, promulgated the M&A Rules, a regulation with respect to the mergers and acquisitions of domestic enterprises by foreign investors that became effective on September 8, 2006 and revised on June 22, 2009. The M&A Rules, among other things, provides that a foreign investor seeking acquisition of the equity interest in a non-foreign-invested PRC enterprise, or purchasing and operating the assets of that enterprise by establishing a foreign-invested enterprise in the PRC, shall obtain the approval of MOFCOM or its counterparts at provincial level.

As advised by our PRC Legal Advisor, no approvals under the M&A Rules are required in respect of our Reorganization.

EQUITY INCENTIVE PLANS

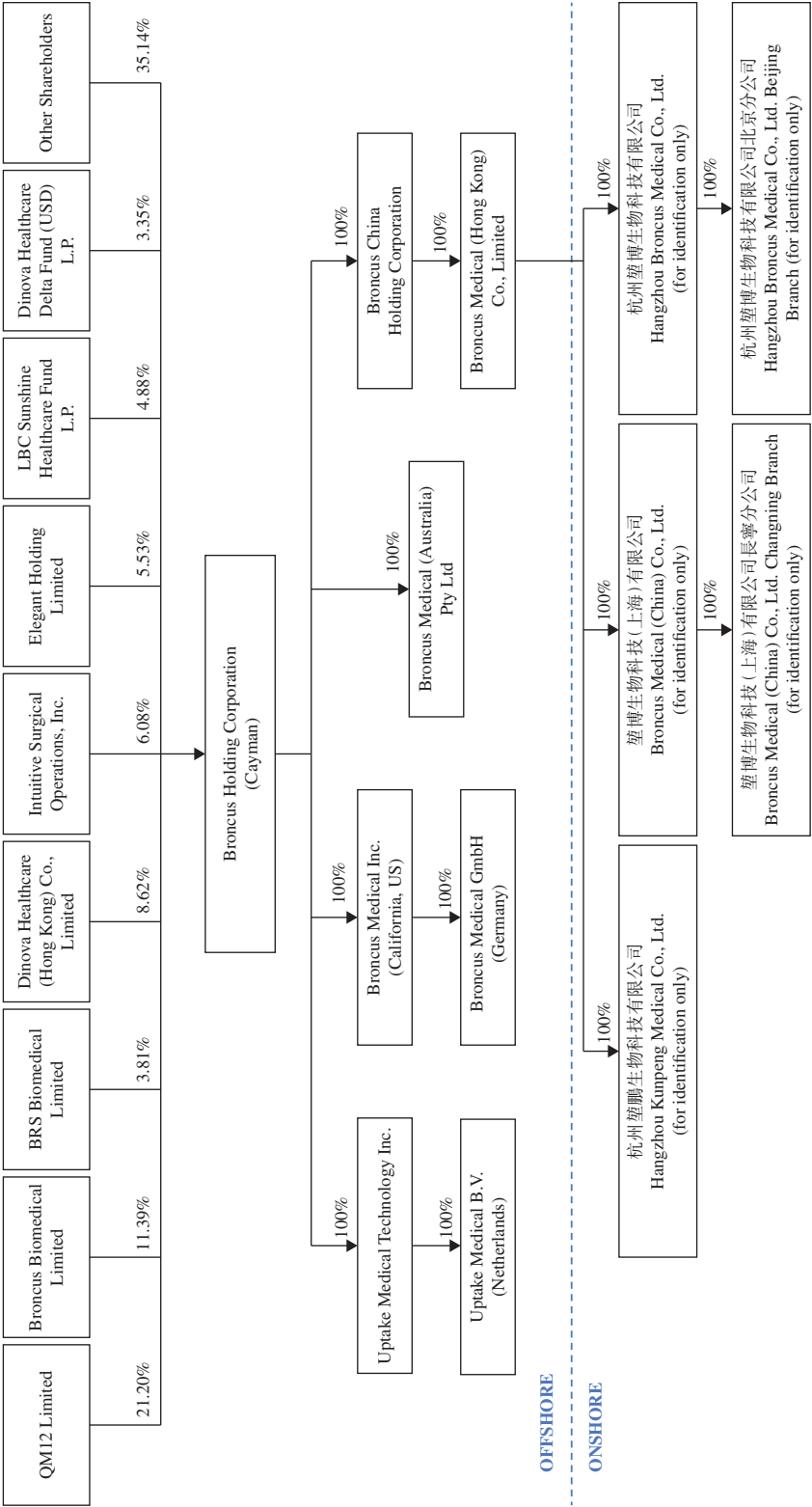
Our Company adopted the Equity Incentive Plans on [●], 2021. The purposes of the Equity Incentive Plans are to attract, motivate, retain and reward certain employees, directors, officers and certain other eligible persons of our Group. The principal terms of the Equity Incentive Plans are set out in the section headed “Statutory and General Information – D. Equity Incentive Plans” in this document. Pursuant to the Equity Incentive Plans, the maximum number of Shares subject to the share options under the Share Option Plan shall not exceed 3,170,566 Shares and the maximum number of Shares subject to the RSUs under the RSU Scheme shall not exceed 9,877,197 Shares. As of the Latest Practicable Date, no share option has been granted under the Share Option Plan.

[SPV] is a special purpose vehicle managed by the Trustee established for the purpose of holding RSUs granted pursuant to the RSU Scheme. As of the Latest Practicable Date, no RSUs of our Company have been allotted and issued to the Trustee under the RSU Scheme.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OUR STRUCTURE IMMEDIATELY UPON COMPLETION OF REORGANIZATION

The following chart sets forth our corporate and shareholding structure upon completion of the Reorganization.



The following chart sets forth our corporate and shareholding structure immediately following completion of the [REDACTED], assuming that all of the Preferred Shares have been converted into Shares of our Company on a [one-to-one] basis and the [REDACTED] is not exercised. The following chart assumes that no Shares are issued pursuant to the Equity Incentive Plans.



INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers, from the independent industry report prepared by Frost & Sullivan. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. We believe that the sources of the information in this section and other sections of this document are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. The information from official and non-official sources has not been independently verified by us, the [REDACTED], Joint Sponsors, [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon. For discussion of risks related to our industry, please see the section headed “Risk Factors – Risks Related to our Business.”

PULMONARY DISEASES, DIAGNOSIS AND TREATMENT

Overview of Pulmonary Diseases

The lung has a complex structure with the bronchial tree consisting of bronchi, bronchioles, and alveoli and the width of bronchus within the bronchial tree will reduce when the number of bifurcations increase. After 10 bifurcations, the diameter of bronchus is expected to be around 1.08 mm. Such feature has made the lung a very delicate and complicated organ for diagnosis and treatment, according to Frost & Sullivan. Pulmonary diseases affect the lungs and other parts of the respiratory system. Pulmonary diseases may be caused by infection, smoking tobacco, or breathing in secondhand tobacco smoke, radon, asbestos, or other forms of air pollution. Pulmonary diseases typically include diseases such as lung cancer, chronic obstructive pulmonary disease (“**COPD**”), pneumonia, pulmonary tuberculosis and asthma. Among these, COPD and lung cancer are two of the most prevalent lung diseases with a total global patient population of 214.6 million in 2019, according to Frost & Sullivan.

Growth Drivers for China’s Interventional Pulmonology Device Market

- **Accelerated Aging Population and Changing Disease Patterns:** According to the statistics from the National Bureau of Statistics of China, individuals aged above 65 years old reached 176.0 million in 2019, which accounted for 12.6% of the total population. The population aged above 65 years old is expected to continue to grow significantly in the future. Meanwhile, the prevalence of lung related health problems, such as COPD and lung cancer, grew rapidly over the last decade and is expected to continue to grow significantly in the future due to change of lifestyle. The aging trend and changing disease patterns will create huge demand for medical services and related devices in China.

INDUSTRY OVERVIEW

- **Growing Demands from Healthcare Institutions:** Along with the development and establishment of more hospitals and other healthcare institutions, the demand for medical devices is growing. While public hospitals in China still play a dominant role in providing healthcare services, private hospitals in China developed fast in number from 14,518 in 2015 to 22,424 in 2019 at a CAGR of 11.5%. Driven by the development of downstream healthcare institutions in the industry value chain, the medical device market in China maintains a sustainable growth.
- **Strong Government Policy Support:** The medical device market is a highly regulated and typically policy-driven market. In order to promote the development of China’s medical device market, the Chinese government has introduced a series of policies in recent years. In 2016, the “Health China 2030” was promulgated and emphasized on a further reform in the healthcare sector with a focus on accelerating the approval process of innovative or urgently needed medical devices. In 2018, the “Special Review Procedures for Innovative Medical Devices”, an update on the former “Notice on Issuing the Special Examination and Approval Procedures for Innovative Medical Devices (Trial)” of 2014 issued by the NMPA, detailed the criteria of innovative medical devices and the application process and supporting documents for the prioritized review procedure of innovative medical devices. Many interventional pulmonology devices, especially lung navigation systems, fit the criteria of innovative medical devices, thus they are eligible for speedier review procedures compared with regular medical devices. These policies will stimulate the innovation of the medical device industry in China and further benefit the industry, including the interventional pulmonology sector, in the long term. In addition, according to the 14th five-year plan (covering 2021 to 2025), the government has been, and will keep, implementing graded diagnosis and treatment systems, investing in hospitals of smaller size, reallocating patients and resources fairly among all hospitals. The government also plans to continuously improve the availability of public insurance, making hospital treatment more affordable to the general population. This will increase the demand for medical equipment such as interventional pulmonology medical devices.
- **Continuous Technology Innovation:** Technology innovation in the medical device market helps address the unmet clinical needs and further create additional market opportunities. For example, the innovative pulmonary navigation platforms can benefit patients with minimally invasive procedures. From X-ray fluoroscopy and CT navigation platforms to electromagnetic navigation devices, the technology upgrade of navigation platforms enables reduced operation time and reduces risks for both doctors and patients in targeting lesions, both before and after the procedure. Such technology innovation is believed to meet the huge market demand given the large patient pool in China. Moreover, continuous improvements of pulmonology navigation platforms increase the accuracy of diagnosis and effectiveness of therapy of pulmonary diseases and hence drive the growth of the entire interventional pulmonology device market.

INDUSTRY OVERVIEW

- **Increased Public Awareness:** With the increasing awareness of pulmonary diseases, demand for pulmonology medical services has been increasing in recent years. Hospitals need to upgrade and introduce new high-end interventional pulmonology medical devices to provide high-quality medical services for patients with pulmonary disorders. Additionally, as household income increases, people are able to spend more income on healthcare. Increased patient and doctor demand for interventional pulmonology medical devices contributes to higher revenue growth. In the meanwhile, public education of interventional pulmonology has raised awareness and acceptance of interventional pulmonology therapeutic solutions among the Chinese population. For instance, since 2017, a series of health forums on pulmonology have been hosted by Shanghai Chest Hospital, where lectures of interventional pulmonology solutions, including ablation therapy and bronchoscopy examination, have been presented by well-known KOLs in the related fields.
- **Abundant Training Resources and Improved Training Programs:** The training needed for interventional pulmonologist is not as complex as that of a standard surgery while some interventional pulmonology procedures can be as effective as a surgery for certain lung diseases. This helps lower the costs of medical personnel training for medical institutions, and resolve the problem of shortage of specialized doctors. There are also now more and more interventional pulmonology fellowship programs both online and on-site than before when training opportunities were extremely rare, which has increased the size of well-trained workforce. The currently available interventional pulmonology training programs effectively reduce the learning curve of doctors and incentivize doctors to refine their skillsets through enhanced collaborations with leading medical institutions globally.
- **Lower Medical R&D Cost:** The cost of conducting clinical research in China is approximately 30% of that in the U.S. on average. The cost of conducting animal experiments in China is also around 30% of that in the U.S. In addition, the cost per R&D staff in China can be approximately 20% to 30% to that in the U.S. generally. The low cost of medical R&D promotes technology innovation in China, providing more market potential for the players in China’s interventional pulmonology market.

INDUSTRY OVERVIEW

Overview, Prevalence, Diagnosis and Treatment of Lung Cancer

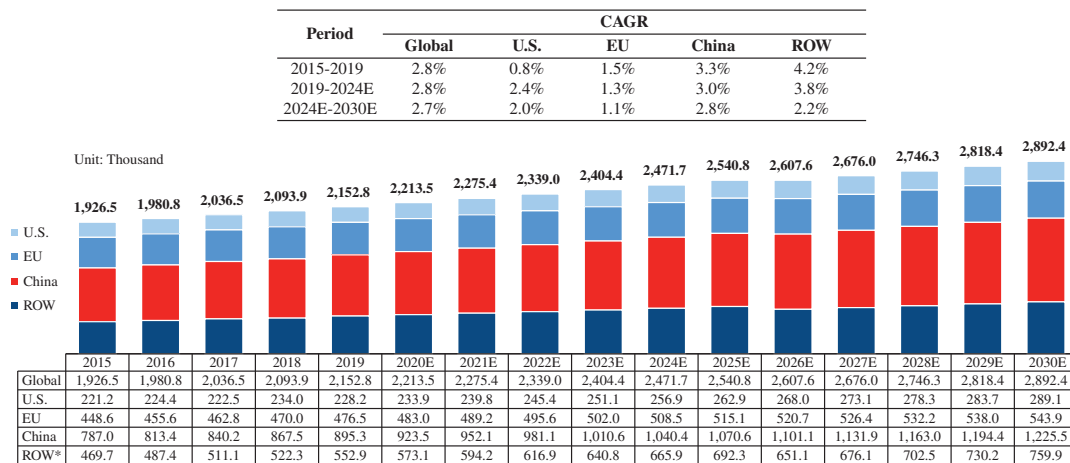
Overview of Lung Cancer

Lung cancer is a type of cancer caused by abnormal and harmful cell growth in tissues of the lung. The main types of lung cancer are small-cell lung carcinoma (“SCLC”), also called oat cell cancer, which accounted for approximately 15% of the total incidence of lung cancer around the world, and non-small-cell lung carcinoma (“NSCLC”), which accounted for approximately 85% of the total incidence of lung cancer as of 2019, according to the Frost & Sullivan Report. NSCLC is any type of epithelial lung cancer other than SCLC. The most common types of NSCLC are squamous cell carcinoma, large cell carcinoma and adenocarcinoma. These three types together account for nearly 85% of all NSCLC. All types can occur in unusual histologic variants and develop into mixed cell-type combinations. Typical symptoms of lung cancer include an intense cough, appearance of blood in cough and shortness of breath.

Incidence of Lung Cancer

Lung cancer has the world’s largest cancer patient pool, of which approximately 85% is NSCLC. Global lung cancer incidence reached 2.2 million in 2019, growing from 1.9 million in 2015 at a CAGR of 2.8%, and is expected to further increase to 2.9 million by 2030, as illustrated in the chart below.

Breakdown of New Cases of Lung Cancer by Region, 2015-2030E



Source: NCCR, Frost & Sullivan Analysis

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In terms of new cases of lung cancer, the U.S. had over 228.2 thousand cases in 2019, which grew at a CAGR of 0.8% from 2015 whereas China had over 895.3 thousand cases during the same period, which grew at a CAGR of 3.3% from 2015. Lung cancer was the most prevalent cancer in China in 2019. The lung cancer incidence in the U.S. is expected to further increase to 256.9 thousand by 2024, representing a CAGR of 2.4% from 2019, and reach 289.1 thousand by 2030. In China, the lung cancer incidence is expected to further increase to 1,040.4 thousand by 2024, representing a CAGR of 3.0% from 2019. Considering the unhealthy lifestyle and smoking habits of the Chinese population in general, it is estimated that the lung cancer incidence would reach 1,225.5 thousand by 2030 in China, representing a CAGR of 2.8% from 2024 to 2030, as shown in the chart above. A high proportion of smoking population and air pollution are two of the major factors contributing to higher lung cancer incidence in China.

Diagnosis and Treatment of Lung Cancer

The survival rate of patients with lung cancer is highly related to the stage of the cancer they are diagnosed with. Due to the nonspecific nature of lung cancer symptoms, most patients are not diagnosed until the cancer has progressed into the more advanced stage. According to Frost & Sullivan, in China, 51.6% of the patients are diagnosed with lung cancer at Stage IV at first diagnosis, with 11.0% at Stage I, 5.7% at Stage II and 31.8% at Stage III. In the U.S., 40.5% of the patients are diagnosed with lung cancer at Stage IV at first diagnosis, with 20.6% at Stage I, 4.0% at Stage II and 26.4% at Stage III. In EU, 52.4% of the patients are diagnosed with lung cancer at Stage IV at first diagnosis, with 14.0% at Stage I, 7.7% at Stage II and 26.0% at Stage III. More patients in China are diagnosed with lung cancer at later stages and fewer at earlier stages due to lack of access to effective diagnosis methods.

Furthermore, based on the Frost & Sullivan Report, lung cancer has the highest mortality rate of all cancers globally, implying a significant demand for clinical development of lung cancer diagnosis and treatment. Lung cancer has a low survival rate compared to other forms of cancer. According to Frost & Sullivan, the latest five-year survival rate of lung cancer (calculated for the period between 2012 and 2015) is 19.7% in China whereas such rate is 19.4% in the U.S. (calculated for the period between 2009 and 2015).

Early diagnosis of lung cancer is important for ensuring effective treatment. For lung cancer, there is more proportion of advanced cancer diagnosed than early-stage cancer with only 11.0% for Stage I lung cancer and 51.6% for Stage IV lung cancer and the five-year survival rate of Stage I lung cancer can reach 56.6% as compared to a significant lower survival rate of 2.9% for Stage IV lung cancer. Furthermore, the cost of lung cancer treatment is generally lower when the disease is caught at an earlier stage. Diagnosis and accurate staging of lung cancer is essential for selection of appropriate curative or palliative therapy and affects patient prognosis. Hence, the market is in strong need of diagnostic solutions that are effective for early diagnosis of lung cancer.

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Overview, prevalence, diagnosis and treatment of COPD

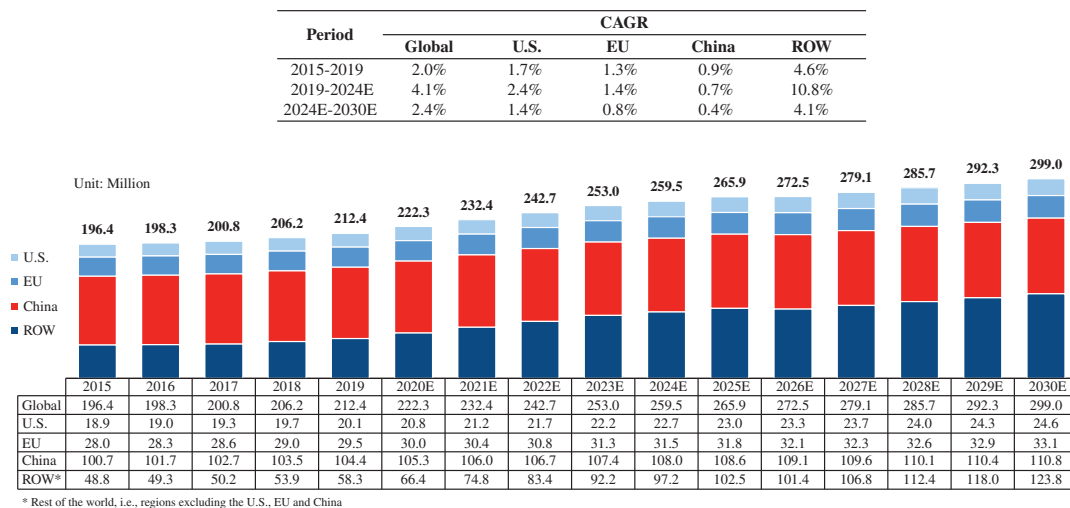
Overview of COPD

COPD is a common disease characterized by persistent respiratory symptoms and airflow restrictions, including chronic cough, sputum production and progressive dyspnea. The diagnosis of COPD is predicated upon the recognition of its two major forms: emphysema and chronic bronchitis. These two forms represent different manifestations of COPD although they frequently coexist in the same individual. Emphysema is a lung condition that causes shortness of breath. Chronic bronchitis is inflammation (swelling) and irritation of the bronchial tubes.

Prevalence of COPD

According to the Frost & Sullivan Report, in 2019, the COPD prevalence reached 212.4 million globally at a CAGR of 2.0% from 2015 to 2019, and is expected to grow at a higher CAGR of 4.1% from 2019 to 2024 to reach 259.5 million by 2024 and ultimately reach 299.0 million by 2030, representing a CAGR of 2.4% from 2024 to 2030, as showed in the chart below.

Breakdown of Prevalence of COPD by Region, 2015-2030E



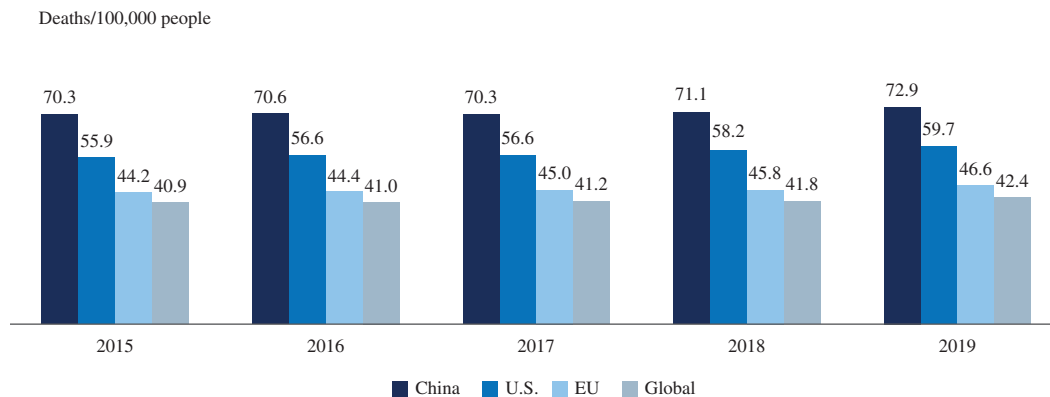
Source: Literature research, the GDB study, Frost & Sullivan Analysis

In the U.S., the prevalence of COPD reached 20.1 million people in 2019 with a CAGR of 1.7% from 2015 to 2019, and is expected to grow at a CAGR of 2.4% from 2019 to 2024 to reach 22.7 million people by 2024 and ultimately reach 24.6 million people by 2030, representing a CAGR of 1.4% from 2024 to 2030. In China, the prevalence of COPD reached 104.4 million people in 2019 with a CAGR of 0.9% from 2015 to 2019, and is expected to reach 108.0 million people by 2024 with a CAGR of 0.7% from 2019 to 2024 and ultimately reach 110.8 million people by 2030, representing a CAGR of 0.4% from 2024 to 2030, as shown in the chart below. The mortality rate of COPD is higher in China as compared to the U.S. and EU, leading at 72.9 deaths/100,000 people, which shows unmet market need for diagnosis and

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treatment options in China. In addition, the majority of the COPD patients in China have a mild or moderate disease with 29.8% of the entire COPD patient population suffering from GOLD stage I as defined in Global Initiative for Chronic Obstructive Lung Disease (“**GOLD**”) and 43.1% GOLD stage II while GOLD stage III patients account for 26.1% and the rest of the 0.9% patients have GOLD stage IV. The U.S. has similar COPD patient demographics with 22% of the entire COPD patient population suffering from GOLD stage I, 55% GOLD stage II, 21% GOLD stage III and 2% GOLD stage IV. However, the five-year mortality rate for severe COPD patients (GOLD stage III & GOLD stage IV) in China is as high as 54.0% as compared to 34.0% in the U.S., according to Frost & Sullivan.

Mortality Rate of COPD by Regions, 2015-2019



Source: the GDB study, Frost & Sullivan Analysis

Diagnosis and treatment of COPD

Despite the overall large COPD patient pool in China, the actual diagnosis rate is less than 30%, far lower than the 68.3% diagnosis rate in the U.S., according to Frost & Sullivan. The major diagnosis method for COPD is lung function test, and the diagnosis is confirmed when the FEV1/FVC ratio, a ratio commonly used for COPD diagnosis that represents the proportion of a person’s vital capacity they are able to expire in the first second of forced expiration (“**FEV1**”) to the full forced vital capacity (“**FVC**”), is less than 70% after using bronchodilator. For healthy individuals, the FEV1/FVC ratio is normally above 80%. After the diagnosis is confirmed, the severity of airflow restriction will be subsequently assessed.

COPD drug treatment can be divided into four categories, bronchodilator, long-acting β_2 receptor agonist (“**LABA**”), long-acting muscarinic antagonist (“**LAMA**”) and inhaled glucocorticoid (“**ICS**”), based on different symptoms and assessment of exacerbation levels. COPD treatment is based on bronchodilators, which cause airway dilation by changing the tension of airway smooth muscles. Regular use can effectively prevent or reduce the symptoms of COPD. The initial treatment of COPD is usually LABA and LAMA. For patients with moderate to very severe COPD, combined therapy of ICS with LABA can effectively improve lung functions and more efficiently reduce the incidence of acute exacerbations than a single agent. Triple therapy improves symptoms and reduces risk better than single medication. The

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drug treatment of COPD is mainly used to relieve symptoms, reduce the frequency and severity of disease deterioration, and improve cardio endurance and health. As of now, there is no conclusive clinical trial evidence that existing drugs can adjust the long-term decline in lung function. There are also non-pharmacological treatments for COPD such as education, self-management, and pulmonary rehabilitation, vaccination, intervention bronchoscopy, surgery and nutrition. For late-stage COPD patients, currently available treatment options are limited as clinical research results indicated that improvement in exercise capability was reported in only 2% of patients after 24 months of standard medical treatment and none reported improved health-related quality of life. Thus, there are significant unmet clinical needs from COPD patients.

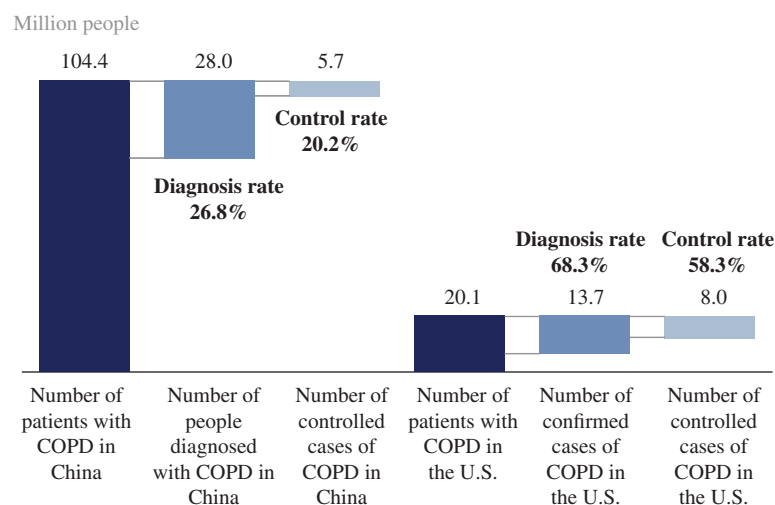
PULMONARY DISEASE DIAGNOSIS AND TREATMENT MARKET

Current Pulmonology Diagnosis and Treatment Paradigm

The pulmonology diagnosis and treatment paradigm in China currently has the following challenges which urge for transformation.

- High prevalence and low diagnosis and control rates:** The prevalence of COPD in China is 7.4%. The number of COPD patients in China is 104.4 million compared against a 20.1 million COPD patient population in the U.S. in 2019. The prevalence of COPD in men is almost two times of that in women and the prevalence rate in rural areas is approximately 25% higher than that in urban. On the other hand, the diagnosis rate of COPD in China is only 26.8% as compared to a diagnosis rate of 68.3% in the U.S. There has been material difference in the control rate of COPD between China and U.S. with only 20.2% in China compared against 58.3% in the U.S.

Current Status of COPD Diagnosis and Treatment in China and the U.S., 2019



Source: Frost & Sullivan Analysis

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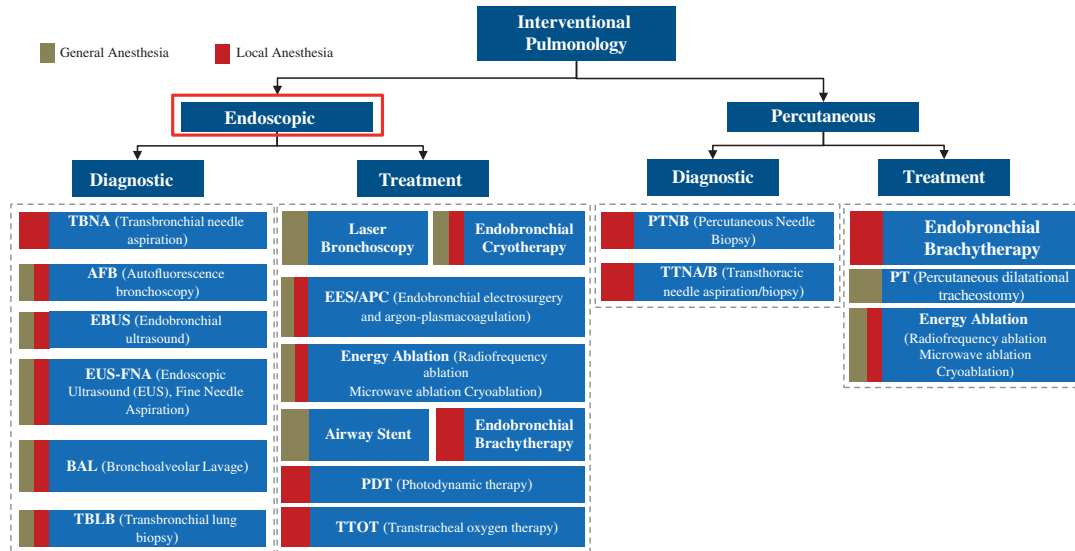
- **Lack of standardized diagnosis and treatment:** The conventional treatment rate, i.e., the percentage of patients diagnosed with the disease that are under active treatment, for patients with COPD in China is only 7.9%, and the patients’ health service needs have not been met. There still exists a strong need to enhance prevention and management of COPD in China. Although there are standardized diagnosis and treatment plans, few doctors strictly follow the diagnosis and treatment plans to guide their decision-making.
- **Disease risk factors are difficult to control:** Smoking and air pollution are the two major risk factors for COPD in China. In recent years, the smoking rate of people aged 15 and over in China was 26.6% overall, of which 50.5% of males and 2.1% of females smoked cigarettes. China also has high indoor bituminous coal emissions, making COPD more prevalent in the country.
- **Current treatment options are limited:** Traditional pharmaceutical treatment options for COPD are mainly designed to slow down the exacerbation of patients’ conditions or enhance the prevention. However, these traditional pharmaceutical treatment options are proven to have low effectiveness for late stage COPD patients. Surgeries in the meanwhile are too invasive for COPD patients whose health conditions especially lung functions are too fragile to endure the operation process including post-procedure care.

Interventional Pulmonology Market

Overview of Interventional Pulmonology

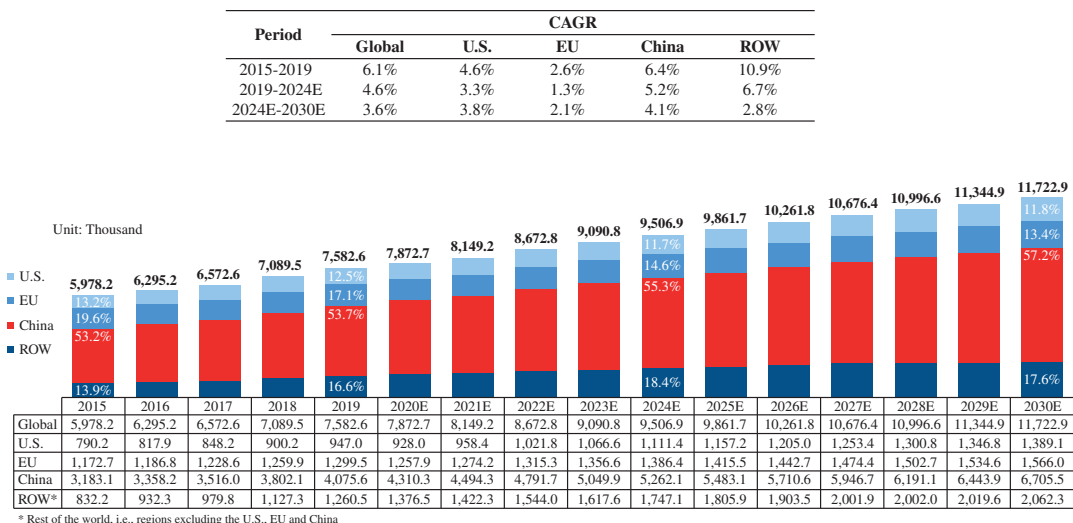
Main procedures of interventional pulmonology consist of endoscopic procedures and percutaneous procedures. These procedures often involve different requirements of medical personnel, medical devices, and use of anesthesia. Treatment procedures of interventional pulmonology are often based off of diagnostic procedures with additional technologies for specific conditions of diseases. Diseases for which interventional pulmonology is applicable include COPD, lung cancers and pleural disorders. Compared to traditional surgery, interventional pulmonology offers the benefits of low cost and minimal risks to patients. The fact that interventional pulmonology procedures can be performed before any surgery makes it the first choice for diagnosis and treatment of almost any lung disease.

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Interventional pulmonology therapy with minimally invasive methods has been increasingly used in the treatment of pulmonary diseases such as COPD and lung cancer. In 2019, the number of bronchoscopy examination procedures conducted globally reached 7.6 million units at a CAGR of 6.1% from 2015 to 2019. Such number is expected to reach 9.5 million units by 2024 and 11.7 million units by 2030. In 2019, the number of bronchoscopy examination procedures conducted in China reached 4.1 million units at a CAGR of 6.4% from 2015 to 2019 and such number is expected to reach 5.3 million units by 2024 and 6.7 million units by 2030.

Breakdown of Bronchoscopy Examination Procedure Number by Region, 2015-2030E



Source: Frost & Sullivan Analysis

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Entry barriers of interventional pulmonology market

- **Technology:** Interventional pulmonology medical devices are high-value medical devices, which demand solid technology capabilities. For example, due to the complex structure of the bronchus and numerous branches, it requires high quality and high accuracy of interventional pulmonology navigation devices to be effectively used in interventional pulmonology procedures. A qualified navigation device should be able to plan ahead or even display the path of the bronchoscope into the bronchus and reach the lesion in real time.
- **Industry regulation:** The interventional pulmonology medical device industry is subject to heavy regulations by different government administrations. Regulation certifications incentivize manufacturers to improve the quality of their devices and manufacturing environment, which also entails higher costs for production.
- **Professional barriers:** Highly skilled labors are essential to interventional pulmonology medical device companies. There is a strictly high requirement for both research and development of interventional pulmonology medical devices and the operation of relevant medical procedures. The availability of highly skilled labors which have both research and development capabilities and market regulatory knowledge is important to manufacturers of interventional pulmonology medical devices. Slow and non-organized talent training programs may restrict the development of the interventional pulmonology medical device market.
- **Underserved public education on interventional pulmonology medical devices:** There is still ample room to raise awareness of interventional pulmonology medical devices due to a lack of profound understanding of this field currently from both the doctors and patients in China. It is important for companies to educate hospitals and doctors on the effectiveness and application scenarios of their products. Currently, interventional pulmonology therapeutic devices are not mainstream treatment options. Whether hospitals would adopt these devices and from which specific company hospitals would adopt the therapeutic devices is highly dependent on how the companies manage their commercialization and promotion.

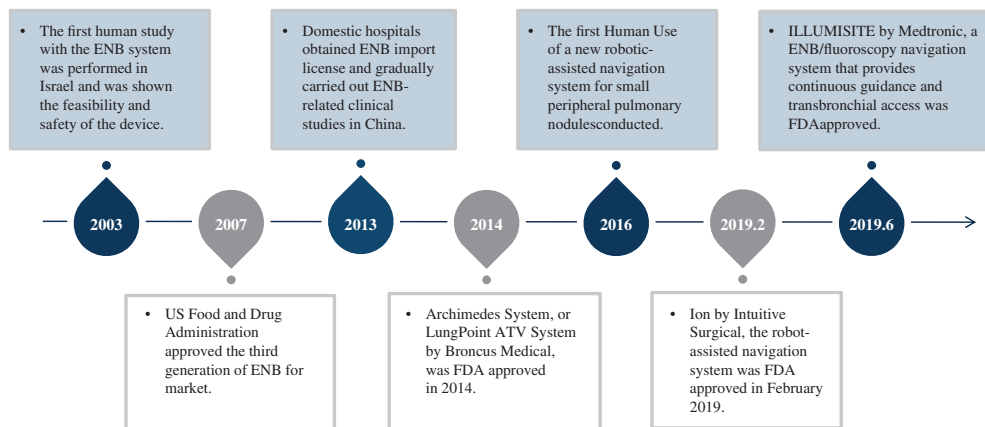
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Lung Navigation

Overview

Interventional pulmonology navigation platform refers to navigation technologies that doctors utilize to perform diagnosis and treatment for pulmonary diseases. Interventional pulmonology navigation platforms include ultrasound, electromagnetic and optical navigation systems.

Electromagnetic navigation systems, as “GPS for the lungs”, use an electromagnetic field to track instruments through the airways or skins. Electromagnetic navigation bronchoscopy relies on a pre-procedural CT of the chest to create a three- dimensional (3D) virtual airway map for real-time tracking to the lesion of interest. Optical navigation is based on X-ray fluoroscopy or CT to guide for percutaneous and transbronchial lung biopsy. Virtual bronchoscopic navigation (“VBN”) is an optical navigation method in which virtual images of the bronchial route to the lesion are produced based on CT images obtained before VBN, and the bronchoscope is guided using these virtual images, improving the diagnostic yield of peripheral pulmonary lesions. The success of electromagnetic navigation bronchoscopy led to the development of many new bronchoscopy navigation systems such as the VBN system and robotic-assisted system. Renowned international players in the interventional pulmonology medical device industry have focused on developing innovative lung navigation systems as illustrated in the below chart.



Source: Frost & Sullivan Analysis

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The table below lists out the commercialized interventional pulmonary navigation platforms globally. The Archimedes System developed by Broncus, also known as LungPro in the mainland of China, is the world’s only navigation system capable of whole lung access augmented reality real-time image navigation, according to Frost & Sullivan.

Product Name	LungPro /Archimedes	superDimension™ Navigation System (Newest Generation)	Auris Robotic Endoscopy System	LungVision	SPiN Thoracic Navigation System	Monarch	Ion	ILLUMISITE	LungCare
Manufacturer	Broncus	Medtronic, USA	AURIS, USA	Body Vision Medical	Veran Medical Technologies	Johnson & Johnson AURIS, USA	Intuitive Surgical, USA	Medtronic, USA	LungCare Medicals, China
Classification	Optical Navigation	Electromagnetic Navigation	Electromagnetic Navigation	Optical Navigation	Electromagnetic Navigation	Electromagnetic and Optical Navigation	Fiber Optic RealShape Navigation	Electromagnetic Navigation	Electromagnetic Navigation
Key Technology	VBN Whole Lung Access with BTPNA	Real-time continuous guidance	Robotic-assisted bronchoscopy	Fluoroscopic navigation	Stereotactic accessories	Robotic-assisted navigation	Robotic-assisted Lung Biopsy	Real-time continuous guidance	Combination of ENB and VBN
Whether Whole Lung Access	Yes by BTPNA	Yes by CrossCountry™ *No blood vessel reconstruction	No	No	Yes by TTNA	No	No	Yes by CrossCountry™ *No blood vessel reconstruction	No
FDA Approval Time	2014.02	2015.01	2016.05	2017.04	2017.05	2018.03	2019.02	2019.08	N/A
NMPA Approval Time	2017	2017	N/A	N/A	2017	N/A	N/A	N/A	2016

Source: Frost & Sullivan Analysis

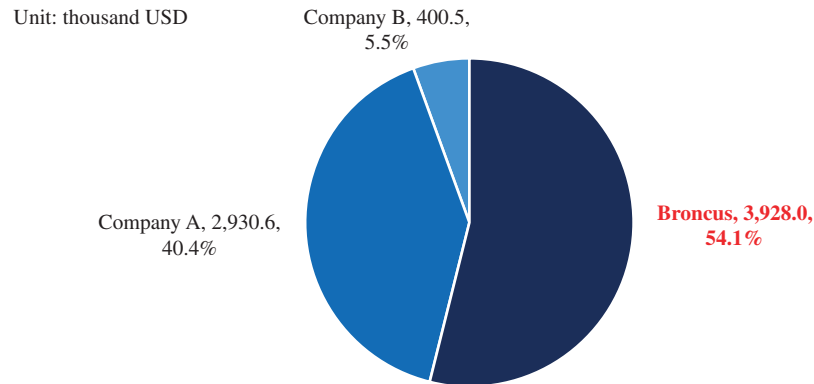
The average ex-factory prices of lung navigation systems marketed in China have stayed relatively stable in the past few years and the major raw materials used for manufacturing the systems have also stayed relatively stable and is expected to remain so. A wider market acceptance of advanced navigation technologies may drive up the unit price for future lung navigation products.

Market size of China’s interventional pulmonology navigation device market

In 2019, the interventional pulmonology navigation platform market in China reached US\$7.3 million with a high CAGR of 93.3% from 2015 to 2019, and is expected to reach US\$140.5 million by 2024. In 2019, the sales of interventional pulmonology navigation platform in China reached 29 devices at a CAGR of 95.1% during the period from 2015 to 2019, and is expected to reach 877 devices by 2024 at a CAGR of 97.7%. There are three major players in China’s interventional pulmonology navigation device market, including Broncus, which share the entire market of interventional pulmonology navigation platform sales. Broncus is the largest market player in China’s interventional pulmonology navigation device market with a market share of 54.1% measured by sales revenue and 62.1% measured by sales volume respectively in 2019, followed by Company A with a market share of 40.4% measured by sales revenue and 31.0% measured by sales volume respectively and Company B with a market share of 5.5% measured by sales revenue and 6.9% measured by sales volume, respectively, as illustrated in the charts below.

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Breakdown of China Interventional Pulmonology Navigation Platform Sales Revenue by Manufacturers, 2019

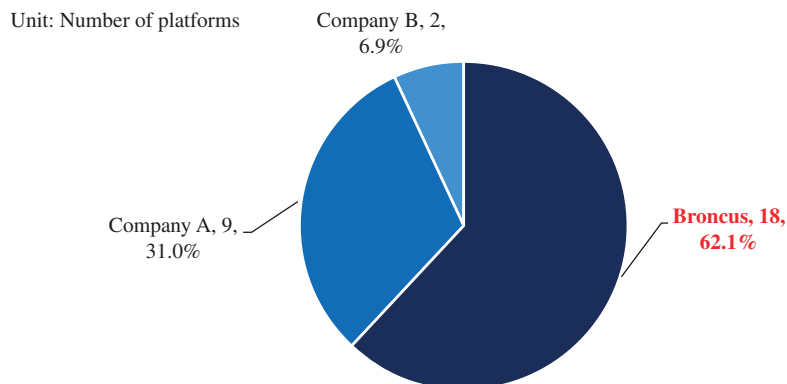


Source: Frost & Sullivan Analysis

Notes:

- (1) Company A is an American Ireland-domiciled medical-device company covering four business segments: cardiac and vascular, minimally invasive therapies, restorative therapies, and diabetes.
- (2) Company B is a navigation technology company in China focused on early detection, accurate and minimally invasive diagnosis and treatment of lung diseases.

Breakdown of China Interventional Pulmonology Navigation Platform Sales Volume by Manufacturers, 2019



Source: Frost & Sullivan Analysis

Notes:

- (1) Company A is an American Ireland-domiciled medical-device company covering four business segments: cardiac and vascular, minimally invasive therapies, restorative therapies, and diabetes.
- (2) Company B is a navigation technology company in China focused on early detection, accurate and minimally invasive diagnosis and treatment of lung diseases.

Future trends of interventional pulmonology navigation device market

The future trends of the interventional pulmonology navigation device market include the following:

- **Increasing awareness for early diagnosis and treatment of lung disorders drives the acceptance of high-end medical devices:** Lung diseases are among the most common medical conditions in China. With the increasing awareness for early diagnosis and treatment of lung diseases, people will be more willing to adopt more effective diagnostic and therapeutic solutions for pulmonary diseases, thus driving

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the growth of the interventional pulmonology navigation device market, which is featured by precision targeting and minimal invasiveness, resulting in significant increase in market penetration.

- Advanced technology tools make precise treatment available:** The application of advanced techniques such as artificial Intelligence (AI), augmented reality (AR) and big data will lead to more precise positioning for lung biopsy and therapies. The improvement of technologies will optimize the management of lung diseases and therefore maximize patients’ survival rate. In particular, BTPNA as opposed to navigation through small and distal airways will become a viable means for future treatment of lung cancer.

Pulmonary Disease Diagnosis

Overview

Pulmonary disease diagnostics include open lung biopsy, interventional pulmonology diagnosis and the traditional approach of radiological scanning. Traditional scanning includes approaches such as X-ray, CT scanning, PET-CT scanning and MRI, the accuracy of which are often doubted. In addition, the radiation used in these procedures can be detrimental to patients. For open lung biopsy, the surgeon makes a small cut in the left or right side of the patient’s chest and a viewing scope would be inserted through a small hole between the ribs to check the area to be biopsied. As for interventional pulmonology diagnosis, it uses endoscopy and other tools to diagnose and treat conditions in the lung and chest. Open lung biopsy is always considered the last option to adopt as it entails great risks to the biopsied patients. It is too invasive for patients with coexisting diseases such as COPD and heart failure. Among all currently available diagnosis options for lung cancer, including radiological scanning, interventional pulmonology, percutaneous diagnosis and open lung biopsy, interventional pulmonology has the unique advantages of precise positioning with limited side effects and high diagnostic yields. The below chart compares different diagnosis options for lung cancer.

	Radiological scanning	Interventional pulmonology	Percutaneous diagnosis	Open lung biopsy
Location of reach	Radiological scanning creates pictures of the whole lung field.	Advanced interventional pulmonology get access to peripheral nodules beyond the reach of conventional bronchoscopes.	The average pleura-to-lesion distance is less than 30mm.	It can reach lung tissues that can be exposed by open lung surgery.
Procedure duration	Less than a few minutes for X-ray and CT. About 3 hours for PET-CT.	22.9-33.5 min	8.8-43.2 min	37.0-79.0 min
Hospital stay	Does not require a hospital stay	Does not require a hospital stay	No more than an overnight stay	2.8-3.2 days
Compatibility with other devices/clinical applications	Radiological scanning should be performed before other diagnostic and therapeutic procedures.	Treatment path is established. Different devices put on the end of a bronchoscope can be used to treat blocked airways or some other types of problems in the lung.	No treatment path is established.	It is always considered the last option as it entails great risks.
Major players	GE Healthcare, Fujifilm Healthcare, Hitachi Healthcare	Broncus, Medtronic, LungCare Medical, Body Vision Medical	Argon Medical, Merit Medical	Scalpel manufacturers such as Aspen Surgical
Diagnostic yield	The accuracy of these tests are often doubted. X-ray misses about 23% of those who have it. CT and MRI scans have a chance of missing a potential patient with lung cancer.	Traditional transbronchial biopsy with bronchoscopy has a diagnostic yield of only 14-63%. EBUS with real-time confirmation improves yield over conventional transbronchial biopsy. The diagnostic yield of ENB alone is reported to range from 59-74%	TTNA/B has an overall diagnostic sensitivity of 68-96%, an accuracy of 74-96% in lesions of all sizes.	It has sensitivity and specificity of 95%
Safety and side effects	The radiation used in these procedures can be detrimental to the patient. Traditional radiology methods for lung biopsy often lead to a higher risk of potential complications such as pneumothorax, including occasional reports of death	Patients who present poor general conditions or severe hypoxemia due to coexisting diseases (such as COPD and heart failure) may not be possible to use invasive procedures for diagnosis and staging. It can sometimes cause pneumonia, pneumothorax, self-limited minor bleeding and an inadvertent puncture of the adjacent structure.	It can cause pneumonia, pneumothorax, self-limited minor bleeding and an inadvertent puncture of the adjacent structure. A pneumothorax rate of 25% in TTNB was reported.	It is too invasive for patients with coexisting diseases such as COPD and heart failure. Complications include pneumonia, pneumothorax, severe bleeding, wound infection, and blood clot.

Source: Literature research, Frost & Sullivan Analysis

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Interventional pulmonology diagnostic methods can be generally classified into two types – bronchoscopy and percutaneous method. Bronchoscopy is the most common form of interventional pulmonology diagnostic methods and the percutaneous method is a complementary method performed when bronchoscopy cannot obtain the biopsies accurately and safely. In general, bronchoscopy methods have a safer profile than percutaneous methods. The most basic form of bronchoscopy is transbronchial lung biopsy (“**TBLB**”), which uses transbronchial needle aspirations (“**TBNA**”) or forceps to obtain cells or tissues for diagnosis. The most basic form of percutaneous interventional pulmonology diagnostic methods is called transthoracic needle aspiration/biopsy (“**TTNA/B**”) or percutaneous transthoracic needle biopsy (“**PTNB**”), which involves a possible incision on the skin and the insertion of a needle into a suspected lesion or an organ to obtain cells or tissues for diagnosis. The interventional pulmonology methods can become extremely complicated and advanced with the addition of various technologies, such as ultrasonography, electromagnetic guidance system, radiofrequency ablation system, to achieve different therapeutic functions. Depending on the severity of the diseases, patients may need multimodality treatment, which is the combination of various endoscopic techniques or the combination of endoscopy with non-endoscopic modalities or even surgery and radio/chemotherapies to treat tracheobronchial lesions. The table below summarizes the major interventional pulmonology diagnostic methods, and Broncus’ diagnostic technique which involves TBNA:

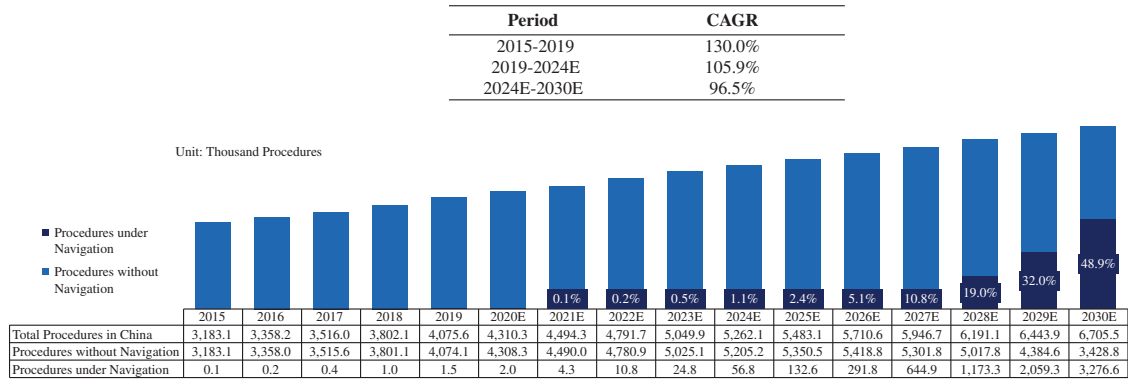
Name	Approach	Reach lesions outside airways	Accuracy	Application	Complications
Transbronchial Needle Aspiration (TBNA)	One of the most basic approaches using a flexible bronchoscope to obtain cellular material with a needle that is passed through the bronchial wall.	Yes	Increase the diagnostic yield of flexible bronchoscope by 20-25%. The diagnostic sensitivity of EBUS-TBNA ranges from 67-90%. EBUS-TBNA reduces the need for additional procedures.	Bronchogenic carcinoma, peribronchial/tracheal masses, submucosal disease, peripheral lung nodules. It is used to obtain tissue from lung or hilar/mediastinal lesions that are in close proximity to the endobronchial tree.	Complication rate ranges from 1.9-2.9%. Complications include pneumothorax (1.3%), hypoxemic respiratory failure (0.6%), and self-limited minor bleeding.
Transthoracic needed aspiration/biopsy (TTNA/B)	Percutaneous sampling of lesions involving the chest wall, lung parenchyma, and mediastinum by inserting a long needle into the chest wall between ribs for cytological, histopathological, or microbiological examinations.	Yes	TTNA/B has an overall diagnostic sensitivity of 68-96%, an accuracy of 74-96% in lesions of all sizes. In smaller lesions, its diagnostic accuracy is lower.	Peripheral lung nodules or infiltrates, pleural masses, selected cavitary lesions, mediastinal masses, and other thoracic lesions accessible via percutaneous approach. Complementary to endoscopic approaches. Relative contraindications range from pulmonary hypertension to emphysematous disease and COPD.	Complication rate ranges from 36.4-42.9%. The incidence of pneumothorax is ~20-40%; self-limiting haemorrhage and haemoptysis are infrequent (1.2%).

Source: Frost & Sullivan Analysis

Based on Frost & Sullivan’s analysis, in 2019, the number of bronchoscopy examination procedures performed under navigation platform guidance in China reached 1.5 thousand units at a CAGR of 130.0% from 2015 to 2019, and is expected to reach 56.8 thousand units by 2024 at a CAGR of 105.9% from 2019 to 2024, accounting for 1.1% of total bronchoscopy procedures in China. The market penetration of bronchoscopy examination procedures performed under navigation platform guidance is expected to ultimately reach almost 50% of total bronchoscopy procedures in China by 2030, presenting a significant market potential for the growth of lung navigation system sales. Furthermore, in 2019, the market size of interventional pulmonology diagnostic consumables in China reached US\$25.1 million at a CAGR of 39.8% from 2015 to 2019, and is expected to reach US\$43.1 million by 2024.

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Number of Bronchoscopy Examination Procedures Performed under Navigation Platform Guidance in China, 2015-2030E



Source: Frost & Sullivan Analysis

Competitive benchmarking of diagnostic medical consumables manufacturers

The table below lists out the interventional pulmonology diagnostic medical consumables for navigation platform and market players in China.

Navigation Platform	Product Name	Manufacturer	Picture
LungPoint/LungPro	FlexNeedle	Broncus	
	ATV Tools (FlexNeedle, ATV Sheath, ATV Balloon)		
	BioStarNeedle		
	Steerable Sheath		
SPiN Thoracic Navigation System	SPiN Needles	Veran Medical	
	vPad ® Patient Tracker		
	Always-On vTrack Universal Tracker		
LungCare System	LungCare Bronchoscopies kit	LungCare Medical	N/A
SuperDimension	SuperDimension Navigation Accessories	Medtronic	

Source: Frost & Sullivan Analysis

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Pulmonary Disease Treatment

Interventional pulmonology therapeutic methods for lung cancer

The procedure of interventional pulmonology therapeutic methods for lung cancer can be mainly divided into two types: vascular route and non-vascular route. Vascular route includes vasoconstriction therapy and chemotherapy. Vasoconstriction therapy relieves low blood pressure and chemotherapy helps to kill cancer cells. Non-vascular route includes routes such as radiofrequency ablation (“**RFA**”), thermal vapor ablation, and microwave ablation. Energy ablation system heats the tumor and therefore kills the cancer cells. Common energy ablation technologies include RFA, microwave ablation, cryoablation and laser ablation. Among these, RFA is the most widely used ablative technique for treatment of lung malignancies, according to Frost & Sullivan.

According to Frost & Sullivan’s analysis, RFA, as the first commercially viable ablation device, is currently available and widely adopted with the following advantages:

- **Cost effective:** It is relatively cost effective compared with other newer devices, such as microwave ablation and high-intensity–focused ultrasound scan.
- **Safety:** Using small electrode size (14–17 gauge), it gently burns with a better safety profile than that of microwave ablation and cryoablation.
- **Adverse event rates:** It generally produces relatively lower adverse event rates than microwave ablation with a range between 23.9% and 39.5% as compared to a 43.5% average adverse event rate for microwave ablation.
- **Compatibility:** It is compatible with imaging devices such as magnetic resonance imaging and computerized tomography.

Interventional pulmonology therapeutic methods for COPD

The procedure types of COPD interventional pulmonology therapeutic methods include thermal vapor ablation, valve therapy and coils therapy. Thermal vapor ablation uses heated water vapor to produce a thermal reaction leading to an initial localized inflammatory response followed by permanent fibrosis and atelectasis. Valve therapy is a kind of lung volume reduction operation, an operation to disable a lobe without removing any lung tissue. Coils therapy serves as a potential treatment option for patients with presence of interlobar collateral ventilation because compression of the lung parenchyma by the coils devices results in less hyperinflation and simultaneously better transmits the elastic recoil pressure. However, currently there is no commercially viable coils therapy.

Among these approaches, thermal vapor ablation systems offer the following competitive advantages, which include (i) larger target population: thermal vapor ablation is proven to be effective for most heterogeneous emphysema patients because BTVA is not influenced by collateral ventilation, whereas valve therapy is effective only among patients without collateral ventilation; and (ii) improved efficacy and safety profile: thermal vapor ablation targets most-diseased segments to be treated while preserving the healthier segment and treatment can be given through multiple times.

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Competitive benchmarking for radiofrequency ablation (“RFA”) and thermal vapor ablation

Major global commercialized RFA systems for interventional pulmonary treatment include the following:

Device	Manufacturer	Ablation system	Key technology	Indications	Mean tumor diameter	Procedure duration	Median overall survival (months)	Adverse effects
EMPOWER RF Energy Ablation Catheter 1.0 (RF-I)	Broncus	RFA	Flexible catheter	Lung soft tissue	18.9 mm - 22.8 mm	8 min	N/A	No device-related adverse events reported
RF Generator + RF Ablation Catheter (RF-II)	Broncus	RFA	RFA system used in conjunction with a disposable lung RFA catheter through bronchoscopy	Lung cancer	<30 mm	N/A	N/A	N/A
dNerva® Lung Denervation System	Nuvaira	RFA	TLD to reduce clinical consequences of neural hyperactivity	COPD	N/A	Total procedure time is 89±16 min	N/A	Serious gastric events can occur
RITA® - RFA System	Balmer Medical	RFA	RF generator for RF energy in percutaneous, open or laparoscopic surgical procedures; compatible with full family of AngioDynamics RFA-based electrodes	Liver, kidney, lung, breast, bone; for lung: small lung malignancies both primary and secondary	26 mm	5-9 min	33.4	No device-related adverse events reported
RF3000™ Radiofrequency Ablation System	Boston Scientific	RFA	thermal coagulation necrosis of soft tissues	Ablation of soft tissue (including lung neoplasms); unresectable liver lesions	21 mm	15 min	59	Grade 3 adverse event rate is 6%
Cool-tip™ RF Ablation	Medtronic	RFA	Unique Cool-tip™ electrodes internally circulate chilled water, cooling the tissue adjacent to the exposed electrode to maximize energy deposition and eliminate tissue charring resulting in decreased treatment time and controlled ablation volume.	Percutaneous, laparoscopic and intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions.	20 mm	12 min	30	Pleural effusion (21%), pneumonia (16%), minor hemoptysis (16%), pneumothorax (13%)
Cool-tip™ RF Ablation System E Series	Medtronic	RFA	Improves on the trusted Cool-tip™ RFA system with a simple, intuitive design and new safety features.	Soft-tissue tumors	21 mm	12 min	59	No device-related adverse events reported

Source: Frost & Sullivan Analysis

Major global commercialized products for COPD-related interventional pulmonology therapeutic methods include the following:

Device	Manufacturer	Category	Key Technology	Indications	Marketed Region	Approval Time
InterVapor®	Uptake Medical (Broncus)	Thermal vapor ablation	By instillation of heated water vapor, an inflammatory reaction is induced, leading to fibrosis and scarring of the lung parenchyma, resulting in lobar volume reduction. With a controlled spray of precisely targeted vapor, it selectively ablates only the diseased lung tissue segments.	Heterogeneous upper lobe emphysema	CE	2018
Zephyr® Valve	Pulmonx	Valve therapy	A oneway silicone duckbill valve attached to a nickel-titanium (Nitinol) self-expanding retainer that is covered with a silicone membrane.	Emphysema with little to no collateral ventilation	CE, US	2003, 2018
Spiration® Valve System	Olympus	Valve therapy	An umbrella shaped one-way valve comprised of a flexible nickel-titanium (Nitinol) frame that supports a polymer membrane.	Heterogeneous emphysema with low collateral ventilation	CE, US	2008, 2018

Source: Frost & Sullivan Analysis

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Features needed for players to succeed in the interventional pulmonology therapeutic sector

- **Proven therapeutic value:** Currently, drugs, surgery and/or radiation therapies are still the mainstream treatment options for lung diseases. Interventional pulmonology therapeutic devices are deemed as an alternative treatment option. Therefore, the devices must show proven and even higher therapeutic value to make hospitals recognize their true therapeutic effects.
- **Good marketing capability:** As therapeutic interventional pulmonology is not yet a mainstream treatment option in hospitals and among doctors, the capability to gain endorsement from hospitals and doctors can be essential for players in this market. Good marketing capability within the medical system can help obtain support from hospitals and doctors. Therefore, players with premier marketing capability will likely capture market shares more quickly.

Future trends of interventional pulmonology therapeutic device market

Minimally invasive methods drive the market demand for interventional pulmonology therapeutic devices. In recent years, minimally invasive methods become more mature and are widely accepted and used by doctors and patients. The increasing popularity of minimally invasive methods for pulmonary disease diagnosis and treatment help generate demand for interventional pulmonology therapeutic devices as a typical minimally invasive means.

Favorable public policies in support of medical device supply chains will also benefit the development of a healthy and sustainable interventional pulmonology therapeutic device market:

- In 2017, “Measures for the Supervision and Administration of Medical Device Operation” stated regulations on business activities such as the supply chains of the medical devices.
- In 2019, “Notice on Expanding the Pilot Work of the Medical Device Registrant System” emphasized on the importance that the registrant was responsible for problems during the logistics procedure, creating more pressure for the registrant to supervise the deliveries.
- In addition, provincial policies such as “Notice of the Beijing NMPA on the Pilot Work of Third-Party Logistics for Medical Devices” (2013) provided more detailed regulations on the logistics of the supply chain such as the low temperature or sterility during the transportation and storage process. This will ensure the safety and quality of the logistics of large high value medical equipment such as interventional pulmonology therapeutic devices, thus creating a healthy and sustainable market for the interventional pulmonology therapeutic devices.

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- Hospitals/Doctors
 - **Personnel:** The personnel are dependent on the type of interventional pulmonology procedures, suspected diseases or patient conditions.
 - **Learning curve for doctors:** The learning curve depends on the specific therapeutic devices, and how the manufacturers operate their training for the doctors. Nonetheless, compared to that of traditional surgery, the learning curve of interventional pulmonology is significantly shorter overall.
 - **The type of diseases/diagnostics/treatment device could apply to:** It depends on the device that is designed for what indications. For example, Broncus’s InterVapor is designed for COPD and lung cancer and RF-II is for lung cancer.
 - **Market development:** Hospitals prefer innovative therapeutic technologies to meet unmet clinical needs and increase profitability and tend to work with innovative companies to train doctors, form industry standards and guidelines and succeed as such innovative technology becomes widely used. Likewise, players in the market will likely cooperate more with hospitals to educate doctors and patients to exert their own brand influence.
- Patients
 - **Preference for minimally invasive methods:** Patients often present poor general conditions or severe hypoxemia due to coexisting diseases (such as heart failure), it may not be possible to use invasive procedures for diagnosis and treatment in some of the patients with lung cancer or COPD. In contrast, minimally invasive methods such as interventional pulmonology often involve shorter hospital stay time and procedure time and less degree of adverse effects/risks.
 - **Increasing affordability:** As disposable income has grown in China, the healthcare expenditure has increased as well. Healthcare expenditures per capita in China reached RMB4,646.8 by 2019 and expect to reach RMB7,116.6 by 2024. The growth of per capita annual healthcare expenditure of Chinese residents generates positive impacts over personal healthcare management and helps raise the level of health awareness among the Chinese population.
 - **Increasing patient population:** According to the statistics from the National Bureau of Statistics of China, individuals aged above 65 years old reached 176.0 million in 2019, which accounted for 12.6% of the total population. The proportion is expected to further increase to 16.0%, representing a population of 228.5 million by 2024. As the overall metabolic and immune capacities of elderly people gradually decline, the aging population is more likely to rely on medical healthcare management.

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REPORT COMMISSIONED BY FROST & SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the interventional pulmonology market in China and worldwide. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the U.S.. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries.

We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the worldwide and China interventional pulmonology market for potential investors. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

We have agreed to pay Frost & Sullivan a fee of 158,800 USD for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED]. We confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan, which may qualify, contradict or have an impact on the information set forth in this section in any material respect.

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Our products are medical devices subject to extensive regulation in the markets in which we operate, and such regulations vary from jurisdiction to jurisdiction in an increasingly complex global regulatory environment. The time required to obtain the necessary regulatory approval or CE Marking certification may 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.

PRC REGULATORY OVERVIEW

Laws and Regulations Related to Foreign Investment in the PRC

Company Law of the PRC

The Company Law of the PRC (《中華人民共和國公司法》) (the “Company Law”), which was promulgated on December 29, 1993 and came into effective on July 1, 1994, last amended on October 26, 2018 and came into effective on the same day, provides that companies established in China may take the form of limited liability company or joint stock company with limited liability. Each company has the status of a legal person and owns the assets itself. The Company Law applies to foreign-invested companies unless relevant laws provide otherwise.

Foreign Investment Law of the PRC

On March 15, 2019, the National People’s Congress promulgated the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “FIL”) which became effective on January 1, 2020 and replaced the Wholly Foreign-Owned Enterprise Law (《中華人民共和國外資企業法》). The FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition.

According to the FIL, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the “negative list.” The FIL provides that foreign invested entities operating in foreign “restricted” or “prohibited” industries will require entry clearance and other approvals. The FIL does not comment on the concept of “de facto control” or contractual arrangements with variable interest entities, however, it has a catch-all provision under definition of “foreign investment” to include investments made by foreign investors in China through means stipulated by laws or administrative regulations or other methods prescribed by the State Council. Therefore, it still leaves leeway for future laws, administrative regulations or provisions to provide for contractual arrangements as a form of foreign investment.

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The FIL also provides several protective rules and principles for foreign investors and their investments in the PRC, including, among others, that local governments shall abide by their commitments to the foreign investors; foreign-invested enterprises are allowed to issue stocks and corporate bonds; except for special circumstances, in which case statutory procedures shall be followed and fair and reasonable compensation shall be made in a timely manner, expropriate or requisition the investment of foreign investors is prohibited; mandatory technology transfer is prohibited, allows foreign investors’ funds to be freely transferred out and into the territory of PRC, which run through the entire lifecycle from the entry to the exit of foreign investment, and provide an all-around and multi-angle system to guarantee fair competition of foreign-invested enterprises in the market economy. In addition, foreign investors or the foreign investment enterprise should be imposed legal liabilities for failing to report investment information in accordance with the requirements. Furthermore, the FIL provides that foreign invested enterprises established according to the existing laws regulating foreign investment may maintain their structure and corporate governance within five years after the implementing of the FIL, which means that foreign invested enterprises may be required to adjust the structure and corporate governance in accordance with the current Company Law and other laws and regulations governing the corporate governance.

On December 26, 2019, the State Council promulgated the Regulation for Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “Implementation Rules”) which became effective on January 1, 2020. The Implementation Rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

Catalog of Industries for Encouraging Foreign Investment and Special Management Measures (Negative List) for the Access of Foreign Investment (2020 Version)

On June 30, 2019, Ministry of Commerce of the PRC (中華人民共和國商務部) (“MOFCOM”) and the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會) (the “NDRC”), released the Catalog of Industries for Encouraging Foreign Investment (2019 Version) (《鼓勵外商投資產業目錄(2019年版)》) (the “2019 Encouraging Catalog”) which became effective on July 30, 2019, to replace the previous encouraging catalog. On December 27, 2020, MOFCOM and the NDRC released the Catalog of Industries for Encouraging Foreign Investment (2020 Version) (《鼓勵外商投資產業目錄(2020年版)》) (the “2020 Encouraging Catalog”) which became effective on January 27, 2021, to replace the 2019 Encouraging Catalog. On June 23, 2020, MOFCOM and the NDRC released the Special Management Measures (Negative List) for the Access of Foreign Investment (2020 Version) (《外商投資准入特別管理措施(負面清單)(2020年版)》) (the “2020 Negative List”) which became effective on July 23, 2020, to replace the Special Management Measures (Negative List) for the Access of Foreign Investment (2019 Version) (《外商投資准入特別管理措施(負面清單)(2019年版)》), which was promulgated on June 30, 2019. The 2020 Encouraging Catalog and the 2020 Negative List lay out the basic framework for foreign investment in China, classifying businesses into three categories with regard to foreign investment: “encouraged,” “restricted” and “prohibited.” Industries not listed in the 2020 Encouraging Catalog or the 2020 Negative List are generally deemed as falling into a fourth category “permitted” unless specifically restricted by other PRC laws.

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Measures for the Reporting of Foreign Investment Information

On December 30, 2019, MOFCOM and the State Administration for Market Regulation ("SAMR") jointly promulgated the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which became effective on January 1, 2020. Pursuant to the Measures for the Reporting of Foreign Investment Information, where a foreign investor carries out investment activities in China directly or indirectly, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department.

Laws and Regulations Related to Medical Devices

The Classification, Registration and Filing of Medical Devices

Regulation on the Supervision and Administration of Medical Devices

Pursuant to the Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) which was promulgated on January 4, 2000 and last amended on December 21, 2020 and will take effect on June 1, 2021, the China Food and Drug Administration (now known as NMPA) is in charge of the national supervision and administration of medical devices. The relevant departments under the State Council shall be responsible for the supervision of medical devices within their respective scope of authorities. The medical products administration department of the local governments at the county level and above are responsible for the supervision and administration of medical devices within their own administrative districts.

In the PRC, medical devices have been classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with low degree of risk and whose safety and effectiveness can be ensured through routine administration. Class II medical devices shall refer to those devices with medium degree of risk and whose safety and effectiveness shall be strictly controlled and administered. Class III medical devices shall refer to those devices with high degree of risk and whose safety and effectiveness must be strictly controlled and administered with special measures.

Measures for the Administration of Registration of Medical Devices

According to the Measures for the Administration of Registration of Medical Devices (《醫療器械註冊管理辦法》) promulgated on April 5, 2000, last amended on June 27, 2014 and came into effect on October 1, 2014, for the filings of the domestic Class I medical devices, the parties undergoing the filings of medical devices shall submit the filing materials to the local branches at the prefectural city level of the NMPA. In case of any amendment to matters stated in the filings, such amendment shall be filed with the original filing department. Medical devices of Class I are subject to recordation administration, while medical devices of Class II and Class III are subject to registration administration. For domestic medical devices of Class I, the parties undergoing recordation shall submit recordation materials to the food and

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drug administrative departments at the city level. For domestic medical devices of Class II, the food and drug administrative departments of provinces, autonomous regions and municipalities directly under the Central Government shall be responsible for examination, and shall issue registration certificates for medical devices in the case of approval. For domestic medical devices of Class III, the NMPA shall be responsible for examination, and shall issue registration certificates for medical devices in the case of approval. For imported medical devices of Class I, the parties undergoing recordation shall submit recordation materials to the NMPA. For imported medical devices of Class II or III, the NMPA shall be responsible for examination, and shall issue registration certificates for medical devices in the case of approval. The Medical Device Registration Certificate is valid for five years and the registrant shall apply to medical products administration departments for renewal at least six months prior to its expiration date.

Clinical trials are not required for the filing of the Class I medical devices, but necessary for the application for the registration of the Class II and Class III medical devices. However, medical devices may be exempt from clinical trials under any of the following circumstances:

- (i) The medical device has clear working mechanisms, finalized design and mature manufacturing processes, and the medical devices of the same type that are available on the market have been used in clinical application for years without records of any serious adverse events, and the medical device will not change the general purposes;
- (ii) The safety and effectiveness of such medical device can be proved through non-clinical evaluation; or
- (iii) The safety and effectiveness of such medical device can be proved through the analysis and evaluation of the data obtained from the clinical trials or clinical application of the same categories of medical devices.

The medical device catalog of clinical trial exemption shall be formulated, amended and promulgated by the NMPA, such as the Notice of the Newly Revised Catalogue of Medical Devices Exempted from Clinical Trials (《關於公佈新修訂免於進行臨床試驗醫療器械目錄的通告》) promulgated by the NMPA on September 28, 2018, the Notice of New and Revised Catalogue of Medical Devices Exempted from Clinical Trials (《關於公佈新增和修訂的免於進行臨床試驗醫療器械的通告》) promulgated by the NMPA on December 13, 2019 and the Notice of the Catalogue of Medical Devices Exempted from Clinical Trials (2nd Revision) (《關於發佈免於進行臨床試驗醫療器械目錄(第二批修訂)的通告》) promulgated by the NMPA on January 14, 2021. Medical device products that are not included in the exemption catalog shall be analyzed and evaluated through the data obtained from the clinical trials or clinical application of the same categories of medical devices. As for certain high risk Class III medical devices, the NMPA's approvals are required before clinical trials can be carried out. Under such requirement, the NMPA promulgated the Notice of Publication of the List of Class III Medical Devices Requiring Clinical Trial Approval (《關於發佈需進行臨床試驗審批的第

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三類醫療器械目錄的通告》) on August 25, 2014, which was last amended and came into effect on September 14, 2020. Where the safety and effectiveness of such medical devices can be proved, the applicant may specify in the course of registration application and submit relevant proofing materials.

Besides, the Administrative Measures for the Registration of Medical Devices stipulates the technical specifications for product registration testing, clinical evaluation (which includes clinical trials if required by applicable laws and regulations), product registration application and acceptance, inspection and approval as required by the NMPA for product registration.

Production Quality Management of Medical Devices

Regulations of Medical Devices and the Administrative Measures on the Production of Medical Devices

The Regulations of Medical Devices and the Administrative Measures on the Production of Medical Devices (《醫療器械生產監督管理辦法》), promulgated on July 20, 2004, last amended on November 7, 2017 and came into effect on November 17, 2017, stipulates the following conditions which a manufacturer of medical devices shall meet the following conditions:

- (i) has the production premise, environmental conditions, production equipment and professional technicians commensurate with the medical devices produced by it;
- (ii) has the institution or full-time inspectors and the inspection equipment for the quality inspection of medical devices produced by it;
- (iii) has management rules guaranteeing the quality of medical devices;
- (iv) has the after-sales service capability commensurate with the medical devices produced by it; and
- (v) satisfies the requirements as prescribed in production research and development and production technique documents.

The enterprises engaging in the production of Class I medical devices shall make filings or such Class I medical devices with the local branches at the prefectural city level of the NMPA and submit proofing materials of qualification to engage in the production of such medical devices. The enterprises engaging in the production of Class II and Class III medical devices shall apply for Manufacture License for Medical Devices (醫療器械生產許可證) to the provincial branches of the NMPA, and submit proofing materials of qualification to engage in the production of such medical devices and registration certificates for such medical devices produced. The Manufacture License for Medical Devices for a medical device is valid for five years and the registrant shall apply to the original department that issued such permit for renewal at least six months prior to its expiration date.

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Good Manufacturing Practice for Medical Devices

Good Manufacturing Practice for Medical Devices (GMP) (《醫療器械生產質量管理規範》) (the “GMP”) which was promulgated on December 29, 2014 and came into effect on March 1, 2015, stipulates that an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system in accordance to the requirements of the Standards on Production Quality Management. The enterprise engaging in the production of medical devices shall regularly conduct comprehensive self-inspection on the operation of quality management system in accordance with the requirements of the Standards on Production Quality Management and submit a self-inspection report to the provincial branches of the NMPA or the local branches at the prefectural city level before the end of every year. The enterprise shall establish its procurement control procedure and assess its suppliers by establishing an examination system to ensure the purchased products are in compliance with the statutory requirements. The enterprise shall record the procurement, production and inspection of raw materials. Such records shall be true, accurate, complete and traceable. The enterprise shall apply risk management to the whole process of design and development, production, sales and after-sale services. The measures being adopted shall be applicable to risks associated with the related products.

The Notice of Four Guidelines including On-site Inspection Guidelines for the Standards on Production Quality Management of Medical Devices

Pursuant to The Notice of Four Guidelines including On-site Inspection Guidelines for the Standards on Production Quality Management of Medical Devices (《關於印發〈醫療器械生產質量管理規範現場檢查指導原則〉等四個指導原則的通知》) promulgated and came into effect on September 25, 2015, during the course of on-site verification of the registration of medical devices and on-site inspection of production permit (including changing production permit), the inspection team shall, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which shall be divided into “Passed,” “Failed” or “Reassessment after rectification.” During the supervision and inspection, if it is found that the requirements of the key items or ordinary items that may have direct impact on product quality are not satisfied, the enterprise shall suspend production and go through rectification. If it is found that the requirements of the ordinary items are not satisfied, and it does not directly affect product quality, the enterprise shall rectify in a prescribed time. The regulatory authorities shall examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group and issue the final inspection results.

Good Clinical Practice (GCP) for Medical Device

Good Clinical Practice (GCP) for Medical Device (《醫療器械臨床試驗質量管理規範》), promulgated on March 1, 2016 and came into effect on June 1, 2016, the clinical trial of medical devices in this standards refers to the process of confirming or verifying the safety and efficacy of the medical device to be registered under normal conditions of use in a qualified medical device clinical trial institution. Prior to the clinical trial, the applicant shall file with the medical products administration department of the the provincial branches of the NMPA. If the safety and performance of a new product that has not been approved for

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marketing in or outside of China have not been medically proven, the clinical trial protocol should be designed by conducting a small sample feasibility test first, and after initial confirmation of its safety, the sample size should be determined according to statistical requirements for subsequent clinical trials.

Good Clinical Practice for Medical Devices Trials

On March 1, 2016, the NMPA and the National Health and Family Planning Commission jointly promulgated the Good Clinical Practice for Medical Devices Trials (《醫療器械臨床試驗質量管理規範》), which became effective on June 1, 2016. The regulation includes full procedures of clinical trial of medical devices, including, among others, the protocol design, conduct, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. For conducting clinical trials of medical devices, an applicant shall organize to formulate scientific and reasonable clinical trial protocols based on the categories, risks and intended use of the medical devices for the clinical study. The applicant shall be responsible for (i) organizing to develop and revise the researcher's manual, clinical trial protocols, informed consent form, case report form, relevant standard operating procedures and other relevant documents, and (ii) organizing necessary training for the clinical trials. The applicant shall select the clinical trial institutions and its researchers from the qualified medical device clinical trial institutions according to the characteristics of the medical devices to be used in the clinical study. An applicant for clinical trials of medical devices shall be responsible for initiating, applying, organizing and monitoring such clinical trials, and shall be responsible for the authenticity and reliability of the clinical trials. For new products that are not approved for marketing inside and outside the PRC and are not medically proven in safety and performance, a feasibility trial on a small sample size shall be conducted first when designing a protocol. Upon preliminary confirmation of safety, subsequent clinical trials shall be conducted on the statistical sample sizes required.

Tender Process for Medical Devices

According to the Notice on Further Strengthening the Administration of Centralized Procurement of Medical Devices (《衛生部關於進一步加強醫療器械集中採購管理的通知》) issued on June 21, 2007, all not-for-profit medical institutions under all levels of government and state-owned enterprises from different industries shall participate in the centralized procurement of medical devices.

Pursuant to the Notice of Opinions on Reform of Pricing System of Pharmaceuticals and Medical Services (《關於印發改革藥品和醫療服務價格形成機制的意見的通知》) issued on November 9, 2009, the management on the pricing of medical devices will be strengthened. For high value medical devices, especially for implantable and interventional medical devices, reasonable price formation can be guided by measures such as limiting the price difference rate in circulation links and publishing market price information. High value medical devices usually refer to medical devices that directly use on the human body, have strict requirements on safety, have large consumption for clinical use and have relatively high prices.

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According to the Administrative Measures on Centralized Procurement of High Value Medical Consumables (《高值醫用耗材集中採購工作規範(試行)》) issued on December 17, 2012, the online centralized procurement (the “Centralized Procurement”) works of high value medical consumables will be led by government and conducted by each province (region and municipality). Medical institutions and medical consumables production and operation enterprises shall make procurement through the Centralized Procurement platform established by each province (region and municipality). The administrative authorities in charge of the Centralized Procurement in each province (region and municipality) shall be responsible for formulating and preparing a Centralized Procurement list of high value medical devices within its administrative region. High value medical consumables listed on the Centralized Procurement list may be procured by way of public tenders and invitational tenders or by other means stipulated by laws and regulations of the State. After the procurement prices are determined, public medical institutions within relevant regions shall make procurement strictly at bidding prices.

On July 19, 2019, the General Office of the State Council issued the Circular on 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》) (the “Circular on High Value Medical Consumables”). According to the Circular on High Value Medical Consumables, high value medical consumables are defined as medical consumables directly used on human, with strict requirement on safety, in great demand clinically, relatively highly-priced, and that can pose heavy burdens on patients. The Circular on High Value Medical Consumables releases several reform initiatives aiming at managing high value medical consumables, including: (i) the classification and codes of high value medical consumables in the national medical insurance system will be unified gradually, and rules on unique device identification in full life cycle of the high value medical consumables, including but not limited to registration, procurement and usage, will be implemented by the National Healthcare Security Administration, the National Medical Products Administration, and the National Health Commission of the PRC by the end of 2020; (ii) the mechanism for including high value medical consumables in basic medical insurance shall be built, and a list of high value medical consumables shall be compiled, to strengthen the dynamic adjustment mechanism. The access regulations shall be promulgated by the National Health Commission and the Ministry of Finance (the “MOF”) by the end of June 2020; (iii) the price markups placed on medical consumables at public hospitals will be abolished, and all medical consumables, including high value medical consumables will be sold at procurement price at all public hospitals by the end of 2019; and (iv) the medical insurance payment policy shall be formulated and implemented by the National Healthcare Security Administration, the MOF and the National Health Commission of the PRC. Meanwhile, the medical insurance payment standards on high value medical consumables will be formulated and the dynamic adjustment mechanism will be established. The medical insurance funds and patients will share the cost of high value medical consumables according to the medical insurance payment standards, and medical institutions shall further reduce procurement prices under the guidance of the Circular on High Value Medical Consumables.

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Laws and Regulations Related to Medical Devices Operation

Measures for the Supervision and Administration of Medical Devices Operation

Pursuant to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》), promulgated on July 30, 2014 and amended on November 17, 2017, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation scale and scope, and shall have a quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class II medical devices shall file with the municipal level medical products administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of medical devices, while an enterprise engaged in the operation of Class III medical devices shall apply for a Business Operation License of Medical Devices (醫療器械經營許可證) to the municipal level medical products administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of such medical devices.

The medical products administration department which receives operation permit application shall grant the Business Operation License of Medical Devices if the enterprise meets the prescribed requirements. A Business Operation License of Medical Devices is valid for five years and may be renewed pursuant to the relevant regulations. An enterprise engaging in medical devices operation shall not operate or use any medical device that has not been legally registered, without qualification certificate, out-dated, invalid or disqualified.

Measures for the Supervision and Management of Medical Device Operation

According to Measures for the Supervision and Management of Medical Device Operation (《醫療器械經營質量管理規範》), which promulgated and came into effect on December 12, 2014, an enterprise engaging in the operation of medical devices shall take effective quality control measures to ensure the quality and safety of products in every business process, including procurement, acceptance check, storage, sales, transportation, after-sales service and other aspects.

Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices

On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “Innovation Opinions”), which aims to encourage the innovation for medical devices. Pursuant to the Innovation Opinions, the priority review and approval will be applicable to innovative medical devices supported by the National Science and Technology Major Projects and the National Key R&D

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Program (國家科技重大專項和國家重點研發計劃支持項目) of the PRC, and the clinical trials of which have been conducted by the National Clinical Research Center, and approved by the management department of the National Clinical Research Center.

Medical Device Recalls

Pursuant to 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, in light of the severity harm, medical device recalls are divided into: (i) Class I recall where the circumstances leading to the recall may cause or have caused serious health hazards; (ii) Class II recall where the circumstances leading to the recall may cause or have caused temporary or reversible health hazards; or (iii) Class III recall where the circumstances leading to the recall are not likely to cause harm.

Medical device manufacturers shall determine the recall class based on the specific situation and properly design and implement the recall plan based on the recall class and the sale and use of the medical devices. In terms of Class I recall, the recall notice shall be published on the NMPA website and major media. In terms of Class II and Class III recalls, the recall notice shall be published on the website of the medical products administrative authority of the provinces, autonomous regions or municipalities.

Laws and Regulations Related to Anti-Unfair Competition

Since early 1990s, the legislative authorities at different levels in China have promulgated certain laws and regulations in respect of commercial bribery. According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) (the “Anti-Unfair Competition Law”), which was passed by the Standing Committee of the National People’s Congress (the “SCNPC”) on September 2, 1993, became effective as of December 1, 1993 and was most recently amended on April 23, 2019, unfair competition refers to that the operator disrupts the market competition order and damages the legitimate rights and interests of other operators or consumers in violation of the provisions of the Anti-unfair Competition Law in the production and operating activities. Pursuant to the Anti-unfair Competition Law, operators shall abide by the principle of voluntariness, equality, impartiality, integrity, and adhere to laws and business ethics during market transactions. Operators in violation of the Anti-unfair Competition Law shall bear corresponding civil, administrative or criminal liabilities depending on the specific circumstances.

According to the Interim Provisions on the Prohibition of Commercial Bribery (《國家工商行政管理局關於禁止商業賄賂行為的暫行規定》) (the “Prohibition Commercial Bribery Provisions”), which was promulgated by SAIC on November 15, 1996, commercial bribery refers to an act of offering money or property or using other means by an operator to the other entity or individual for the purposes of selling or buying goods, among which “other means” refer to the means used to provide any types of benefits other than money or property, such as

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offering overseas or domestic travel. According to the Anti-Unfair Competition Law and the Prohibition Commercial Bribery Provisions, regulatory authorities may impose fines depending on the seriousness of the cases and if there is any illegal income, such income shall be confiscated.

Regulations Related to Customs

According to the Customs Law of the PRC (《中華人民共和國海關法》) (the “Customs Law”) which was passed by the SCNPC on January 22, 1987 and last amended and became effective on April 29, 2021, the Customs of the PRC is the state’s entry and exit customs supervision and administration authority and is responsible for the supervision of the transport vehicles, goods, freight items, postal items and other items entering into and departing from the PRC and collecting tariff and other duties and charges. Where a consignee or consignor of import or export goods or a Customs clearing enterprise handles Customs declaration procedures, they shall be subject to filing with Customs in accordance with law.

Laws and Regulations Related to Production Safety and Liability

Production Safety Law of the PRC

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) amended on August 31, 2014 and coming into effect on December 1, 2014, an enterprise shall (i) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (ii) establish a comprehensive production safety accountability system and production safety rules, and (iii) develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

The person-in-charge of an enterprise shall be fully responsible for the safety of production of the enterprise. An enterprise having more than 100 employees shall establish a department or engage in personnel managing production safety specifically. Personnel who is responsible for managing production safety shall inspect the safety of production regularly based on the characteristics of production of the enterprise and shall deal with any safety issue identified during the inspection in a timely manner. Any unsolved issue shall be reported to the person-in-charge in a timely manner and the person-in-charge shall solve such issue immediately. The inspection and measures taken shall be duly recorded. Enterprises and institutions shall provide their employees with training on production safety and shall truthfully inform their employees of any potential risks in relation to the workplace and duties, preventive measures and emergency measures. In addition, an enterprise shall provide its employees with protective equipment that meet the national or industry standards and supervise and train them to use such equipment.

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Product Quality Law of the PRC

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) was promulgated by the SCNPC on February 22, 1993, and amended and came into effect on December 29, 2018, producers and sellers shall have their own proper regulations for the management of product quality, rigorously implementing post-oriented quality regulations, quality liabilities and relevant measures for their assessment. Producers and sellers are responsible for the product quality according to the provisions of the laws.

The product quality supervision and administration departments of the State Council are responsible for the supervision and administration of the quality of products of the whole country. All relevant departments of the State Council shall be responsible for the supervision of product quality within their own functions and duties.

Quality of products shall pass standard examinations and it is not allowed to pass off sub-standard products as standard ones. Industrial products which may be hazardous to the health of the people and the safety of lives and property shall conform to the State and trade standards for ensuring the health of the people and safety of lives and property. In absence of such State or trade standards, the products shall conform to the minimum requirements for ensuring the health of the people and the safety of lives and property. It shall be prohibited to produce or sell industrial products that do not meet the requirements and demands for physical health and safety of body and property. Producers or sellers shall be responsible for any compensation arising from their unlawful acts such as production or sales of defective, eliminated or ineffective products, faking the place of origin or quality marks, mixing or adulterating products or passing off imitations as genuine, substandard products as quality ones or non-conforming products as conforming. Proceeds from the sales may be confiscated, the business license may be revoked and penalties may be imposed. If the case is serious, criminal responsibilities shall be investigated. Producers or sellers shall be liable for any damage to any person or property due to the defects of products resulting from the default of the producers or sellers.

Tort Law of the PRC

Pursuant to the Tort Law of the PRC (《中華人民共和國侵權責任法》) promulgated on December 26, 2009 and coming into effect on July 1, 2010, a patient may make a claim against a medical institution or producer for any damage arising from defects of a medical device. In respect of any claim made by a patient, the medical institution is entitled to make a claim against the producer after the settlement of the compensation paid to the patient. On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which became effective on January 1, 2021 and simultaneously replaced the current effective Tort Law of the PRC. The Civil Code of the PRC does not make material changes on the substance of aforementioned provisions of the Tort Law of the PRC.

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Laws and Regulations Related to Environmental Protection

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) promulgated on December 26, 1989 and became effective on the same day, last amended on April 24, 2014 and became effective on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge medical sewage to water bodies directly or indirectly shall obtain a waste discharge license. Furthermore, installations for the prevention and control of pollution at a construction project must be designed, built and commissioned together with the principal part of the project.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated on October 28, 2002, became effective on September 1, 2003 and last amended on December 29, 2018, the State implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report, or an environmental impact form or complete an environmental impact registration form (the “Environmental Impact Assessment Documents”) for reporting and filing purpose. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works.

Laws and Regulations Related to Intellectual Property Rights

Trademark Law of the PRC and its Implementing Rules

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and last amended on April 23, 2019 and took effect on November 1, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and revised on April 29, 2014. In the PRC, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks. The Trademark Office of National Intellectual Property Administration handles trademark registrations and grants a term of 10 years to registered trademarks, renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term.

Patent Law of the PRC and its Implementing Rules

According to the Patent Law of the PRC (《中華人民共和國專利法》), which was revised by the SCNPC on October 17, 2020 and will take effect on June 1, 2021, and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on January 19, 1985, and last amended on January 9, 2010 and came into effect on February 1, 2010, the term “invention-creations” refers to inventions, utility models and designs. The duration of the patent right for inventions shall be 20 years and the duration of the patent right for utility models shall be 10 years and the

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duration of the patent right for designs shall be 15 years, both commencing from the filing date. In the event that a dispute arises due to a patent being exploited without the prior authorization of the patentee, that is to say an infringement upon the patent right of the patentee.

According to the Patent Law of the PRC, any entity or individual that seeks to exploit a patent owned by another party shall enter into a patent license contract with the patent owner concerned and pay patent royalties to the patent owner. The licensee does not have the right to allow any entity or individual not specified in the contract to exploit such patent.

Pursuant to the Measures for the Filing of Patent Licensing Contracts (《專利實施許可合同備案辦法》) promulgated by the State Intellectual Property Office on June 27, 2011 and became effective on August 1, 2011, the State Intellectual Property Office shall be responsible for filing of patent licensing contracts nationwide and the parties concerned shall complete filing formalities within three months from the effective date of a patent licensing contract.

Laws and Regulations Related to Employment and Social Security

Labor Law of PRC

The Labor Law of PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009 and December 29, 2018, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaged in special operations shall have received specialized training and obtained the pertinent qualifications.

Labor Contract Law of PRC and its Implementation Regulations

The Labor Contract Law of PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and came into effect on 1 July 2013, and the Implementation Regulations Related to Labor Contract Law (《中華人民共和國勞動合同法實施條例》) which was promulgated and came into effect on September 18, 2008 by the State Council, regulate the relations of employer and the employee, and contain specific provisions involving the terms of the labor contract.

Regulations Related to Supervision Over the Social Security and Housing Funds

According to the Provisional Regulations Related to the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations Related to Work Injury Insurance (《工傷保險條例》), the Regulations Related to Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), enterprises in China must provide benefit plans for their employees, which include basic pension insurance, unemployment insurance, maternity

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insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies, and must pay or withhold relevant social insurance premiums for or on behalf of employees.

The Law on Social Insurance (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and came into effect on July 1, 2011, and was amended on December 29, 2018 regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of employers who do not comply with relevant laws and regulations related to social insurance.

In accordance with the Regulations on the Administration of Housing Funds (住房公積金管理條例) which was promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, enterprises must register at the competent managing center for housing funds and upon the examination by such managing center of housing funds, these enterprises shall complete procedures for opening an account at the relevant bank for the deposit of employees' housing funds. Enterprises are also required to pay and deposit housing funds on behalf of their employees in full and in a timely manner.

Laws and Regulations Related to Taxation

Enterprise Income Tax Law

According to the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》), or the EIT Law, which was issued by the NPC on March 16, 2007 and last revised by the SCNPC on December 29, 2018, and the Regulation on the Implementation of the Enterprise Income Tax Law (《中華人民共和國企業所得稅法實施條例》), or the EIT Regulation, issued by the State Council on December 6, 2007 and became effective on January 1, 2008 and partly amended on April 23, 2019 and became effective on the same date, both domestic and foreign-invested enterprises established under the laws of foreign countries or regions whose “de facto management bodies” are located in the PRC are considered resident enterprises, and will generally be subject to the EIT Law at the rate of 25% of their global income. The defined “de facto management bodies” are “establishments that carry out substantial and overall management and control over production and operations, personnel, accounting, and properties” of the enterprise. If an enterprise is considered a PRC resident enterprise under the above definition, its global income will be subject to enterprise income tax at the rate of 25%. The Notice on Issues about the Determination of Chinese-Controlled Enterprises Registered Abroad as Resident Enterprises on the Basis of Their Body of Actual Management (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by the State Administration of Taxation, or the SAT, on April 22, 2009 and effective on January 1, 2008 and partly amended on December 29, 2017 and became effective on the same date, sets up a more specific definition of “de facto management bodies” standard.

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Value Added Tax

According to the Interim Regulation of the PRC on Value Added Tax (《中華人民共和國增值稅暫行條例》), or the VAT, issued by the State Council on December 13, 1993 and last revised on November 19, 2017, and the Detailed Rules for the Implementation of the Interim Regulation of the PRC on Value Added Tax (《中華人民共和國增值稅暫行條例實施細則》) issued by the Ministry of Finance, or the MOF, on December 25, 1993 and last revised on October 28, 2011, entities and individuals selling goods in the PRC or providing processing services, repair services and importation services should be subject to VAT, and the payable tax amount shall be calculated by deducting input tax for the current period from output tax for the current period.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the Ministry of Finance, the State Administration of Taxation and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value added tax rate was reduced to 13% and 9%, respectively.

On November 16, 2011, the MOF and the STA promulgated the Trial Scheme for the Conversion of Business Tax to Value-added Tax (《營業稅改徵增值稅試點方案》), pursuant to the government launched gradual taxation reforms from January 1, 2012, where a value-added tax is imposed in lieu of business tax on a trial basis in regions and industries showing strong economic performance, such as transportation and certain modern service industries.

The Notice on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax (《財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知》), which was promulgated by the MOF and the STA on March 23, 2016 and came into effective on May 1, 2016, amended on July 1, 2017, December 25, 2017 and March 20, 2019 and became effective on April 1, 2019, all business tax payers in the consumer service industry shall pay value-added tax instead of business tax from May 1, 2016. If the taxpayer of the pilot project has already enjoyed tax incentives of business tax according to relevant policies and regulations before the application of the pilot collection of value-added tax in lieu of business tax, he/she may, in the remaining period of tax incentives, enjoy tax incentives of value-added tax in accordance with the relevant provisions.

Withholding Income Tax

According to the EIT Law and the EIT Regulation, dividends generated after January 1, 2008 and dividends payable by foreign enterprises in the PRC to foreign investors shall be subject to a 10% withholding tax unless a tax treaty with different withholding tax arrangements has been made between the PRC and the jurisdiction where any of those foreign

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investors are registered. According to the Arrangement between the Mainland of China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) issued by SAT on August 21, 2006 and came into effect on December 8, 2006, if the shareholders of a PRC company are Hong Kong residents holding at least 25% of the registered capital of the PRC company, a withholding tax rate of 5% applies to any dividends declared by the PRC company, or if the shareholders of a PRC company are Hong Kong residents holding less than 25% of registered capital, a withholding income tax rate of 10% applies.

The Notice on the Several Issues of the Implementation of Tax Treaty (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》), which was promulgated by the STA on February 20, 2009 and came into effect on the same date, stipulates that the non-resident taxpayer or the withholding agent is required to obtain and keep sufficient documentary evidence proving that the recipient of the dividends meets the relevant requirements for enjoying a lower withholding tax rate under a tax treaty if the main purpose of an offshore transaction or arrangement is to obtain a preferential tax treatment.

According to the Administrative Measures on Non-resident Taxpayers to Enjoy the Treatment under Tax Treaties (《非居民納稅人享受協定待遇管理辦法》) promulgated by the STA on October 14, 2019 and came into effect on January 1, 2020, where a non-resident taxpayer self-assesses and concludes that it satisfies the criteria for claiming treaty benefits, it may enjoy treaty benefits at the time of tax declaration or at the time of withholding through the withholding agent, simultaneously gather and retain the relevant materials for future inspection, and accept follow-up administration by the tax authorities.

Pursuant to the Announcement on Matters Concerning “Beneficial Owners” in Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》), issued by the SAT on February 3, 2018 and came into effect on April 1, 2018, when determining an applicant’s “beneficial owner” status regarding tax treatments in connection with dividends, interests or royalties in tax treaties, several factors set forth below will be taken into account, although the actual analysis will be fact-specific: (i) whether the applicant is obligated to pay more than 50% of his or her income in 12 months to residents in a third country or region; (ii) whether the business operated by the applicant constitutes a substantial business operation; and (iii) whether the counterparty country or region to the tax treaties does not levy any tax or grant tax exemption on relevant incomes or levy tax at an extremely low rate. The applicants shall submit relevant documents to the competent tax authorities to prove his or her “beneficial owner” status.

Regulations Related to Foreign Exchange

The Regulations Related to the Control of Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》), which were promulgated by the State Council on January 29, 1996, came into effect on April 1, 1996, and amended on January 14, 1997 and August 5, 2008, set out that foreign exchange receipts of domestic institutions or individuals may be transferred to

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China or deposited abroad and that the SAFE shall specify the conditions for transfer to China or overseas and other requirements in accordance with the international receipts, payments status and requirements of foreign exchange control. Foreign exchange receipts for current account transactions may be retained or sold to financial institutions engaged in the settlement or sale of foreign exchange. Domestic institutions or individuals that make direct investments abroad are engaged in the distribution, sale of valuable securities or derivative products overseas should register according to SAFE regulations. Such institutions or individuals subject to prior approval or record-filing with relevant authorities shall complete the required approval or record-filing prior to foreign exchange registration. The exchange rate for RMB follows a managed floating exchange rate system based on market demand and supply.

The SAFE Circular 37, which has replaced the Circular on Issues relating to Foreign Exchange Administration for Financing and Round-trip Investments by Domestic Residents through Overseas Special-purpose Companies (《國家外匯管理局關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》), states that (i) a PRC resident, including a PRC resident natural person or a PRC legal person, shall register with the local branch of the SAFE before it contributes its assets or equity interest into a special purpose vehicle for the purpose of investment and financing and (ii) when the special purpose vehicle undergoes change of basic information, such as change in PRC resident natural person shareholder, name or operating period, or occurrence of a material event, such as change in share capital of a PRC resident natural person, performance of merger or split, the PRC resident shall register such change with the local branch of the SAFE in a timely manner.

According to the SAFE Circular 13 which became effective on June 1, 2015, banks are required to review and carry out foreign exchange registration under offshore direct investment directly. The SAFE and its branches shall implement indirect supervision over foreign exchange registration of direct investment via the banks.

The SAFE Circular 19, promulgated on March 30, 2015 and amended on December 30, 2019, allows foreign-invested enterprises to make equity investments by using RMB fund converted from foreign exchange capital. Under the SAFE Circular 19, the foreign exchange capital in the capital account of foreign-invested enterprises upon the confirmation of rights and interests of monetary contribution by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operation needs of the enterprises. The proportion of discretionary settlement of foreign exchange capital of foreign-invested enterprises is currently 100%. SAFE can adjust such proportion in due time based on the circumstances of the international balance of payments. However, SAFE Circular 19 and SAFE Circular 16 continues to prohibit foreign-invested enterprises from, among other things, using RMB fund converted from its foreign exchange capitals for expenditure beyond its business scope, investment and financing (except for security investment or guarantee products issued by banks), providing loans to non-affiliated enterprises or constructing or purchasing real estate not for self-use.

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According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital, foreign credits and the income under capital accounts of overseas listing, without the need to provide the evidential materials concerning authenticity of such capital for banks in advance, provided that their utilized capital shall be authentic and in line with provisions, and conform to the prevailing administrative Regulations Related to the use of income under capital accounts. The concerned bank shall conduct spot checks in accordance with the relevant requirements.

Regulations Related to M&A Rules

In Accordance with the Rules on the Acquisition of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, promulgated by the MOFCOM on August 8, 2006 and amended on June 22, 2009 and became effective on the same date, a foreign investor was required to obtain necessary approvals when (i) a foreign investor establishes a foreign-invested enterprise either by acquiring equity in a domestic non-foreign invested enterprise, or subscribing for new equity in a domestic enterprise via an increase of registered capital; or (ii) a foreign investor establishes a foreign-invested enterprise which purchase and operates the assets of a domestic enterprise, or which purchases the assets of a domestic enterprise and injects those assets to establish a foreign-invested enterprise. Approval from MOFCOM is required if a domestic company or enterprise, or a domestic natural person, through an overseas company established or controlled by it/him, acquires a domestic company which is related to or connected with it/him.

Regulations Related to Employee Stock Incentive Plan

Pursuant to the Notice of Issues Related to the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Listed Company (《關於境內個人參與境外上市公司股權激勵計畫外匯管理有關問題的通知》), which was issued by the SAFE on February 15, 2012, employees, directors, supervisors, and other senior management who participate in any stock incentive plan of an publicly-listed overseas company and who are PRC citizens or non-PRC citizens residing in China for a continuous period of no less than one year, subject to a few exceptions, are required to register with SAFE or its local branches through a qualified domestic agent, which may be a PRC subsidiary of such overseas listed company, and complete certain other procedures with respect to the stock incentive plan. In addition, the State Administration for Taxation has issued circulars in relation to employee stock incentive awards, under which our employees based in the PRC shall be subject to PRC individual income tax for exercising their incentive awards. Our PRC subsidiaries shall be responsible to file documents related to employee stock incentive plan with relevant tax authorities and to withhold individual income taxes of those employees who opt to exercise their stock incentive awards.

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U.S. REGULATORY OVERVIEW

Government Regulation

Government authorities in the United States at the federal, state, and local level extensively regulate the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of medical devices.

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.

The Premarket Process

Unless an exemption applies, as described further below, any medical devices commercially distributed in the United States must first be the subject of a marketing authorization from FDA. FDA classifies medical devices into one of three classes based on the safety concerns associated with the product and the level of control necessary to provide reasonable assurance of the device’s safety and effectiveness.

Class I Devices

Class I devices present minimal potential harm for the user and are often simpler in design than Class II and Class III devices. Class I devices include medical devices that generally pose the lowest risk to patients and are devices 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 mandatory reporting;

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- Good Manufacturing Practice requirements embodied in FDA’s Quality System Regulation (“**QSR**”); and
- in limited instances, premarket notification.

Class II Devices

Class II devices fall in the middle of the risk spectrum between Class I and Class III devices. Most medical devices are considered Class II devices. Class II medical devices are devices for which the general controls outlined above are not sufficient for ensuring safety and effectiveness of the devices. The FDCA imposes general controls as well as special controls, which are usually device-specific and include performance standards, postmarket surveillance, patient registries, special labeling requirements, and premarket data requirements, on Class II medical devices. Importantly, Class II medical devices are oftentimes subject to premarket notification requirements (i.e., 510(k) clearance). Our LungPoint/Archimedes System is an example of a Class II device.

Class III Devices

Class III devices are usually devices that sustain or support life, are implants, or present potential unreasonable risk of illness or injury. Class III devices are medical devices for which general and special controls alone cannot assure the safety and effectiveness of the device. Class III devices are also subject to premarket approval requirements.

An Overview of the Premarket Notification and Premarket Approval Processes

Premarket Notification (510(k) Clearance)

The FDCA requires any person who wishes to market a medical device for which a premarket approval application is not required to submit a premarket notification (a 510(k)) unless exempt (e.g., Class I, 510(k)-exempt medical devices). Some of our products may be subject to this requirement. This notification must be submitted to FDA at least 90 days before the introduction of the device into interstate commerce. The premarket submission must demonstrate to FDA that the device to be marketed is at least as safe and effective (“substantially equivalent”) to a legally marketed device (a “predicate” device) that is not subject to premarket approval. This process is commonly referred to as the 510(k) clearance process.

Manufacturers must identify for FDA the predicate device to which they are claiming substantial equivalence. Manufacturers prove substantial equivalence by providing to FDA a combination of thorough technological details about both their device and the predicate device, performance data, non-clinical bench performance testing, non-clinical animal and biocompatibility information, and non-clinical laboratory studies. In approximately ten percent (10%) of cases, FDA will request clinical performance data to demonstrate substantial equivalence.

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A legally marketed device or a predicate is:

- a device that was legally marketed prior to May 28, 1976;
- a device which has been reclassified from Class III to Class II or I;
- a device which has been found substantially equivalent through the premarket notification process; or
- a device that was granted marketing authorization via the De Novo classification process (as elaborated below) under section 513(f)(2) of the FDCA that is not exempt from premarket notification requirements.

FDA will review the notification, and determine that a device is substantially equivalent if (1) the device has the same intended use and technological characteristics as the predicate, or (2) the device has the same intended use and different technological characteristics, but does not raise different questions of safety and effectiveness, and the information submitted to FDA demonstrates to FDA that the device is at least as safe and effective as the predicate. A claim of substantial equivalence does not mean that the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

In order for the device to be marketed, FDA must first issue a letter stating that the device is substantially equivalent to the predicate, which is also called a 510(k) clearance letter. FDA does not perform 510(k) pre-clearance facility inspections. The submitter may market the device immediately after 510(k) clearance is granted. The Company has received 510(k) clearances from FDA for Empower RF Catheter (RF-I).

The manufacturer should be prepared for an FDA quality system inspection at any time after 510(k) clearance. The Quality System Requirements are found in the U.S. Code of Federal Regulations ("C.F.R.") at 21 C.F.R. 820.

After a device receives FDA's 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new 510(k) clearance or, if the modified device is not substantially equivalent, could require a premarket approval (as defined below) or De Novo classification through the De Novo classification process.

Premarket Approval

Premarket approval (the "**PMA**") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Through PMA, applicants must provide to FDA's satisfaction reasonable assurance of safety and effectiveness for the intended use(s) of the device. A PMA application must be supported by valid scientific

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evidence, including extensive preclinical (including bench tests and laboratory and animal studies) and clinical studies as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The outside advisory panel review may be initiated by the agency, or the applicant may request the outside advisory panel’s review. The panel consists of members that have the relevant expertise and experience to assess the safety and efficacy of the applicable devices, such as physicians, nurses, and scientists. FDA will forward a copy of the PMA to each member of the panel for review. The panel will hold a public meeting to review the application. Subsequent to the meeting, the panel will submit a report to FDA with its recommendation on whether to approve or deny the device. FDA will then consider the report, transcript, and other relevant information to issue a decision. In addition to the above, the FDA will also conduct a preapproval inspection of the manufacturing facility as part of the PMA application review to ensure compliance with the QSR. PMA is the most rigorous type of marketing application required by FDA, and it typically takes several years and investment of significant financial resources to obtain FDA’s approval.

Even if FDA approves the premarket approval application, it may place restrictions on the device or the labeling or require additional clinical studies, monitoring or other post-market requirements. FDA may also impose post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device. If the FDA’s evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny the PMA application or issue a “not approvable” letter. The FDA may also require additional clinical trials, which can delay the PMA process by several years or otherwise make obtaining PMA infeasible.

If the appropriate classification and the regulatory pathway for a medical device is not clear, it is possible to seek guidance from FDA on the proper classification of a medical device and applicable regulatory requirements for such a device through a request for classification (“**513(g) Request**”). Upon receipt of the 513(g) Request, FDA will provide a response with the proper classification of the device, as well as requirements applicable to such a device under the FDCA.

De Novo Classification Process

The De Novo classification process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. The De Novo classification process is a risk-based classification process.

This regulatory route is also available for devices of a new type that are classified automatically as Class III, or a device that FDA has determined is not substantially equivalent to a predicate after the agency reviewed a premarket notification. If the Company develops products that fit into either of these two scenarios, then it will need to pursue the De Novo classification process in order to market the device in the United States.

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A request for the De Novo classification process should include a risk-benefit analysis demonstrating that, when subject to general controls or general and special controls, the probable benefits to health from use of the device outweigh any probable injury or illness from such use. If a product is classified as Class I or II through the direct De Novo classification process, then that device may serve as a predicate device for subsequent 510(k) premarket notifications, including by competitors. FDA recommends holding a pre-submission meeting with FDA prior to submitting a request for the De Novo classification process.

Unless a specific exemption or waiver applies, premarket notification submissions, requests for the De Novo classification process, and PMA applications are subject to user fees to be paid by the applicant. The PMA and De Novo classification process user fees are significantly higher than the user fees for 510(k) notifications.

Pre-Clinical and/or Clinical Studies

Prior to seeking marketing authorization for medical devices, a developer of a medical device must prepare information demonstrating the safety and effectiveness of the medical device in development. Such information is often derived from preclinical or clinical studies. During the preclinical stage, the developers oftentimes test the prototype devices in controlled laboratory settings. Preclinical studies are intended to reduce risk of harm in human subjects and are designed to provide evidence to support the safety of the device. However, it may not be possible to eliminate the risk of harm to human subjects entirely.

In addition, for certain devices (e.g., implantable devices) the safety and effectiveness of a device may need to be demonstrated through clinical studies. Clinical studies are required for a small percentage of 510(k) clearance and most PMA applications. When conducting clinical studies, manufacturers, sponsor², clinical investigators³, and institutional review boards are subject to FDA regulatory requirements known as Good Clinical Practices, and must comply with various regulations regarding informed 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).

² Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation. They also are responsible for maintaining certain study records.

³ Investigators are responsible for ensuring that an investigation is conducted according to the signed agreement into which they enter with the sponsor; the investigational plan and applicable FDA regulations; for protecting the rights, safety, and welfare of subjects under the investigator’s care; and for the control of devices under investigation. Investigators are also responsible for ensuring that informed consent is obtained in accordance with FDA regulations and for maintaining certain study records.

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Investigational Device Exemptions

Prior to beginning clinical studies, FDA may require the sponsors to submit Investigational Device Exemption (“**IDE**”) applications, including when using a significant risk device in the clinical study, when conducting an investigation that is exempt from the informed consent requirement, or when FDA otherwise requires an IDE application to be submitted. In such instances, the clinical study cannot proceed until FDA approves the IDE application. A significant risk device is a device that (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or (4) otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.

If the device to be studied is a non-significant risk device, the clinical study may begin without FDA’s review of the IDE application; FDA considers such investigations to have approved IDEs, if the sponsor complies with the labeling requirement for the device, informed consent requirement, and the sponsor receives an IRB approval for the investigation, after providing an explanation to the reviewing IRB on why the device is not a significant risk device, among other requirements. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness; study indication; or the rights, safety, or welfare of human subjects.

For clinical studies with significant risk devices, FDA will expect to see in the IDE application:

- names and address of the sponsor;
- complete reports of prior investigations, such as prior clinical, animal, and laboratory testing of the device;
- a summary of the investigational plan for the device, including the proposed indications for use, objectives, protocol, risk analysis, and monitoring procedures;
- manufacturing information;
- an example investigator agreement;
- a list of investigators;
- a list of IRBs that has been or will be asked to review the investigation;
- labeling; and
- informed consent materials.

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Regardless of whether a clinical study is with a significant risk device or a non-significant risk device, clinical studies may need to be registered on the National Institute of Health’s clinical trials registry at www.clinicaltrials.gov, unless subject to certain exceptions (e.g., small studies for determining the feasibility and for testing prototype devices). Information related to the product, patient population, study sites, investigators, and other aspects of the clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion.

Types of Clinical Studies for Medical Devices

Several types of clinical studies may be required to demonstrate the safety and effectiveness of a medical device. An early feasibility study is a limited clinical investigation of a device when nonclinical testing methods cannot be used or are not sufficient for obtaining the information needed for advancing the developmental process. The device design at this point typically is not yet final, and information from early feasibility studies may provide guidance for device modifications. Early feasibility studies are designed for testing a specific indication (e.g., innovative device for a new or established intended use, marketed device for a novel clinical application), and typically involve only a small number of subjects (e.g., less than ten). A traditional feasibility study is a clinical study designed to provide preliminary information on a final or near-final device’s safety and effectiveness data for the purpose of preparing an appropriate pivotal study. Traditional feasibility studies do not necessarily need to be preceded by early feasibility studies. Finally, pivotal studies provide definitive evidence of a device’s safety and effectiveness for a specific indication. Pivotal studies are typically conducted on a statistically justified number of subjects, and may or may not be preceded by early or traditional feasibility studies. While reviewing feasibility studies proposed in IDE applications, FDA will review whether the study is conceptually reasonable, whether preclinical trial results support continued study of the investigational device, and whether the potential risks are adequately mitigated. When reviewing a proposed pivotal study, FDA will review the trial endpoints; methodology such as randomization, follow-up, and blinding; and the statistical analysis plan for the study. The sponsor may begin the investigation 30 days after FDA receives the IDE application; however, the sponsor may not conduct the investigation if the agency notifies the sponsor that the investigation may not begin.

FDA may also disapprove the IDE application after reviewing the application. FDA may do so when there is a reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, informed consent (as elaborated below) is inadequate, the investigation is scientifically unsound, or there is a reason to believe that the device as used is ineffective. FDA may also disapprove the application when the sponsor fails to respond to the agency’s request for additional information, when an untrue statement of a material fact or omission of material information in the application is discovered, or if the agency has other concerns.

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Informed Consent

Because many devices used in clinical studies have not previously received FDA’s review for safety and effectiveness, or even if they have, receiving the subjects’ informed consent is critical to ensuring that the subjects are fully aware of the potential risks involved with participating in the clinical study, in addition to having other necessary information. For this reason, most clinical trials are subject to FDA’s regulations on informed consent. FDA regulations require the investigator of a clinical investigation to obtain legally effective informed consent from the subjects before the investigation can begin. While certain clinical uses of investigational devices may be exempt from informed consent requirements, in most cases, informed consent is required for investigational uses of a device.

For informed consent to be effective, the informed consent must include elements such as:

- a statement that the study involves research, an explanation of the research and the expected duration of the subject’s participation, and identification of any procedures which are experimental;
- an explanation of the purposes of the research;
- the amount of time the study subject is expected to be in the trial;
- the procedures that the subject is expected to undergo, identifying any that are considered experimental;
- reasonably foreseeable risks or discomforts to the subject;
- any benefits to the subject reasonably expected from the research;
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- a description on how confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records;
- an explanation of what happens if the subject is injured, including whether compensation or medical treatment is available and how to get more information;
- an explanation of whom to contact about the research and research subjects’ rights, and whom to contact in the event of an injury; and
- a statement that participation is voluntary, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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In addition, if a clinical trial prospectively compares a device-based intervention subject to FDA regulation against a control in human subjects, or the clinical trial is a pediatric post-market surveillance trial (“applicable clinical trial”), the following sentence must be included in informed consent documents: “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.”

In certain cases when the subjects are children or others with impaired consent capacity, guardians, parents, or legally authorized representatives may be able to provide the required consent. However, informed consents may need to be modified to further protect the subjects’ rights, and safeguards such as providing a waiting period to allow additional time for decision making, re-assessing the subjects’ consent capacity after initiation of the clinical study, or having the IRB or another third party observe the consent process may be necessary to ensure that the informed consent is and remains valid throughout the investigation.

Institutional Review Boards

Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. The IRBs review serves an important role in the protection of the rights, safety and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights, safety and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., the informed consent documents referenced above). The IRB must monitor and review an investigation throughout the clinical study.

If an IRB determines that an investigation involves a significant risk device, it must notify the investigator and, if appropriate, the sponsor. The sponsor may not begin the investigation until approved by FDA.

FDA requires IRBs to be registered. The institutions where the study is to be conducted should be contacted to determine if they have their own IRB. If the study is conducted at a site that does not have its own IRB, the investigators should be queried to see if they are affiliated with an institution with an IRB that would be willing to act as the IRB for that site in the study. There are also independent/contract IRBs that can serve as the IRB for a site.

An IRB must comply with all applicable requirements of the IRB regulation referenced above and the IDE regulations in reviewing and approving device investigations involving human testing. FDA does periodic inspections of the IRB’s records and procedures to determine compliance with the regulations.

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Post-market Requirements

Once FDA issues marketing authorization for a medical device, including the Company’s devices, the medical device will be subject to various post-approval requirements, including registration and listing, compliance with current Good Manufacturing Practices (“cGMP”) through the QSR, labeling and packaging requirements, as well as compliance with regulations concerning advertising and promotion.

Prohibition against Adulteration and Misbranding

Medical device manufacturers must ensure that they introduce into interstate commerce devices that comply with the FDCA. Section 301(a) of the FDCA prohibits introduction into interstate commerce of adulterated or misbranded medical devices. According to the General Controls for Medical Devices of the FDA, a device may be deemed adulterated for several reasons, including, but not limited to, that (1) it consists of any filthy, putrid, or decomposed substance; (2) it is prepared, packed, or held under unsanitary conditions; (3) (A) the device’s container is composed, in whole or part, of any poisonous or deleterious substance, (B) the device contains, for the purposes of coloring only, an unsafe color additive, and the strength of the device differs from, or its purity or quality falls below, that which it claims to represent; (4) the device does not comply with performance standards, cGMP or IDE; or (5) there is no PMA that covers the device even though the device is subject to such requirement. In addition, the FDA may consider a device to be misbranded for several reasons, including (1) a false or misleading label or labeling; (2) lack of pre-market notification for devices that are subject to the requirement; and/or (3) non-compliance with label requirements, such as a lack of a manufacturer, packer, or distributor statement, net quantity statement, statement of identity, or adequate directions for use.

Registration and Listing

The FDCA requires all persons and parties that own or operate any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a medical device to register annually with the FDA. This registration enables the agency to keep track of the establishment information for medical devices that are being marketed in the United States. In particular, the regulations require an owner or operator of an establishment that has not previously engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices to register the establishment with FDA within 30 days of entering into operation. All facilities must renew their registrations between October 1 and December 31 of each fiscal year. The failure to properly register constitutes a violation of the FDCA.

In addition, FDA requires a list of medical devices in commercial distribution to be submitted to FDA by the owner or operator of an establishment (including specification developers, medical device sterilizers, medical device repackagers or relabelers, reproducers of a single use device, manufacturers of components or accessories that are packaged for commercial distribution, or initial importers of medical devices), or in certain circumstances

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by the parent, subsidiary, or affiliate of the owner or operator. The owner or operator must at the time of registering the establishment also list its devices. Any updates to information provided to FDA during the registration and listing process must be reflected on FDA’s database within 30 days of such change. The failure to properly register and list constitutes a violation of the FDCA.

Labeling and Packaging

In order to market a medical device in the United States, manufacturers must also comply with FDCA requirements for labeling and packaging. Labeling and packaging requirements include:

- adequate directions for use, which may include:
 - quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions;
 - frequency of administration or application;
 - duration of administration or application;
 - time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors;
 - route or method of administration or application;
 - preparation for use, i.e., adjustment of temperature, or other manipulation or process; and
 - 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.
- the net quantity statement, expressed in terms of the weight, measure, and numerical count of the device (i.e., the number or weight of the product);
- manufacturer, packer, or distributor’s name and address;
- warning statements for certain devices; and
- device-specific user labeling requirements for certain products.

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Prescription devices are exempt from the adequate directions for use requirement, but instead must include information for use, including indications, effects, routes, frequency and duration of administration, contraindications, and other information with which licensed practitioners can use the device safely and effectively.

Moreover, FDA requires medical devices to bear a Unique Device Identifier (“UDI”), in order to allow for identification of medical devices through distribution and use. All medical devices distributed in the United States must bear a UDI, unless an exception or alternative applies. A medical device label must display the UDI in two forms – plain text that is easily readable, and using automatic identification and data capture technology. FDA regulations also require that the UDI be marked directly on the device if the device is intended to be used more than once and intended to be reprocessed before each use. However, the direct- marking requirement does not apply to devices whose safety or effectiveness can be affected by such method of marking.

Quality System Regulation

Medical devices marketed in the United States are also subject to cGMPs. FDA promulgated the cGMP requirements in the QSR, outlined in 21 C.F.R. Part 820. The QSR provides principles for finished device manufacturers to follow during the design, manufacture, storage, labeling, and packaging of finished devices (including certain components) intended for human use and commercial distribution. Manufacturers must develop their quality system and comply with the QSR by considering the risk posed by their respective device, and the complexity of and risks inherent in the manufacturing processes.

Additionally, company management must establish a policy for ensuring quality and must ensure that the policy is implemented at the organization. The organizational structure must also be developed to enable the design and manufacture of the devices in compliance with the QSR. When developing a medical device, the manufacturer must prepare procedures to ensure that appropriate design controls are in place to prevent potential deficiencies in the device. Procedures must involve appropriate verification, review, and approval of design changes before implementation of design changes, and each manufacturer must maintain a design history file for each type of device.

Medical device manufacturers must also establish and implement procedures for proper medical device storage to prevent mix-ups, damage, contamination, or other adverse effects pending use or distribution. The procedures must ensure that no obsolete, rejected, or deteriorated products can be used or distributed. The procedures must include methods for authorizing the receipt from and the dispatch to the storage areas. Additionally, manufacturers must maintain and store all required records at a location reasonably accessible to responsible officials of the manufacturer and to FDA employees during FDA inspections. It is recommended that manufacturers mark records as confidential to assist FDA in determining which records should not be released to the public.

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Manufacturers must also maintain a device master record, which includes or refers to the location for the device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and installation, maintenance, and servicing procedures and methods. Device history records must include or refer to the location of information regarding the dates of manufacture, the quantity manufactured, the quantity released for distribution, acceptance records, any UDI or universal product code, and the primary identification label and labeling used for each production unit. All required records must be stored for a minimum of two years or for a period as long as the time equivalent to the design and expected life of the device, whichever is longer.

Each manufacturer is required to develop and monitor the production process so that its devices are produced according to the specifications. Where deviation is possible, control procedures must be established to ensure conformance to specifications. All inspection and test equipment must be capable of verifying and producing valid results, and procedures for routine calibration, inspection, and maintenance must be established. There must be a set of procedures designed for controlling non-conforming products. Such procedures must address the identification, documentation, evaluation, segregation, and disposition of the non-conforming products. Each manufacturer must also establish procedures for corrective and preventive actions, including analyzing quality audit reports, processes, operations, and other sources of quality data to identify the potential causes of non-conformance. Such causes must be investigated, and corrective and preventive actions must be implemented and verified to prevent future non-compliance.

Quality audits must also be conducted to ensure that the quality system complies with the QSR. These audits may be conducted by internal personnel, or at other times, by external independent auditors. Corrective and preventive actions may be necessary following the company’s quality audits, depending upon the results of the audits. The manufacturer must document the quality audits taken, and the management must review the results of the audit. A manufacturer’s non-compliance with the QSR may render the manufacturer’s medical devices adulterated, and may invite FDA scrutiny and enforcement actions.

Promotion and Advertising

FDA classifies and regulates products based on a product’s intended use. This allows the agency to determine the regulatory scheme (e.g., drug, device, food, cosmetic and consumer product) to which the product must be subjected. Intended use is defined as the objective intent of the parties legally responsible for the labeling of devices. To determine the intended use, FDA may consider such parties’ expressions or the circumstances surrounding the distribution of the product. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements. The agency takes a holistic view of the many factors outlined above and does not necessarily rely on just one factor, although label and labeling claims always remain critical in determination of a product’s intended use.

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FDA regulates the label and labeling of medical devices – including both over-the-counter and prescription devices – and advertising of restricted medical devices. Under the FDCA, “label” is defined as a display of written, printed, or graphic matter upon the immediate container of any article. In addition, “labeling” is defined as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. FDA interprets this definition broadly to mean that any materials supplementing or explaining an article is labeling, and that no physical attachment needs to connect the product and the materials. FDA considers as labeling materials such as brochures, booklets, mailing pieces, catalogs, letters, exhibits, literature, audio, or visual matter. In addition, while the FDCA does not define “advertising,” FDA considers advertising to include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

Medical device label and labeling information must comply with the regulatory requirements and must contain specific pieces of information. Such required information includes:

- statement of identity;
- manufacturer, packer, or distributor statement;
- net quantity statement;
- adequate directions for use (unless exempt);
- any warning statements; and
- indications for use.

In addition, medical device label and labeling must disclose required risk information, and such requirements may apply to communications made in various venues, including social network services. In particular, information on medical device labels, labeling, and advertisements cannot claim that the device is safe and effective for uses that FDA has not reviewed. Non-compliance or violation of such 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 further enforcement actions.

Moreover, even if FDA has already cleared or approved a medical device for a particular use, promotion of uses other than those that FDA has cleared or approved may constitute off-label promotion, which FDA considers to be unlawful. FDA is concerned about off-label promotion because while the device at issue may have been cleared or approved as safe and effective for certain uses, in off-label promotion the device is being marketed for indications for which the agency has not reviewed the safety and effectiveness. Off-label promotion may

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render a device adulterated or misbranded, and can expose 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.

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 information such as patient information (e.g., name and gender), 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. Non-compliance with the Medical Device Reporting requirement is a prohibited act under the FDCA, and may result in FDA enforcement action (as detailed below).

Import & Export of FDA-Regulatory Products and FDA’s Enforcement Authority

FDA has the authority to bring regulatory enforcement actions against products that fail to comply with the FDCA. This authority is strengthened at the border, where the agency can refuse products based on their *appearance* of violation. Certain products may be subject to specific regulatory requirements for export.

FDA’s Authority at the Border against Imported Products

All medical devices being imported into the United States must comply with the FDA regulatory requirements. In fact, FDA exercises a much stronger regulatory authority at the border against products being imported into the United States than against products in domestic commerce. Section 801 of the FDCA grants FDA the authority to refuse imported products if

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it *appears* from the examination of such products or from other sources that the products violate the FDCA (e.g., labeling non-compliance, lack of premarket notification or PMA); in other words, the burden falls on the owner or the consignee of the products to prove that the products comply with the FDCA and the regulations promulgated pursuant to the law, rather than FDA needing to prove the products’ non-compliance.

If FDA determines through the examination of the products or from other sources that the products that are being imported appear to violate the FDCA, the agency will detain the products and will provide the owner or consignee an opportunity to introduce testimony to demonstrate the product’s compliance with the law. In certain circumstances, FDA may permit reconditioning of the products and will release the products from detention if subsequent to reconditioning, the products comply with the FDCA and its regulatory requirements. However, if the importer or manufacturer fails to recondition the products or otherwise demonstrate that the products comply with the law, FDA will refuse the products and the products must be destroyed or exported out of the United States within 90 days of the refusal.

Based on this authority, FDA also operates Import Alerts, which list products that FDA has determined to have the appearance of violation. If FDA finds that a product that is being imported into the United States is on an Import Alert, FDA will automatically detain the product upon its arrival to the United States without physical examination, and the owner or consignee of the products will need to introduce testimony to prove that the products comply with the laws, and to eventually seek the products’ release. To be completely removed from an Import Alert, the manufacturer, owner, or consignee of the products subject to the Import Alert will need to submit a petition to FDA proving that the conditions causing the products to violate the law have been addressed.

Export Requirements

Products exported from the United States are subject to foreign countries’ import requirements and the exporting requirements of FDA, as applicable. In particular, international sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Medical devices that are marketed lawfully in the United States may be exported without prior FDA notification or approval.

Foreign countries often require, among other things, a Certificate of Foreign Government (“CFG”) for export. To obtain a CFG, the device manufacturer must submit an application to FDA asking FDA to certify that the product is in compliance with the U.S. law (subject to a valid premarket notification or PMA) or that the manufacturing facilities were in compliance with the FDA’s QSR regulations at the time of the last FDA inspection.

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FDA Enforcement Action

In general, FDA employs a risk-based enforcement approach to identify non-compliance and violations of the FDCA and its implementing regulations, and to bring enforcement actions against the medical device manufacturer, distributor, marketer, or other responsible parties as necessary depending on the severity of the non-compliance and violations. FDA’s enforcement actions may include:

- *Warning Letters, Untitled Letters, It-Has-Come-to-Our-Attention (“IHCTOA”) Letters.* If FDA finds non-compliance or violations of the FDCA or the regulations through inspections or other market monitoring activities, FDA may send correspondence to the responsible party notifying the party of the non-compliance or violations. These correspondences may allege non-compliance with the QSR, unlawful advertising and promotion of medical devices, non-compliance with medical device labeling regulations, or any other violation of the FDCA. FDA typically outlines the alleged non-compliance and violations in these correspondences, and requests that the recipient respond with the proposed steps for correcting and preventing future violations. If the response does not sufficiently address FDA’s concerns, FDA may bring additional enforcement actions.
- *Recall.* FDA has the authority to order recall of medical devices that do not comply with the FDCA, if the agency finds that there is a reasonable probability that the devices could cause serious, adverse health consequences or death. FDA exercises this authority rarely and the responsible parties usually carry out the recall voluntarily. Insanitary manufacturing conditions, marketing of unapproved devices, or defective products, among others, may result in a medical device recall.
- *Seizure.* FDA may attempt to remove from interstate commerce medical devices that are adulterated or misbranded, pursuant to Section 334 of the FDCA. FDA files a Complaint for Forfeiture and upon obtaining a warrant, directs the United States to marshal to seize the violative medical devices. Before commencing seizure actions, the agency may send prior warnings to attempt to convince the responsible party to voluntarily recondition and bring the products into compliance. If the responsible party does not comply, the agency may institute seizure actions.
- *Injunction.* An injunction is a civil judicial process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur. FDA may seek to enjoin the actions of the party or parties responsible for non-compliance or conduct violative of the FDCA. If FDA considers the non-compliance or violation to be serious, FDA may file a complaint for injunction by coordinating with the Department of Justice to enjoin the responsible party from further engaging in violative conduct.

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- *Criminal Prosecution.* Criminal prosecution may be recommended in appropriate cases for violation of Section 331 of the FDCA. Misdemeanor convictions, which do not require proof of intent to violate the FDCA, can result in fines and/or imprisonment up to one year. Felony convictions, which apply in the case of a second violation or intent to defraud or mislead, can result in fines and/or imprisonment up to three years.
- *Criminal Fines.* Fines under the FDCA may reach up to USD1,000,000 depending on the severity of the circumstances. Specifically, fines may reach USD15,000 for each violation that relates to devices and shall not to exceed USD1,000,000 for all such violations adjudicated in a single proceeding.

United States Reimbursement

Once a medical device is approved, cleared, or otherwise determined to be not subject to approval or clearance requirements, the medical device may be marketed in the United States. While medical devices are sold and used in various healthcare settings, medical devices, including devices such as the Company’s *LungPoint/Archimedes System and InterVapor*, are typically sold to hospitals, which in turn submit claims to government or commercial payers. Thus, the ability to successfully market and sell medical devices is dependent on the availability of third-party reimbursement to hospitals. Payment methodologies and coverage parameters can vary significantly based on payer and site of care, and these policies are subject to change.

The largest U.S. government health program is Medicare, which is administered by the Centers for Medicare and Medicaid Services (CMS) in accordance with broad program requirements established by Congress in the Social Security Act. Medicare reimburses acute care hospitals under the Medicare inpatient prospective payment system (IPPS). Under the IPPS, upon the discharge of a patient, CMS assigns the patient to stay a Medicare severity diagnosis related group (MS-DRG), which is a classification system that groups clinically similar procedures/conditions that require comparable inpatient resources. For each discharge, CMS makes a single MS-DRG payment to the hospital, subject to certain adjustments. The MS-DRG payment is intended to compensate the hospital for the patient’s room and board, medicine, surgical and diagnostic procedures, and supplies that were provided to the patient during the encounter. Medicare may make additional payment under the IPPS on a temporary basis for the use of certain costly new technologies that provide substantial clinical improvement. For procedures that are furnished in the outpatient hospital setting, the Medicare outpatient prospective payment system (OPPS) is based on the procedure’s ambulatory payment classification (APC) assignment. The APC payment typically includes all integral, ancillary, supportive, dependent, and adjunctive services associated with the primary procedure or service, subject to various adjustments. Separate, temporary pass-through payments may be available for the cost of new medical devices. Medicare payments to physicians are based on the relative amount of physician work, practice expenses, and malpractice insurance costs associated with a procedure. Payments also vary based on whether a procedure is performed in a physician office (non-facility) or in a facility setting (e.g., a hospital). CMS updates the

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IPPS, OPPIs, and physician fee schedule regulations and payment rates annually through the rule making process. There can be no assurance that Medicare payment policies for procedures using the Company’s products will be sufficient to cover facility costs or otherwise support adoption.

Because hospitals typically receive a single prospective payment for treating a Medicare patient, rather than reimbursement for all costs incurred, hospitals have an incentive to provide care efficiently. CMS has increasingly emphasized value-based care in recent years, including by launching various innovative bundled payment models under which hospitals and other entities are accountable for financial and quality performance for episodes of patient care. Such models may allow hospitals and physicians to share savings achieved by certain procedure cost reductions.

CMS and its contractors may establish specific criteria governing the conditions under which a medical device or procedure is covered by Medicare; that is, FDA clearance is not sufficient to guarantee coverage. In order to qualify for Medicare coverage, a technology must fall within a Medicare benefit category as established by the Social Security Act, and meet a statutory “reasonable and necessary” standard based on an assessment of published and peer-reviewed clinical evidence. In some cases, CMS will cover technologies only if they are performed within the context of a clinical study. CMS has proposed revising this policy to provide hospitals with more flexibility in meeting the procedural volume requirements.

About one-third of Medicare beneficiaries voluntarily enroll in a Medicare Advantage plan. Under the Medicare Advantage program, CMS contracts with private health plans to provide benefits to enrollees. Medicare Advantage plans negotiate directly with hospitals, physicians, and other providers on payment amounts.

Commercial health plans also typically negotiate rates with hospitals for services provided to plan members; in some cases, rates are tied to Medicare reimbursement. Commercial insurers likewise have taken an increasingly active role in assessing the clinical efficacy and cost effectiveness of medical technologies. Payers may deny coverage of a new medical device or procedure on the basis of being experimental or investigational, or they may impose significant restrictions on the parameters under which a medical device or procedure will be covered. Favorable coverage policies for new technologies typically require peer-reviewed published literature demonstrating clinical effectiveness, and in some cases an assessment of cost- effectiveness.

Congress periodically considers legislation to control costs within government-financed health care programs. In the past, such legislation has included reductions to Medicare and Medicaid payments to hospitals, expanded value-based purchasing, and other payment reforms. In addition, under the sequestration provisions of the Budget Control Act of 2011, as subsequently amended, a 2% cut is applied to Medicare payments to providers and health plans through fiscal year 2025, although Congress and the Administration could enact legislation at

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any time that modifies this requirement. Adoption of future legislation changing the level of government spending on health care or other coverage reforms could impact the ability of hospitals to adopt new medical technologies.

Federal insurance and health care reform legislation known as the Patient Protection and Affordable Care Act (ACA) became law in 2010. The ACA is intended to expand health insurance coverage, including for at least a portion of drug costs, through a combination of insurance market reforms, an expansion of Medicaid and subsidies. It contains many provisions designed to generate the revenues necessary to fund the coverage expansions and reduce the costs of Medicare and Medicaid. Among other things, the ACA also included provisions that created programs to shift the industry to value-based care, required all individuals to have health insurance with limited exceptions, and imposed increased taxes. One of these taxes is a 2.3% excise tax on United States sales of most medical devices. Such tax was suspended for calendar years 2016 through 2019, and is currently slated to go into effect on January 1, 2020.

Additional reforms affecting payment for health care services have been considered by state legislatures. State budget pressures have resulted in the adoption of Medicaid provider payment reductions in some states, and state Medicaid programs increasingly provide benefits through managed care programs under contracts with private health plans.

Federal and State Fraud and Abuse Laws

For our products that have received regulatory approval in the United States, and to the extent that we receive further regulatory approval of our products, we are and will continue to be subject to various federal and state laws aimed at prohibiting fraud and abuse in the healthcare industry. These laws may impact, among other things, our sales, marketing, technical support and education programs, and other relationships with hospitals, other referral sources and key opinion leaders. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business prior to and after receiving regulatory approval of our product candidates.

Federal health care laws apply when we interact with health care providers who are in a position to refer patients to our customers and/or when our customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally-funded health care programs, including laws summarized below related to kickbacks, false claims, self-referrals and health care fraud. There are often similar state false claims, anti-kickback, and anti-self-referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third-party payers.

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The laws that may affect our ability to operate include:

- *the federal Anti-Kickback Statute* – which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs, in each case unless such arrangement meets a regulatory “safe harbor” (see below for additional information regarding Anti-Kickback Statute safe harbors);
- *the federal Stark Law* – which prohibits, among other things, a physician from referring a patient to an entity for certain “designated health services” reimbursable by Medicare if the physician (or a close family member) has a financial relationship with that entity, including an ownership or investment interest, a loan or debt relationship or a compensation relationship, unless an exception to the Stark Law is fully satisfied. Some states have self-referral laws similar to the Stark Law for Medicaid and commercial claims;
- *federal civil and criminal false claims and civil monetary penalty laws, such as the federal False Claims Act* – which impose criminal and civil penalties, and authorize civil whistleblower or qui tam actions (an action brought by an individual on behalf of a government) against individuals or entities for, among other things: knowingly presenting or causing to be presented to the federal government, claims for payment that are false or fraudulent; making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay money to the federal government. In addition, the government may assert that a violation of the federal Anti-Kickback Statute also constitutes a violation for purposes of the False Claims Act. Further, the government may take the position that off-label promotion results in a company receiving reimbursement for an off-label use in violation of the federal False Claims Act;
- *the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA)* – which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing, or covering up by any trick or device, a material fact, or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters;

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- *HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and the Privacy and Security Rules promulgated thereunder* – which govern the use, disclosure, and security of protected health information by “Covered Entities,” (which are health care providers that submit electronic claims, health plans, and health care clearing houses) and by their “Business Associates” (which is anyone that performs a service for or on behalf of a Covered Entity involving the use or disclosure of protected health information and is not a member of the Covered Entity’s workforce). Rules under HIPAA and HITECH include specific security standards and breach notification requirements. The U.S. Department of Health and Human Services (HHS) (through the Office for Civil Rights) has direct enforcement authority against Covered Entities and Business Associates with regard to both the Security and Privacy Rules, including civil and criminal liability;
- *the federal false statements statute* – which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- *the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act* – which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to HHS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- *federal consumer protection and unfair competition laws* – which generally prevent fraud, deception and unfair business practices.

The federal fraud and abuse laws summarized above are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS), and various state agencies. For example, the federal Anti-Kickback Statute’s definition of “remuneration” has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the federal Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the OIG for HHS has issued a series of regulatory “safe harbors.” These safe harbor regulations (e.g., personal services, warranty and discount safe harbors) set forth certain requirements that, if met, assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions protects against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal, or that prosecution under the federal Anti-Kickback Statute will occur.

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The healthcare industry has also experienced increased enforcement of the federal False Claims Act and, in particular, “qui tam” or “whistleblower” actions. The federal False Claims Act’s qui tam provisions allow a private individual to bring actions on behalf of the federal government. Such individuals are permitted to share in any amounts paid by the entity to the government in a judgment or settlement. In addition, states have enacted false claim laws similar to the federal False Claims Act, including some applicable to any third party payer. A violation of the False Claims Act may subject an actor to treble damages, or payment of up to three times the actual damages, in addition to significant civil monetary penalties.

EUROPE UNION AND EEA REGULATORY OVERVIEW

Law and Regulations Relating to Medical Devices

In the European Economic Area (EEA), which consists of the member states of the European Union (“EU”) and three states of the European Free Trade Association, namely Iceland, Liechtenstein and Norway, (EEA Member States), our devices are required to comply with the Essential Requirements laid down in Annex I to the Council Directive 93/42/EEC concerning medical devices, commonly referred to as the Medical Devices Directive. The manufacturer is also required to demonstrate compliance with the quality management system requirements of the relevant Annexes to the Directive (Except for Class I manufacturers). Compliance with these requirements entitles us to affix the CE mark to the relevant medical devices, without which they cannot be commercialized in the EEA.

To demonstrate compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive, the quality management system requirements in the relevant Annexes to the Directive and to obtain the right to affix the CE mark to our medical devices, manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. According to Annex IX of the Medical Devices Directive, medical devices are divided into four risk classes: Class I, Class IIa, Class IIb and Class III. Class I represents the lowest risk class and Class III represents the highest risk one. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements laid down in the Medical Devices Directive, a conformity assessment procedure requires the intervention of a notified body, which is an organization designated by the competent authorities of an EEA country to conduct conformity assessments related to medical device. The notified body typically audits and examines the Technical File for the medical device and the manufacturer’s quality management system for the manufacture, design and final inspection of our devices.

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As a general rule, demonstration of conformity with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The clinical evidence collected by the manufacturer must be sufficient to demonstrate compliance with the Essential Requirements.

The notified body will issue a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity the requirements of the Medical Device Directive. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after the manufacturer has prepared and signed a related EC Declaration of Conformity.

Once the conformity assessment procedure is completed, the medical device and the manufacturer remain under scrutiny of the Notified Body. The Notified Body is obliged to perform regular surveillance audits of the manufacturer and, before the expiry date of the CE Certificate of Conformity, a more in depth renewal certification audit should take place. Notified Bodies may also conduct unannounced audits. During these audits the Notified Bodies may find minor and major non-conformities which must be addressed by the manufacturer.

If the requirements of the Medical Devices Directive are not (or no longer) fulfilled:

- the notified body may decide to withdraw, suspend or limit the scope of the applicable CE Certificate of Conformity;
- the Competent Authority of the EEA Member State may enforce the provisions of the Medical Device Directive, e.g. by preventing the product from being put on the market, ordering a recall or shutting down a manufacturing site;
- criminal, civil or administrative penalties (e.g. fines) may apply;
- In case of potential damages to the patients, manufacturer may also be held liable for damages to the patients or the users of the medical device.

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In principle, the manufacturer is responsible to ensure compliance with applicable provisions including affixing the CE Marking certification to his products. Medical devices manufacturers who do not have an establishment within the EEA and who wish to affix a CE Mark to medical devices and to market these products in the EEA must either, establish an EEA presence or, select a local representative to serve as its “Authorised Representative”.

The Authorised Representative must register with the Competent Authority of the EEA Member State in which it is established, and provide the Competent Authority with information concerning its registered place of business and with the description of the medical devices for which it will be responsible. An Authorised Representative serves as the manufacturer’s point of contact with competent authorities. It does not provide marketing services, but is responsible for holding any files that must be kept available for possible inspection by the authorities, for example the Declaration of Conformity of the medical device. The Authorised Representatives also interact with EEA Competent Authorities on behalf of the manufacturer. They forward to the manufacturer potential inquiries from the authorities and forward correspondence from the manufacturer to the relevant authority.

In the EEA, manufacturers must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the EEA Member States, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or instructions for use or an unanticipated adverse reaction or side effect which, directly or indirectly, might lead to or might have led to the death of a patient, user or other person or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. The guidance document MEDDEV 2.12-1 describes the requirements for a Medical Device Vigilance.

On May 26, 2021, the current EU legislation applicable to medical devices will be replaced by the Medical Device Regulation (Regulation (EU) 2017/745) (MDR).

Advertising and Promotion of Medical Devices

The advertising and promotion of medical devices is subject to the Medical Devices Directive, general legislation such as Directive 2006/114/EC concerning misleading and comparative advertising, Directive 2005/29/EC on unfair commercial practices, as well as the EEA Member State legislation governing the advertising and promotion of medical devices.

In general the advertising and promotion of medical devices must be consistent with the intended purpose for which the medical device was CE Marked, be consistent with the Instructions for Use for the medical device that is being promoted and not discuss or relate,

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even indirectly, to medical devices that are not CE Marked or the off-label use of CE Marked medical devices. In addition, any claims must be scientifically rigorous, truthful, accurate, objective, balanced, fair and factual.

The legislation of certain EEA Member States limits or restricts the advertising and promotion of medical devices to the general public and may impose limitations on our promotional activities with healthcare professionals.

EU Personal Data Protection Legislation

The EU, and therefore also the EEA Member States, have adopted data protection laws and regulations, which impose significant compliance obligations concerning personal data protection. The EU General Data Protection Regulation, or GDPR, became applicable on May 25, 2018 and is directly applicable in each EEA Member State. It is intended to result in a more uniform application of data privacy laws across the EU and the EEA. The GDPR imposes strict requirements and onerous accountability obligations on companies that process personal data, especially if they process sensitive personal data (such as data concerning personal health), including significant fines for non-compliance with the GDPR.

Furthermore, the GDPR is applicable to the conduct of clinical studies and, potentially, adverse event reporting to competent authorities where these reports include pseudonymized personal data of patients. In the event we enroll subjects in our ongoing or future clinical investigations in the EEA, we may be subject to additional privacy restrictions, including restrictions relating to the collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the EEA as governed by the GDPR.

The GDPR imposes several requirements on companies that process personal data, strict rules on the transfer of personal data out of the EEA and fines and penalties for failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States. Any personal data that is exported from the EU or the EEA to a third country that is not subject to an Adequacy Decision of the European Commission, must be subject to one of the appropriate safeguards provided by the GDPR. An Adequacy Decision is a formal legal act adopted by the European Commission which act provides that the level of data protection is equivalent to that of the EEA Member State.

The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Therefore, patients may potentially seek damages from manufacturers in case of a personal data breach suffered by the manufacturer of medical devices or one of the manufacturer’s subcontractors.

Where a manufacturer that processes personal data is not established in an EEA Member State, that manufacturer may designate a data protection representative established in an EEA Member State.

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Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities. Furthermore, the United Kingdom’s exit of the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In light of the above, the requirements of the GDPR may result in additional challenges and costs for manufacturers of medical devices active in the EU and the EEA.

Changes to the Regulatory Framework

Introduction

The Regulation (EU) 2017/745 of April 5, 2017 on medical devices (“**MDR**”) will replace the Medical Devices Directive on 26 May 2021. Unlike directives, which must be implemented into the national laws of the EEA Member States, the MDR is directly applicable, i.e., without the need for adoption of EEA Member State laws implementing them, in all EEA Member States and is intended to eliminate current differences in the regulation of medical devices among EEA member States. The EU Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The MDR imposes new and sometimes more stringent requirements compared to the MDD

The MDR will lead to changes of the risk classification of certain medical devices which may be “up-classified” by the MDR from the Medical Devices Directive and may be subject to additional requirements. Up-classified means that a medical devices that was example given a medical device of Class I under the Medical Devices Directive may be regulated in a higher risk Class such as Class IIb. In the example provided, this will require the relevant manufacturer to involve a notified body as part of the conformity assessment procedure.

In accordance with the MDR, the 14 essential requirements set out in the Medical Devices Directive to which conformance is mandatory will be extended to and replaced by 23 general safety and performance requirements. The MDR will increase the level of clinical data necessary to demonstrate the conformity of the device with these general safety and performance requirements of the MDR. The conduct of clinical investigations will become the rule in particular for higher risks medical devices such as implantable and Class III medical devices.

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The MDR also includes additional requirements (regulatory review, additional labeling information, specific vigilance obligations) for economic operators in the manufacturer’s supply chain, such as importers, distributors and authorised representatives. Manufacturers are expected to have agreements with these economic operators which reflects the obligations laid down in the MDR.

Furthermore, in accordance with the MDR, manufacturers are subject to another new requirement, which is to appoint a person responsible for regulatory compliance (PRRC). A PRRC is qualified regulatory expert who is responsible for ensuring that the company is meeting EU requirements at all times. Authorised Representatives will also be required to have a PRRC at their disposal.

Post-market surveillance and the vigilance requirements will generally become more stringent under the MDR. The MDR distinguishes between vigilance as the identification, reporting and trending of serious incidents and the conduct of safety related corrective actions, and post market surveillance as the monitoring of information from various sources used to periodically reconfirm that the benefits of the device continue to outweigh its risks. The vigilance requirements in the MDR share a lot of similarities with the current MEDDEV 2.12-1 guidelines on a medical device vigilance system and are therefore not entirely new.

For the implementation of the MDR, the European Commission is developing a new IT system or medical device database called Eudamed. It is intended to improve transparency and information exchange concerning medical devices available on the EEA market. Eudamed is structured around 6 interconnected modules, Actors registration, UDI/Devices registration, Notified Bodies and Certificates, Clinical Investigations and performance studies, Vigilance and post-market surveillance and Market Surveillance. Manufacturers and other economic operators will be required to register and conduct certain of their activities through this IT system.

The MDR establishes an EU identification system for medical devices based on a Unique Device Identifier (“UDI”). The UDI will be mandatory for all medical devices. The MDR imposes a number of UDI related requirements on medical device manufacturers. These include the assignment of the UDI, the UDI registration in the Eudamed database and the placement of the UDI carrier on the label of the device. The main goal of the UDI System is to improve the traceability of devices. The UDI is also intended to enhance the effectiveness of the post-market safety-related activities for devices and allow for better monitoring by competent authorities. Article 27.5 of the MDR provides that the UDI System shall be used for reporting serious incidents and field safety corrective actions.

Furthermore, the above mentioned requirements may be challenging to fulfill for medical device manufacturers, and, may in general increase the costs of doing business in the EEA.

REGULATORY ENVIRONMENT

Transitional Provisions

Article 120 of the MDR provides transitional provisions related to medical devices that are already regulated under the Medical Devices Directive. A medical device which is either a Class I device pursuant to Directive 93/42/EEC, for which the EC Declaration of Conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to the MDR requires the involvement of a notified body (e.g. Class I device up-classified as Class IIa under the MDR), or which has a CE Certificate of Conformity that was issued in accordance with the Medical Devices Directive may be placed on the market or put into service until 26 May 2024 provided that the following conditions are met:

- (a) the medical device continues to comply with the Medical Devices Directive and if applicable the CE Certificate of Conformity remain valid;
- (b) there must be no significant changes in the design and intended purpose of the medical device;
- (c) the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices apply in place of the corresponding requirements in the Medical Devices Directive.

These transitional provisions will provide additional time to manufacturers to fully comply with the MDR.

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OUR VISION

Our vision is to be a global leader in the transformation of lung disease treatment.

OUR MISSION

Our mission is to establish our interventional diagnosis and therapeutic solutions as the gold standard for the treatment of lung diseases.

OVERVIEW

We are a pioneer in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Leveraging our whole lung access navigation technology and encompassing navigation, diagnosis and treatment, our integrated interventional pulmonology platform addresses the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases.

Led by our experienced management team with an average of over 20 years of experience in designing, developing and commercializing medical devices, we believe that by leveraging on their expertise, we are well positioned to capture the significant commercial opportunities in the large and fast-growing market for the lung disease treatment with a focus on chronic obstructive pulmonary disease (“**COPD**”) and lung cancer in China and globally. We also benefit from our stable and dedicated senior management personnel with complimentary background and expertise. Members of our board and management team have experience in commercializing medical devices such as peripheral vascular intervention products, and our transcatheter aortic valve replacement systems in China, the U.S. and Europe.

We are backed by a number of large institutional investors focused on the healthcare sector, such as Qiming Venture Capital, DiNovA Capital, LAKE Bleu Capital and FountainVest, and strategic investors including Intuitive Surgical, a global technology leader in robotic-assisted, minimally invasive surgical platforms and diagnostic tools listed on the Nasdaq Stock Market (NASDAQ: ISRG).

Under the leadership of our management team and with the support of our investors, we have successfully developed the world’s first and only real-time image whole lung access augmented reality navigation system, which enabled us to build an integrated product portfolio for lung disease diagnosis and treatment supported by the navigation system. Our whole lung access navigation system enables access to any part of the entire lung, both inside and outside of the airways, based on which we are able to develop revolutionary medical devices and solutions to transform the diagnosis and treatment paradigms of lung diseases. Our LungPoint ATV System, also known as LungPro in the mainland of China or the Archimedes

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System outside the mainland of China (the “**Archimedes System**”)¹ is the world’s only navigation system capable of whole lung access augmented reality real-time image navigation, according to Frost & Sullivan. Our proprietary Bronchoscopic Trans-Parenchymal Nodule Access (“**BTPNA**”) technology supporting the Archimedes System is able to precisely access any part of the entire lung and lead directly to lesions away from or adjacent to an airway by establishing a standard 2mm working channel through pulmonary parenchyma, creating a direct path to further diagnosis and treatment. Fully integrated with our lung navigation system, we offer a comprehensive portfolio of industry-leading interventional diagnostic and therapeutic products. Our InterVapor system (the “**InterVapor**”) is the world’s first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer, according to Frost & Sullivan. We are also developing RF Generator + RF Ablation Catheter (“**RF-II**”), a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer. We have also developed a pulmonary surgery marker, H-Marker, to mark the location of the lung nodule to achieve precise positioning during surgical pneumonectomy. We also offer a variety of diagnostic medical consumables. Our diagnostic solutions facilitate the early diagnosis and treatment of lung diseases, which could in turn help increase survival rates for patients. We believe that our three-in-one pulmonology platform which delivers the features of navigation, diagnostics and treatment with high accuracy, minimal side effects and lower costs has created high entry barriers to market followers and resulted in high switch cost for doctors or patients, thereby strengthening our market position in the interventional pulmonology medical device space in China and globally.

¹ LungPro and the Archimedes System are used interchangeably in this document.

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The following chart summarizes the development status of our products and product candidates on our three-in-one pulmonology platform as of the Latest Practicable Date. For details, please refer to “– Our Products and Product Pipeline.”

	Indication	Portfolio	Region	Preclinical	Clinical Trial	Registration
Treatment	COPD	InterVapor® for COPD ⁽²⁾	China	Clinical trial and expert review completed, technical review in process		
			US	FDA 510(K); registration application in preparation		
			EU	Launch for sale (2018)		
			Others	Launch for sale		
	Lung Cancer / Lung Nodules	InterVapor® for Lung Cancer ⁽³⁾	China	In design stage		
			US/EU	In design stage		
		RF Generator + RF Ablation Catheter (RF - II)*	China ⁽⁴⁾	Clinical trial in process		
			US/EU ⁽⁵⁾	FDA 510(K)/CE		
		EMPOWER RF Ablation Catheter (RF-I)	US	Launch for sale (2019)		
			EU	Launch for sale (2019)		
Navigation	Navigation Platform ⁽¹⁾	LungPoint	China	Launch for sale (2014)		
			US	Launch for sale (2009)		
			EU	Launch for sale (2010)		
		LungPoint Plus / Archimedes Lite	China	Launch for sale (2020)		
			US/EU	Launch for sale (2021)		
		LungPro / Archimedes System	China	Launch for sale (2017)		
			US	Launch for sale (2014)		
			EU	Launch for sale (2014)		
	lung Cancer / Lung Nodules	FlexNeedle	China	Launch for sale (2014)		
			US	Launch for sale (2009)		
			EU	Launch for sale (2013)		
		ATV FlexNeedleCN ⁽⁷⁾	China	Launch for sale (2019)		
			China	Launch for sale (2020)		
		ATV Sheath	China	Launch for sale (2018)		
			US	Launch for sale (2013)		
			EU	Launch for sale (2014)		
Diagnosis	lung Cancer / Lung Nodules	ATV Balloon	China	Launch for sale (2018)		
			US	Launch for sale (2013)		
			EU	Launch for sale (2014)		
		Steerable Sheath	China	Launch for sale (2020)		

Notes:

* Our Core Products

- Our navigation systems have been approved for marketing in the U.S., EU and PRC. Post-market study (EAST 2 Trial) for the Archimedes System has been completed.
- The expert review by NMPA has been completed and technical review is currently in process.
- R&D clinical trial (VAPORIZE trial) is currently in process.
- The first-in-man clinical trial has been completed with a registration clinical trial currently in process.
- Expect to leverage clinical data collected in China to apply for registrations in the U.S. and EU.
- The clinical trial has been completed and the registration in the PRC is expected to be approved in the second quarter of 2021.
- The version of FlexNeedle manufactured in China.

We are a fully-integrated interventional pulmonology platform with an efficient R&D model, global commercialization capabilities and strong production capacity.

Efficient R&D model. We believe we will continue to strengthen our competitive advantages through our R&D model combining international technologies with local R&D cost advantages and operational efficiencies to support a strong intellectual property portfolio and rapid product iterations to meet real-time clinical demands. On the one hand, we leverage our software and hardware expertise, mature interventional pulmonology technology and proven medical device development experience in the U.S., and our global network with KOLs to promote our products; and on the other hand, we leverage the cost advantages of the R&D environment and clinical research capabilities in China. Our innovation capabilities and patent

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portfolio have been endorsed by international industry giants, such as Intuitive Surgical, the manufacturer of the globally-renowned da Vinci surgical robots, who strategically invested in us in 2018. As of the Latest Practicable Date, we owned 476 patents and patent applications which consisted of 87 issued patents (including pending announcements) and 248 patent applications in China and 95 issued patents and 46 patent applications overseas including key markets such as the U.S. and the EU.

Global commercialization capabilities. We believe the significant clinical data generated under our R&D model provides a solid clinical foundation for our global commercialization. Our ability to commercialize our technologies is further strengthened by the promotion of our brand through early market education efforts and extensive training, hospital cooperation, local clinical trials and tailored commercialization strategies. To achieve the most effective commercialization outcome, we employ different sales models in different countries and regions. We have a dedicated in-house sales team which conducts academic marketing and clinical training driven by our extensive expertise and clinical resources. In particular, as the provider of the world’s only real-time image whole lung access augmented reality navigation system, our products have contributed to the clinical experience of leading experts in China in setting up the guidelines for doctors conducting endoscopy procedures.

Strong production capacity. Our production centers are based in China and the U.S. with an approximately 3,122 sq.m. facility in Hangzhou, China and an approximately 863 sq.m. leased facility in San Jose, the U.S. We currently manufacture LungPoint, LungPoint Plus, the Archimedes System and InterVapor in the U.S. and most of the consumables in China. Over the years, we have been gradually localizing the manufacturing process by moving it to China while maintaining quality production in manufacturing pulmonology diagnostic and therapeutic products, which we believe forms a solid basis for our long-term growth.

To accomplish our mission, we plan to strengthen our presence in the interventional pulmonology market in China and globally by growing sales in hospitals that already use our products and penetrating into new hospitals with doctor education and patient engagement. We plan to continue to expand our international R&D team based in China and the U.S. and leverage our R&D model to stay abreast with technological developments and medical device development experience in the U.S. and Europe while leveraging the cost advantages of clinical research capabilities based in China. To enhance our understanding of patient needs for technology and product innovation, we plan to increase investment in artificial intelligence and machine learning.

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OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors.

China’s first and only three-in-one in-house pulmonology platform supported by real-time image whole lung access navigation technology

We are a pioneer in real-time image lung navigation technologies and have developed the world’s first and only real-time image whole lung access augmented reality navigation system. Extending our footprint to interventional pulmonology treatment, through strategic expansion, we have established the world’s first thermal vapor energy ablation system, InterVapor, to treat lung diseases including COPD and lung cancer. Our self-developed RF-II is the only catheter-based radiofrequency ablation system that specifically targets lung cancer. We have also developed H-Marker to locate lung nodules through the natural cavity of the human body. As a pioneer in the field of interventional pulmonology, we are the only three-in-one in-house pulmonology platform with whole lung access navigation in China providing solutions throughout all stages of lung disease treatment. We believe that our portfolio technologies and full spectrum product offerings set high entry barriers for market followers and translate into high switch costs in each of the three dimensions with whole lung access navigation for doctors and patients to adopt those products of our competitors.

Our comprehensive product offerings diversify our revenue sources and offer an integrated product line with a treatment plan, increasing switch cost for doctors and patients to adopt other products as use of our navigation systems makes it more likely for them to adopt our interventional pulmonology diagnostic and therapeutic consumables. Leveraging our proprietary BTPNA technology, we developed the world’s first virtual bronchoscopic navigation (“VBN”) product, the Archimedes System, with whole lung access navigation capability. Complementary to and fully integrated with our proprietary navigation system, we provide a series of precise, interventional diagnostic products such as FleXNeedle®, a bronchoscopy needle biopsy for peripheral lesions and BiostarNeedle®, a central lymph node biopsy that is suitable for central lymph node biopsy sampling of the lung. We further expand our product portfolio to cover therapeutic products for lung diseases. As the world’s first thermal vapor energy ablation system, InterVapor is a therapeutic device that delivers thermal vapor bronchoscopically to the lung to achieve targeted ablation in a proven efficient and safe manner. We have also developed RF-II, the only catheter-based radiofrequency ablation system that specifically targets lung cancer and H-Marker to locate lung nodules through the natural cavity of the human body.

From whole lung access navigation to comprehensive diagnostic and therapeutic solutions, we aim to stay at the forefront of technology innovation and to deliver a full suite of interventional pulmonology products with the following features.

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Whole lung access navigation with accuracy. Our proprietary navigation technology is capable of navigating inside and outside of the airway to achieve whole lung access. The patent-protected BTPNA technology supporting our Archimedes System is able to reach any part of the entire lung and lead directly to lesions away from or adjacent to an airway. The diagnostic yield of BTPNA for pulmonary nodules can reach 90.2% while for nodules without CT bronchus sign, the overall weighted diagnostic yield is only 49.6%. Our augmented reality navigation system is also able to achieve a navigation accuracy of less than 3mm calculated calibration. This increases the potential for doctors to more effectively cure the lesion whilst preventing further damage to the healthy lung tissues. LungPoint, our optical navigation system and the only such system in China, is also immune from interference by medical device containing ferromagnetic, a major problem associated with electromagnetic navigation systems which establish a magnetic field. Our navigation technology supports simultaneous display of real-time image and virtual/simulated image with software-computed planned paths to precisely locate the target. As we understand many doctors prefer using image-guided technology to find the best path to access and biopsy nodules, regardless of the size or location, we believe our BTPNA-enabled systems bring breakthrough in various fronts of navigation technologies and meet the market demand for whole lung access with high accuracy profile.

Fully integrated and streamlined procedure. The procedure enabled by our navigation technology is simple for doctors to perform and requires no accompanying cone-beam computed tomography (“CBCT”) equipment or CT-guided puncture during the operation, whereas traditional procedures require costly and invasive accompanying CBCT equipment or CT-guided puncture, which carries the potential risk of the patient experiencing pneumothorax and bleeding due to the much more invasive puncture wound. Our navigation technology establishes a direct tunnel to nodules around the lungs which allows immediate biopsy and treatment. Our whole lung access navigation system derived from the BTPNA technology is also compatible with a wide range of laser, microwave and radiofrequency ablation equipment and consumables, which in practice can streamline the patient treatment process by performing navigation, diagnosis and treatment with one single bronchoscopic operation.

Minimal patient complications. Our procedure features minimal pre- and post-procedure complications and side effects for the patients. Traditional imaging technology can cause respiratory depression in people with severe lung diseases or liver cirrhosis and also dehydration. In contrast, our navigation technology utilizes harmless materials with proven safety profiles. In addition, our navigation technology is not contraindicated for medical electrical implants, which allows us to provide unique solutions for patients with pacemakers, scaffolds, or other existing implants.

Installation of equipment as an anchor. On the one hand, our equipment products do not set specification requirements for diagnostic consumables to be used together and are compatible with a wide range of thermal ablation systems, therefore providing us with an advantage in procurement tenders to hospitals. On the other hand, the installation of our equipment products at hospitals can serve as an anchor to further boost sales of our consumables, deepen hospital penetration and enhance product loyalty from both patients and doctors.

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As the pioneer in the real-time image lung navigation technologies, we have enjoyed significant competitive advantages by virtue of being the world’s first and only real-time image whole lung access augmented reality navigation system and through our early market education and relationships with KOLs and pulmonologists and hospitals around the world. The technology, equipment and industry resources we hold in hand through our in-house development set entry barriers for potential competitors. We believe that these advantages will help drive sales of our products and advance our other product candidates, which will further solidify our leadership position in product coverage and technology and enhance the foundation for the only three-in-one platform with whole lung access navigation in China.

Pioneer in a large untapped and fast-growing interventional pulmonology market with huge unmet medical needs

Our technology has made us a pioneer in the fast-growing interventional pulmonology lung navigation, diagnosis and treatment market. According to Frost & Sullivan, we are the leading interventional pulmonology navigation platform player in China in terms of sales volume in 2019, with a comprehensive product portfolio covering lung navigation, diagnosis and ablation-based therapeutic products. According to Frost & Sullivan, we had a 62.1% market share in China by sales volume in 2019 and a 54.1% market share in China by sales revenue for interventional pulmonology navigation platforms in 2019. Facing the global prevalence of COPD and lung cancer that has been propelled by aging population, air pollution and smoking habit, we see a huge market need for minimally invasive solutions to treat lung diseases. According to Frost & Sullivan, there was a COPD-affected population of 212.4 million globally and 104.4 million in China in 2019, respectively, and such population is expected to increase to 259.5 million globally and 108.0 million in China by 2024, respectively. According to Frost & Sullivan, among the COPD patients, 27.0% are at severe or extreme severe stages in China, who would face a mortality rate of 54.0% within five years without proper treatment and hence the overall COPD-affected population is in active demand of effective COPD therapeutic solutions that can accurately target varying stages. Global lung cancer incidence reached approximately 2.2 million people in 2019 and is expected to further increase to 2.5 million by 2024. China has the highest incidence of lung cancer in the world with a lung cancer population accounting for 41.6% of that of global while the overall Chinese population accounts for 18.2% of the global population. In China, the number of new lung cancer patients reached approximately 0.9 million in 2019 and is expected to further increase to more than 1 million by 2024. Among these patients, over half of them are diagnosed with the cancer already at late stages at first diagnosis with a five-year survival rate as low as 12.6% for stage III patients and 2.9% for stage IV patients, according to Frost & Sullivan. The overall lung cancer population is in active demand of diagnostic solutions that can effectively enable earlier diagnostics and hence higher survival rate as well as alternative to existing treatment options of lung cancer.

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We believe the significant unmet medical needs are not only driven by the number of patients, but also the urge for accessible, accurate and streamlined diagnosis and treatment path, especially in China. According to Frost & Sullivan, among the COPD-affected population in China, only around 28.0 million people were diagnosed in 2019 with a diagnostic yield as low as 26.8% and a control rate of 20.2%. In comparison, around 13.7 million people out of a COPD-affected population of 20.1 million were diagnosed in the U.S. in 2019, demonstrating a diagnostic yield as high as 68.3% and a control rate of 58.3%. The mortality rate of COPD has been the highest in China among China, the U.S. and the EU, with a mortality rate of 72.9 deaths per 100,000 people in 2019. Although COPD cannot be cured, it can be effectively controlled. The actual number of deaths resulted from COPD in China is approximately one million, far exceeding those resulted from lung cancer. Therefore, there is a huge unmet clinical demand for COPD therapeutic solutions in China. Lung cancer has the world’s largest cancer patient pool with a relatively low five-year survival rate if discovered late with a survival rate of 12.6% if discovered at Stage III and only 2.9% if discovered at Stage IV. However, the five-year survival rate is significantly higher at 56.6% if discovered at Stage I. Given the early screening, detection and treatment of lung cancer provides patients with a much higher survival rate, there is strong demand to distinguish benign lung nodules from cancerous nodules as early as possible through effective and minimally invasive diagnostic procedures. Increased awareness in application of bronchoscopic navigation, radiofrequency ablation and thermal vapor ablation through hospital adoption, doctor training and indication expansion has led to an increase in the number of hospitals providing navigation and ablation operations in China. A total of 69 navigation systems were adopted in China in 2019 while such number is expected to grow to 2,096 by 2024. However, in comparison with a total number of 832 navigation systems adopted in the U.S. in 2019, which increased 4.5 times from 2015 and expected to further grow to 3,769 by 2024, China’s interventional pulmonology diagnostic and therapeutic product market remains largely untapped for us to further penetrate into.

We believe we are well positioned to capture these market opportunities by leveraging our proprietary real-time image whole lung access navigation technology and series of innovative diagnostic and therapeutic products. Compared with our peers, our products are designed based on our deep understanding of the industry pain points and market needs, together with the aim to deliver the most effective and safe diagnostic and therapeutic solutions to help patients who suffer from lung diseases.

At the forefront of transforming the diagnosis and treatment paradigms of lung diseases

Guided by our mission of making interventional pulmonology a gold standard for the treatment of lung diseases, we are committed to transforming the diagnosis and treatment paradigms of lung diseases by providing a three-in-one interventional pulmonology platform with navigation serving as the foundation to establish a direct path to diagnosis and treatment. We believe interventional pulmonology has the potential of becoming more widely utilized by doctors and patients as the preferred treatment of lung diseases with minimal invasiveness and implications, greater operational convenience and uncompromised effectiveness. Our proprietary BTPNA technology establishes a direct tunnel to lesions, including those located outside airways and deeper in the lung tissue, which leads to more immediate and effective diagnosis and treatment. We continuously seek and evaluate new opportunities and take the initiative to lead industry development, which has allowed us to further strengthen our market position. Our therapeutic solution is also recommended as another treatment option by treatment guideline for treatment of lung diseases besides pharmaceutical and surgical

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treatment solutions, according to Frost & Sullivan. GOLD Guidelines has included thermal vapor ablation therapy as a treatment option for heterogeneous emphysema.

Diagnostic Solutions to Enable Early Diagnosis and Treatment

We offer diagnostic solutions that can precisely locate lesion at any location within the whole lung area and cause minimum damage or complication to the patient with minimal invasion, thus effectively enabling earlier diagnosis of lung diseases for successful lung disease treatment and improving the living quality of patients. Existing diagnostic methods are not satisfactory due to low diagnostic yield, imprecise positioning and complication to patients. With the popularization of low-dose CT, the diagnostic yield of lung nodules is steadily increasing. About 74.3% of lung nodules are located at peripherals of the lung and for such nodules, the diagnostic yield of conventional bronchoscopy can only reach 37%, and as a result, the risk for missing the early treatment window for lung cancers is increased. Current diagnostic methods also do not provide access to the peripheral lesions that are not adjacent to the airway. For nodules without CT bronchus sign, the overall weighted diagnostic yield is 49.6%, which means that most nodules cannot be diagnosed and treated appropriately in time. Our Archimedes System, on the other hand, offers image-guided whole lung access with navigation accuracy of within 3mm deviation from the exact location of the target lesion, together with the capability to reach SPNs that are not visible under X-rays and a diagnostic yield for pulmonary nodules of 90.2%.

Lung Cancer Therapeutic Solutions

Our therapeutic solutions for lung cancer feature more precise targeting of lesions, more thorough ablation and minimal side effects, which effectively address multiple pain points with the existing paradigm, such as performance being limited by nodule size and location, lack of positioning accuracy and complications during and post the procedure.

InterVapor for Lung Cancer

We are developing the world’s first interventional product in clinical stage that could release thermal vapor energy continuously into the lung to treat lung cancer. It destroys lung lesions in a quick and minimally invasive manner with injury limited to target airways and adjacent parenchyma.

Radiofrequency Ablation (“RFA”) Products

We have developed the EMPOWER RF Ablation Catheter (RF-I) and are also in the process of developing RF Generator + RF Ablation Catheter (RF-II) which delivers radiofrequency ablation energy directly into lung tumors to cure lung cancer with small tumors limited to the lungs at a very low rate of complications or slow the progression of larger tumors. The RF energy we adopt has the highest level of safety among all energies. In terms of radiation level, the RF energy has a safer profile compared to the microwave energy and cryoablation energy, which are the other two major ablation methods for lung cancer treatment, due to the fact that RFA technology has more supporting research and clinical practice, resulting in more experienced doctors in the field with proficiency in the performance of procedures.

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H-Marker

Our self-developed pulmonary surgical marker can be used to mark the location of the lung nodule to achieve precise positioning during surgical pneumonectomy. Compared with traditional methods, H-Marker can not only help surgeons to locate nodule on pleura but also to identify the depth of wedge resection.

COPD Therapeutic Solutions

We provide therapeutic solutions to patients with COPD, which have innovatively changed the treatment paradigm for these patients.

InterVapor for COPD

Our InterVapor for COPD received CE Marking certification in 2018 and has been launched in selective European markets since then. Our InterVapor system can be used to complete the tissue ablation procedure as fast as 15 minutes which targets the most diseased lung segments with the healthier segments preserved to sustain pulmonary function and improve the living quality of emphysema patients. There have been several valve therapeutic products focused on severe emphysema treatment approved by FDA in the recent years, including the Zephyr Valve System, which received the FDA approval for the treatment of severe emphysema on June 29, 2018. Thermal vapor ablation is proven to be effective for heterogeneous emphysema and can be applied to a much broader base of patients. We have submitted the application for InterVapor for COPD to the NMPA and received the priority review of InterVapor for COPD by the NMPA.

The results of one of the core clinical trials related to InterVapor for COPD, the STEP-UP trial, was published in the world’s authoritative medical journal *The Lancet*. As the only lung reduction therapy that has been reported to be successfully performed at the segmental rather than lobar level, the InterVapor treatment was recommended by the GOLD Guidelines for the treatment of patients with emphysema for three consecutive years from 2019 to 2021. InterVapor for COPD was also granted designation as a Breakthrough Device by the FDA in 2019 due to technology innovation and medical value to patients in need.

Efficient R&D capabilities creating strategically designed IP portfolio endorsed by global industry pioneers

We believe in our efficient R&D model to ensure innovativeness with cost efficiency within shorter time frame for product development. Our RF-II is expected to complete commercialization within seven years since we initiated the R&D process. We adopt a highly efficient R&D model that combines international technologies with local R&D cost advantages to support a strong intellectual property portfolio and fast product iterations. We believe our R&D model allows us to stay abreast with global-leading technologies and medical device development experience in the U.S. and Europe while taking advantage of the cost-effective and highly efficient clinical research capabilities in China. We collaborate with well-known pulmonologists and professionals from top hospitals and research institutions both in China

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and overseas, such as West China Hospital Sichuan University and The First Affiliated Hospital of Guangzhou Medical University, and also maintain long-established and close relationships and communications with KOLs in the industry to understand the clinical needs of interventional pulmonology medical devices and stay at the forefront of the industry, which helps us quickly map out the latest patent pipeline. Our technologies and devices under development will also seek approval and promotion by experienced U.S. and EU pulmonologists who either lead or advise on our clinical trials or we have direct access to, which helps keep our R&D and marketing priorities constantly in line with market demand. As we stay innovative with the latest technology development around the globe, we leverage the cost-effective and highly efficient clinical research capabilities in China to effectively implement innovations and achieve rapid product iterations closely in line with market demand with R&D efficiency. Our R&D cost in China is significantly lower than that of our global peers, which includes cost of animal experiment, clinical trial, R&D staff and procedures. According to Frost & Sullivan, in particular, for clinical trial cost, the cost of conducting clinical research in China is approximately 30% of that in the U.S. on average. The cost of conducting animal experiments in China is also around 30% of that in the U.S. In addition, the cost per R&D staff in China can be approximately 20% to 30% to that in the U.S. generally.

Built upon our R&D model, we have established a diverse intellectual property portfolio endorsed by global industry leaders, mapping across existing and future technologies with precise market positioning, and keep bringing innovative ideas to life with our efficient R&D capabilities. Our experienced international R&D team led by Mr. Hong Xu, the former CTO of Access Point Technologies Medical Inc. with 10 years of industry experience, and consisting of members from industry leading players with over 10 years’ R&D expertise. Many have specific experience in the development of navigation systems, medical equipment and consumables in the U.S. and China.

We believe our patent portfolio is the backbone of our global expansion. After eight years of R&D efforts, as of the Latest Practicable Date, we owned an aggregate of 476 patents and patent applications which consisted of 87 issued patents (including pending announcements) and 248 patent applications in China and 95 issued patents and 46 patent applications overseas. Our robust intellectual patent portfolio and solid leadership position in the pulmonary disease diagnosis and treatment space have been recognized and endorsed by global industry leaders, such as Intuitive Surgical, the manufacturer of the globally-renowned da Vinci surgical robots, who also strategically invested in us in 2018. We have also received a number of awards and recognitions in China for our innovation and technology advancement. For example, Broncus Shanghai participated in the Key R&D Program of National 13th Five-year Plan (國家十三五重點研發計劃項目) and Science and Technology Innovation Action Program of Shanghai (上海市科技創新行動計劃項目) and obtained the winner prize of the enterprise group in the 4th Innovation and Entrepreneurship Contest of China (Shanghai Region) (第四屆中國創新創業大賽(上海賽區)企業組優勝獎) and Shanghai 2015 “Star of Innovation and Entrepreneurship – Most Promising Project” Award (上海市2015年度“雙創之星—最具發展潛力項目”大獎). For more information, please refer to “– Awards and Recognition.”

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Strong branding and commercialization capability with a focus on clinical training and early market education

We rely on our brand and expertise to increase market demand for our products and commercialize our technologies through training and education that can start as early as at the clinical trial stage, hospital cooperation and engagement, public initiatives to raise patient awareness, and tailored commercialization strategies and overseas partnership.

Continuous training and education efforts to increase market demand for our products.

We engage in early market education when we are still in the stage of conducting clinical trials for product candidates to draw attention from hospitals, doctors and patients for faster access to commercialization when time ripens. We also have the education expertise and resources to quickly replicate the successfully proven education model to accommodate newly introduced products and train doctors. For example, The First Affiliated Hospital of Guangzhou Medical University has been collaborating with us as a training center for education on our navigation technology, COPD treatment technology and RFA technology and assists in training doctors at various local sites. From 2019 up to the Latest Practicable Date, we had provided operation trainings for doctors in a number of hospitals in China, the U.S. and EU, respectively. We believe in the important role that doctor education plays in promoting market awareness, therefore we focus on delivering quality training related to our products and technologies. We also emphasize on clinical training where we connect hospitals and medical professionals with our technology know-how and pipeline products and aim to build connection with hospitals at a much earlier stage as we cumulate real-world clinical trial data. We maintain close and long-term relationships with KOLs and leading pulmonologists and hospitals in China and globally, such as The First Affiliated Hospital of Guangzhou Medical University and Thoraxklinik Heidelberg.

Clinical data serving a solid foundation. We use scientific data to educate the market and prove the effectiveness of our products in their applications. The comprehensive clinical data generated in China by our highly-efficient and cost-effective R&D model provide a solid clinical foundation for our global commercialization. Drawing upon innovative ideas from experienced pulmonologists across the globe, we will conduct increasing clinical trials in China to efficiently derive a substantial amount of rigorous and scientific clinical data. These clinical data are crucial to our sales and marketing process, where we promote our products and even technologies still under development to engage attention from hospitals, doctors and patients for market need cultivation and faster access to commercialization when time ripens. Such data, combined with our focus on early market education, translate our efficient R&D model into marketing advantages, providing solid scientific foundation upon which to execute our commercial marketing efforts. We are also carrying out post-market real-world studies for our products including our navigation system and diagnostic tools.

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Public initiatives to raise patient awareness through diverse promotion channels. We participate in public activities and promote our technologies and products across diverse platforms such as social media, and academic forums by enhancing awareness and recognition of interventional pulmonology diagnostic and therapeutic solutions among patients in certain markets. In particular, we cooperate with hospitals in setting up bulletins to conduct patient education on our technologies and products such as the augmented reality navigation systems and the BTPNA technology. Through these public initiatives, we deliver the message to patients suffering from lung diseases that their living quality and survival rate could be greatly improved through early stage diagnosis and treatment.

Regulatory communication. We benefit from the public healthcare policies that help with the commercialization of our products through policy endorsement. We received the NMPA approval for two generations of our VBN systems as early as in 2017 and since then we have been perceived as the benchmarking company by NMPA to look to for future applications in the interventional pulmonology medical device space. Recognition by regulatory authorities is expected to help pave the way for further market penetration.

Tailored commercialization strategies by region and overseas partnership. We customize our commercialization strategies in different geographical locations and market segments to effectively achieve market penetration, customer development, hospital collaboration and communication with local regulatory authorities. For example, we expand our footprint in the U.S. through our in-house sales capabilities by promoting bundle sales of our navigation system with consumables for COPD and lung cancer while in China, we market our products through our distributor network and our direct sales forces, and segment the market for sales purposes based on city size and affordability for precise marketing. We have established multi-jurisdictional sales network globally and have forged strategic cooperation with leading medical system manufacturers to promote further commercialization. As of the Latest Practicable Date, our sales team consisted of 84 members. Our sales team consisted of 63 members in China, five in India, nine in North America and seven in Europe, covering 586 hospitals in total and managing sales in China, the U.S., Canada, Australia and a number of European countries, such as Germany, U.K., France, Italy and Spain.

Experienced board and management backed by renowned shareholders

Our business is led by our experienced board members and management team with an average of more than 20 years in designing, developing and commercializing medical devices with a focus on lung disease diagnosis and treatment in China and globally and experience in commercializing medical devices in China, the U.S. and Europe. We believe our success to a large extent is driven by our management’s leadership with global vision as well as local expertise in R&D, clinical trials, regulatory affairs, manufacture and commercialization of interventional pulmonology medical devices. Our management is committed to introducing interventional pulmonology diagnostic and therapeutic solutions to permanently transform the diagnosis and treatment paradigm for lung diseases.

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Our chairman of the Board, Mr. Zhao, has over 23 years of experience in medical device industry and proven successful career track record. He led the IPO of LifeTech Scientific Corporation (1302.HK). During his tenure as the executive director and chief executive officer of Lifetech, he developed strategic partnership with Medtronic, brought in Medtronic’s quality system and pacemaker technology, and facilitated the increase of enterprise value of LifeTech Scientific Corporation significantly. Under his leadership, LifeTech Scientific became the world’s second largest supplier of occluders, and the first Chinese brand of peripheral vascular intervention products. Our director, Mr. Zhenjun Zi, has over 18 years’ experience in medical device industry. Currently serving as the general manager and executive director of Venus Medtech (Hangzhou) Inc. (2500.HK), he led the company to become China’s first manufacturer of transcatheter aortic valve replacement systems with implantation achieved in 20 countries and regions. Our director, Mr. Oscar Zhang, has over seven years’ experience in investment in healthcare and serves as a Principal of Qiming Venture Partners. For more information, see “Directors and Senior Management.”

Our CEO, Mr. Zhan, has more than 20 years of management experience in several multinational companies and domestic companies in the medical device space. Our President of U.S./Europe business units, Mr. Todd Cornell has 27 years of experience in the medical device industry and has held numerous sales and marketing management positions at Abbott Vascular, Boston Scientific Corporation and U.S. Surgical Corporation.

We are backed by a number of large institutional investors focused on the healthcare sector, such as Qiming Venture Capital, DiNovA Capital, LAKE Bleu Capital and FountainVest. Our strategic investors include Intuitive Surgical and BC Mars L.P., who have been empowering us with their surgical robot and machine learning capabilities to strengthen our platform of interventional pulmonology navigation, diagnosis and treatment.

OUR STRATEGIES

We plan to execute the following strategies to achieve our vision and mission.

Continue to enhance global commercialization of our products by cultivating market needs, raising patient awareness and taking education initiatives

We plan to expand our sales network by providing more doctor training and patient education, promoting equipment installations and deepening our penetration in hospitals. With our proprietary BTPNA technology, we plan to promote the awareness of our navigation platform as an indispensable tool for interventional pulmonology diagnosis and treatment among hospitals, doctors and patients.

We plan to continue to leverage our highly efficient R&D model to support rapid product iterations and deep penetration in hospitals with a competitive pricing strategy, facilitate differentiated commercialization in different target markets and provide differentiated products to meet different market needs.

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We plan to leverage our direct access to KOLs and offer systematic trainings and post-sales services to doctors and hospitals to expand our market education. As of the Latest Practicable Date, there were approximately 35 thousand pulmonologists in China, according to Frost & Sullivan. Experienced doctors will be invited to train teams on-site in new hospitals to expedite the education process. With our vision to permanently transform the diagnosis and treatment paradigms for lung diseases, besides enriching our product offerings, we are also cooperating with industry associations and KOLs to formulate new paradigm standards and provide the greatest therapeutic benefits to patients through product innovation and further hospital penetration. We plan to continue to refine our existing education efforts and techniques to motivate doctors who are interested in getting trained to perform interventional pulmonology procedures.

By leveraging our more established experience in sales and marketing of LungPoint and the Archimedes System, we plan to expand our sales of LungPoint Plus and other medical consumables in China and accelerate the NMPA’s and other markets’ regulatory approval or CE Marking certification process for InterVapor for COPD. We plan to work with national and local governments to enhance our commercialization efforts with preferential government policies such as subsidies and expedited approval process.

Expand our international R&D team to enrich our intellectual property pipeline and achieve rapid product iterations to facilitate our vertical and horizontal expansions

Efficient R&D capability is key to our continued success in innovation and commercialization. We plan to expand our R&D team globally to ensure continuous technology and product innovation and enrich our intellectual property portfolio mapping across existing and future technologies with precise market positioning. A more global R&D center will help us identify evolving clinical needs and innovative ideas to keep us staying at the forefront of the pulmonology diagnosis and treatment field. We plan to further leverage our cost-effective clinical research capabilities in China to develop and implement these innovative ideas. We will in turn use the robust clinical data we cumulate in China to promote and commercialize technologies around the world. Leveraging our R&D resources, we will continue to enhance the performance of our existing products on one hand and plan to develop more innovative technologies and expand into new areas for product development on the other hand. Currently we are seeking to enhance R&D for InterVapor and develop new indications. We plan to expand our interventional pulmonology treatment product portfolio to cover all kinds of available energy ablation techniques. We also plan to continue to increase our pulmonary disease coverage by investing in technological innovations globally in line with our aspiration to maintain global competitiveness.

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Currently our navigation platform has been the foundation to support treatment for COPD and lung cancer. We plan to develop more therapeutic solutions for unmet indications utilizing our navigation system in the future. Currently our navigation system can import computed tomography (“CT”) imaging data and perform pre-procedure planning and intraoperative navigation. We will add new functions to the next generation of our navigation system, including intraoperative real-time therapeutic result feedback, in the future. The feedback mechanism will in turn help refine the algorithm on the navigation system to deliver more accurate navigation and treatment guidance.

Increase spending on artificial intelligence and machine learning to upgrade and optimize solutions for patients with lung diseases

We plan to increase spending on artificial intelligence and machine learning to accumulate large sets of clinical data and cases in the application of diagnosis and treatment procedures guided by our navigation systems, which will help optimize our algorithm for even more precise and accurate lung mapping and navigation route design through augmented reality and virtual reality. Our proprietary whole lung access navigation system is empowered by the algorithm constantly being optimized through imported and accumulated patient data generated from VBN operations to continuously increase accuracy of procedure planning. We also plan to continuously optimize our algorithm to assist COPD patients’ compliance with and adherence to the instructions of doctors. We plan to leverage our extensive first-hand real-world procedure experience for accurate prediction of lesion progressing and optimization of our therapeutic solutions. In this way, we will further solidify the entry barriers for late comers and strengthen our leadership in lung navigation and the overall interventional pulmonology diagnosis and treatment fields.

Selectively partner with and invest in key players along the healthcare supply chain

We plan to strategically partner with leading players along the healthcare supply chain, including but not limited to health check-up centers, cancer screening companies, insurance companies and pharmaceutical companies, to capture unmet market demand, absorb innovative ideas, boost our market penetration, refine our algorithm and ultimately cement our position along the industry chain.

We also seek potential partnership and acquisition opportunities with complementary product providers to enhance our product portfolio and market position. We are building up the global manufacturing and operation center in China as product demands increase. We plan to continue to leverage the existing KOLs and industry connections to benefit from first-in-line knowledge of innovations that will help complete or improve our existing product offerings. We will also enhance R&D collaboration through strategic partnerships with, or equity investments in, other companies to help us expand horizontally and vertically.

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OUR PRODUCTS AND PRODUCT PIPELINE

As China’s leading interventional pulmonology medical device company, we have built a portfolio of proprietary products providing interventional pulmonology diagnosis and treatment solutions, with complementary accessories. We focus on our proprietary whole lung access virtual navigation technology, with our therapeutic ablation devices and diagnostic medical consumables built from this core navigation technology to provide comprehensive lung solution offerings from navigation and diagnostics to therapeutic treatment.

Our navigation platform consists of three marketed products, including LungPoint, LungPro (or “Archimedes”) and LungPoint Plus (or “Archimedes Lite”). We offer five interventional therapeutic products and product candidates for lung diseases including our Core Products, InterVapor and RF-II. In addition, we offer six interventional diagnostic medical consumables products.

The following chart summarizes the development status of our products and product candidates as of the Latest Practicable Date:

	Indication	Portfolio	Region	Preclinical	Clinical Trial	Registration
Treatment	COPD	InterVapor® for COPD ⁽²⁾	China	Clinical trial and expert review completed, technical review in process		
			US	FDA 510(K); registration application in preparation		
			EU	Launch for sale (2018)		
			Others	Launch for sale		
	Lung Cancer / Lung Nodules	InterVapor® for Lung Cancer ⁽³⁾	China	In design stage		
			US/EU	In design stage		
		RF Generator + RF Ablation Catheter (RF - II)*	China ⁽⁴⁾	Clinical trial in process		
			US/EU ⁽⁵⁾	FDA 510(K)/CE		
		EMPOWER RF Ablation Catheter (RF-I)	US	Launch for sale (2019)		
			EU	Launch for sale (2019)		
Navigation	Navigation Platform ⁽¹⁾	LungPoint	China	Clinical trial completed, expect to be approved in Q2, 2021		
			US	Launch for sale (2014)		
			EU	Launch for sale (2009)		
		LungPoint Plus / Archimedes Lite	China	Launch for sale (2010)		
			US/EU	Launch for sale (2020)		
			China	Launch for sale (2021)		
		LungPro / Archimedes System	China	Launch for sale (2017)		
			US	Launch for sale (2014)		
			EU	Launch for sale (2014)		
			China	Launch for sale (2014)		
Diagnostics	lung Cancer / Lung Nodules	FlexNeedle	China	Launch for sale (2014)		
			US	Launch for sale (2009)		
			EU	Launch for sale (2013)		
		ATV FlexNeedleCN ⁽⁷⁾	China	Launch for sale (2019)		
			China	Launch for sale (2020)		
		BioStarNeedle	China	Launch for sale (2018)		
			China	Launch for sale (2018)		
		ATV Sheath	US	Launch for sale (2013)		
			EU	Launch for sale (2014)		
		ATV Balloon	China	Launch for sale (2018)		
			US	Launch for sale (2013)		
			EU	Launch for sale (2014)		
		Steerable Sheath	China	Launch for sale (2020)		

Notes:

* Our Core Products

- Our navigation systems have been approved for marketing in the U.S., EU and PRC. Post-market study (EAST 2 Trial) for the Archimedes System has been completed.
- The expert review by NMPA has been completed and technical review is currently in process.
- R&D clinical trial (VAPORIZE trial) is currently in process.
- The first-in-man clinical trial has been completed with a registration clinical trial currently in process.
- Expect to leverage clinical data collected in China to apply for registrations in the U.S. and EU.
- The clinical trial has been completed and the registration in the PRC is expected to be approved in the second quarter of 2021.
- The version of FlexNeedle manufactured in China.

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Our product candidates are subject to by relevant authorities, such as the NMPA, the FDA and CE, before commercialization in relevant jurisdictions. For details, see “Regulatory Environment.” We believe that as of the date of this document, we had not received any material comments or concerns raised by the relevant regulatory authorities with respect to our Core Products that we are not able to address in a timely manner, and we believe we are on track to file for approval related to our product candidates as described in “– Our Products and Product Pipeline.”

Interventional Therapeutic Products for COPD and Lung Cancer

InterVapor – Our Core Product

Overview

As a global innovative leader in delivering integrated diagnostic and therapeutic solutions to different lung diseases, we provide minimally invasive interventional therapy for lung disease treatment leveraging our unique whole lung access navigation technology. Through our acquisition of Uptake Medical Corporation’s assets in July 2016, we were able to own all the patents related to an innovative technique for thermal vapor ablation delivered bronchoscopically developed by Uptake Medical Corporation. Based on such technique, we have developed InterVapor, which is a therapeutic device that delivers thermal vapor bronchoscopically to the lung to achieve targeted ablation. It is a minimally invasive interventional system that can release thermal vapor energy continuously into the lung targeting treatment of COPD and lung cancer. InterVapor is classified as a Class III medical device in China. For InterVapor for COPD, the expert review by NMPA has been completed and registration is currently in process. We expect NMPA to complete the technical review of InterVapor for COPD by the end of May 2021. We are also in the process of preparing the FDA 510k clearance of InterVapor for COPD and the registration of the product in South Korea and Hong Kong.

(1) InterVapor for COPD

InterVapor for COPD is designed for COPD treatment through thermal vapor energy ablation. It delivers thermal vapor to the airway and lung parenchyma of the targeted location of the lung, which requires precise catheter placement and enhanced imaging. The transmission of energy is achieved through air convection, which overcomes the obstacle to energy transmission due to the high air volume in the lung. Therefore it is effective for treating heterogeneous emphysema and it is also the world’s first interventional pulmonology device using thermal vapor based energy, according to Frost & Sullivan. In 2018, an EC certificate (CE 678945) was issued by the BSI Group, The Netherlands B.V. (“**BSI**”), a notified body designated by the competent authorities to conduct conformity assessment of medical devices under the EU regulations. BSI confirmed that the quality assurance system for InterVapor for COPD meets the requirements under relevant EU regulations. InterVapor for COPD was also granted designation as a Breakthrough Device by the FDA in 2019 due to technology innovation and medical value to patients in need.

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InterVapor for COPD has the following features, which makes it a highly desirable therapeutic solution for COPD treatment.

- *Accuracy.* It performs targeted lung ablation and thus provides effective treatment with high accuracy.
- *Multi-time treatment opportunities.* It can be applied to multi-focus or recurrent disease and can be used for multi-time treatment without damaging the entire lung lobe at once.
- *Safety.* It treats COPD, through non-surgical operation, thus causing minimal damage to patients which reduces the risk of incurrence of pneumothorax. There is also no permanent implant associated with its operation.
- *Efficiency.* It only asks for a few extra seconds of treatment time after the routine endoscopy examination is completed.
- *Broad patient coverage.* Due to the fact that it does not require the intactness of interlobular fissure for the patient, it can be applied to a much broader base of patients.

(2) InterVapor for lung cancer

InterVapor for lung cancer is designed for lung cancer treatment through continuous release of thermal vapor energy into the lung. It is designed to ablate lung lesions with a surrounding margin by the application of heated water vapor to the bronchus of the lung region targeted for treatment, and can sufficiently cover the lesion area with low dose of energy. This application of thermal energy causes an acute injury to the tissues, destroying lung lesions in a quick and minimally invasive manner with injury limited to target airways and adjacent parenchyma. Thermal vapor passes through the airway and delivers heat energy during the process of condensation. Ablation is achieved through energy transmission from the outside to the inside via the small airway and destroying the surrounding tissues.

Product Structure

The InterVapor system consists of three major components, which are InterVapor Generator, InterVapor Personalized Procedure Program IP3 and InterVapor Catheter. InterVapor Generator is an electronically controlled pressure vessel that produces heated water vapor from sterile water and delivers the vapor to a dedicated catheter to achieve bronchoscopic lung volume reduction. InterVapor Personalized Procedure Program IP3 is a software for treatment planning for use only with the InterVapor system, which specifies the diseased segments and treatment time for each target airway and includes labeled figures to identify each targeted airway. To determine a patient’s optimal treatment time, the algorithm built in the software analyzes information relating to density, volume, and disease state of the targeted tissue as assessed by HRCT imaging. InterVapor Catheter is a sterile, disposable,

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single-use device used to deliver vapor from InterVapor Generator to the targeted airway. The catheter hub, located at the proximal end of the catheter, has a stopcock for attachment of a 1-ml syringe to inflate the compliant balloon. The hub quick-connect attaches the catheter to the generator hand piece. The compliant balloon at the distal end of the catheter shaft allows occlusion of the lung airway during vapor treatment. The catheter is packaged with a sterile clearing adapter to construct a clearing assembly.



Figure 1: InterVapor Personalized Procedure Program (IP3®)

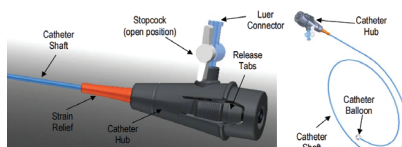


Figure 2: InterVapor® Catheter with detail of hub

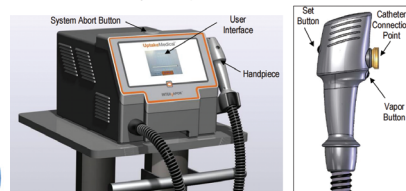


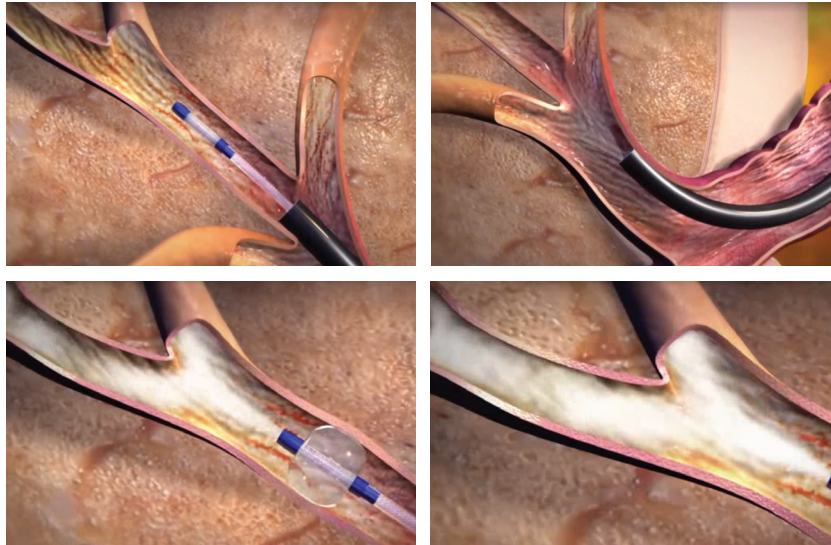
Figure 3: InterVapor® Generator with detail of handpiece

Operation Procedure

The InterVapor system uses heated water vapor to ablate the airways and parenchyma within targeted regions of the lung. Lung remodeling occurs after an initial localized inflammatory response and a subsequent healing and repair. The remodeling of the tissue results in reductions in tissue and air volume in the targeted regions of the lung. InterVapor works independent of collateral ventilation (“CV”) – ventilation of alveolar structures through passages or channels that bypass the normal airways.

To operate the InterVapor system, the doctor enters a treatment time on the front panel before each treatment based on the information stored in InterVapor Personalized Procedure Program IP3, which reflects a particular patient’s personalized data file for analysis and treatment computation and can be downloaded to an iPad by the treating doctor. Delivery of vapor to the patient is triggered manually by the doctor and a controller automatically ends the treatment after the entered treatment time has been reached. Procedurally, to have the vapor delivered, the doctor will prepare the patient for bronchoscopy following patient management protocols and attach the correct biopsy valve to the bronchoscope, which will be introduced to visualize, inspect and confirm the segmental anatomy. The doctor will then use InterVapor Personalized Procedure Program IP3 to determine the airway location for treatment and place InterVapor Catheter into the target segment airway. The vapor disperses distally from the InterVapor Catheter tip through the targeted bronchial segment and into the parenchyma of the segment. The lung volume reduction of diseased hyper-inflated lung segments after the InterVapor treatment is expected to increase elastic recoil by reducing the most compliant segments of the lung, decompressing segments of healthier lung allowing for alveolar recruitment, and improving the mechanical efficiency of the respiratory muscles. These mechanical changes are anticipated to improve pulmonary function, exercise capacity and quality of life. The following chart illustrates how ablation is performed through InterVapor for COPD.

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Market Opportunity and Competition

The InterVapor system is designed for treatment of COPD and lung cancer. According to Frost & Sullivan, there is an accelerating population of COPD and lung cancer patients worldwide and in China. Globally, the number of lung cancer new cases increased from 1.9 million in 2015 to 2.2 million in 2019, and is expected to further increase to 2.5 million by 2024. In China, the number of lung cancer new cases increased from 787.0 thousand in 2015 to 895.3 thousand in 2019, and is expected to further increase to over 1.0 million by 2024. For details, see “Industry Overview – Pulmonary Diseases, Diagnosis and Treatment – Overview, Prevalence, Diagnosis and Treatment of Lung Cancer.” Globally, the number of COPD patients increased from 196.4 million in 2015 to 212.4 million in 2019, and is expected to further increase to 259.5 million by 2024. In China, the number of COPD patients increased from 100.7 million in 2015 to 104.4 million in 2019, and is expected to further increase to 108.0 million by 2024. For details, see “Industry Overview – Pulmonary Diseases, Diagnosis and Treatment – Overview, Prevalence, Diagnosis and Treatment of COPD.” With the prevalence of lung disease globally and in China, there is a huge market potential for effective pulmonology therapeutic solutions.

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Interventional pulmonology therapy with minimally invasive procedures has been increasingly used in the treatment of pulmonary diseases such as COPD and lung cancer. Interventional pulmonology therapeutic solutions for COPD treatment include thermal vapor ablation, valve therapy and coil therapy. According to Frost & Sullivan, although different interventional pulmonology therapeutic solutions aim to reduce lung volume through different mechanisms, thermal vapor ablation has the most competitive advantages among all currently available solutions, including proven effectiveness for a larger target population and can be used for multi-time treatment. For details, see "Industry Overview – Pulmonary Disease Diagnosis and Treatment Market – Interventional Pulmonology Market – Pulmonary Disease Treatment."

Summary of Clinical Trial Data

We have completed a number of clinical trials to evaluate the performance, safety and efficacy of InterVapor. The clinical history of InterVapor up to the Latest Practicable Date primarily includes the following five clinical studies: (1) the STEP-UP trial, (2) the NEXT-STEP trial, (3) the VAPORIZE trial, (4) the West China Hospital trial and (5) the BTVA Registry study. The STEP-UP trial was initiated and sponsored by Uptake Medical Corporation, whose assets were acquired by us in 2016.

STEP-UP Trial

The STEP-UP Trial adopted a staged vapor ablation procedure that included treatments that were separated by a three-month interval in the treatment arm and comprised of 1-2 segments treated per session per lobe. Based on the results of the STEP-UP Trial, it was concluded that the InterVapor System is a safe and effective bronchoscopic treatment for severe emphysema patients with heterogeneous disease, as evidenced by the low severity of procedure-related complications and improvement of lung function, quality of life and exercise capacity when compared to a control group in which the patients would be provided with optimal medical care alone with no bronchoscopic intervention while the treatment group would receive the InterVapor treatment in addition to optimal medical care.

From June 19, 2013 to September 30, 2014, a total of 69 subjects were enrolled for the trial conducted at 12 clinical sites located in Europe and five clinical sites located in Australia and New Zealand. Of the 69 subjects enrolled, 45 were treated and 24 were control patients. Following randomization to the treatment arm, the patients were treated by the InterVapor system between July 25, 2013 and January 25, 2015 under a prospective randomized controlled protocol that was reviewed and approved by competent authorities in Germany, Austria, the United Kingdom, Ireland and Australia. The patients were followed up for 12 months with evaluation of AEs, changes in lung function, SGRQ-C score and exercise capacity. All of the subjects were patients with heterogeneous upper lobe predominant emphysema and met the following physical conditions:

- the patient was aged between 40 and 75 years old at screening;

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- the patient had heterogeneous emphysema with upper lobe predominance in both lungs per HRCT measured Heterogeneity Index no less than 1.2;
- FEV₁ of the patient was between 20% and 45% predicted;
- the total lung capacity of the patient was no less than 100% predicted;
- the residual volume was no less than 150% predicted;
- the arterial blood gas level of PaCO₂ and PaO₂ was not higher than 50 mm Hg and higher than 50 mm Hg, respectively, on room air;
- the patient did not smoke for 6 months prior to the enrollment;
- the patient was under optimized medical management (treatment consistent with GOLD Guidelines); and
- there was evidence of completed pulmonary rehabilitation.

The primary efficacy endpoints of the trial are the between group differences in FEV₁ or the SGRQ-C total score (units) at 12 months following the first scheduled InterVapor treatment (or randomization data for the control group). The trial’s primary safety endpoint is the incidence of serious adverse events during the follow-up period after the ablation procedure. It was concluded after the trial that the InterVapor system is a safe and effective bronchoscopic treatment for severe emphysema patients with heterogeneous disease, as evidenced by the low severity of procedure-related complications, improvement of lung function, quality of life, and exercise capacity, when compared to a control group. Given the safety and efficacy data demonstrated with primary and secondary endpoints being met, InterVapor has a favorable benefit-risk profile in severe emphysema patients with heterogeneous upper lobe emphysema.

- *Efficacy Results*

Improvements in FEV₁ and SGRQ-C total score were statistically significant at 12 months post the InterVapor procedure. Hence, the primary efficacy objectives for the study were met. At 6 months, the between-group difference of FEV₁ was 14.7% (p-value <.0001) and the between-group difference of SGRQ-C was -9.7 units (p-value 0.0021). At 12 months, the between-group difference of FEV₁ was 12.8% (p-value = 0.0039) and the between-group difference of SGRQ-C was -12.1 units (p-value = 0.0021). Secondary endpoint results at 6 months showed clinically meaningful improvement for FEV₁, SGRQ-C and 6MWD (6-minute walk distance), which typically goes over 450 meters for a normal healthy person. Secondary endpoints were clinically meaningful for FEV₁ and SGRQ-C at 12 months.

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- *Safety Results*

The procedure was well tolerated. There were no unanticipated AEs related to the use of InterVapor in this trial. All patients were discharged from hospital following the procedure with a hospitalization period ranged between 0 and 21 days (with a mean of 5.2 days). Of the 45 patients treated, 34 were discharged within 48 hours. Severe adverse events occurring subsequent to discharge were predominantly respiratory in nature and were managed with standard medical care. The AE rates observed in this trial at 12 months were consistent with published severe adverse events for similar devices.

NEXT-STEP Trial

Subsequent to the STEP-UP Trial, we commenced the NEXT-STEP Trial in September 2018 and is primarily intended to assess the safety and efficacy of InterVapor in treating patients with homogeneous emphysema that are not candidates for endobronchial valve therapy. The secondary objective of the study is to prospectively document efficacy as reflected in changes in additional pulmonary function parameters, exercise capacity, dyspnea, quality of life, and lung volume following sequential segmental treatment with BTVA. The patient enrollment and follow-up visits were completed by December 2020.

The study is designed as a prospective, single arm, single center pilot study following outcomes for 12 months after the initial BTVA treatment with a 12-month enrollment phase and patient follow up of 12 months for a total study duration of approximately 24 months. The study includes patients with severe emphysema as defined by pulmonary function tests, a homogeneous distribution of emphysema as determined by CT, who are not eligible for endobronchial valve therapy based on fissure integrity as determined by CT. Under the study, BTVA at a dose of 8.5 calories/gram will be administered according to the Instructions for Use (IFU) with the most diseased segments targeted for treatment. Patients will undergo up to two treatment procedures, separated by a three-month interval. A treatment procedure will be comprised of vapor delivery to one to two segments within a lung, not to exceed 1700ml air *plus* tissue volume per treatment. Follow-up visits will be scheduled at 4, 12, 18, 26, and 52 weeks following the first BTVA procedure, with the second BTVA treatment occurring around 13 weeks after the first treatment. Testing performed at follow-up visits will include pulmonary function testing (spirometry, body plethysmography, diffusing capacity of the lung for carbon monoxide (“**DLCO**”)), and 6-minute walk test (“**6MWT**”). Dyspnea score (mMRC) and quality of life questionnaire (SGRQ-C) information will be obtained. Information regarding adverse events, serious adverse events, and major medical complications will also be collected at each visit.

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The primary safety endpoints of the study include the occurrence of severe adverse events, major medical complications, and unanticipated serious adverse device effects within 6 months (26 weeks) of initial the BTVA treatment. The primary efficacy endpoints include the change in FEV₁ and change in quality of life (SGRQ-C) at 6 months (26 weeks) relative to pre-treatment baseline. As for secondary endpoints, the following will be assessed at 6 months (26 weeks) relative to pre-treatment baseline:

- change in lung function (FVC, functional residual capacity (“**FRC**”), residual volume (“**RV**”), total lung capacity (“**TLC**”), RV/TLC, DLCO)
- change in dyspnea score (mMRC)
- change in 6MWD
- change in volume of the treated lobe(s)

As of December 31, 2020, 11 patients were enrolled and treated in the NEXT-STEP Trial. None of the patients treated with InterVapor required critical care stay post treatment and successful vapor delivery was achieved in all 11 patients. The efficacy is to be further analyzed and a formal study report is expected to be completed by the second quarter of 2021.

VAPORIZE Trial

Subsequent to the STEP-UP Trial, we commenced the VAPORIZE trial in December 2018 to explore the use of InterVapor to a new indication (lung cancer). The trial demonstrates our ongoing R&D and clinical work after we obtain the CE Marking certification in the EU.

The objective of this trial is to establish the safety, feasibility, and ablative efficacy of InterVapor for minimally invasive ablation of lung cancer. During the trial InterVapor delivered 330Cal thermal vapor energy via bronchoscopy to target lesion. Patients then underwent planned lobectomy to complete oncologic care. All patients were followed until 30 days post-resection. All adverse events in the period between ablation and resection and up through 30 days after resection would be recorded. Resected tissue would undergo pathological evaluation for tissue viability.

The safety endpoints of this study are the 30-day (or date of Day 30 follow-up) number of reported adverse events, serious adverse events related to the procedure. The feasibility endpoints of this study include successful delivery of the thermal vapor ablation treatment according to the navigation plan, histological evidence of ablation, and CT imaging, between ablation and resection procedures, to identify ischemic tissue within the treatment areas.

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Six patients were enrolled, who met the following major criteria:

- the patient must be at least 18 years old;
- the patients have non-small cell lung cancer tumor(s) less than 2cm suitable for resection or metastatic lung tumor(s) less than 2cm suitable for resection; and
- the location of tumor is in periphery of lung (outermost 1/3).

No major procedure-related complications occurred. The findings demonstrate bronchoscopic thermal vapor ablation of lung tumours is feasible and well tolerated, with preliminary evidence suggesting high potential for effective ablation of tumours.

West China Hospital Trial

We have completed a prospective, single-center, non-blinded, randomized controlled trial. From November 2017 to December 2020, a total of 20 eligible subjects were enrolled, and 18 successfully completed the trial. The purpose of the trial is to evaluate the therapeutic effect (including lung function and quality of life) and safety of thermal vapor ablation for lung volume reduction in patients with heterogeneous emphysema (mainly in the upper lobes of the lungs) among Asian populations. The subjects in the experimental group received the BTVA treatment. Three months after the initial treatment, the subjects returned to the hospital for the second BTVA treatment. The subjects in the control group received conventional standard treatment (inhaled drug treatment).

The primary endpoint of the trial is the occurrence and reporting of severe adverse events within 6 months after the initial treatment; the secondary endpoint are the patient's quality of life, SGRQ-C and a full set of lung function results.

The enrolled patients met the following main criteria:

- on the basis of routine medical treatment and completion of pulmonary rehabilitation, the patient has severe heterogeneous emphysema (GOLD III or GOLD IV) (mainly in the upper lobes of the lung) who still has persistent dyspnea symptoms (the marked dyspnea scoring is more than 2 on the modified Medical Research Council scale (mMRC) of 0-4) while maintaining a normal life;
- the patient is aged between 40 and 75 years old; and
- the predicated value of FEV1 is between 20% and 45%, the predicated value of TLC is more than 100%, and the predicated value of RV is more than 150%.

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During the trial, the occurrence and frequency of severe adverse events reported between the two groups were similar. The main complications were acute exacerbation of chronic obstructive pulmonary disease and pneumonia (pulmonary infection). The number of pulmonary infections observed in the experimental group was slightly higher than that in the control group; it occurred as expected and mainly manifested as the nature of the respiratory system. In terms of metrics such as lung function, quality of life and respiratory-related scores, such metrics improved significantly for the patients in the experimental group as compared to the baseline period, and the improvement was continuing; at the same time, the improvement for the experimental group was much better than that for the control group, and the difference in the mean between the groups exceeded the threshold of clinical significance. In summary, the study confirmed the safety and effectiveness of thermal vapor ablation on lung volume reduction among Asian populations with heterogeneous emphysema (mainly in the upper lobes of the lung), which works a safe and effective treatment option for such patients.

BTVA Registry Study

Following the CE Marking certification of InterVapor and its commercialization on the EU market, we initiated the BTVA Registry Study in April 2018 and have been conducting the ongoing post-market clinical follow-up study to evaluate the long-term safety and effectiveness of InterVapor in real-world practice. The BTVA Registry is a post-market registry for patients with emphysema treated with BTVA and a retrospective and prospective, observational, multi-center post-market registry of patients prescribed with the InterVapor treatment. The BTVA Registry shows consistency and continuity in study and analysis methodology with the STEP-UP Trial. Procedurally, similar to the STEP-UP trial, patients participating in the BTVA Registry will first be administered with the InterVapor treatment by the doctor. After the treatment, clinic visits are subsequently scheduled over a long period of time to perform patient testing (including pulmonary function tests, 6MWT, and a quality of life questionnaire) and collect information regarding serious and non-serious adverse events. The BTVA Registry further develops and expands the clinical work conducted during the STEP-UP Trial to a more extensive scope both in terms of duration and geographic coverage. The BTVA Registry Study is anticipated to have a total registry duration of approximately seven years, which includes a 24-month enrollment phase and a long-term post-treatment patient follow-up period of five years. Geographically, approximately 70 centers in EU and other selected countries that recognize CE Marking certification are included in the BTVA Registry Study, with a total of up to 300 patients to be treated with InterVapor during the course of the clinical study. The subjects need to meet the following conditions to be enrolled for the study:

- the patient has heterogeneous emphysema, as evidenced by HRCT demonstrating a heterogeneity index of more than 1.2 in at least one segment to be treated; and

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- the patient must be at least 18 years old.

The BTVA Registry has identical or closely related primary and secondary endpoints as those for the STEP-UP Trial. Its primary objective is to evaluate the long-term impact of the InterVapor treatment on quality of life with secondary objectives to monitor the overall safety of the InterVapor treatment through the incidence of serious adverse events and evaluate the long-term effectiveness of the InterVapor treatment as to pulmonary function, exercise capacity and lung volume reduction. Follow-up visits will be scheduled at each of the 1, 3, 6, 12, 24, 36, 48 and 60 months following the baseline/first procedure and discharge. Unscheduled follow-up visits due to new or unresolved signs or symptoms will be documented as an adverse event, as applicable. Follow-up visits will be based on the institution standard of care. Testing performed at clinic visits may include pulmonary function tests, including spirometry (FEV₁ and FVC), body plethysmography (FRC, RV, IC and TLC), DLCO, PFTs, a bronchodilator, 6MWT and a brief quality of life questionnaire (SGRQ-C). Information relating to serious and non-serious adverse events will also be collected at each clinic visit. Imaging such as chest X-rays and CT will be performed at the discretion of the investigator.

The primary endpoints of the study include the change in the SGRQ-C score at 24 months' post treatment relative to the pre-treatment baseline. Secondary endpoints include 1) serious adverse events, which are further categorized into procedure-related and device-related serious adverse events and major medical complications, 2) the change in SGRQ-C at twelve months post treatment relative to the pre-treatment baseline, 3) the change in FEV₁, FVC, RV, TLC, and DLCO at twelve months post treatment assessed by pulmonary function tests relative to the pretreatment baseline, 4) the change in exercise tolerance at twelve months post treatment assessed by 6MWT relative to the pre-treatment baseline, and 5) lung volume reduction at six months post treatment assessed by HRCT. From the commencement of the BTVA Registry study to June 2020, we have completed site initiation for 20 sites, with 17 sites currently enrolling patients and a total of 194 treatment procedures completed for 124 patients.

Preliminary results supported favorable risk profile for patients with severe heterogeneous emphysema and the safety results were consistent with those of the STEP-UP trial.

The study is planned to carry out five-year follow-up visits to the enrolled patients and expected to be completed by 2027. We expect to complete the patient enrollment by the end of 2021.

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Clinical Development Plan

To evaluate the use of BTVA for the treatment of emphysema with middle and/or lower lobe predominance, for which no existing data are available, our subsidiary UMT plans to conduct a prospective, multi-center, randomized controlled study under the title of *Bronchoscopic Lung Volume Reduction using the InterVapor System for the Treatment of Emphysema with Middle and/or Lower Lobe Predominance – Expanding InterVapor Trial* in 2021, and aim to complete the trial in 2023. UMT aims to enroll 75 subjects in total in up to 10 clinical sites in Europe and Asia and follow up with each subject at one, three, four, six and 12 months after the procedure. The co-primary endpoints are FEV1 changes and SGRQ-C changes between the treatment group and control group at six months, and the secondary endpoints include improvement in other measures of pulmonary function from the control group at six months, rate of serious adverse events at 12 months, binary responder analysis using Minimal Clinically Important Difference regarding FEV1, SGRQ-C and 6MWD at six months.

UMT also plans to conduct a prospective, multi-center, single blind, randomized controlled study under the title of *Targeted Segmental Vapor Ablation Treatment of Emphysema with Upper Lobe Predominance: A randomized controlled trial of InterVapor® in France* (the “**TARGET Trial**”), which is planned to commence in 2021 and is expected to be completed in 2023. Besides assessing the efficacy and safety of the InterVapor system, the TARGET Trial also focuses on a few health economic objectives to achieve in France, which include to estimate the real productivity costs of BTVA using the InterVapor system, to assess the efficiency of BTVA using the InterVapor system in addition to medical management in comparison with the medical management alone using cost-utility and cost-effectiveness analyses from a societal perspective and to assess the budgetary impact of the implementation of BTVA using the InterVapor system on the payer’s budget (French healthcare insurance) at five years. UMT aims to enroll 150 subjects in total in up to 17 clinical sites in France and follow up with each subject at 12 months after the procedure.

In addition, we plan to carry out a series of clinical studies for InterVapor with a focus on lung cancer indication and certain post-market clinical studies in a few other regions. Clinical trials are expected to be conducted in China and Europe between 2022 and 2024 for lung cancer indications. Our planned post-market clinical studies include studies to be conducted in China between 2021 and 2023 and in India between 2021 and 2028.

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET INTERVAPOR IN CHINA OR THE U.S.

RF Generator + RF Ablation Catheter (RF-II) – Our Core Product

RF-II is a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter, which acts on lung tumors via a bronchoscope to perform ablation to the lung tumors. It is currently the only RFA system that specifically focuses on lung cancer treatment globally, according to Frost & Sullivan. We have completed the first-in-man clinical trial with a registration clinical trial currently in process in China, and are preparing the application for the FDA 510k clearance of RF-II.

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Through bronchoscopy, radiofrequency energy is applied to lung tumors to perform minimally invasive interventional energy ablation therapy on such lung tumors. The radiofrequency ablation system adopts a unipolar discharge method for radiofrequency energy output. The radiofrequency ablation system is connected to the patient through a radiofrequency ablation catheter and a neutral electrode. The ablation catheter is inserted into the patient's body and reaches the parts to be ablated; the neutral electrode is in contact with the patient's skin surface. The radiofrequency current flows through the radiofrequency ablation catheter, patient tissue and the neutral electrode to form a loop. The radiofrequency ablation system can be activated by a foot switch or a manual switch.

Summary of Animal Study Data

An in vivo canine study was performed to demonstrate the feasibility and safety of RF-II in the bronchoscopy setting guided by bronchoscopy navigation system. A total of 11 Labrador experimental dogs were randomly divided into three groups: the 1-day group (n=3), the 30-day group (n=4) and the 90-day group (n=4). During the procedure, an access was established for each mimic lesion according to the planned path, and the ablation catheter was placed into the lesion through the sheath. The arrival of the target lesion was confirmed by C-arm, and then the RFA system was activated to perform ablation. Ablation of mimic lesions was performed according to preset parameters (15w, 3min). Animal vital signs (such as blood pressure, heart rate and blood oxygen saturation) were monitored, safety and complications were assessed and ablation-related parameters were recorded during the operation. Chest CT images were taken before all animals were sacrificed, and the animals in the 90-day group were followed up at 7 days, 30 days and 60 days using chest CT to observe the changes in the imaging morphology, size and other metrics. At the end of the follow-up period, the animals were euthanized, and the lung tissue including the ablation area was sampled for hematoxylin and eosin ("H&E") staining. The ablation area and the effect on the surrounding lung tissue and its changes were investigated under an optical microscope.

A total of 14 ablation procedures were performed, and ablation accesses were successfully established and the ablation procedures were completed. The immediate operation success rate was 100% (14/14). No related complication was found during the operation and in the follow-ups. According to chest CT and anatomical pathology, it can be found that RFA can cause lung tissue coagulation necrosis and necrosis peripheral congestion/hemorrhage, accompanied by inflammation caused by thermal ablation. CT imaging showed that most of the thermal damage caused by ablation was absorbed seven days after operation. The scar formation was obviously observed on the 30th day after the operation, and the scar persisted or disappeared on the whole 90 days after the operation, and the fibrosis was obvious. H&E staining confirmed the process of the cell necrosis and tissue repair after ablation.

The in vivo study presents a safe and feasible modality in pulmonary parenchyma. Radiofrequency ablation guided by bronchoscopy navigation system appears to be well-established with acceptable tolerance, which might provide therapeutic benefit in pulmonary malignancies.

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Summary of Clinical Trial Data

First-in-Man Trial

We have completed a single-center, small-sample clinical trial of RF-II, with the purpose of preliminarily evaluating the safety and product performance of RF-II as a bronchoscopic radiofrequency ablation system for treatment of early-stage peripheral lung cancer. The primary endpoint was the incidence of complications related to the device and ablation surgery within 1 month after the operation. The success rate of the operation immediately after the operation was calculated and the effectiveness of the ablation was evaluated. From August to December 2020, a total of 15 patients with lung tumors were enrolled in the trial and received the RFA treatment with prescribed follow-up visits. The enrolled patients met the following main criteria:

- the patient is more than 18 years old;
- the patient met one of the following criteria:
 - (1) the patient is discovered with peripheral lung lesions that have demonstrated to be lung cancer by pathology with the clinical stage no later than IIA;
 - (2) the patient has recurrent or progressive single lesion or solitary intrapulmonary metastasis after surgery, radiotherapy, chemotherapy or other treatment;
 - (3) the patient has multiple primary lung cancer with the number of tumors no more than 5 and no metastasis; or
 - (4) the patient has pulmonary metastases with effective treatment of primary disease and the number of metastases is no more than 5 with no other metastasis;
- chest CT shows the diameter of the tumor is more than 8mm but no more than 50mm in length; and
- the patient is unsuitable for surgery assessed by multidisciplinary team and agrees to the primary treatment of ablation.

The enrolled patients received the RF-II treatment for lung tumors, and completed the follow-up visits during the operation, 24 hours after the operation, and 1 month after the operation. During the operation, there was no operation failure due to equipment failure, and the operation success rate was 100%. No complications such as pneumothorax and bleeding were recorded during ablation. During the trial period, no complications related to RF-II were observed. Compared with the pre-operation CT, the effective rate of ablation reached 100% as shown in the chest CT within 24 hours after the operation. The trial results prove that RF-II has significant safety and efficacy performance in the treatment of peripheral lung tumors, and it has been preliminarily proved that the ablation is effective.

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Confirmatory Clinical Trial

We are conducting a confirmatory clinical trial for RF-II, which is a domestic, multicenter, single group target value clinical trial to evaluate the safety and effectiveness of radiofrequency ablation system in the treatment of peripheral lung tumors.

A total of 126 eligible subjects with primary NSCLC or pulmonary metastasis will be enrolled and undergo RFA procedure with RF-II in multiple study centers, such as The First Affiliated Hospital of Guangzhou Medical University and Shanghai Chest Hospital. Subjects will first undergo interventional bronchoscopy to reach the target lesion and undergo RFA using RF-II. Subjects will be followed up intraoperatively, 24 hours after operation, before discharge/7 days after operation (whichever occurs first), 30 days (± 7 days) after operation, 3 months (± 7 days) after operation, 6 months (± 15 days) after operation, 9 months (± 15 days) after operation, and 12 months (± 15 days) after operation. Generally, the subjects will be patients with lung tumors that meet the following physical conditions:

- the patient is at least 18 years old;
- planned ablated lesions are pathologically confirmed as primary NSCLC or pulmonary metastasis, and the primary lesions of lung metastasis subjects have been completely resected;
- the number of lung lesions is no more than 3 (except for multiple primary lung cancers);
- each lung lesion in size is no more than 3 cm;
- the patient refuses surgery or is considered intolerant of surgery;
- the patient refuses or is considered unsuitable for radiotherapy or chemotherapy, or is a non-responder for previous radiotherapy or chemotherapy, or has disease progression after radiotherapy or chemotherapy;
- it is feasible to arrive at the target lesions through bronchial pathway and carry out ablation operations, assessed by investigators;
- the patient's eastern oncology cooperative group physical state score is no more than 3.

The primary efficacy endpoint is complete ablation rate of the main lesion at 6 months, which is defined as the proportion that subjects whose main lesions maintain completely ablated at 6 months after the overall ablation procedure account for all evaluable subjects who receive radiofrequency ablation. The secondary efficacy endpoints include technical success rate, complete ablation rate at 6 months and 12 months (in terms of ablation lesions), complete ablation rate at 6 months and 12 months (in terms of subjects), intrapulmonary progression-free survival rate at 6 months and 12 months respectively, overall survival rate at 1 year, quality of life and safety outcomes.

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For safety evaluation, all adverse events will be recorded during operation and during the follow-ups. The correlation between the use of the device and operation will be assessed and the incidence of device-related and operation treatment-related adverse events and serious adverse events will be calculated.

As of the Latest Practicable Date, eight study centers had been initiated and continued to actively enroll patients. Nine patients had been enrolled and underwent RFA followed with scheduled follow-up visits per protocol. Preliminary data indicate the safety and effectiveness of RF-II with good procedure tolerance.

Clinical Development Plan

We expect to leverage clinical data collected in China to apply for registrations of RF-II in the U.S. and EU. We plan to initiate clinical trials in the U.S. and EU if further required by relevant regulatory authorities.

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET RF-II IN CHINA OR THE U.S.

EMPOWER RF Ablation Catheter (RF-I)

RF-I adopts a flexible design and can be used conveniently. It demonstrates excellent performance in soft tissue ablation in the ablation testing. The following table sets forth the difference between RF-I and RF-II.

	RF-I	RF-II
<i>Product components</i>	Ablation catheter	Ablation generator and catheter
<i>Ablation scope</i>	1.89 cm - 2.28 cm	3 cm
<i>Electrode length</i>	17.5 mm	4.0 mm
<i>Smart saline infusion control</i>	/	Yes
<i>Temperature monitor</i>	/	Yes
<i>Impedance monitor</i>	/	Yes
<i>Steerable for catheter tip</i>	/	Yes
<i>Regulatory approvals</i>	FDA, CE	/
<i>Indication</i>	Soft tissues of the lungs	Lung cancer
<i>Clinical trial</i>	Post-market clinical trials	Pre-market clinical trials

Market Opportunity and Competition

The application of energy ablation, as one of the interventional pulmonology therapies, has been increasing and such increase is expected to continue. Common energy ablation systems include radiofrequency ablation, thermal vapor ablation, microwave ablation, cryoablation and laser ablation. According to Frost & Sullivan, radiofrequency ablation is the most widely used ablative technique globally for the treatment of lung malignancies. Radiofrequency ablation has the advantage of being the first commercially viable ablation device with the benefits of cost-effectiveness, safety and compatibility. For details, see “Industry Overview – Pulmonary Disease Diagnosis and Treatment Market – Interventional Pulmonology Market – Pulmonary Disease Treatment.”

BUSINESS

H-Marker

H-Marker is a self-developed pulmonary surgery marker that is used to mark the location of the lung nodule to achieve precise positioning during surgical pneumonectomy. When used, it is temporarily implanted into the lung through the airway and removed afterwards by surgery. Compared with traditional methods, H-Marker can not only help surgeons to locate nodule on pleura but also to identify the depth of wedge resection. One of the difficulties in surgical diagnosis and treatment of pulmonary nodules is how to accurately localize nodules intraoperatively. H-Marker was developed based on a new concept of placing self-expanding markers near the nodules via airway to overcome the difficulty in intraoperative localization of nodules and detecting nodules in resected pulmonary specimens. As a single-use pulmonary surgery marker, H-Marker has the following advantages:

- When compared with the operation process of other existing positioning tools, that of H-Marker is simpler, more reliable and easier to understand and master with a proven smooth learning curve;
- H-Marker is inserted to reach the lesion through the natural cavity of human body, which can solve the problem of target lesion inaccessibility associated with percutaneous placement due to puncture risk, anatomical structure and other reasons;
- It is less likely for H-Marker to damage blood vessels with its self-expanding characteristics and spindle shape as compared to percutaneous hook-shaped markers, thus helping avoid vascular injury risk that is typically associated with the traditional hook-shaped needle; and
- H-Marker can hardly be moved once implanted, therefore making it detectable and perceivable during the operation. It can also locate pulmonary nodules more easily as compared to percutaneous hook-shaped markers.

We have received the designation of H-Marker as a Class II “innovative medical device”, which is eligible for expedited approval, by Zhejiang MPA (浙江省藥品監督管理局) in October 2020 and expect to obtain the Zhejiang MPA approval in the second quarter of 2021.

Summary of Clinical Trial Data

H-Marker Trial

As of the Latest Practicable Date, we completed the patient enrollment and all follow-up visits for a prospective, multi-center, single group clinical study of our H-Marker (the “**H-Marker Trial**”) to evaluate the safety and effectiveness of H-Marker in the localization of pulmonary nodules, which was led by the Cancer Hospital of Chinese Academy of Medical Sciences together with Yunnan Provincial Cancer Hospital, and Shenzhen Cancer Hospital of Chinese Academy of Medical Sciences with a total of 76 eligible subjects enrolled and all follow-up visits completed from July 2020 to January 2021. We believe the successful completion of H-Marker clinical trial allowed us to move a big step towards the clinical application of H-Marker, which provides a new solution and option for doctors to achieve accurate nodule positioning during surgeries. The development of H-Marker enriches our comprehensive product portfolio and expands our product layout for thoracic surgery.

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During the trial, the marker was first placed through transbronchial insertion operation, video-assisted thoracic surgery (“VATS”) was performed within 24 hours after the completion of the marker placement to remove the marker together with the marked lung nodule(s). The enrolled patients received follow-up visits at multiple times (intraoperatively, immediately after the placement procedure, at the end of VATS resection, seven days after the placement procedure or before discharge (whichever occurs earlier), and 30 days after the placement procedure) to enable us to evaluate the safety and efficacy of H-Marker to locate lung nodules before the resection of the lung nodules through performance of VATS.

- *Efficacy Endpoint*

The primary endpoint of the H-Marker Trial is the positioning success rate, calculated as the proportion of patients who completed the VATS resection of the target pulmonary nodules divided by the number of patients receiving localization of target pulmonary nodules before the operation, to evaluate the effectiveness of disposable pulmonary surgical markers in the localization of pulmonary nodules in surgery. Secondary endpoints include positioning success rate, immediate operation success rate of marker placement, operation time of marker placement, operation time of marker release through bronchoscopy and operation time of exploration and removal of target lesion during VATS, in terms of marker placement.

- *Safety Endpoint*

The safety endpoints include (1) the incidence of device-related adverse events and serious adverse events during the marker placement, including but not limited to pneumothorax and bleeding; (2) the incidence of device-related adverse events and serious adverse events during the period from the time the marker is placed to the completion of the VATS operation, including but not limited to the displacement of the marker; (3) the conversion rate to thoracotomy during the VATS operation; (4) the incidence of device-related adverse events and serious adverse events within seven days after the placement procedure or before discharge (whichever occurs earlier); and (5) the incidence of device-related adverse events and serious adverse events within 30 days after the placement procedure.

The final clinical results indicate the positioning success rate was 97.4% with an immediate operation success rate of the marker placement of 95.1%. With respect to the safety endpoint, during the trial, whether it was during the marker placement period or the follow-up period, no related adverse events and serious adverse events occurred. The H-Marker Trial data have confirmed that the pre-VATS localization of lung nodules through H-Marker has good safety and effectiveness profiles.

BUSINESS

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET H-MARKER IN CHINA OR THE U.S.

Lung Navigation Products

Overview

As the world’s only provider of transbronchial whole lung augmented reality navigation technology, we focus on the development of globally-leading navigation systems for lung biopsy and pulmonology diagnosis and treatment. We currently have three marketed navigation products, including LungPoint, LungPoint Plus (known as “Archimedes Lite” outside Asia) and LungPro (known as “Archimedes” outside the mainland of China). LungPoint procedure planning and navigation system, or the VBN system, provides real-time path navigation within the lungs for lung biopsy and other diagnosis and treatment procedures. Archimedes is a software tool designed to assist in the process of diagnostic bronchoscopy by providing access to lung tissues chosen for biopsy. The Archimedes System is a whole lung access, diagnosis and treatment navigation platform that integrates CT-based images, image-guided navigation and fused fluoroscopy to provide three-dimensional, real-time airway and proprietary Bronchoscopic Transparenchymal Nodule Access (“**BTPNA**”). As of the Latest Practicable Date, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval.

(1) LungPoint

LungPoint, or LungPoint® Virtual Bronchoscopic Navigation, is a computer-assisted image-based navigation software system which, along with a set of biopsy tools, provides doctors with real-time path navigation within the airways and further localization guidance to a targeted area of interest in the lung for lung biopsy and other procedures. The system was designed to facilitate a higher biopsy diagnostic yield rate than that of any existing bronchoscopic biopsy modality by allowing for improved access to pulmonary peripheral lesions and nodules. It reconstructs CT-based images of the thoracic cavity into a 3D model by superposing them with 3D simulated images and provides real-time navigation functions including displaying both actual and simulated images as well as planned paths to the target to enable the doctor to mark a specific target, i.e., a suspicious lesion or solitary pulmonary nodule (“**SPN**”). The software system computes several appropriate routes for precise navigation and localization, and then guides the bronchoscope down the path selected by the user to reach the pre-determined target location. It assists doctors in guiding endoscopic tools or catheters in the pulmonary tract and enables accurate marker placement within soft lung tissues.

LungPoint was approved for marketing and commercial use in the U.S. by the FDA in 2009, the EU by the BSI in 2011, and the PRC by the NMPA in 2014. LungPoint is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

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(2) *LungPoint Plus/Archimedes Lite*

Based on the same augmented reality navigation technology as LungPoint, we launched an advanced version of LungPoint, LungPoint Plus, also known as Archimedes Lite outside Asia, in 2020. Similar to LungPoint, LungPoint Plus provides real-time navigation within the airways for lung biopsy and other procedures through reconstruction of CT-based images and simultaneous display of actual and simulated images for more accurate and effective pathway planning to the target. It further enhances the performance of navigation with capabilities to help doctors perform more complex bronchoscopic procedures. It significantly improves CT data reading and analysis capabilities and enhances operational flexibility by adding a series of new functions, including airway extension and flexible path selection.

LungPoint Plus has been commercialized internationally since late 2020. LungPoint Plus is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

(3) *The Archimedes System*

The LungPoint ATV System, also known as LungPro in the mainland of China or the Archimedes System outside the mainland of China (the “Archimedes System”), is an upgraded product based on the LungPoint VBN system. The Archimedes System takes the application of the VBN technology to the next level by adopting a novel approach to enable precise navigation and localize peripheral lesions away from or adjacent to the airway. As an advancement to the LungPoint VBN system, the Archimedes System also starts with synchronizing virtual navigation plan with the real-time bronchoscope video. The Archimedes System can further provide navigation into the parenchyma with a ATV tool kit including FlexNeedle, balloon and sheath. When the system guides the bronchoscope to the point-of-entry (“POE”) inside the airway, FlexNeedle will create a hole at the POE on the airway wall. A balloon is then inserted into the POE and dilate the hole. Finally, the sheath is inserted into the dilated hole. The system can overlay the planned target onto real time fluoroscopy image and lead the sheath to go through lung parenchyma directly to the SPN. This pathway is also planned to avoid vessel by the system and enhance safety profile. The Archimedes System can also provide guidance for sampling SPNs through adjacent airways.

The Archimedes System was approved for marketing and commercial use in the U.S. by the FDA in 2014, the EU by the BSI in 2014, and the PRC by the NMPA in 2017. The Archimedes System is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

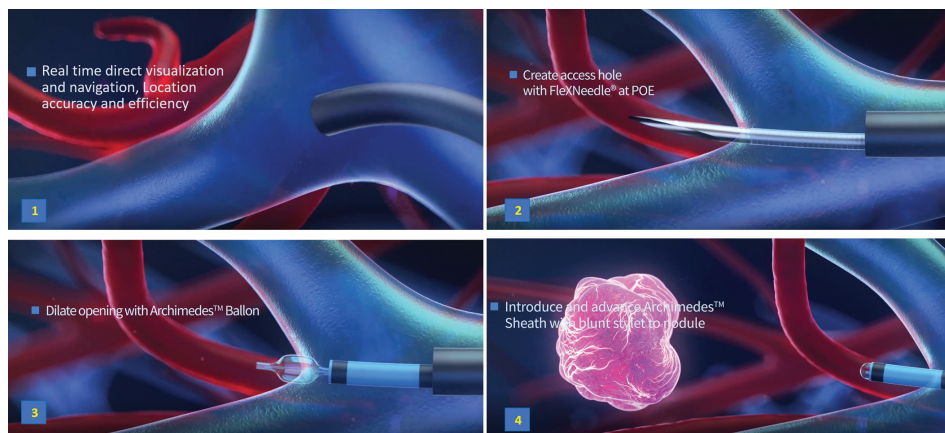
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Augmented Reality Whole Lung Access Navigation Technology

Our Archimedes System is the world’s only whole lung access augmented reality real-time image navigation systems, according to Frost & Sullivan. Employing image registration to guide bronchoscopic biopsies, our navigation platforms offer virtual bronchoscopic animations and a 3D airway tree enabling review and assessment of different airway paths to the target and localization of the target with respect to the airway. The navigation system provides the option to segment previously acquired CT DICOM (Digital Imaging and Communications in Medicine) format data sets and overlay and register these segmented data sets, including information relating to default pathways, blood vessels and lesion locations, with the real-time bronchoscopic video of the same anatomy in order to support navigation.

As a result, real-time guidance with LungPoint® Virtual Bronchoscopic Navigation simultaneously displays live and virtual views and provides path planning with navigation accuracy. During bronchoscopy the virtual pathway is synchronized with the real-time bronchoscopic video image, revealing the best pathway for the bronchoscope to reach the target. Our LungPoint augmented reality navigation system is able to reach bronchus level 9 with navigation accuracy of less than 3mm calculated calibration.

The Archimedes System further advances the development of bronchoscopic navigation and guidance techniques by realizing transbronchial whole lung access navigation. With our proprietary and globally unique BTPNA technology, a standard 2mm working channel is created to establish a tunnel that can reach any part of the entire lung and lead directly to lesions away from or adjacent to an airway. The BTPNA technology is able to precisely locate such lesions, especially peripheral SPNs that are not visible under X-rays, and establish pathway leading directly to the targeted lesion through parenchyma, laying the foundation for whole lung diagnosis and follow-up treatments. When the bronchoscope is operated to pass through the airway, the real view, virtual animation and planned path are displayed simultaneously to confirm the accurate position and direction for bronchoscope placement. In addition, the airway diameter is measured to help determine the diameter of the bronchoscope, stent, valve and implanted accessories. Our Archimedes System is able to achieve navigation accuracy of within 3mm deviation from the exact location of the target.



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Product Structure

The Archimedes System consist of Planning and Procedure modules. Each Archimedes System is provided with a USB security key, without which the system does not work. The Archimedes software is pre-installed on the Archimedes System and we provide a user-name and password for log-in onto the system together with the USB security key. The Archimedes System also includes a video grabber card which captures the bronchoscope's and fluoroscope's video output on the Procedure Navigation page and allows for merging of the bronchoscopic and fluoroscopic video with target overlays.

Depending on the features of the Archimedes software to be used and the type of procedures (airway or tunnel) to be performed, different hardware requirements apply. For bronchoscopic navigation, the relevant Archimedes equipment includes the navigation system, a bronchoscope and associated cables and bronchoscope calibration fixture. To use the function of fluoroscopic guidance, additional hardware is needed besides the equipment required for bronchoscopic navigation, which includes a fluoroscope and associated cables, C-Arm calibration fixture, Archimedes Board, a tracker with two tracking tools and Foot Pedal, a hands-free software control option that can assist with calibrating the C-Arm, verifying C-Arm calibration, registering the patient and navigating with guided fluoroscopy.

Operation Procedure

To get started with the Archimedes System for navigation and bronchoscopy operation, the pulmonologist simply turns on the computer with the security key inserted into a USB port on the back of the computer. During installation of an Archimedes System, at least one bronchoscope is added to the system, calibrated, and set as the default bronchoscope. The path planning system uses three preset bronchoscopes that cannot be modified. After user log-in and module selection, the Archimedes software shows the Patient Case Selection page. From here, the pulmonologist can import patient scans from a drive or DICOM node to bring them into the system. After a patient's CT scan is imported, the patient will be listed on the Patient Case Selection page. In the Procedure module, once planning is completed, the Patient Case Selection page is used to select a patient for a live procedure. After the patient is selected, the virtual bronchoscopy allows the pulmonologists to review the virtual pathway to the target before a live procedure. The pulmonologists can perform the virtual bronchoscopy in both the Planning and Procedure modules. During the operation of the virtual bronchoscopy, Procedure navigation provides side-by-side comparison of the real bronchoscopy video and Virtual Branch animation, the virtual animation enabled by the Archimedes System, as well as tools to synchronize these images and guide the procedure. As a result, the Archimedes software overlays CT information onto live fluoroscopic video to allow the pulmonologist to accurately guide a sheath through lung tissue and access more distal targets for diagnosis or treatment.

Additionally, navigating with fluoroscopic guidance involves guiding endoscopic accessories through tissue to the target, which is performed using guided fluoroscopy and requires additional setup steps. Normally, to prepare for fluoroscopic guidance, the pulmonologist will navigate to the airway access point using our navigation system and then

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use our diagnosis tool, FleXNeedle, to make a hole in the airway wall at the airway access point. Afterwards, FleXNeedle will be withdrawn from the bronchoscope and a sheath placed through the bronchoscope’s accessory channel with the stylet further withdrawn and a dilation balloon used through the sheath to dilate the airway such that the sheath can be inserted. The balloon will be finally removed from the sheath and the stylet gets replaced. To conduct the fluoroscopic guidance, the pulmonologist will use the fused fluoro view on the Fluoro navigation page to guide the sheath along the projected path while advancing the sheath towards the target for precise positioning.

Market Opportunity and Competition

Our navigation systems have been used for virtual bronchoscopic navigation and lesion localization to access and sample pulmonary peripheral lesions. According to Frost & Sullivan, there is an accelerating population of lung cancer patients worldwide and in China. Globally, the number of lung cancer new cases increased from 1.9 million in 2015 to 2.2 million in 2019, and is expected to further increase to 2.5 million by 2024. In China, the number of lung cancer new cases increased from 787.0 thousand in 2015 to 895.3 thousand in 2019, and is expected to further increase to over 1.0 million by 2024. For details, see “Industry Overview – Pulmonary Diseases, Diagnosis and Treatment – Overview, Prevalence, Diagnosis and Treatment of Lung Cancer.” Lung cancer at advanced stages has a relatively low 5-year survival rate as compared to other types of cancers. However, if lung cancer is detected at early stages, the 5-year survival rate can be significantly increased to 56.6% and 34.1% for Stage I and Stage II lung cancer, respectively while the 5-year survival rate for Stage IV lung cancer is as low as 2.9%, according to Frost & Sullivan. Therefore, if lesions can be precisely accessed to achieve more successful biopsy diagnosis results, it will significantly increase the likelihood of identifying the lung disease for timely and effective treatment.

The application of interventional pulmonology diagnosis tools has been increasing and such increase is expected to continue. Bronchoscopy is used as one of the interventional pulmonology diagnosis tools for lung disease biopsy. According to Frost & Sullivan, in 2019, the number of bronchoscopy examinations in China reached 4.1 million examinations at a CAGR of 6.4% from a total of 3.2 million examinations in 2015. Such number is expected to reach 5.3 million by 2024. As bronchoscopy is more widely adopted and the market need for minimally invasive precision interventional pulmonology diagnosis products keeps growing, it is expected that there will be a significant increase in the patients’ willingness to choose more advanced navigation procedures for bronchoscopy operation, leading to potential market expansion of pulmonology navigation systems. For details, see “Industry Overview – Pulmonary Disease Diagnosis and Treatment Market – Interventional Pulmonology Market.”

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Summary of Clinical Trial Data

EAST 2 Trial

We have completed a multi-center, single arm, open-label, prospective post-marketing clinical trial worldwide to evaluate the efficacy and safety of the Archimedes System in aiding pulmonologists in guiding endoscopic tools to pulmonary nodules located more distally in parenchymal tissue. The procedures were completed in 10 centers, the majority of which were in the U.S. (six locations) and the China (two locations in the mainland of China and one in Hong Kong) with one location in Germany. In conclusion, the comprehensive trial results showed that a high biopsy yield was obtained independent of nodule location, size or absence of a bronchus sign, which resulted in an overall diagnostic yield similar or higher than that of previously reported bronchoscopic navigation technologies, which proved the favorable safety and efficacy profile of the Archimedes System. In other words, we believe the Archimedes System can aid the safe and effective sampling of lung nodules.

As of September 2020, the time when the database was locked for the analysis, there were 166 patients provided written informed consent in the trial. Eligible subjects met the following physical conditions:

- the patient was aged between 21 and 75 years old at screening;
- the patient had highly suspicious pulmonary nodule(s), defined as distinct nodule(s) with a diameter of no less than 8mm in its largest dimension;
- no known endobronchial tumor was identified; and
- the patient had a tumor located somewhere in parenchymal tissue more than 1 cm from pleura and accessible bronchoscopically through a POE.

The trial’s primary efficacy endpoint is biopsy yield, defined as the number of nodules with at least one biopsy sufficient for a tissue diagnosis divided by the number of nodules sampled by the Archimedes System. The trial’s secondary efficacy endpoints include procedure planning time, defined as the time starting from selection of the patient CT until the tunnel path has been selected, reviewed, and exported, nodule access time, defined as the time starting from navigation initiation until the sheath has been placed at the first biopsy target, fluoroscopy time, defined as the total fluoroscopy time used from the start of fused-fluoroscopic navigational guidance to the time when the devices are removed from the POE, and patient registration time, defined as the total time it takes to correlate the patient’s position via fluoroscopy with the navigational guidance system. The trial’s primary safety endpoint is the incidence of serious adverse events during the study (including during the bronchoscopic navigation operation, lung tissue sampling procedure and follow-up period).

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- *Efficacy results*

Biopsies were performed successfully in 106 patients resulting in tissue samples taken from 116 nodules of 125 nodules eligible. The Archimedes System performance summary indicates biopsy yield was 95.2% (80 of 84 biopsy samples contained tissue from the nodules) using per-protocol tools, and 90.6% (29 of 32 biopsy samples contained tissue from the nodules) using off-protocol tools, showing the ability of the Archimedes System to reach the targeted nodules. In comparison, traditional transbronchial biopsy with bronchoscopy has a diagnostic yield ranging from 14% to 63% only.

- *Safety results*

The procedure was well tolerated. No patient was reported as requiring admission to intensive medical care after the procedure. All patients were discharged from hospitals following the procedure with routine hospital ward recovery prior to discharge.

Complications were minimal with only three adverse events reported, of which two were assessed as possibly related to the procedure (1.5%) and none related to the Archimedes System. The two events possibly related to the procedure were both pneumothoraces, with one requiring a prolongation of hospitalization of two days but did not require a chest tube. Pneumothorax was anticipated following bronchoscopic biopsy procedures and the rate was within the expected likelihood. None of the patients developed respiratory failure.

Our Other Product and Product Candidates

Our comprehensive platform that integrates interventional pulmonology navigation, diagnosis and treatment also offers a variety of interventional diagnostic products and product candidates.

Interventional Diagnosis Products for Lung Nodules

FleXNeedle

FleXNeedle is a single use coring needle for retrieval of tissue samples. It is placed through a flexible bronchoscope. When used together with our navigation systems, the needle can be guided to a targeted area within the respiratory organs. With an 18 gauge coring needle tip, it also enables a larger sample collection compared to conventional contraneedles.

BioStarNeedle

BioStarNeedle is a single use ultrasound-guided aspiration needle for retrieval of tissue samples. Needle tip with nitinol materials provides excellent puncture with flexibility, while the special tip design offers precise retrieval. It obtained approval from Zhejiang MPA in June 2020.

ATV Tools

The ATV Tools includes FleXNeedle, ATV Balloon and ATV Sheath. It is designed to access lesions and perform a biopsy sampling during BTPNA.

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ATV Balloon is a sterile single use flexible tube with a balloon at or near the distal tip that is inserted through the bronchoscope or sheath and used to dilate the target lung tissue of the bronchial tree. ATV Sheath is a sterile single use flexible tube that provides a working channel during a bronchoscopic procedure through which other devices may be introduced to the targeted area within the respiratory organs. The sheath is advanced through the working channel of a bronchoscope and allows for the repeated placement of endoscopic devices to a specified lesion(s) during a procedure.

Steerable Sheath

The steerable sheath consists of a steerable sheath adjustment handle and a working channel. The traction system of the adjustment handle can adjust the position and angle of the distal end of the sheath, so that the sheath can reach the lesion position accurately. The damping system of the adjustment handle can lock the angle, so that the sheath can stay at any position when the surgeon performs the bending operation. The working channel is connected with the adjustment handle through a connector.

The steerable sheath is single use only. It is expected to be used in conjunction with a bronchoscope to establish a channel for surgical instruments.

COLLABORATION AND LICENSING ARRANGEMENTS

Collaboration with PSRF (In-Licensing Arrangement)

On June 12, 2008, a license agreement (the "**PSRF Agreement**") was entered into between The Penn State Research Foundation ("**PSRF**"), a non-profit corporation formed in 1934 for the purpose of fostering and advancing scientific research, and Broncus Technologies, Inc. ("**BTI**") concerning the exclusive right and license to certain software (including Virtual Navigator Suite, Lymph Node Mapping System and Tree Analyzer) and patent rights (the "**PSRF Licensed IP**"). Such right and license to the PSRF Licensed IP were acquired by LifeTech Scientific (Hong Kong) Co. Ltd. ("**LifeTech**") and Shanghai Biomedical Enterprise, LLC ("**SBE**") from BTI pursuant to an Asset Purchase Agreement dated May 9, 2012. Under a Bill of Sale and Assignment and Assumption Agreement (collectively with the Asset Purchase Agreement, the "**Assignment Arrangement**") dated June 11, 2012 by and among Broncus Medical ("**BMI**"), our major subsidiary, BTI, LifeTech, and SBE, BTI would, amongst others, transfer the right and license to the PSRF Licensed IP to BMI.

Pursuant to the PSRF Agreement and the Assignment Arrangement, PSRF granted BMI a worldwide, exclusive, sublicensable, royalty-bearing right and license to the PSRF Licensed IP to develop, reproduce, make, have made, use, lease, distribute, offer for sale, sell, import, perform, display, modify and make derivative works of products using the PSRF Licensed IP ("**PSRF Licensed Products**") for all medical applications related to the lungs and/or respiratory system, including without limitation therapeutic, surgical, interventional, prophylactic, diagnostic and prognostic applications. PSRF reserves the rights for itself and The Pennsylvania State University to practice under the PSRF Licensed IP for their own academic, charitable or non-profit research and educational purposes.

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Under the PSRF Agreement, BTI shall be responsible for the development and marketing of PSRF Licensed Products. It must use reasonable efforts to develop and commercialize PSRF Licensed Products, and is responsible for all costs and expenses incurred by itself or on behalf of itself associated with such activities. Such efforts shall include (a) having a first PSRF Licensed Product complete and ready for clinical testing and/or 510(k) submission within one year from the date of the PSRF Agreement, and (b) having received 510(k) clearance for the first PSRF Licensed Product within two years from the date of the PSRF Agreement.

Subject to the terms and conditions of the PSRF Agreement as further amended in October 2013, BTI paid PSRF a non-refundable payment in the amount of US\$200,000 and issued to PSRF certain shares as the upfront payments and a running royalty based on net sales generated from the PSRF Licensed Products. Under the Assignment Arrangement, BMI is obligated to pay a minimum amount of \$150,000 royalty each year, which was reduced to \$100,000 for 2013 and 2014 each year under the First Amendment to the PSRF Agreement entered into between PSRF and BMI.

The PSRF Agreement may be terminated by BMI in its entirety, without cause, and for any or no reason, upon 6 months’ prior notice to PSRF. PSRF may early terminate the PSRF Agreement upon bankruptcy, failure to pay royalties, or any other material breach of the PSRF Agreement by BMI.

As of the Latest Practicable Date, PSRF is an Independent Third Party.

Collaboration between BMI and Intuitive (*Out-Licensing Arrangement*)

On April 6, 2017, BMI entered into a license agreement (the “**BMI Agreement**”) with Intuitive Surgical Operations, Inc. (“**ISI**”), a company that designs, manufactures, and markets surgical systems, concerning the exclusive right and license to certain IP rights owned by or licensed to BMI, including the PSRF Licensed IP, (the “**BMI Licensed IP**”). On March 2, 2018, BMI entered into a co-development agreement (the “**CDA**”) with ISI and its subsidiary, Intuitive Surgical Sarl, whose line of business includes the wholesale distribution of surgical and other medical instruments, apparatus, and equipment, (together with ISI, “**Intuitive**”) to co-develop therapeutic products compatible with the Archimedes systems and Intuitive’s robot-assisted systems in accordance with the statement of work. Under the CDA, Intuitive is responsible for preparing clinical model and generator specification and selection report with other responsibilities shared by both BMI and Intuitive, including a series of analyses to be conducted for the product development. The agreement can be terminated upon both parties’ mutual written agreement or the failure of settlement over either party’s material breach.

Pursuant to the BMI Agreement, BMI granted ISI a non-exclusive license, which was converted into an exclusive license upon execution of the CDA and certain equity investment by the ISI to us. The exclusive license granted ISI a worldwide, exclusive, royalty-bearing, sublicensable, transferable, assignable right and license to make, have made, use, offer for sale, sell, market, import, export, distribute, and commercialize the BMI Licensed IP in the field of robotic-assisted medical interventions.

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Subject to the terms and conditions of the BMI Agreement, ISI has paid BMI a non-refundable payment in the amount of US\$5,000,000 as the upfront payments. In addition, ISI will be obligated to pay BMI royalties of US\$250,000 per year for ten years for the non-exclusive license. Upon the conversion to exclusive license on March 2, 2018, ISI will be obligated to pay BMI royalties of US\$1,000,000 per year for five years. The aggregate total amount of royalties payment shall not exceed US\$5,000,000.

The BMI Agreement may be terminated early by either party upon material breach of the other party.

As of the Latest Practicable Date, ISI held approximately 6% of our interest.

BMI further negotiated and entered into a separate agreement with ISI on May 4, 2021 (the “**ISI Amendment**”) pertaining to the rights to certain patent rights that BMI obtained under the PSRF Agreement which BMI licensed to ISI under the BMI Agreement. Pursuant to the ISI Amendment, BMI continues to hold the same worldwide exclusive rights to the BMI Licensed IP, including PSRF Licensed IP, for all medical applications that are not robotic-assisted. Under a separate agreement between ISI and PSRF signed on May 4, 2021, the terms of which BMI expressly agreed to, PSRF directly granted ISI exclusive rights to the PSRF Licensed IP for medical applications related to the lungs and/or respiratory system that are robotic-assisted, as well as for all other fields outside the lung and/or respiratory system. Meanwhile, ISI granted BMI certain nonexclusive rights to the BMI Licensed IP for medical applications that are robotic-assisted in regions outside the United States, Canada, Europe, the United Kingdom, Japan, Australia, New Zealand and South Korea. Accordingly, under the ISI Amendment, BMI will be able to focus its product development in the region of Greater China with their retained IP rights. BMI also simultaneously entered into a separate agreement with PSRF to evidence the determined scope of the relevant licensing arrangement between BMI and ISI regarding the PSRF Licensed IP, among other things.

OUR PLATFORM

We have developed a fully-integrated platform for the discovery, development, manufacture and commercialization of a comprehensive suite of diagnosis and treatment solutions for lung diseases. The integration of our platform promotes seamless collaboration among different functional groups at key stages in the lifecycle of a product candidate and helps ensure the speed of development and likelihood of success while at the same time reducing the cost of development and nourishing the market needs at early stages. Since our inception, we have successfully built up the necessary capabilities of a fully-integrated platform focused on precision diagnosis and minimally invasive therapy for lung disease treatment.

These capabilities are housed in four main functional platforms: R&D, clinical development, manufacturing and commercialization. These individual functional platforms have been optimized and great attention has been given to building cross-functional integration. In addition, we have developed the capacity to communicate with and educate the market during the clinical trial stage of the product candidates, which potentially cultivates promising targets with clinical and commercial potential and speeds up the commercialization process of the products.

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R&D

We focus on developing innovative technologies and products for navigation, diagnosis and treatment of pulmonary diseases. We believe that the success of our operations has depended and will continue to depend to a large extent on our ability to develop new or improved medical devices. We have a proven track record of developing and commercializing interventional pulmonology medical devices. To strengthen our R&D capabilities, we adopt a highly efficient R&D model that combines international technologies with local R&D cost advantage to support our strong intellectual property portfolio and fast product iterations. We believe our R&D model allows us to stay abreast with global-leading technologies and medical device development experience in the U.S. and Europe while taking advantage of the cost-effective and highly efficient clinical research capabilities in China.

We are engaged in ongoing R&D activities to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, reliability, and to expand the applications of our products as appropriate. As of the Latest Practicable Date, we had 12 product candidates in various stages of development.

The time required from developing to commercializing a new product varies by product candidate and can be affected by various factors which may be beyond our control, such as clinical trial results and government policies and approvals. We incurred R&D costs of US\$11.4 million and US\$9.4 million in 2019 and 2020, respectively.

Our R&D Team

We have a strong in-house R&D team of 80 people, with 73 team members based in China, seven members based in the U.S. as of the Latest Practicable Date. As of the Latest Practicable Date, 24 members of the R&D staff possessed a master or doctorate degree. The team is led by Mr. Hong Xu, who has more than ten years of experience of pre-clinical practice and R&D in the industry. In addition, we have experienced researchers and practitioners serving on our R&D team who have provided important insights and recommendations for our R&D team.

Our R&D capabilities in China are reflected by our strong intellectual property portfolio. As of the Latest Practicable Date, we owned an aggregate of 476 patents and patent applications which consisted of 87 issued patents (including pending announcements) and 248 patent applications in China and 95 issued patents and 46 patents applications overseas. We believe the establishment of our R&D center in China will help lower costs in connection with in vitro experiments, animal testing and clinical trials and shorten the R&D cycle.

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Product Design and Pre-Clinical Development

In-House plan and design

We often collaborate with major hospitals, labs and universities in China and globally in the R&D of our products. Dr. Felix JF Herth, Head of Department of Internal Medicine, Pulmonology and Critical Care of the Chest Hospital of Heidelberg University, serves as our R&D and medical advisor.

In the product development process, we collaborate with doctor consultants to conduct R&D activities from concept input, in vitro and animal testing to clinical trials. For example, for the development of RF-II radiofrequency ablation system, our Company and The First Affiliated Hospital of Guangzhou Medical University jointly completed the preliminary in-vitro experiments and animal experiments. The First Affiliated Hospital of Guangzhou Medical University organized multi-center research as the clinical trial PI. We also develop intellectual property and contribute to researches with Pennsylvania State University and other academic or technology institutions. For certain outsourced electrical safety tests, we entered into a framework agreement with a third-party testing company to complete the electrical safety and EMC tests efficiently.

CLINICAL TRIALS

Our clinical affairs team has significant experience in conducting clinical trials for our products. As of the Latest Practicable Date, we had 13 clinical staffs, 11 in China and two in the U.S.

We conduct clinical trials of our new products in order to obtain the requisite regulatory approvals. In addition, solid clinical data provide support for increasing credibility for our brand and products. The goal of a clinical trial is to measure the clinical efficacy and safety of a device. Primary parameters for clinical trials are selected based on the intended use of the medical device.

We have a regulatory affairs team, mainly in charge of regulatory approval to submit our clinical report together with other materials to the relevant authorities. Our clinical data and practices are designed to meet the standards of applicable regulations.

Collaboration with Clinical Trial Institutions

We select a number of leading hospitals which have been confirmed by NMPA to be qualified clinical trial institutions with desirable expertise, professional staffs, management capability and medical conditions to conduct our clinical trials. We will meet with the selected participating hospitals to discuss the trial’s goals and requirements, as well as to select the lead institution for the trial, which typically will be an authoritative and reputable institution in relevant clinical areas, as well as being the largest and best-equipped among the participating institutions.

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We typically enter into an agreement with each selected hospital for each clinical trial, under which we and the participating hospitals prepare a clinical trial protocol following applicable regulations that describes in detail the goal of the clinical trial, the risks involved, the overall design, the methods and the procedures of the trial. We submit the relevant documents to the ethics committee of each participating hospital for review. Such documents typically include our clinical trial protocol, draft informed consent to be filled out by patients, draft case report forms to be completed by investigators supervising the clinical trial, and agreement with the hospital to perform the clinical trial. The ethics committees may ask us to revise the clinical trial protocol or other documents before their approvals. Once the protocol is approved, any amendment thereafter is required to be reviewed and consented by the ethics committee and the clinical trial is required to be conducted strictly pursuant to the approved protocol.

Pursuant to the agreement, each participating hospital is obligated to conduct clinical trials following the protocol and at the end of the clinical trial, issues a case report based on the collected data and keep trial records for 10 years after trial completion. The lead institution gathers case report forms from all participating hospitals, and prepares formal reports of the clinical trial. We make payments according to the agreed schedules and items for the hospitals' services. Under the agreement, we own all related intellectual property and results from the trial.

The participating trial institutions have the right to publish information in connection with this trial for academic research. The participating trial institutions shall obtain our written consent prior to publishing their paper. Before the primarily results are officially published at an academic conference, such institutions shall obtain our written consent in advance. We retain the intellectual property rights. However, we may consider entering into separate arrangements with participating trial institutions centers should they contribute significantly to our product quality and efficacy.

Relationships with CROs

We use CROs to manage, monitor, conduct and support certain of our clinical trials. We select our CROs based on various factors, such as their qualifications, academic credentials and professional experience of their employees and their industry reputations. We generally enter into an agreement regarding each clinical research project with the CROs. We closely monitor our CROs to help ensure their performance will comply with our protocols and applicable laws, regulations and guidelines, which in turn protect the integrity and authenticity of the data from our clinical trials and studies.

We have worked with CROs for certain of our clinical trials including trials for the InterVapor system. Under the relevant agreements, the CROs are generally responsible for enrolling subjects strictly pursuant to the trial's protocol, launching, managing and monitoring the implementation of trials in each clinical center, to ensure that the entire trial is compliant and authentic. We provide the CROs with their required materials and information and make payments in accordance with the payment schedule agreed by parties. The CROs are obligated to keep all non-public information and data from the trials confidential, and return related materials to us at the end of our contract term.

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MANUFACTURING

Our principal manufacturing facility is located at our headquarters with an aggregate gross floor area of approximately 3,122 sq.m. in Hangzhou, Zhejiang province, China. We also leased one manufacturing facility in San Jose, California in the U.S. with an aggregate area of approximately 863 sq.m. As of the Latest Practicable Date, our facility in Hangzhou is primarily used for the production of medical device system, and single use sterile medical device for interventional pulmonology diagnosis and treatment, including ATV FleXNeedleCN, ATV Balloon, ATV Sheath, BioStarNeedle and Steerable Sheath, and product candidates, and our facility in San Jose, California is used for the production of our navigation systems and the ATV Tools.

Manufacturing of our therapeutic products and product candidates

Our subsidiary Uptake Medical Technology Inc. (“UMT”) is ISO 13485 compliant and is the manufacturer of record for the European CE Marked InterVapor system. The InterVapor generators are manufactured by the OEM supplier Minnetronix Inc. in Minnesota in the U.S. for UMT. The InterVapor catheters and drain bags are manufactured by the OEM supplier Medical Murray Inc. in Illinois in the U.S. for UMT. We expect to commence manufacturing of H-Marker in our Hangzhou facility starting in the second quarter of 2021. We are also preparing our Hangzhou facility for the manufacturing of our other therapeutic products, including the InterVapor products. We may commence such manufacturing in 2021, subject to CE Marking certification. Our RF-II will be produced according to clinical and other relevant needs in our Hangzhou facility as well.

Manufacturing of our navigation systems

Our navigation systems, including our LungPoint, LungPoint Plus and Archimedes System, are manufactured in our San Jose, California facility in the U.S. This facility is ISO13485 compliant and Broncus Medical is the manufacturer of record in US 510(k) clearance and European CE Marked LungPoint products.

The following table sets forth the production capacity, actual production volume and utilization rate for our navigation systems in our San Jose facility for the periods indicated. We have strategically reduced productions of LungPoint in the U.S. due to product upgrade, which is reflected in the number of productions below.

	For the year ended December 31,	
	2019	2020
<i>LungPoint</i>		
Production capacity (units) ¹	96	96
Actual production volume (units)	8	0
Utilization rate (%) ²	8%	—

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Notes:

- (1) Our production capacity is based on the assumption that it takes on average 2 technicians to produce 8 LungPoint products per month. During the Track Record Period, we had 2 technicians allocated to system manufacturing (including LungPoint, LungPoint Plus, Archimedes System).
- (2) Utilization rate equals actual production volume divided by production capacity.

	For the year ended December 31,	
	2019	2020
<i>Archimedes System</i>		
Production capacity (units) ¹	48	48
Actual production volume (units)	30	13
Utilization rate (%) ²	63%	27%

Notes:

- (1) Our production capacity is based on the assumption that it takes on average 2 technicians to produce 4 LungPro products per month. During the Track Record Period, we had 2 technicians allocated to system manufacturing (including LungPoint, LungPoint Plus, Archimedes System).
- (2) Utilization rate equals actual production volume divided by production capacity.

Manufacturing of our diagnosis medical consumables and product candidates

Our main production facility for diagnosis medical consumables and product candidates is our Hangzhou facility. We can expand our production capacity quickly in response to market demand. The following tables set forth the production capacity, actual production volume and utilization rate for FlexNeedle and BioStarNeedle in our Hangzhou facility for the periods indicated.

	For the year ended December 31,	
	2019	2020
<i>FlexNeedle</i>		
Production capacity (units) ¹	1,080	1,080
Actual production volume (units)	100	816
Utilization rate (%) ²	9%	76%

Notes:

- (1) Our production capacity is based on the assumptions that it takes on average 1 technician to produce 210 finished products per month and that two technicians use three months for this product each year.
- (2) Utilization rate equals actual production volume divided by production capacity.

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	For the year ended December 31,	
	2019	2020
<i>BioStarNeedle</i>		
Production capacity (units) ¹	N/A	1,200
Actual production volume (units)	N/A	591
Utilization rate (%) ²	N/A	49%

Notes:

- (1) Our production capacity is based on the assumptions that it takes on average one technician to produce 200 finished products per month and that two technicians use three months for this product for the year ended December 31, 2020.
- (2) Utilization rate equals actual production volume divided by production capacity.

SALES AND MARKETING

Currently, we primarily sell and market our interventional pulmonary products in the U.S., Europe and Asia. As our current products and product candidates receive more marketing approval or CE Marking certification, we expect to generate more sales globally. For example, the InterVapor for COPD has received approval in India on March 22, 2021.

We use a combination of our in-house sales and marketing team, our connections with hospitals and a network of independent distributors to sell our products in China and overseas. As of the Latest Practicable Date, we had a sales and marketing team of 68 people in Asia, led by Zhenhua Li, our Head of Sales and Marketing and Clinical Education Affairs in Asia Region, who has years of sales and marketing experience in the medical device industry, and a sales and marketing team of a total of 16 people in the U.S. and Europe. Sales team members based in different regions report to their own regional heads respectively for regional sales efforts coordination.

Our marketing model

We employ a strategic marketing model to promote our products. Under this model, we promote our products to hospitals by establishing research and clinical collaboration and training relationships with hospitals and by leveraging our network with KOLs. We also emphasize on clinical training where we connect hospitals and medical professionals with our technology know-how and pipeline products and aim to build connections with hospitals at a much earlier stage as we cumulate real-world clinical trial data.

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To increase awareness of our products and technologies, we conduct educational symposia and provide training to doctors, hospital executives and researchers in the field. Our trained sales and marketing team interacts with doctors to educate them about, and train them in the use of, our products. Such interaction is fostered through regular visits to and communications with doctors, on-site demonstration of our products to doctors, our sponsorship of conferences, seminars and doctor education programs and other activities. Although patients are the end users of our products, doctors and procurement departments of hospitals decide what products to stock and doctors typically recommend to patients what products to use. Based on our experience, as doctors become more knowledgeable and experienced with our products, they will be more likely to recommend our products. In addition to accelerating market awareness and adoption of our products, our communications with doctors provide us with continual feedback on our products which helps guide our R&D projects.

We have marketing members dedicated to training and education. We leverage various resources and channels to train doctors on a large scale, including three main training centers, two animal laboratories, online and offline training meetings and clinical department meetings. Through such training and education, we help doctors understand the technologies of our products for treatment of COPD and lung cancer to deepen our market penetration. We have also established two organizations, BTPNA Expert Panel and Broncus Campus, to host discussions on new technologies, surgical experience sharing and indication expansion and seek potential collaboration on new technology development.

Increasing patient awareness is equally important to us. To enhance awareness and recognition of interventional pulmonology diagnosis and treatment solutions among patients, we promote our technologies and products across diverse platforms such as social media, online and offline patient communities, pulmonary disease-focused foundations and academic forums. We also plan to cooperate with academic institutions, cancer screening companies, intelligent image readers and other institutions to collaboratively conduct patient education on early screening of COPD and lung cancer.

Besides our primary educational marketing model that focuses on promoting product awareness, we also rely on our distributors to sell our products. Distributors have engaged in promoting our products through their network of hospitals and doctors. For details, see “– Our Sales Arrangements – Sales through distributors.”

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Our sales arrangements

We sell products, including the Archimedes System, LungPoint and InterVapor both directly to hospitals and through distributors. In line with market practice, we sell a significant portion of our Archimedes System and LungPoint to distributors who resell our products to hospitals. As of the Latest Practicable Date, we had 8, 5 and 13 distributors in China, Europe and Asia (excluding China) and other regions, respectively, and we directly sold our products to 103 hospitals.

We set annual and quarterly sales targets of our navigation systems at the beginning of each year and each quarter. We also refer to the historical numbers of installations for our sales projections. We believe that the information provided by our sales and marketing team allows us to estimate market demand for our products. Normally we sign up distributorship agreements with our selected distributors, for whom it may take more than one year to achieve desirable sales target.

The following table sets forth a breakdown of our revenue generated from distributors and direct sales:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Sales to distributors	5,686	70.4	1,033	31.7
Direct sales	2,386	29.6	2,226	68.3
Total	8,072	100.0	3,259	100.0

Sales through distributors

Our sales and marketing team screens and selects distributors whom we believe have the required qualifications and capabilities and are suited to our strategic marketing model, and establishes and maintains resource sharing with our distributors to effectively execute our marketing strategies specifically tailored to each geographic location and the hospitals located within their locations.

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Upon selecting distributors, we will first evaluate their qualifications. Our distributors primarily engage in the medical device distribution business. We select our distributors based on their experience in the medical device industry, particularly in interventional pulmonology medical devices. In addition, they must possess the requisite business licenses and permits to sell medical devices in the respective jurisdiction and have established relationships with hospitals and doctors within their designated territory. Before we appoint a distributor, we assess its sales staff and management to help ensure that they have the appropriate educational background and professional skills. We review the qualifications of our distributors when our contracts with them are due to be renewed. During the Track Record Period, none of our distributors had any past or present relationship (business or otherwise) with our Group, our shareholders, directors, senior management or any of their respective associates.

- *Rights and obligations relating to the sales of navigation systems*

We do not allow overlap of distributors at the same hospital; distribution relationships between our distributors and the respective hospitals are exclusive. We generally prohibit our distributors from engaging sub-distributors to sell our products without our consent. The amount of the products we sell to a distributor depends on clinical education, technology adoption by hospitals and patient education in the designated area. Specifically, our invoice to each distributor is generally issued after the delivery of the systems to such distributor are completed.

We normally store and deliver our products directly to hospitals with our in-house facility and team. Our distributors are responsible for collecting payments from hospitals, and are required to pay us for the products regardless of whether they receive payments from the hospitals.

We enter into a master agreement with each distributor, with addendums that specify terms that may include their designated distribution area and hospitals, target order amount, rebates and credit terms. The principal terms are summarized below.

Duration and option to renew	The distribution agreements typically have a term of one year and can be renewed upon either party’s written notice at least 30 days prior to the termination date.
Designated geographical regions and hospitals	The geographical regions and hospitals for which a distributor is responsible are designated. A distributor is prohibited from selling our products outside its designated geographical regions or hospitals.

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Exclusivity	A distributor is prohibited from promoting and selling competing products in the designated geographical region.
Target order amount	A target order amount and schedule is set for each quarter, based on patient demand and market conditions in regions where the distributors operate. The target order amount is to facilitate our planning for production purposes and is not intended to replace or override the minimum purchase amount.
Transportation	We are obligated to arrange for transportation and bear the cost except for special packing. The distributor should bear the cost for special packing.
Product returns	In general, the distributor will have the right to reject defective and non-conforming products. We should replace the defective product at our own costs as promptly as possible after the receipt of the properly rejected product.
Warranty	Limited product warranty is available for any item that is defective in material or workmanship, or not in conformity with our published product specifications, in which case the distributor has the right to reject the item and inform us in written form within three business days after receiving the product
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 the minimum purchase amount, or breaches the exclusivity or no-sub-promotion provisions. The distributor can terminate when we fail to correct our breach of contract within 120 days after receiving their notice of correction.

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Regulatory compliance

The distributor is required to comply with all applicable laws and regulations, including, among other things, anti-bribery and anti-kickback laws and regulations.

Use of the trademark

The distributor shall have a non-sublicensable, nontransferable, non-assignable and non-exclusive right to use our trademark for selling our products in the designated area during the term of our distribution agreement. Our distributor shall not use the trademark for any other product and shall use the trademark only for the purpose of selling our products in accordance with the agreement.

We may conduct annual review of our distributors, based on their financial performance and business performance. Distributors’ financial performance is primarily evaluated by their credit records with us during each period, and the evaluation of their business performance is primarily based on the distributors’ sales performance, specifically whether they meet the target order amount. We may also conduct audit on new and existing distributors’ qualification. We may adjust their credit terms, renegotiate order price and certain other commercial terms with them based on the review results. We monitor, manage and support the activities of our distributors to help ensure that they comply with our guidelines, policies and procedures.

We generally provide credit term for up to 120 days to our distributors based on their credit profile and credit history, which is in line with the industry practice. According to Frost & Sullivan, manufacturers of high-value medical consumables in general offer credit term of 90 to 180 days to their distributors in China. The credit term may be extended upon distributor’s application depending on the designated hospitals’ time of payment to the distributor. During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial contribution.

- *Rights and obligations relating to the sales of our diagnostic medical consumables*

We generally enter into a distributorship agreement with each distributor of our diagnostic medical consumables, under which, each distributor’s rights are limited to its designated geographic area. Broncus Hangzhou is responsible for delivering the products to the distributor in China. During the Track Record Period, our distributors generally purchased our diagnostic consumables on an as-needed and frequent basis. Under a typical distribution agreement, the distributor shall take the responsibility to deliver the relevant products and our own personnel are responsible for training the end users. We currently don’t grant credit term to our distributors for our diagnostic medical

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consumables generally. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial contribution.

- *Relationship with distributors*

As of December 31, 2019 and December 31, 2020, we had a total of 24 and 36 distributors for the sales of our products, respectively. The following table sets forth the changes in the number of our distributors for the periods indicated:

	For the year ended December 31,	
	2019	2020
As of the beginning of the period	21	24
Additions of new distributors	9	17
Termination of existing distributors ⁽¹⁾	6	5
Net increase (decrease) in distributors	3	12
As of the end of the period	24	36

Note:

- (1) Our sales arrangement with a distributor is terminated when either party terminates the distribution agreement within the term of the agreement or chooses not to renew the agreement. In the year ended December 31, 2020, our sales arrangement with a total of three distributors was terminated due to distributors’ failure to meet their sales target or change of business.

Sales of our products generated through distributors decreased in 2020 as compared to those in 2019 due to the negative impact of Covid-19 on the overall interventional pulmonology medical device market.

To the best of our knowledge, all of our distributors are independent third parties. To the best of our knowledge, during the Track Record Period and as of the Latest Practicable Date, none of our distributors is wholly owned or controlled by or has any past or present relationship or arrangements, including family relations, business, financing, guarantee and others, with our Company or our subsidiaries, their directors, shareholders, senior management or any of their respective associates, save for acting as a distributor of our product.

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Direct sales to hospitals

In addition to the sales through our distributors, we sell our products directly to hospital. The following table sets forth the number of hospitals to which we sold products directly for the periods indicated.

	For the year ended December 31,	
	2019	2020
Europe	29	18
US	18	13
PRC (Mainland)	1	3
Others	7	4
Total	<u>55</u>	<u>38</u>

We generally do not provide credit terms to hospitals for our navigation and ablation systems. We generally provide credit term to hospitals for medical consumables only according to their standard credit term, which is usually ranged from three to six months.

During the Track Record Period, we did not have any disputes with the hospitals relating to the settlement of trade receivables.

Pricing

For the sales of our navigation systems and InterVapor, we normally negotiate pricing directly with customers and fix the price in contract terms, unless a tender is required, in which case we would submit a tender for the business. We sell our diagnostic medical consumables to distributors at the contract price. We generally set a fixed purchase price of diagnostic medical consumables in the distributorship agreement, which may vary depending on the market conditions in different regions.

CUSTOMERS

During the Track Record Period, we derived substantially all of our revenues from the sale of our navigation systems LungPro and LungPoint, which was commercially launched in 2014 and 2011, respectively.

For the years ended December 31, 2019 and 2020, the aggregate sales to our five largest customers were US\$3.8 million and US\$1.8 million, representing 47.1% and 54.9% of our revenue, respectively. Sales to our largest customer for the same periods were US\$2.0 million and US\$0.6 million, representing 25.3% and 17.3% of our revenue, respectively. We sell a

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significant portion of our products to distributors, and all of our five largest customers in December 31, 2019 were distributors. Please see below a summary of the sales to our five largest customers for the periods indicated:

**Five Largest
Customers for the year
ended December 31,
2019**

	Company Background	Covered Region	Sales Amount	Percentage of Revenue
			<i>US\$'000</i>	
Customer A	A private company that engages in the sales of Class I, II and III medical devices	The Mainland of China	2,045	25.3%
Customer B	A private company that engages in the sales of Class I, II and III medical devices	The Mainland of China	640	7.9%
Customer C	A private company that engages in the sales of medical devices	India	410	5.1%
Customer D	A private company that engages in the sales of medical devices	Hong Kong	367	4.5%
Customer E	A private company that engages in the sales of medical goods and equipment	The Region of Taiwan	348	4.3%
Total			<u>3,810</u>	<u>47.1%</u>

**Five Largest
Customers for the year
ended December 31,
2020**

	Company Background	Covered Region	Sales Amount	Percentage of Revenue
			<i>US\$'000</i>	
Customer F	Hospital	The Mainland of China	565	17.3%
Customer G	Hospital	The Mainland of China	449	13.8%
Customer H	Hospital	Hong Kong	315	9.7%
Customer D	A private company that engages in the sales of medical devices	Hong Kong	237	7.3%
Customer I	A private company that engages in the sales of Class I, II and III medical devices	The Mainland of China	221	6.8%
Total			<u>1,787</u>	<u>54.9%</u>

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During the Track Record Period, none of our Directors or any Shareholders who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following the completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest customers.

AFTER-SALE SERVICE

Since our Archimedes System, LungPoint and InterVapor products are installed in hospitals, as part of our customer service, hospitals conduct follow-up as designed for the procedure to observe the performance of our products based on the patients’ physical conditions. We also provide channels for complaints regarding our products, including complaints on the quality of our products and adverse events after relevant procedures are performed on the patients. Under the regulation of the NMPA, we have established an adverse event monitoring system and submit trend report when applicable. We have a quality management department dedicated to tracking and recording severe adverse events and handling customer complaints and queries with online tracking system. If an incident involving our product constitutes a major adverse event under NMPA regulations, we will report the incident to the NMPA and assess the cause for the adverse events. Our quality control department also investigates and analyzes the cause of issue raised by our customers and refers the quality issue to our management and relevant responsible departments for resolution and correction. We will recall our products for quality issues when necessary. During the Track Record Period and up to the Latest Practicable Date, there had not been any product recalls due to quality issues.

Because the Archimedes System, LungPoint and InterVapor devices involve relatively new technology, we provide technical support for hospitals and pulmonologists through our sales and marketing personnel directly or indirectly with the help of our distributors. Our marketing and technical support personnel study patients’ CT scans together with pulmonologists and help determine whether interventional procedures are suitable for the patients and whether they need to be specifically made to order.

RAW MATERIALS AND SUPPLIERS

Suppliers

For the years ended December 31, 2019, and 2020, purchases from our five largest suppliers in aggregate accounted for 28.5% and 26.4% of our total purchases (excluding value added tax), respectively, and purchases from our largest supplier accounted for 8.9% and 13.8% of our total purchases for the same periods (excluding value added tax), respectively. During the Track Record Period, our purchases mainly included raw materials, machines and equipment and services from third parties such as CROs and manufacturers.

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All of our five largest suppliers during the Track Record Period were Independent Third Parties. None of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest suppliers during the Track Record Period. Please see below a summary of the purchases from our five largest suppliers for the periods indicated:

**Five Largest Suppliers
for the year ended
December 31, 2019**

	Purchases	Purchase Amount	Percentage of Total Purchase
		<i>US\$'000</i>	
Supplier A	Raw materials	483	8.9%
Supplier B	Raw materials	304	5.6%
Supplier C	Raw materials	287	5.3%
Supplier D	Clinical services	245	4.5%
Supplier E	R&D equipment	226	4.2%
Total		<u>1,545</u>	<u>28.5%</u>

**Five Largest Suppliers
for the year ended
December 31, 2020**

	Purchases	Purchase Amount	Percentage of Total Purchase
		<i>US\$'000</i>	
Supplier C	Raw materials	710	13.8%
Supplier F	Product licenses	193	3.8%
Supplier D	Clinical services	165	3.2%
Supplier G	R&D consultancy services	154	3.0%
Supplier H	Employee health insurance	131	2.6%
Total		<u>1,353</u>	<u>26.4%</u>

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Raw Materials

For production of our Archimedes System, our principal raw materials are computer workstations, medical optical trackers, metal fabrication assemblies (cart) and other system accessories. The manufacturing of H-Marker requires the supply of implantable nickel-titanium alloy, polymer materials and stainless steel. The main raw materials of RF-II include ABS components, PCBA and LCD screens for the manufacturing of the generator and stainless steel for the manufacturing of the catheter.

For production of our InterVapor Catheter, our primary raw materials are the manifold, the catheter and the distal silicone balloon. During the Track Record Period, these are purchased/fabricated by our OEM (third-party manufacturer) following the requirements listed in the component specifications, and following our manufacturing agreement.

We primarily use a limited number of suppliers for our principal raw materials, although there are alternate suppliers available for most of such materials. As of the Latest Practicable Date, we had five principal suppliers for our Archimedes System. We are currently in the process of bringing in house the generator and catheter manufacturing for InterVapor to be located in our manufacturing facility in Hangzhou.

We generally enter into quality agreements with our principal suppliers which are critical to the performance of our device. We generally maintain current suppliers which are part of our validated processes for the medical devices which we produce. All materials are received and inspected to verify compliance with the written specifications. The specifications for the custom components are governed by confidentiality agreements and cannot be shared with other entities.

For approved medical device related supplier we generally have a quality agreement or other agreements in place to control the material, device quality and responsibilities for support of the regulatory compliance to maintain production capability. No Change Agreement is in place to control the change notification as well.

We normally settle with our principal suppliers for raw materials on terms of 30 days.

INVENTORY

Our inventories consist of raw materials, work in progress and finished goods. For our systems, we generally maintain an inventory level of one month ahead of forecasted sales for our near finished goods sub-assemblies and three to six months' supply of our raw materials. Levels will vary according to the demand of our customers, sales and production plans.

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We generally consider three to six month’s supply of raw materials to be sufficient for our system production, primarily because the procurement for our raw materials usually takes at most 12 weeks.

Our raw materials are typically not subject to expiration, except for adhesive glues with at least three-month effective period. For these materials that expire, we ordered quarterly and discard all old stock upon receiving new material. We store substantially all our inventories in locked inventory cages.

The Archimedes system and planner have a service life of five years. The InterVapor Generator has a service life of five years which can be extended via servicing. The InterVapor Catheter has a shelf life of three years. Consumable medical devices made in our Hangzhou facility have a shelf life of three years. All our products are sold on a first-in-first-out basis. To minimize the risk of building up inventory, we regularly review our inventory levels. We also carry out physical stock counts and stock inspections from time to time to identify damaged products or obsolete or about-to-expire products. Our procurement department manages our inventory levels by monitoring in real time our production activities and sales orders and also taking into consideration any emerging trends through discussions with our sales and marketing department. Based on this information, the planning department develops a production and inventory plan, which is updated on a monthly basis, and places orders with suppliers for any inventory which is expected to decline below targeted levels.

During the Track Record Period, we did not experience any material shortage of inventory.

QUALITY MANAGEMENT

We have a quality management department to control the quality of our products. We have our own quality management system and devote significant attention to ensure the quality of the designing, R&D manufacturing, testing and transportation of our products and product candidates. Our management team is actively involved in setting quality policies and managing our internal and external quality performance. We have established a strict quality management system through certification to the ISO13485:2016 standard, in accordance with regulations in China, EU, the U.S. and any other applicable region.

Our quality management department consists of a quality control team and a quality assurance team. Our quality control team is responsible for inspecting raw materials, production process and the quality of finished goods. Our quality assurance team focuses on the establishment, implementation and maintenance of our quality management system, as well as monitoring our operation in real time throughout the entire development and production process to ensure its compliance with the applicable regulatory and industry requirements.

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Quality Control of Raw Material Supply

Prior to entering into supply agreements with our raw material suppliers, we perform background checks on the operating history, track record and market reputation of a list of potential suppliers, procure different product samples from the potential suppliers for inspection and testing by our quality management department, conduct site visits and examine the production facilities of the potential suppliers to help ensure that the suppliers that we select meet our quality requirements.

For our principal raw materials, critical to the performance of our device, suppliers are obligated to take measures to comply with our quality control standards for their products and production process. We are entitled to conduct on-site audits at the suppliers’ premises to monitor their compliance with agreed quality assurance actions, which may be effected in the form of system, process or product audits. We also conduct off-site information assessments to evaluate the suppliers’ performance. Traceability of the raw material supplies is required for our principal suppliers. Upon receiving supplies, we retain the right to reject or return based on our inspection and examination results.

Quality Control of Inventory

Our quality management department and our warehouse personnel take responsibilities and collaborate to help ensure the quality of our raw materials and products inventory. The quality management department is in charge of inspecting and examining raw materials and products before they are accepted as inventory.

The warehouse personnel is responsible for recording the inventory to ensure the traceability of our raw materials and products, the regular storage, maintenance and inspection of the inventory and warehouse maintenance. Designated warehouse personnel inspect the inventory on a regular basis according to the required storage and maintenance conditions of relevant inventory.

Quality Control of Design and Development

All the procedures of our design and development activities must strictly follow our design and development control policy and procedures, which specifically lists the six stages to develop a new product. As discussed in the section headed “– R&D – Product Design and Pre-Clinical Development” above, the project team for each project consists of representatives from various departments who contribute to our R&D work in their respective expertised fields. At the same time, the project team strictly follows each step of our internal protocol, and the design and development committee closely monitors and reviews key stages along the design and development process.

- (1) Concept Generation. The purpose of this phase is to achieve a conceptual design of the product. Input into this phase comes from sources including but not limited to marketing activities and customers’ specified requirements and typically needs to be further developed. At a minimum, the intended use of the device must be stated. This functional description shall be used during the proof of concept phase to demonstrate the functionality of the design concept.

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- (2) Proof of Concept. The primary purpose of this phase is to demonstrate that the design concept functions as intended and to further define the design requirements.
- (3) Design and Process Development. Formal design controls begin during this phase of the development process. As part of the design and development validation, we or the customers will conduct clinical evaluations and/or evaluations of the performance of the medical device, as required by the regulations.
- (4) Design Verification and Validation. The purpose of this phase is to verify and validate the design using product manufactured under controlled conditions, with adequate traceability that demonstrates conformity to specified requirements. Design and development validation shall be performed in accordance with planned arrangement to ensure that the end product is capable of meeting the requirements for the specified application or intended use.
- (5) Process Validation and Transfer. The purpose of this phase is to demonstrate that the manufacturing process can produce products that consistently meet specifications. This includes production system transfers. A design transfer checklist shall be completed prior to phase review. Primary focus in this phase is in training personnel and demonstrating that manufacturing systems are capable of consistently producing products that meet specifications.
- (6) Commercialization. The purpose of this phase is to complete the product launch activities, including the release of product registration certification notification.

Quality Control for Manufacturing

Our quality management department is responsible for ensuring that we comply with applicable regulatory and industry standards throughout the entire manufacturing process through regular on-site inspections. After completing each step of the production process, we perform cleaning and maintenance procedures to prevent contamination or cross contamination before we proceed to the next production cycle. In addition, we perform regular dust and microbiological testing in our production facilities in accordance with our detailed manufacturing standards.

Each batch of our products is subject to a strict sample inspection before sales. We conduct sample testing on certain work in progress and semi-finished products at particular stages of production. In addition, our quality control team inspects the documentation relating to product quality, including its batch records, laboratory control records, production process records and other information that may impact product quality. Thereafter, they conduct a final review on all documents and determine whether a specific product can be released for shipment.

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After-Sale Quality Control

We are able to track our products sold to our end customers. We analyze feedback from our distributors and hospitals and handle any customer complaints with respect to the quality of our products. Quality complaints, both verbal and written, are documented and investigated pursuant to standard procedures.

If any product falls short of the relevant quality standards, we will replace the defective product at our own costs. During the Track Record Period and up to the Latest Practicable Date, we did not experience any product returns or product liability claims.

INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are important to our business. Our future commercial success depends, in part, on our ability to obtain and maintain patents and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we owned 476 patents and patent applications, including more than 190 invention patents and patent applications, 185 utility models, 13 PCT applications and 49 industry designs. We own 87 issued patents (including pending announcements) and 248 patent applications in China, and 95 issued patents and 46 patent applications overseas. Among the overseas patents, there are 58 issued patents and 20 patent applications in the U.S., 31 issued patents and seven patent applications in Europe, three issued patents and one patent applications in Japan and three issued patents and five patent applications in other overseas countries and regions, and 13 valid applications under the Patent Cooperation Treaty, or PCT, relating to certain of our products, product candidates and technologies.

We obtain patents through primarily self-development or, in limited circumstance, from third parties through patent or asset purchase. Among the 476 patents and patent applications, a majority of them were self-developed, 21 were acquired through purchasing, and 24 patents related to InterVapor, which were formerly owned by Uptake Medical Corp., which we acquired through the asset purchase agreement signed in July 2016, and the legal titles for such patents were transferred to our subsidiary. Besides the patents and patent applications we owned, as of the Latest Practicable Date, we also in-licensed a total of 33 issued patents.

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The table below lists the portfolio of patents and patent applications of our Core Products as of the Latest Practicable Date:

Name of Patent	Application/ Patent number	Status	Related products	Granting authority	Covered region	Inventor identity	Validity until
Device And Method For Lung Treatment	CN200580046606.8	Issued	InterVapor	SIPO	China	ROBERT L. BARRY BRIAN CRAN DEAN T. CORCORAN SHELDON K LEE	November 16, 2025
Device And Method For Lung Treatment	US13/073, 660	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN DEAN CORCORAN SHELDON K LEE.	March 26, 2028
Device And Method For Lung Treatment	US15/582, 765	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN DEAN T. CORCORAN SHELDON K LEE.	January 29, 2026
Device And Method For Lung Treatment	US14/703, 580	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN THOMAS DEAN T. CORCORAN SHELDON K LEE.	November 16, 2025
Device And Methods For Lung Treatment	JP2007-543222	Issued	InterVapor	JPO	Japan	ロバート・エル・パリー ブライアン・クラン・ディ ーン・コーコラン・シエル ドン・ケイ・リー	November 16, 2025
Device And Method For Lung Treatment	US11/281, 212	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN DEAN CORCORAN SHELDON K LEE.	January 9, 2030
Treatment With High Temperature Vapor	US11/598,362	Issued	InterVapor	USPTO	United States	ROBERT BARRY DEAN CORCORAN BRIAN CRAN MICHAEL HOEY SHELDON LEE PETER LYONS	January 17, 2032
High Pressure And High Temperature Vapor Catheters And Systems	US13/073, 660	Issued	InterVapor	USPTO	United States	ROBERT BARRY DEAN CORCORAN BRIAN CRAN MICHAEL HOEY SHELDON LEE PETER LYONS	November 21, 2027

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Name of Patent	Application/ Patent number	Status	Related products	Granting authority	Covered region	Inventor identity	Validity until
High Pressure And High Temperature Vapor Catheters And Systems	US11/589, 383	Issued	InterVapor	USPTO	United States	ROBERT BARRY DEAN CORCORAN BRIAN CRAN MICHAEL HOEY SHELDON LEE PETER LYONS	December 25, 2027
Determining Patient-Specific Vapor Treatment And Delivery Parameters	US12/409, 370	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN ERIK HENNE DANIEL REDDY DEAN CORCORAN	March 3, 2031
Determining Patient-Specific Vapor Treatment And Delivery Parameters	US13/675, 989	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN ERIK HENNE DANIEL REDDY DEAN CORCORAN	October 22, 2028
Determining Patient-Specific Vapor Treatment And Delivery Parameters	US12/256, 197	Issued	InterVapor	USPTO	United States	ROBERT L. BARRY BRIAN CRAN ERIK HENNE DANIEL REDDY DEAN CORCORAN	September 6, 2030
Determining Patient-Specific Vapor Treatment And Delivery Parameters	JP2011-501015	Issued	InterVapor	JPO	Japan	ロバート・エル・パリー ブライアン・クラン エリ ック・ヘンダニエル・レデ イ デイーン・コーコラン	March 23, 2029
Preferential Volume Reduction Of Diseased Segments Of A Heterogeneous Lobe	US14/504, 042	Issued	InterVapor	USPTO	United States	ROBERT BARRY LAWRENCE ERIK HENNE AVINA GUPTA SOURISH BANDYOPADHYAY	August 7, 2035
Vapor Treatment Of Lung Nodules And Tumors	US14/957, 433	Issued	InterVapor	USPTO	United States	ERIK HENNE ROBERT BARRY LAWRENCE ROBERT ALAN MEST	April 17, 2038
Medical Vapor Generator	US15/013, 748	Issued	InterVapor	USPTO	United States	JOSHUA PIETER KROON ERIK HENNE DANIEL REDDY LAWRENCE ROBERT ALAN MEST RYAN WELTY	May 14, 2037

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Name of Patent	Application/ Patent number	Status	Related products	Granting authority	Covered region	Inventor identity	Validity until
Steam type ablation equipment (一種蒸汽式消融設備)	ZL201922453861.6	Issued	InterVapor	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
Box body of steam ablation instrument (一種蒸汽消融儀箱體)	ZL201922453703.0	Issued	InterVapor	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Rear handle structure of box body of steam ablation instrument (蒸汽消融儀的箱體後側把手結構)	ZL201922463852.5	Issued	InterVapor	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Inlet trigger device (進水口觸發裝置)	ZL201922453702.6	Issued	InterVapor	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
Outlet trigger device (出水口觸發裝置)	ZL201922459894.1	Issued	InterVapor	CNIPA	China	Wei Jiang Hong Xu Le Zhou	December 31, 2029
Fastener trigger device (緊固件觸發裝置)	ZL201922459374.0	Issued	InterVapor	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
Condensation cycle device of steam ablation equipment (蒸汽消融設備的冷凝循環裝置)	ZL201922457717.X	Issued	InterVapor	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Detection and control device for steam ablation equipment (蒸汽消融設備的檢測控制裝置)	ZL201922457705.7	Issued	InterVapor	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
Overpressure protection device for steam ablation equipment (蒸汽消融設備的過壓保護裝置)	ZL201922457699.5	Issued	InterVapor	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Ionized water identification device of steam ablation equipment (蒸汽消融設備的離子水識別裝置)	ZL201922466281.0	Issued	InterVapor	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
The structure of the handle of the steam ablation instrument (蒸汽消融儀的把手的結構)	ZL201922464640.9	Issued	InterVapor	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
High-pressure disinfection device for steam ablation equipment (蒸汽消融設備的高壓消毒裝置)	ZL201922459407.1	Issued	InterVapor	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Steam ablation catheter and steam ablation equipment (蒸汽消融導管及蒸汽消融設備)	ZL202021208749.2	Issued	InterVapor	CNIPA	China	Hong Xu Maoqiang Wang Xiangxiang Qin	June 24, 2030

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Name of Patent	Application/ Patent number	Status	Related products	Granting authority	Covered region	Inventor identity	Validity until
Radio frequency ablation catheter, lung radio frequency ablation system, and corresponding control method, control device and computer readable storage medium (射頻消融導管、肺部射頻消融系統、以及相應的控制方法、控制裝置和計算機可讀存儲介質)	PCT/CN2019/082546	Published	RF II	WIPO	PCT	Hong Xu Huazhen Zhou Liming Wang Song Jiang Chenhui Su	N/A
Radiofrequency ablation catheter (射頻消融導管)	ZL201920492840.2	Issued	RF II	CNIPA	China	Changgao Zhong Shiyue Li Hong Xu Huazhen Zhou Liming Wang Song Jiang Chenhui Su	April 12, 2029
Lung radio frequency ablation system, control method, control device and computer readable medium, and radio frequency ablation catheter (肺部射頻消融系統以及控制方法、控制裝置和計算機可讀介質,以及射頻消融導管)	2019102926888	Issued	RF II	CNIPA	China	Jie He Bin Qiu Hong Xu Huazhen Zhou Liming Wang Song Jiang Chenhui Su	April 12, 2039
Radiofrequency ablation catheter conducive to heat exchange medium distribution (利於換熱介質分配的射頻消融導管)	ZL201920492839.X	Issued	RF II	CNIPA	China	Shiyue Li Changgao Zhong Hong Xu Huazhen Zhou Liming Wang Song Jiang Chenhui Su	April 12, 2029
Adjustable bendable radiofrequency ablation catheter (可調彎的射頻消融導管)	ZL201920491933.3	Issued	RF II	CNIPA	China	Jie He Bin Qiu Hong Xu Huazhen Zhou Liming Wang Song Jiang Chenhui Su	April 12, 2029

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Name of Patent	Application/ Patent number	Status	Related products	Granting authority	Covered region	Inventor identity	Validity until
Radio frequency ablation catheter capable of monitoring temperature at multiple points (可多點監控溫度的射頻消融導管)	ZL201920492108.5	Issued	RF II	CNIPA	China	Jie He Hong Xu Huazhen Zhou Liming Wang Song Jiang Chenhui Su	April 12, 2029
A remote display device applied to ablation system (一種應用於消融系統的遠程顯示設備)	ZL201922453805.2	Issued	RF II	CNIPA	China	Hong Xu Wei Jiang	December 31, 2029
Radio frequency ablation instrument with folding support frame (一種帶有折疊支撐架的射頻消融儀)	ZL201922463868.6	Issued	RF II	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Dust-proof knob of radio frequency ablation instrument (一種射頻消融儀防塵旋鈕)	ZL201922458707.8	Issued	RF II	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029
Display panel for ablation instrument convenient for maintenance (一種便於檢修的消融儀用顯示面板)	ZL201922467185.8	Issued	RF II	CNIPA	China	Wei Jiang Hong Xu	December 31, 2029

The term of an individual patent may vary based on the countries/regions in which it is granted. In most countries and regions in which we file patent applications, including China and the U.S., the term of an issued patent generally ranges from 10 to 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the U.S., a patent’s term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in excess of a patent applicant’s own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly-owned patent having an earlier expiration date.

In addition, with respect to any issued patents in the U.S. and Europe, we may be entitled to obtain an extension of the patent’s term provided we meet the applicable requirements for obtaining such patent term extension. The exact duration of the extension depends on the time we spend in clinical studies, as well as obtaining approvals from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of five years from the date of product approval, only one patent may be extended, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country 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 country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue 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 or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

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We may 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 agreements with consultants, and contractors. We have entered into confidentiality agreements and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we use to employ our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. See “Risk Factors – Risks Relating to Our Operations – Our internal computer systems may fail or suffer security breaches.”

We also own a number of registered trademarks and pending trademark applications. As of the Latest Practicable Date, we had registered trademarks for our Company and our corporate logo in PRC and other jurisdictions and are seeking trademark protection for our Company and our corporate logo in the U.S. and other countries where available and appropriate.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent. The Joint Sponsors have discussed with our management and our intellectual property counsel on whether there are any instances of infringement of third parties intellectual property rights by us, and have also reviewed the due diligence report on our intellectual property rights prepared by our intellectual property counsel. As far as our Directors are aware, there had not been any instances of infringement of third parties’ intellectual property rights by us as of the Latest Practicable Date. For details, see “Appendix VI – Statutory and General Information – Further Information about Our Business – Intellectual Property Rights.”

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COMPETITION

The market in which we operate is characterized by rapid changes resulting from technological advances and scientific discoveries. In addition, it is subject to changes in the overall healthcare industry in China and globally. While we believe that our product development experience and robust R&D capabilities provide us with competitive advantages, we face potential competition from various sources, including major international medical device companies as well as domestic medical device manufacturers which are also developing the navigation system and interventional diagnosis or treatment devices.

We compete primarily on the basis of our products’ proven track record of efficacy and safety, our first-mover advantage in the international market, brand recognition among hospitals and doctors and the level of technical support and training we provide to doctors. We believe that our continued success depends on our ability to (i) innovate and develop advanced technology; (ii) apply our technology across product lines; (iii) develop a broad portfolio of proprietary products; (iv) maintain our efficient and cost-effective R&D model; (v) attract and retain skilled personnel; (vi) maintain high quality standards; (vii) obtain and maintain regulatory approval or CE Marking certification; and (viii) effectively market our products.

Several of our competitors have significantly greater financial and other resources and may have longer track records and greater expertise in R&D, clinical trial, obtaining regulatory approval or CE Marking certification and commercialization of approved or CE Marked products and may enjoy wide brand name recognition globally. Mergers and acquisitions in the medical device industry may result in even more resources being concentrated among a small number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies or products complementary to, or necessary for, our products.

Our competitors dedicate, and we believe they will continue to dedicate, significant resources to promote their products aggressively. They may develop technologies and products that are safer, more effective, easier to use or less expensive than ours. They may also obtain FDA, NMPA or other regulatory approval or CE Marking certification for their products earlier than we obtain approval or CE Marking certification for ours, which could result in our competitors establishing a strong market position ahead of us. We may encounter doctors, especially in the global market, who are committed to or prefer the products offered by our competitors due to existing relationships with our competitors. Any of these events could reduce or eliminate our commercial opportunities.

For competitive landscape of our products and product candidates, see “– Our Products and Product Pipeline” and “Industry Overview.”

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EMPLOYEES

As of the Latest Practicable Date, we had 234 employees in total. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number
Product Development (R&D, clinical trial, registration, intellectual property)	100
Manufacturing and Quality Control	29
Sales and Marketing	84
General ⁽¹⁾	21
Total	234

Note:

(1) General includes human resource department, finance department, legal department and others.

Among the 234 employees, 190 of our employees are stationed in China, and 44 of our employees are stationed overseas primarily in the U.S. In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, bonuses, employee benefits, confidentiality obligations, non-competition and grounds for termination.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and stock incentive plans to some employees especially key employees.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes, labor disputes or industrial action which had a material effect on our business, and we consider our relations with our employees to be good. As of the Latest Practicable Date, we did not have any non-compliance with statutory social security insurance fund and housing fund obligations applicable to us under applicable laws in all material respects.

Employment Agreements with Key Management and R&D Staff

We enter into standard confidentiality and employment agreements with our key management and R&D staff. The contracts with our key personnel typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for no more than two years after the termination of his or her employment. The contracts also typically include undertakings regarding

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assignment of inventions and discoveries made during the course of his or her employment. For further details regarding the terms of confidentiality and employment agreements with our key management, see “Directors and Senior Management.”

None of our employees is currently represented by any labor union. We believe that we maintain good working relationships with our employees and we did not experience any significant labor disputes or any significant difficulty in recruiting staff for our operations during the Track Record Period and up to the Latest Practicable Date.

INSURANCE

Our principal insurance policies cover property loss due to accidents, product damage during shipment and adverse events in clinical trials. We currently do not maintain product liability insurance or key person insurance.

PROPERTIES AND FACILITIES

We are headquartered in Hangzhou, China with an aggregate leased area of approximately 5,188 sq.m. currently in use. This includes approximately 2,702 sq.m. of floor area for manufacturing facilities including storage, 420 sq.m. for laboratories, and 2,066 sq.m. for office use. We have also rented offices in other provinces in China. In addition, we have an aggregate rented area of approximately 373 sq.m. in Shanghai and 77 sq.m. in Guangzhou for sales and clinical team and an aggregate rented area of approximately 863 sq.m. in San Jose, CA, the U.S. for manufacturing facilities.

The relevant lease agreements generally provide a duration of four years. As of the Latest Practicable Date, we had completed all of our lease registrations except for six leases with the relevant regulatory authorities. With respect to unregistered leases, our PRC Legal Advisor is of the view that the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations. Therefore, we have the right to use such properties in accordance with the lease agreement but we may be subject to the risks of fines if the lease registration is not completed as required by the relevant local housing administrative authorities. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. During the Track Record Period, we did not experience any dispute arising out of our leased properties.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of December 31, 2020. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 38(1) of the

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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 of our Group’s interests in land or buildings.

ENVIRONMENTAL PROTECTION, OCCUPATIONAL HEALTH AND SAFETY

We are subject to various environmental protection and occupational health and safety laws and regulations. Our operations involve the use of hazardous and flammable chemical materials. Our operations also produce such hazardous waste. We contract with a third-party company for the disposal of these materials and wastes. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations during the period.

We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. Our employees responsible for manufacturing and quality control and assurance are required to hold relevant qualifications, as well as wear the proper safety gear when working. We conduct regular safety inspections and maintenance for our manufacturing facility.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the Chinese and global medical device markets, our ability to develop, manufacture and commercialize our products and product candidates, and our ability to compete with other medical device companies. For details of various risks and uncertainties we face, see “Risk Factors.” We also face various financial risks. In particular, we are exposed to credit, liquidity, interest rate and foreign exchange risks that may arise in the normal course of our business.

We have adopted a consolidated set of risk management policies 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 Directors supervise the implementation of our risk management policies. Risks identified by our management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

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The following key principles outline our Group’s approach to risk management and internal control:

- Our Audit Committee oversees and manages the overall risks associated with our business operations, including:
 - o reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives;
 - o reviewing and approving our corporate risk tolerance;
 - o monitoring the most significant risks associated with our business operation and our management’s handling of such risks;
 - o reviewing our corporate risk in light of our corporate risk tolerance; and
 - o monitoring and ensuring the appropriate application of our risk management framework across our Group.
- Our senior management are responsible for:
 - o formulating and updating our risk management policy and objectives;
 - o reviewing and approving major risk management issues of our Company;
 - o promulgating risk management measures;
 - o providing guidance on our risk management approach to the relevant departments in our Company;
 - o reviewing the relevant departments’ reporting on key risks and providing feedback;
 - o supervising the implementation of our risk management measures by the relevant departments;
 - o ensuring that the appropriate structure, processes and competences are in place across our Group; and
 - o reporting to our Audit Committee on our material risks.

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- The relevant departments in our Company, including the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments shall:
 - o gather information about the risks relating to their operation or function;
 - o conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives;
 - o prepare a risk management report annually for our chief executive officer’s review;
 - o monitor the key risks relating to their operation or function;
 - o implement appropriate risk responses where necessary; and
 - o develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Intellectual Property Rights Risk Management

Compliance with applicable PRC and overseas laws and regulations, especially laws and regulations governing the protection of our intellectual property rights and the prevention of liabilities resulting from potential illegal content of publication and intellectual properties infringement are major focus areas of our operational risk management. Our legal department is responsible for approving contracts, monitoring any changes in the applicable laws and regulations and ensuring the ongoing compliance of our operations with the applicable law and regulations.

Our intellectual property department assists in conducting searches to help ensure that all of our intellectual property is under the protection of relevant laws and regulations, and also helps ensure the application for trademark, copyright or patent registrations for, as well as filing with relevant authorities of all of our products. For example, under our internal policies, during the product development phase, our intellectual property department shall assess the potential legal issues surrounding the product being developed. The intellectual property department shall then administer the execution process of obtaining the necessary filings, approvals, and/or licenses. All the contracts of our Company are required to be reviewed and approved by our legal department prior to execution. In addition, we establish policies for intellectual property infringement notices to help ensure timely monitoring the infringement incidents.

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Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our operations, such as protection of intellectual property, environmental protection and occupational health and safety. We provide periodic training on these measures and procedures to our employees as part of our employee training program. We also regularly monitor the implementation of those measures and procedures through our on-site internal control team for each stage of the produce development process.
- Our Directors (who are responsible for monitoring the corporate governance of our Group) with assistance from our legal advisors, will periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established the Audit Committee which shall (i) make recommendations to our Directors on the appointment and removal of external auditors; and (ii) review the financial statements and render advice in respect of financial reporting as well as oversee the risk management and internal control procedures of our Group. For more details, see “Directors and Senior Management – Board Committees – Audit Committee.”
- We have engaged Red Solar Capital Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [REDACTED] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of the [REDACTED] from the [REDACTED] complies with the section entitled “Future Plans and Use of [REDACTED]” in this document after the [REDACTED], as well as to provide support and advice regarding the requirements of relevant regulatory authorities in a timely fashion.
- We will continue to arrange various training to be provided by external legal advisors from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management and relevant employees on the latest applicable laws and regulations.
- We maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities. We also monitor to ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements, which include restrictions on promoting our products for unapproved uses or patient populations, also known as off-label use, and limitations on industry-sponsored scientific and educational activities.

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LEGAL PROCEEDINGS AND COMPLIANCE

We may be involved in legal proceedings in the ordinary course of business from time to time. During the Track Record Period and up to the Latest Practicable Date, none of us or our Directors were involved in any litigation, arbitration or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations. As advised by our legal advisers, during the Track Record Period and up to the Latest Practicable Date, we had complied with the applicable laws and regulations in all material respects.

LICENSES AND PERMITS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material licenses required for our operation in the PRC and overseas:

License/Permit	Holder	Grant Date	Expiration Date
PRC Class II medical device business license (滬嘉食藥監械經營許20159015號)	Broncus Hangzhou	March 4, 2020	March 3, 2025
PRC Class II medical device manufacture license (浙食藥監械生產許20180031號)	Broncus Hangzhou	March 30, 2021	September 2, 2023
NMPA registration of FleXNeedle (國械注進20142145589)	Broncus Medical	November 14, 2019	November 13, 2024
NMPA registration of Bronchoscopic Path Planning Software (國械注進20143215540)	Broncus Medical	December 23, 2019	December 22, 2024
ZJMPA registration of Disposable Endoscope Suction Biopsy Needle (一次性內窺鏡吸引活檢針) (浙械注准20192020448)	Broncus Hangzhou	August 6, 2019	August 5, 2024
ZJMPA registration of Disposable Endoscope Suction Biopsy Needle (一次性內窺鏡吸引活檢針) (浙械注准20202020594)	Broncus Hangzhou	June 18, 2020	June 17, 2025

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License/Permit	Holder	Grant Date	Expiration Date
ZJMPA registration of Disposable Bronchoscope Guiding Sheath (一次性使用支氣管鏡導引鞘管) (浙械注准20182220310)	Broncus Hangzhou	June 11, 2018	June 10, 2023
ZJMPA registration of Disposable Bronchoscope Balloon Dilatation Catheter (一次性使用支氣管鏡球囊擴張導管) (浙械注准20182220311)	Broncus Hangzhou	June 11, 2018	June 10, 2023
PRC Class III medical device business license (滬嘉食藥監械經營許20159015號)	Broncus Shanghai	March 4, 2020	March 3, 2025
PRC Class II medical device business license (浙杭食藥監械經營備20210335號)	Broncus Hangzhou	February 2, 2021	Permanent
PRC Class III medical device business license (浙杭食藥監械經營許20180903號)	Broncus Hangzhou	July 30, 2020	September 11, 2023
NMPA registration of LungPro (國械註進20143015541)	Broncus Medical	December 23, 2019	December 22, 2024
ZJMPA registration of disposable adjustable curved sheath of bronchoscope (一次性使用支氣管鏡可調彎鞘管) (浙械註准20202020681)	Broncus Hangzhou	July 14, 2020	July 13, 2025
Quality management system – ISO 13485:2016 (MD 666917)	Broncus Hangzhou	May 11, 2020	May 10, 2023
EC certificate – Full quality assurance system (CE 562232)	Broncus Medical	June 25, 2020	May 26, 2024
Quality management system – ISO 13485:2016 (FM 701870)	Broncus Medical	May 7, 2019	May 6, 2022
EC certificate – Full quality assurance system (CE 678945)	Uptake Medical B.V.	December 17, 2020	May 26, 2024
Quality management system – ISO 13485:2016 (FM 694785)	Uptake Medical B.V.	February 24, 2020	February 23, 2023

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AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and projects for which we received government grants as of the Latest Practicable Date:

<u>Award/Project</u>	<u>Award/ Grant year</u>	<u>Award/ Grant Authority</u>	<u>Grant Amount</u>	<u>Expected Completion Date</u>
2018 Hangzhou Technology Start-ups Cultivating Project (Eyas Plan) (2018年杭州市科技型初創企業培育工程企業(雛鷹計劃))	2018	Hangzhou Municipal Science and Technology Bureau	RMB50,000	Completed in 2019
2018 Municipal Technology Start-ups (2018年度市級科技型初創企業)	2018	Hangzhou Municipal Science and Technology Bureau	RMB100,000	Completed in 2019
2019 Hangzhou Eyas Plan Corporate Loan Interest Subsidy (2019年杭州市“雛鷹計劃”企業貸款貼息資助經費)	2019	Hangzhou Municipal Science and Technology Bureau	RMB435,000	Completed in 2019
Zhejiang Science and Technology SMEs (2019年第三批浙江省科技型中小企業資助經費補助)	2019	Zhejiang Provincial Department of Science and Technology	RMB10,000	Completed in 2020
The Key R&D Program of National 13th Five-year Plan (國家十三五重點研發計劃項目) – Research on key technologies for integrated interventional diagnosis and treatment solutions of lung cancer based on augmented reality (AR) navigation system (基於增強現實導航的肺癌介入診治一體化關鍵技術研究)	2017	Ministry of Science and Technology of the People’s Republic of China (中華人民共和國科學技術部)	RMB750,000	Completed in 2021

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<u>Award/Project</u>	<u>Award/ Grant year</u>	<u>Award/ Grant Authority</u>	<u>Grant Amount</u>	<u>Expected Completion Date</u>
Science and Technology Innovation Action Program of Shanghai (上海市科技創新行動計劃項目) – Clinical study of pulmonary lesion sampling planning navigation system (肺部病灶取樣規劃導航系統的臨床研究)	2015	Science and Technology Commission of Shanghai Municipality (上海市科學技術委員會)	RMB462,000	Completed in 2018
Science and Technology Innovation Action Program of Shanghai (上海市科技創新行動計劃項目) – Construction and application of multi-person collaborative immersive virtual and augmented reality surgery demonstration platform (多人協同沉浸式虛擬與增強現實手術示範平台構建及應用)	2017	Science and Technology Commission of Shanghai Municipality (上海市科學技術委員會)	RMB1,210,000	Completed in 2020
Hangzhou High-tech Zone (Binjiang) Science and Technology Bureau window patent and software copyright funding (杭州高新區(濱江)科技局窗口專利與軟件著作權資助)	2019	Hangzhou High-tech Zone (Binjiang) Science and Technology Bureau (杭州高新區(濱江)科技局)	RMB80,000	Completed in 2020
R & D Expenditure Subsidy Scheme for Municipal Science and Technology Enterprises in 2020 (2020年市科技型企業研發費用投入補助計劃)	2020	Hangzhou Municipal Science and Technology Bureau (杭州市科學技術局)	RMB500,000	Expected to be completed in 2021
Rental Subsidies for Industrial Support Funds in Hangzhou High-tech Zone (Binjiang) (杭州高新區(濱江)產業扶持資金房租補貼)	2019	Hangzhou High-tech Zone (Binjiang) Bureau of Commerce (杭州高新區(濱江)商務局)	RMB629,600	Completed in 2020
Hangzhou ‘Eagle Project’ Enterprise Loan Subsidy Scheme 2020 (2020年杭州市“雛鷹計劃”企業貸款貼息資助計劃)	2020	Hangzhou Municipal Science and Technology Bureau (杭州市科學技術局)	RMB415,000	Expected to be completed in 2021

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You should read the following discussion and analysis with our audited consolidated financial information, including the notes thereto, included in the Accountants’ Report in Appendix I to this document. Our consolidated financial information has been prepared in accordance with IFRS, which may differ in material aspects from generally accepted accounting principles in other jurisdictions, including the U.S.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” in this document.

For the purpose of this section, unless the context otherwise requires, references to 2019 and 2020 refer to our financial year ended December 31 of such year. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

We are a pioneer in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Leveraging our whole lung access navigation technology and encompassing navigation, diagnosis and treatment, our integrated interventional pulmonology platform addresses the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases.

Led by our experienced management team with an average of over 20 years of experience in designing, developing and commercializing medical devices, we believe that by leveraging on their expertise, we are well positioned to capture the significant commercial opportunities in the large and fast-growing market for the lung disease treatment with a focus on chronic obstructive pulmonary disease (“**COPD**”) and lung cancer in China and globally. We also benefit from our stable and dedicated senior management personnel with complimentary background and expertise. Members of our board and management team have experience in commercializing medical devices such as peripheral vascular intervention products, and our transcatheter aortic valve replacement systems in China, the U.S. and Europe.

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We are backed by a number of large institutional investors focused on the healthcare sector, such as Qiming Venture Capital, DiNovA Capital, LAKE Bleu Capital and FountainVest, and strategic investors including Intuitive Surgical, a global technology leader in robotic-assisted, minimally invasive surgical platforms and diagnostic tools listed on the Nasdaq Stock Market (NASDAQ: ISRG).

Under the leadership of our management team and with the support of our investors, we have successfully developed the world’s first and only real-time image whole lung access augmented reality navigation system, which enabled us to build an integrated product portfolio for lung disease diagnosis and treatment supported by the navigation system. Our whole lung access navigation system enables access to any part of the entire lung, both inside and outside of the airways, based on which we are able to develop revolutionary medical devices and solutions to transform the diagnosis and treatment paradigms of lung diseases. Our LungPoint ATV System, also known as LungPro in the mainland of China or the Archimedes System outside mainland China (the “**Archimedes System**”)¹ is the world’s only navigation system capable of whole lung access augmented reality real-time image navigation, according to Frost & Sullivan. Our proprietary Bronchoscopic Trans-Parenchymal Nodule Access (“**BTPNA**”) technology supporting the Archimedes System is able to precisely access any part of the entire lung and lead directly to lesions away from or adjacent to an airway by establishing a standard 2mm working channel through pulmonary parenchyma, creating a direct path to further diagnosis and treatment. Fully integrated with our lung navigation system, we offer a comprehensive portfolio of industry-leading interventional diagnostic and therapeutic products. Our InterVapor system (the “**InterVapor**”) is the world’s first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer, according to Frost & Sullivan. We are also developing RF Generator + RF Ablation Catheter (“**RF-II**”), a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung diseases. We have also developed a pulmonary surgery marker, H-Marker, to mark the location of the lung nodule to realize precise positioning. We also offer a variety of diagnostic medical consumables. Our diagnostic solutions facilitate the early diagnosis and treatment of lung diseases, which could in turn help increase survival rates for patients. We believe that our three-in-one pulmonology platform which delivers the features of navigation, diagnostics and treatment with high accuracy, minimal side effects and lower costs has created high entry barriers to market followers and resulted in high switch cost for doctors or patients, thereby strengthening our market position in the interventional pulmonology medical device space in China and globally.

¹ LungPro and the Archimedes System are used interchangeably in this document.

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We have incurred net losses of US\$32.6 million and US\$48.8 million for the years ended December 31, 2019 and 2020. We expect to continue to incur net losses in the near future as we strive to step up R&D operations, continuously develop product candidates, seek regulatory approval or CE Marking certification for product candidates and commercialize product candidates. Our revenue decreased from US\$8.1 million for the year ended December 31, 2019 to US\$3.3 million for the year ended December 31, 2020.

BASIS OF PREPARATION

The consolidated financial information of our Group has been prepared in accordance with International Financial Reporting Standards (“IFRSs”) and the interpretations issued by the International Accounting Standards Board applicable to companies reporting under IFRS. The consolidated financial information has been prepared under the historical cost convention, except for debt investments measured at fair value through profit or loss and convertible redeemable preferred shares which have been measured at fair value. The consolidated financial information of our Group is presented in USD and all values are rounded to the nearest thousand except when otherwise indicated. The preparation of consolidated financial information in conformity with IFRS requires the use of certain reasonable accounting estimates. It also requires management to exercise its judgment in the process of applying our Company’s accounting policies.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below.

Our Ability to Increase Sales Volume of navigation systems, InterVapor, RF-II and H-Marker

As a pioneer in the interventional pulmonology medical device market, our success is highly dependent on our continuous clinical training and early market education efforts to promote market awareness and cultivate market needs of our products. The sales volume of our current products will affect our results of operation in the next several years. Our revenue during the Track Record Period primarily comprised of sales of our navigation systems. We expect that sales of our navigation systems will continue to account for a substantial portion of our total revenue in the near term. We intend to increase sales of our navigation systems and InterVapor to hospitals with which we have existing relationships and expand our sales network to cover more hospitals in China and globally through our in-house sales and marketing team or through our distributors.

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Specifically, we plan to focus on and expand early market education to cultivate market needs for interventional pulmonology diagnostic and therapeutic solutions, and to increase sales efforts to deepen penetration in hospitals to which we currently sell our navigation systems and InterVapor for COPD. We expect the demand for interventional pulmonology medical devices in these hospitals will continue to grow as doctors’ and patients’ awareness of interventional diagnosis and treatment for lung diseases increases in the near future. We also plan to expand into new hospitals and increase the application of interventional diagnosis and treatment for lung diseases by more doctors in China and globally by providing systematic training to doctors and continuing our sponsorship and participation in academic conferences. Furthermore, we will promote the awareness of interventional pulmonology diagnosis and treatment among more eligible patients through our cooperation with public health organizations and foundations. We plan to focus our selling efforts on establishing and maintaining relationships with hospitals that possess top-tier interventional pulmonology technology and resources to further promote our navigation systems, InterVapor, RF-II and H-Marker and increase our revenue in the near future.

Enhancement of Our Platform

Our ability to enhance our platform, develop and commercialize pipeline products and further expand indications leveraging our three-in-one pulmonology platform significantly affects our results of operations. Our market-driven R&D activities focus on product candidates that address rapidly growing clinical needs for interventional pulmonology diagnosis and treatment in China and globally. Our product candidates cover the full spectrum of interventional pulmonology solutions from navigation and diagnosis to treatment. The integration of our platform promotes seamless collaboration among different functional groups at key stages in the lifecycle of a product candidate and helps ensure the speed of development and likelihood of success while at the same time reducing the cost of development and nourishing the market needs at early stages. During the years ended December 31, 2019 and 2020, our total R&D costs amounted to US\$11.4 million and US\$9.4 million, accounting for 140.9% and 287.0% of our total revenue, respectively.

Our results of operations also depend on our ability to successfully commercialize our product candidates upon approval or CE Marking certification. We plan to utilize our experience in selling navigation systems in China to market additional interventional pulmonology products. With increasing doctors’ awareness in interventional pulmonology and our established relationships with KOLs, hospitals and doctors, we believe that we can effectively promote our new products in our covered hospitals and expand to new hospitals. Our ability to successfully develop and commercialize new interventional pulmonology products in the manner we contemplate and to achieve the sales we expect is subject to a number of risks, many of which are beyond our control. For further details of the risks relating to the development and commercialization of new products, see “Risk Factors – Risks Relating to Our Business – Risks Relating to the Development of Our Product Candidates.”

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Changes in Pricing of Our Products

Changes in our products’ selling prices constitute another important factor that affects our operating results. In line with market practice, we sell a significant portion of our products to distributors who resell our products to hospitals. As of the Latest Practicable Date, we had 26 active distributors and we directly sold our products to 103 hospitals. Our navigation systems and InterVapor are priced through the tender or bidding process when directly sold to hospitals from us. We sell our diagnostic medical consumables to distributors at the contract price. Specifically, we sell our diagnosis medical consumables to distributors at the contract price. Hospitals may gain more bargaining power depending on the availability of alternative products, demands of patients and the preference of doctors. If hospitals lower retail prices of our products and therefore reduce the profitability of our distributors, our distributors may have less incentive to purchase and promote our products, and we may need to lower the order price we set for our distributors. However, as hospitals become less sensitive to prices and start to focus more on product performance and medical benefits received from patient treatment, especially when innovative products or treatments can bring diagnostic or therapeutic values, hospitals’ willingness to introduce and adopt new technologies and products will increase regardless of prices. Also, as the role of distributors in the medical device sales chain in China is gradually shifting to purely logistics and distribution providers, the bargaining power of our distributors is expected to reduce in general. As of the Latest Practicable Date, there had been no guidance price set by relevant PRC government authorities on our products. If the government issues pricing guidance, price control, other control measures on our products either at the national or provincial level, our profitability and results of operations may be adversely affected. Moreover, we may also face pricing pressure from competing products or new launch of pipeline products by our competitors. For details, see “Business – Sales and Marketing – Pricing.”

Cost Structure

Our results of operations are significantly affected by our cost structure, which currently and primarily depends on research and development expenses, administrative expenses and selling and distribution expenses.

Since our inception, we have focused our resources on our R&D activities, including conducting pre-clinical studies and clinical trials, and activities related to regulatory filings for our product candidates. Our research and development expenses primarily consist of staff costs that are made of salaries, bonuses, welfare and pension, depreciation and amortization, raw material costs, technical service fees, clinical trial expenses, travel and business related expenses and share awards. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, as we continue to support the clinical trials of our product candidates and as we move these product candidates into additional clinical trials.

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Our administrative expenses consist primarily of staff costs, professional service fees, office expenses, depreciation and amortization, travel expenses and other general expenses incurred for administrative purposes. We expect our administrative expenses to increase in future periods to support our interventional pulmonology product and related AI technology development efforts and support any commercialization activities with respect to our interventional pulmonology product and related AI technology candidates, if approved. We also anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong.

Our selling and distribution expenses primarily consist of staff costs that are made of salaries, bonuses, welfare and pension for our sales and marketing employees, marketing and advertising expenses, travel expenses, share awards and clinical trial expenses. We expect selling and distribution expenses to increase for the foreseeable future as we expand our sales and marketing efforts to deepen the market penetration of our interventional pulmonology products.

We expect our cost structure to evolve as we continue to develop and expand our business. As we continue to progress and expand our pipeline and gradually bring assets of our product pipeline to commercialization, we expect to incur additional costs in relation to our R&D, manufacturing, sales and marketing, among other things. We also anticipate increasing legal, compliance, accounting, insurance, and investor and public relations expenses associated with being a public company in Hong Kong. In addition, pursuant to our agreements with in-licensing partners, we have agreed to pay royalties on our future product sales as contemplated in some case under such licensing agreements.

Funding for Our Operations

For the years ended December 31, 2019 and 2020, we funded our operations primarily through equity and debt financing. Going forward, with the marketing of our current products and the successful commercialization of our product candidates, we expect to fund our operations in part with revenue generated from sales of our products. However, with the continuing expansion of our business and development of product candidates, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations will affect our cash flow and results of operation.

SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

We have identified certain accounting policies that are significant to the preparation of our consolidated financial statements. Some of our accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. Estimates and judgments are continually re-evaluated and are based on historical experience and other factors, including industry practices and expectations of future events that we believe to be reasonable under the circumstances. We have not changed our assumptions or estimates in the past and have not noticed any material errors regarding our assumptions or estimates.

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Under current circumstances, we do not expect that our assumptions or estimates are likely to change significantly in the future. When reviewing our consolidated financial statements, you should consider (i) our critical accounting policies, (ii) the judgments and other uncertainties affecting the application of such policies, and (iii) the sensitivity of reported results to changes in conditions and assumptions.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our significant accounting policies and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in Notes 2 and 3 to the Accountants’ Report in Appendix I to this document.

Significant Accounting Policies

Revenue Recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between us and the customer at contract inception. When the contract contains a financing component which provides us with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sale of medical devices and consumables

Revenue from the sale of medical devices and consumables is recognized at the point in time when control of the asset is transferred to the customer.

(b) Provision of services

Revenue from the product support services is recognised over the service period on a straight-line basis and revenue from research development support services is recognised over time using an input method to measure progress towards complete satisfaction of the service, because the customer simultaneously receives and consumes the benefits provided by us.

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Revenue from other sources

Rental income is recognized on a time proportion basis over the lease terms.

Other income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Fair Value Measurement

We measure certain financial instruments at fair value at the end of each of the Track Record Period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by us. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

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For assets and liabilities that are recognized in the financial statements on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Track Record Period.

Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Intellectual property

Purchased intellectual property is stated at cost less any impairment losses and is amortized on the straight-line basis over its estimated useful life of 12 to 14 years, which is determined by considering the typical product effective life of the intellectual property.

Software

Purchased software is stated at cost less any impairment losses and amortized on the straight-line basis over its estimated useful life of 3 to 10 years.

Research and development cost

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Share-based Payments

Our Company operates a share award plan for the purpose of providing incentives and rewards to eligible participants who contribute to the success of our operations. Our employees (including directors) receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“equity-settled transactions”).

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The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model.

The cost of equity-settled transactions is recognized in expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each of the Track Record Period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. This includes any award where non-vesting conditions within the control of either us or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

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Significant Accounting Estimates

Provision for expected credit losses of trade receivables and finance lease receivables

We use a provision matrix to calculate expected credit losses (“ECLs”) for trade receivables and finance lease receivables. The provision rates are based on ageing for groupings of various customer segments that have similar loss patterns (i.e., by customer type).

The provision matrix is initially based on the historical observed default rates from listed companies in the same sector. We calibrate the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecast economic conditions (i.e., gross domestic product) are expected to deteriorate over the next year which can lead to an increased number of defaults in the medical industry sector, the historical default rates are adjusted. At the end of each of the Track Record Period, the historical observed default rates are updated and changes in the forward-looking estimates are analyzed.

The assessment of the correlation between historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and of forecast economic conditions. Our historical credit loss experience and forecast of economic conditions may also not be representative of customers’ actual default in the future.

Useful lives of intangible assets

Our finite life intangible assets primarily represent patents transferred from third parties. These intangible assets are amortized on a straight-line basis over their useful economic lives, which are estimated to be the patent life. Additional amortization is recognized if the estimated useful lives of patents are different from the previous estimation. Useful lives are reviewed at the end of each of the Track Record Period based on changes in circumstances.

Impairment of non-financial assets

We assess whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Track Record Period. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

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Estimation of the fair value of financial liabilities

Certain financial liabilities are measured at fair value at the end of each of the Track Record Period.

The convertible redeemable preferred shares issued by the Company are not traded in an active market and the respective fair value is determined by using valuation techniques. We applied the discounted cash flow method and back-solve method to determine the underlying equity value of our Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions such as the timing of the liquidation, redemption or the liquidation event as well as the probability of the various scenarios were based on our best estimates.

Fair value measurement of share-based payments

We have set up the certain share plan and granted options to our Company’s directors and our employees. The fair value of the options is determined by a binomial model at the grant dates. Significant estimates on assumptions, including the expected volatility, risk-free interest rate and expected life of options, are made by the board of directors of our Company.

DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS

The table below sets forth our consolidated statements of profit or loss with line items in absolute amounts and as percentages of our revenue for the periods indicated derived from our consolidated statements of profit or loss set out in the Accountants’ Report included in Appendix I to this document:

	For the year ended December 31,			
	2019		2020	
	US\$’000	% of Revenue	US\$’000	% of Revenue
Revenue	8,072	100.0	3,259	100.0
Cost of sales	(2,094)	(25.9)	(753)	(23.1)
Gross profits	5,978	74.1	2,506	76.9
Other income and gains	304	3.8	1,074	33.0
Selling and distribution expenses	(8,609)	(106.7)	(6,352)	(194.9)
Administrative expenses	(8,855)	(109.7)	(7,722)	(236.9)
Impairment losses on financial assets, net	(20)	(0.2)	(214)	(6.6)
Research and development expenses	(11,376)	(140.9)	(9,353)	(287.0)
Finance costs	(517)	(6.4)	(647)	(19.9)

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	For the year ended December 31,			
	2019		2020	
	<i>US\$'000</i>	<i>% of Revenue</i>	<i>US\$'000</i>	<i>% of Revenue</i>
Other expenses	(6)	(0.1)	(456)	(14.0)
Changes in fair value of convertible redeemable preferred shares	(9,448)	(117.0)	(27,620)	(847.5)
Loss before tax	(32,549)	(403.2)	(48,784)	(1,496.9)
Income tax expense	(2)	(0.0)	(2)	(0.1)
Loss for the year	(32,551)	(403.3)	(48,786)	(1,497.0)
Attributable to:				
Owners of the parent	(31,929)	(395.6)	(48,237)	(1,480.1)
Non-controlling interests	(622)	(7.7)	(549)	(16.8)

Revenue

During the Track Record Period, our revenue was mainly generated from sales of medical devices and consumables. In 2019 and 2020, our revenue from sales of medical devices and consumables accounted for 94.2% and 85.5% of our total revenue, respectively. Such medical devices and consumables primarily include our navigation equipment, i.e., LungPoint and the Archimedes System. We expect to continue to generate most of our revenue from sales of medical devices and consumables in the near future. In addition, other revenue consists of revenue generated from product service and support, research sub-award and lease revenue. The following table sets forth a breakdown of our revenue by revenue source for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	<i>US\$'000</i>	<i>% of Revenue</i>	<i>US\$'000</i>	<i>% of Revenue</i>
Sales of medical devices and consumables	7,606	94.2	2,788	85.5
Product service and support	262	3.2	333	10.2
Research sub-award	199	2.5	95	2.9
Lease revenue	5	0.1	43	1.4
Total revenue	8,072	100.0	3,259	100.0

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Cost of Sales

The cost of sales primarily consists of material costs, labor costs, license fee, research sub-award expenses and others. The table below sets forth a breakdown of our cost of sales in absolute amount and as percentage of our total cost of sales for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Cost of Sales				
Material costs	1,616	77.2	442	58.7
Labor costs	106	5.1	53	7.0
License fee	163	7.8	153	20.3
Research sub-award expenses	199	9.5	95	12.6
Others	10	0.4	10	1.4
Total	2,094	100.0	753	100.0

The table below sets forth a breakdown of our cost of sales in absolute amount and as percentage of our total cost of sales by revenue source for the periods indicated:

	For the year ended December 30,			
	2019		2020	
	US\$'000	%	US\$'000	%
Cost of Sales				
Sales of medical devices and consumables	1,895	90.5	658	87.4
Product service and support	–	–	–	–
Research sub-award	199	9.5	95	12.6
Lease revenue	–	–	–	–
Total	2,094	100.0	753	100.0

Our material costs primarily consist of cost of computer workstations, medical optical trackers, metal fabrication assemblies, laptops and catheters and other raw materials. We purchase materials on an as-needed basis at market prices. Material costs comprised a substantial amount of the total cost of sales, accounting for 77.2% and 58.7% of our total cost of sales in the years ended December 31, 2019 and 2020, respectively. The purchase prices of our principal materials remained relatively stable during the Track Record Period. The changes in raw material costs were primarily in line with the changes in cost of sales for our sales of medical devices and consumables.

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Our labor costs primarily include salaries, welfare and pension for employees involved in the production of our products. Labor costs accounted for 5.1% and 7.0% of our total cost of sales in the years ended December 31, 2019 and 2020, respectively.

Our license fee primarily includes the license fee associated with the Archimedes System and LungPoint licensed by Pennsylvania State University and the license fee associated with InterVapor Generator licensed by Tsunami MedTech, LLC. License fee is determined based on the value of the licenses attributable to the revenue generated by the products, accounting for 7.8% and 20.3% of our total cost of sales in the years ended December 31, 2019 and 2020, respectively.

Our research sub-award expenses represent the costs incurred for the interventional pulmonology research services we render to the partnering institutions. Research sub-award expenses accounted for 9.5% and 12.6% of our total cost of sales in the years ended December 31, 2019 and 2020, respectively.

Gross Profit and Gross Profit Margin

Our gross profit represents our revenue less our cost of sales. Our gross profit margin represents our gross profit as a percentage of our revenue. For the years ended December 31, 2019 and 2020, our gross profit was US\$6.0 million and US\$2.5 million, respectively, and our gross profit margin was 74.1% and 76.9%, respectively.

The table below sets forth a breakdown of our gross profit and gross profit margin by revenue source for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	Gross profit	Gross profit margin	Gross profit	Gross profit margin
	US\$'000	%	US\$'000	%
Sales of medical devices and consumables	5,711	75.1	2,130	76.4
Product service and support	262	100.0	333	100.0
Research sub-award	—	—	—	—
Lease revenue	5	100.0	43	100.0
Total	5,978	74.1	2,506	76.9

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Other Income and Gains

Our other income and gains typically consist of government grants, bank interest income and interest income from non-current receivables. The table below sets forth a breakdown of our other income and gains for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Other income and gains				
Other income:				
Government grants	25	8.2	352	32.8
Compensation from termination of a distribution agreement	–	–	632	58.8
Bank interest income	17	5.6	11	1.0
Interest income from non-current receivables	102	33.6	65	6.1
Investment income from debt investments measured at fair value through profit or loss	3	1.0	–	–
Subtotal:	<u>147</u>	<u>48.4</u>	<u>1,060</u>	<u>98.7</u>
Gains:				
Gain on disposal of items of property, plant and equipment	122	40.1	–	–
Gains on termination of a lease	–	–	14	1.3
Foreign exchange gains, net	35	11.5	–	–
Subtotal:	<u>157</u>	<u>51.6</u>	<u>14</u>	<u>1.3</u>
Total	<u><u>304</u></u>	<u><u>100.0</u></u>	<u><u>1,074</u></u>	<u><u>100.0</u></u>

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Government grants mainly represent incentives we received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new product development and expenditure incurred on certain projects. For example, we received government grants from Ministry of Science and Technology of China for our R&D in key technologies of interventional pulmonology therapies. Bank interest income refers to the amount of interest we received from our deposits with commercial banks. Interest income from non-current receivables represents the interest we received from the discounted non-current trade receivables, finance lease receivables and deposits. Investment income represents the return on our investment on the financial instruments we purchased. Foreign exchange gains, net, primarily reflect the increased value of the foreign currency we hold resulting from fluctuated exchange rate.

Selling and Distribution Expenses

Our selling and distribution expenses primarily consist of staff costs, marketing and advertising expenses, travel expenses, share awards, clinical trial expenses and others. The table below sets forth a breakdown of our selling and distribution expenses in absolute amount and as percentage of our total selling and distribution expenses for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Selling and Distribution Expenses				
Staff costs	4,115	47.8	4,135	65.1
Marketing and advertising expenses	984	11.4	760	12.0
Travel expenses	1,185	13.8	720	11.3
Clinical trial expenses	354	4.1	222	3.5
Others	523	6.1	391	6.2
	7,161	83.2	6,228	98.1
Share awards	1,448	16.8	124	1.9
Total	8,609	100.0	6,352	100.0

Our staff costs include salaries, bonuses, welfare and pension for our sales and marketing employees. Our marketing and advertising expenses primarily consist of expenses associated with our sales and marketing activities, such as product promotion expenses, assurance-type after-sales service costs, expense incurred for VBN and ablation procedures training programs and advertising costs. Our travel expenses include any travel expenses incurred for our sales and marketing activities. Share awards refer to the expenses associated with the shares we granted to sales and marketing employees. Our other selling and distribution expenses are mainly comprised of transportation costs, rental expenses, office supplies as well as other expenses that are directly related to our marketing and promotion activities.

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Administrative Expenses

Our administrative expenses primarily consist of staff costs, depreciation and amortization, travel expenses, office expenses, professional service fees, share awards and others. The table below sets forth a breakdown of our administrative expenses in absolute amount and as percentage of our total administrative expenses for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Administrative Expenses				
Staff costs	3,040	34.3	3,104	40.2
Professional service fees	1,939	21.9	3,144	40.7
Office expenses	326	3.7	527	6.8
Depreciation and amortization	367	4.1	405	5.2
Travel expenses	245	2.8	122	1.6
Others	245	2.8	231	3.0
	6,162	69.6	7,533	97.5
Share awards	2,693	30.4	189	2.5
Total	8,855	100.0	7,722	100.0

Our staff costs include salaries, bonuses, welfare and pension for our administrative staff. Depreciation and amortization are primarily related to the depreciation and amortization of our fixed assets for administrative purposes. Travel expenses include any travel expenses incurred during business trips of the administrative employees. Office expenses include utility costs, communication expenses and other general office expenses. Share awards represent the expenses associated with the shares we granted to our administrative employees. Professional service fees primarily consist of the service fees paid to third-party professionals, such as tax advisors, legal advisors, auditors and intellectual property agents, and costs related to the [REDACTED]. Other administrative expenses primarily include office rentals, tax and surcharge and other general expenses incurred for administrative purposes.

Impairment Losses on Financial Assets, Net

Our impairment losses on financial assets, net were US\$20 thousand and US\$214 thousand for the years ended December 31, 2019 and 2020, respectively. Our impairment losses on financial assets, net consist of assets impairment losses on our accounts receivable based on the expected credit loss model.

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Research and Development Expenses

Our research and development expenses incurred in connection with carrying out our product development projects. Our research and development expenses primarily consist of staff costs, depreciation and amortization, raw material costs, technical service fees, clinical trial expenses, travel and business related expenses, share awards, office expenses and other expenses. The table below sets forth a breakdown of our research and development expenses in absolute amount and as percentage of our total research and development expenses for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Research and development expenses				
Raw material costs	648	5.7	854	9.1
Staff costs	4,132	36.3	4,074	43.6
Travel and business related expenses	315	2.8	154	1.6
Office expenses	380	3.3	193	2.1
Technical service fees	1,665	14.6	1,153	12.3
Clinical trial expenses	693	6.1	514	5.5
Depreciation and amortization	1,698	14.9	1,764	18.9
Others	389	3.5	451	4.8
	9,920	87.2	9,157	97.9
Share awards	1,456	12.8	196	2.1
Total	11,376	100	9,353	100.0

Our staff costs include salaries, bonuses, welfare and pension for our research and development employees. Our depreciation and amortization primarily consist of the amortization of intangible assets we purchased historically. Our raw material costs represent expenses on the raw materials used for developing our product candidates. Our technical service fees refer to the service fees we paid to our third-party service providers for complementary services needed for product development, including development of low-value consumables, product testing and other services. Clinical trial expenses include expenses incurred for conducting clinical trials, including payment to CROs and hospitals in relation to our clinical trials. Travel and business related expenses include any travel and administrative expenses incurred for research and development activities. Share awards represent the expenses associated with the shares we granted to our research and development employees. Others are mainly comprised of office rentals, inspection fee and other general expenses incurred for the purpose of research and development.

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Other Expenses

Our other expenses were US\$6 thousand and US\$456 thousand for the years ended December 31, 2019 and 2020, respectively. Our other expenses primarily consist of foreign exchange losses, net, penalty, losses on disposal of property, plant and equipment and intangible assets.

Finance Costs

Our finance costs were US\$0.5 million and US\$0.6 million for the years ended December 31, 2019 and 2020, respectively. Our finance costs mainly consist of interest expenses on bank and other borrowings and interest expense on lease liabilities. The table below sets forth a breakdown of our finance costs in absolute amount and as percentage of our total finance costs for the periods indicated:

	For the year ended December 31,			
	2019		2020	
	US\$'000	%	US\$'000	%
Finance costs				
Interest on bank and other borrowings	359	69.4	465	71.9
Interest on lease liabilities	55	10.7	82	12.6
Interest on other loans from related parties	103	19.9	100	15.5
Total	<u>517</u>	<u>100.0</u>	<u>647</u>	<u>100.0</u>

Changes in Fair Value of Convertible Redeemable Preferred Shares

Changes in fair value of convertible redeemable preferred shares were US\$9.4 million (loss) and US\$27.6 million (loss) for the years ended December 31, 2019 and 2020, respectively. Changes in fair value of convertible redeemable preferred shares represent changes in fair value of our Preferred Shares.

Income Tax Expense

We are tax exempt under the laws of the Cayman Islands.

Our income tax expense consists of the statutory state minimum tax from the U.S.

No provision of Hong Kong Profit Tax was made in these consolidated financial statements as our Group had no assessable profit subject to Hong Kong Profit Tax during the Track Record Period.

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Under the law of the PRC on Enterprise Income Tax (the “**EIT Law**”) and implementation regulations of the EIT Law, our subsidiaries which operate in the mainland of China were entitled to a preferential income tax rate of 20% for small and micro enterprises during the Track Record Period except that Hangzhou Broncus Biological Technology Co., Ltd. was subject to the corporate income tax rate of 25% on the taxable income for the year ended December 31, 2020. However, during the Track Record Period, no provision of PRC profit tax was made as our Group had no assessable profit.

Under the U.S. Tax Cuts and Jobs Act, the U.S. corporate income tax rate has charged at flat rate of 21%. Among our subsidiaries, Broncus Medical was subject to statutory state minimum tax of 8.84% in the State of California of the U.S. during the years ended December 31, 2019 and 2020, respectively.

During the Track Record Period and up to the Latest Practicable Date, we paid all relevant taxes in accordance with tax regulations and did not have any disputes or unresolved tax issues with the relevant tax authorities.

YEAR-TO-YEAR COMPARISON OF RESULTS OF OPERATIONS

Year ended December 31, 2019 Compared to Year ended December 31, 2020

Revenue

Our total revenue decreased by 59.6% from US\$8.1 million for the year ended December 31, 2019 to US\$3.3 million for the year ended December 31, 2020, primarily attributable to the adverse impact over our sales in China, India and the U.S. due to the COVID-19 pandemic, under which hospitals generally decreased their budget on regular medical device purchases with a shift of focus on COVID-19 related equipment purchases. Our revenue is mainly driven by navigation equipment sales, mainly the sales of our LungPoint and Archimedes System. During the year ended December 31, 2020, our equipment sales and marketing activities had been adversely affected globally due to the pandemic, and only a limited number of new orders were generated and delivered for our LungPoint and Archimedes System. However, we believe the impact of the COVID-19 pandemic on our sales performance is temporary. Purchases from hospitals have resumed in China and we expect a gradual recovery in the overseas market as the pandemic gets more controlled.

Cost of Sales

Our cost of sales decreased by 64.0% from US\$2.1 million for the year ended December 31, 2019 to US\$0.8 million for the year ended December 31, 2020, primarily attributable to the decreased raw material costs associated with the decline in our equipment sales. Our cost of sales accounted for 25.9% and 23.1% of our revenue for the year ended December 31, 2019 and 2020, respectively.

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Gross Profit and Gross Profit Margin

As a result of the changes in our revenue and cost of sales described above, our gross profit decreased by 58.1% from US\$6.0 million for the year ended December 31 30, 2019 to US\$2.5 million for the year ended December 31, 2020. Our gross profit margin remained stable for the year ended December 31, 2020 compared to that for the year ended December 31, 2019.

Other Income and Gains

Our other income and gains increased significantly from US\$0.3 million for the year ended December 31, 2019 to US\$1.1 million for the year ended December 31, 2020. Such increase mainly resulted from the increase in government grants, the availability of which depends on whether we have projects entitled to government grants and the budgets of the relevant government entities, and received compensation from the termination of one distributorship arrangement in Europe, partially offset by the decrease in gains on disposal of property, plant and equipment.

Selling and Distribution Expenses

Our selling and distribution expenses decreased by 26.2% from US\$8.6 million for the year ended December 31, 2019 to US\$6.4 million for the year ended December 31, 2020. Such decrease was primarily attributable to (i) our decreased travel expenses from US\$1.2 million for the year ended December 31, 2019 to US\$0.7 million for the year ended December 31, 2020, as a result of less business travel incurred for sales and marketing activities, which were mostly conducted online due to the COVID-19 pandemic, (ii) our decreased share awards for sales and marketing employees from US\$1.4 million for the year ended December 31, 2019 to US\$0.1 million for the year ended December 31, 2020, and (iii) our decreased marketing and advertising expenses from US\$1.0 million for the year ended December 31, 2019 to US\$0.8 million for the year ended December 31, 2020 due to the adverse impact of the COVID-19 pandemic. Selling and distribution expenses as a percentage of our revenue increased from 106.7% for the year ended December 31, 2019 to 194.9% for the year ended December 31, 2020, as a result of the decrease in revenue for the year ended December 31, 2020.

Administrative Expenses

Our administrative expenses decreased by 12.8% from US\$8.9 million for the year ended December 31, 2019 to US\$7.7 million for the year ended December 31, 2020. Such decrease was primarily attributable to (i) our decreased non-[REDACTED] related professional service fees from US\$1.9 million for the year ended December 31, 2019 to US\$1.5 million for the year ended December 31, 2020 as a result of our budget control to maintain operations against the COVID-19 impact, and (ii) our decreased share awards for administrative employees from US\$2.7 million for the year ended December 31, 2019 to US\$0.2 million for the year ended December 31, 2020, partially offset by the [REDACTED] related professional service fees of approximately US\$1.6 million incurred for the year ended December 31, 2020. Administrative expenses as a percentage of our revenue increased from 109.7% for the year ended December 31, 2019 to 236.9% for the year ended December 31, 2020, as a result of the decrease in revenue for the year ended December 31, 2020.

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Impairment Losses on Financial Assets, Net

Our impairment losses on financial assets, net increased by 970.0% from US\$20 thousand for the year ended December 31, 2019 to US\$214 thousand for the year ended December 31, 2020. Such increase was primarily due to a higher proportion of bad debts recorded for more long aging accounts receivable in 2020. Impairment losses on financial assets, net as a percentage of our revenue increased from 0.2% for the year ended December 31, 2019 to 6.6% for the year ended December 31, 2020.

Research and Development Expenses

Our research and development expenses decreased by 17.8%, from US\$11.4 million for the year ended December 31, 2019 to US\$9.4 million for the year ended December 31, 2020. Such decrease was primarily due to (i) decreased technical service fees from US\$1.7 million for the year ended December 31, 2019 to US\$1.2 million for the year ended December 31, 2020 and decreased clinical trial expenses from US\$0.7 million for the year ended December 31, 2019 to US\$0.5 million for the year ended December 31, 2020, as a result of a slow-down in our research and development progress during the year of 2020 due to the adverse impact of the COVID-19 pandemic, and (ii) decreased share awards for our R&D staff from US\$1.5 million for the year ended December 31, 2019 to US\$0.2 million for the year ended December 31, 2020. Our total research and development expenses as a percentage of our revenue increased from 140.9% for the year ended December 31, 2019 to 287.0% for the year ended December 31, 2020, as a result of the decrease in revenue for the year ended December 31, 2020.

Other Expenses

Our other expenses increased from US\$6 thousand for the year ended December 31, 2019 to US\$456 thousand for the year ended December 31, 2020, primarily due to increase of foreign exchange losses of US\$0.3 million resulting from the appreciation of Renminbi against the U.S. dollar during the year of 2020.

Finance Costs

Our finance costs increased by 25.1% from US\$517 thousand for the year ended December 31, 2019 to US\$647 thousand for the year ended December 31, 2020 primarily due to the increase in the interest on our interest-bearing bank and other borrowings and lease liabilities.

Income Tax Expense

We recorded income tax expense of US\$2 thousand in the year ended December 31, 2019 and US\$2 thousand in the year ended December 31, 2020, primarily due to the statutory state minimum tax incurred by Broncus Medical.

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NON-IFRS MEASURES

To supplement our consolidated statements of profit or loss which are presented in accordance with IFRS, we also use adjusted net loss as non-IFRS measures, which are not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measures when shown in conjunction with the corresponding IFRS measures provides useful information to investors and management in facilitating a comparison of our operating performance from year to year by eliminating potential impacts of certain non-operational or one-off expenses that do not affect our ongoing operating performance, including changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses. Such non-IFRS measures allow investors to consider metrics used by our management in evaluating our performance. Changes in fair value of convertible redeemable preferred shares represent the changes in fair value of various rights associated with the Preferred Shares, which is non-recurring and non-operational in nature. Share awards expenses are non-operational expenses arising from granting shares to selected executives, employees and R&D consultants, the amount of which may not directly correlate with the underlying performance of our business operations, and is also affected by non-operating performance related factors that are not closely or directly related to our business activities. With respect to share awards, determining its fair value involves a high-degree of judgment. Historical occurrence of share awards is not indicative of any future occurrence. [REDACTED] expenses are one-off expenses in relation to the [REDACTED] and the [REDACTED]. Therefore, we do not consider changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses to be indicative of our ongoing core operating performance and exclude them in reviewing our financial results. From time to time in the future, there may be other items that we may exclude in reviewing our financial results. The use of the non-IFRS 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 condition as reported under IFRS. In addition, the non-IFRS financial measures may be defined differently from similar terms used by other companies and therefore may not be comparable to similar measures presented by other companies.

The following table shows reconciliation of net loss for the year to our adjusted net loss for the periods indicated:

	For the year ended	
	December 31,	
	2019	2020
	<i>US\$'000</i>	<i>US\$'000</i>
Loss for the year	(32,551)	(48,786)
Add:		
Changes in fair value of convertible redeemable preferred shares	9,448	27,620
Share awards ⁽¹⁾	5,597	509
[REDACTED] expenses	—	1,599
Adjusted net loss for the year (unaudited) ⁽²⁾	(17,506)	(19,058)

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Notes:

- (1) Represent the total expenses associated with the shares we granted to our sales and marketing employees, administrative employees and research and development employees.
- (2) We consider changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the changes in fair value of convertible redeemable preferred shares, share awards and [REDACTED] expenses provides useful information to investors in facilitating a comparison of our operating performance from year to year.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been extracted from the Accountants’ Report set out in Appendix I to this document:

	As of December 31,	
	2019	2020
	US\$’000	US\$’000
Total non-current assets	12,947	13,195
Total current assets	9,056	26,682
Total assets	22,003	39,877
Total current liabilities	14,144	14,227
Net current (liabilities)/assets	(5,088)	12,455
Total liabilities	95,883	162,318
Net liabilities	(73,880)	(122,441)
Share capital	6	6
Reserves	(72,370)	(120,519)
Non-controlling interests	(1,516)	(1,928)
Total equity	<u>(73,880)</u>	<u>(122,441)</u>

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NET CURRENT ASSETS/LIABILITIES

The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of March 31,
	2019	2020	2021
	US\$'000	US\$'000	US\$'000 (unaudited)
Current assets			
Inventories	1,828	3,051	3,623
Finance lease receivables	21	23	23
Trade receivables	3,189	2,936	2,555
Prepayments, other receivables and other assets	810	1,852	2,151
Due from a director	13	–	–
Due from related parties	85	7	7
Pledged deposits	25	25	25
Cash and cash equivalents	3,085	18,788	49,062
Total current assets	9,056	26,682	57,446
Current liabilities			
Trade payables	246	357	82
Other payables and accruals	5,514	9,133	6,172
Interest-bearing bank and other borrowings	5,772	3,730	3,602
Leases liabilities	560	512	458
Due to related parties	1,632	–	–
Contract liabilities	420	495	631
Total current liabilities	14,144	14,227	10,945
Net current (liabilities)/assets	(5,088)	12,455	46,501

We had net current assets of US\$46.5 million as of March 31, 2021, being the latest practicable date for the purpose of liquidity disclosure in this document, compared to net current assets of US\$12.5 million as of December 31, 2020. The change was primarily due to an increase in cash and cash equivalents of US\$30.3 million, which was primarily due to the completion of the series D funding.

We had net current assets of US\$12.5 million as of December 31, 2020, compared to net current liabilities of US\$5.1 million as of December 31, 2019. The change was primarily due to (i) an increase in inventories of US\$1.2 million, (ii) an increase in cash and cash equivalents of US\$15.7 million and (iii) a decrease in interest-bearing bank and other borrowings of US\$2.0 million. Among the above, the increase in cash and cash equivalents was primarily due to the completion of Series C financing. For details, see “History – Reorganization and Corporate Structure – [REDACTED] Investments – 3. Series C “Financing and Share Transfer.” For changes in other key line items, see “– Inventories,” “– Trade Receivables,” “– Prepayments, Other Receivables and Other Assets,” “– Other payables and accruals,” and “– Related-Party Transactions.”

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Inventories

Our inventories consist of raw materials, work in progress and finished goods. We formulate the purchase plan of raw materials according to delivery time needed by our suppliers, our production and sales targets. We formulate and supervise production progress, inventory levels and projected sales of our products, and adjust our sales and purchase plans every month according to sales performance, to minimize the risk of inventory shortage or accumulation. We have also established an inventory management system that monitors each stage of the warehousing process. We did not experience any material shortage or accumulation of inventory during the Track Record Period. For further details of our inventory management, see “Business – Inventory.” The tables below set forth our inventory balances as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Raw materials	756	1,459
Work in progress	289	439
Finished goods	783	1,153
Total	1,828	3,051

Our inventory balance increased from US\$1.8 million as of December 31, 2019 to US\$3.1 million as of December 31, 2020 primarily due to an increase in raw materials of US\$0.7 million, an increase in work in progress of US\$0.2 million and an increase in finished goods of US\$0.4 million. The increase in inventory in 2020 was primarily attributable to our inventory preparation in advance for equipment and consumables production to meet our sales targets in light of the prolonged suppliers’ delivery time and logistics arrangement susceptible to the COVID-19 impact.

The table below sets forth our inventory and finished goods turnover days for the periods indicated:

	For the year ended December 31,	
	2019	2020
	days	
Inventory turnover days ⁽¹⁾	245	546
Average finished goods turnover days ⁽²⁾	102	217

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Notes:

- (1) Inventory turnover days for a year is the arithmetic mean of the beginning and ending balances of inventory for the relevant year divided by the sum of cost of sales and material costs for R&D for the relevant year and multiplied by 360 days for the full-year period.
- (2) Average finished goods turnover days for a year is the arithmetic mean of the beginning and ending balances of finished goods for the relevant year divided by the sum of cost of sales and material costs for R&D for the relevant year and multiplied by 360 days for the full-year period.

For the years ended December 31, 2019 and 2020, our inventory turnover days were 245 days and 546 days, respectively. The increase in inventory turnover days for the year ended December 31, 2020 was primarily due to decreased sales while our inventory level increased due to the COVID-19 impact.

As of March 31, 2021, US\$0.7 million, representing 24.2% of the US\$3.1 million inventory as of December 31, 2020, was utilized.

Trade Receivables

We sell products, including the Archimedes System, LungPoint and InterVapor both directly to hospitals and through distributors. Under the distributorship arrangement, we generally provide credit term for up to 120 days to our distributors for the sales of navigation system based on their credit profile and credit history. We conduct annual review of our distributors, based on their financial performance and business performance. We retain the discretion to adjust their credit terms with them based on the review results. In addition to the sales through our distributors, we sell our products directly to hospital; we generally provide credit term to hospitals for medical consumables only according to their standard credit term, which is usually ranged from three to six months. For details, see “Business – Sales and Marketing – Our Sales Arrangements.”

The table below sets forth our trade receivables as of the dates indicated:

	As of December 31,	
	2019	2020
	<i>US\$'000</i>	<i>US\$'000</i>
Trade receivables		
Current	3,224	3,193
Non-current	936	–
	4,160	3,193
Impairment	(36)	(257)
Total	4,124	2,936

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Our trade receivables decreased from US\$4.1 million as of December 31, 2019 to US\$2.9 million as of December 31, 2020, which was due to the collection of trade receivables due from Intuitive Surgical Operations, Inc. in relation to our license authorization. We do not hold any collateral or other credit enhancements over our trade receivables balance and such receivables are non-interest bearing.

In determining impairment of trade receivables, we conduct regular reviews of aging analysis and evaluate collectability, taking into account of the historical loss patterns of our customers and adjust for forward looking macroeconomic data in calculating the expected credit loss rate. We did not record material provision for impairment of trade receivables during the Track Record Period.

The table below sets forth our trade receivables turnover days for the periods indicated:

	For the year ended December 31,	
	2019	2020
Average trade receivables turnover days ⁽¹⁾	185	390
Adjusted average trade receivables turnover days ⁽²⁾	77	228

Notes:

- (1) Average trade receivables turnover days for a period equals the arithmetic mean of the beginning and ending trade receivable balances divided by revenue (excluding revenue from finance lease) for that period and multiplied by 360 days for the full-year period.
- (2) Adjusted average trade receivables turnover days for a period is calculated by excluding the trade receivable balances due from Intuitive Surgical Operations, Inc with respect to our license authorization.

The average trade receivables turnover days and adjusted average trade receivables turnover days were 185 days and 77 days in 2019, respectively, which were in line with the credit term we generally provide for our customers. The average trade receivables turnover days and adjusted average trade receivable turnover days were increased to 390 days and 228 days in 2020, which was primarily due to the reduced sales revenue in 2020 as a result of the COVID-19 Outbreak.

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The following table sets forth an aging analysis based on the invoice date of our net trade receivables as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Trade receivables		
Within three months	2,023	1,360
Three to six months	66	58
Six to 12 months	100	14
One to two years	–	516
Two to three years	1,935	–
Over three years	–	988
Total	4,124	2,936

The increase in trade receivables with an aging of over three years was related to the trade receivables due from Intuitive Surgical Operations, Inc with respect to our license authorization.

As of March 31, 2021, US\$1.4 million, representing 47.2% of the US\$2.9 million net trade receivables outstanding as of December 31, 2020 were subsequently settled.

Prepayments, Other Receivables and Other Assets

Our current prepayments, other receivables and other assets include prepayments, deposits and other receivables, value-added tax recoverable and prepaid [REDACTED] expenses and other assets. Prepayments primarily include prepayments for material and service purchases. Deposits and other receivables mainly include rent deposits and employee reserve fund. The table below sets forth our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Current		
Prepayments	286	613
Prepaid [REDACTED] expenses	–	525
Deposits and other receivables	266	91
Value-added tax recoverable	258	514
Other assets	–	109
	810	1,852

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	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Non-current		
Advance payments for property, plant and equipment	30	80
Deposits	199	90
	229	170
	1,039	2,022

Our current prepayments, other receivables and other assets increased from US\$0.8 million as of December 31, 2019 to US\$1.9 million as of December 31, 2020, which was primarily attributable to an increase in each of prepayments, prepaid [REDACTED] expenses, and value-added tax recoverable of US\$0.3 million, US\$0.5 million, and US\$0.3 million.

Finance Lease Receivables

Our finance lease receivables refer to finance lease receivables arising from a finance lease in accordance with IFRS 16. The table below sets forth our finance lease receivables as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Finance lease receivables	147	138
Unrealized finance income	(22)	(18)
Finance lease receivables, net	125	120
Analyzed into:		
Current portion	21	23
Non-current portion	104	97

FINANCIAL INFORMATION

Our finance lease receivables remained stable as of December 31, 2020 compared to that as of December 31, 2019. The table below sets forth the aging analysis of our finance lease receivables based on the lease commencement date for the periods indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Within one year	125	–
One to two years	–	120
	125	120

Trade Payables

Our trade payables primarily consist of the balances due to our suppliers of raw materials. Our trading terms with suppliers vary depending on a number of factors, in particular the type of products and transaction volumes. Our trade payables increased from US\$0.2 million as of December 31, 2019 to US\$0.4 million as of December 31, 2020, as a result of our inventory preparation in advance for equipment and consumables production.

The table below sets forth our average trade payables turnover days for the periods indicated:

	For the year ended December 31,	
	2019	2020
Average trade payables turnover days ⁽¹⁾	39	68

Note:

- (1) Average trade payables turnover days for a year equals the arithmetic mean of the beginning and ending trade payables balances divided by the sum of cost of sales and material costs for R&D for the relevant year and multiplied by 360 days for the full-year period.

Our average trade payables turnover days increased from 39 days for the year ended December 31, 2019 to 68 days for the year ended December 31, 2020, primarily due to our accumulation of raw materials in contemplation of the ongoing recovery of the mainland China market.

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The following table sets forth an aging analysis based on the invoice date of our trade payables as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Trade payables		
Within three months	228	346
Three to six months	4	3
Six to 12 months	8	2
Over 12 months	6	6
Total	246	357

As of March 31, 2021, US\$0.3 million, representing 95.2% of the US\$0.4 million trade payables outstanding as of December 31, 2020, were subsequently settled.

Other Payables and Accruals

Our other payables and accruals refer to payables due to our third-party technical and clinical trial service providers during the R&D process and professional service providers, and the related accrued expenses, primarily consisting of other payables, accrued expenses, accrued payroll, taxes payable other than corporate income tax and interest payable. The table below sets forth our trade payables as of the dates indicated:

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Current		
Other payables	2,221	3,566
Accrued expenses	1,900	3,612
Accrued payroll	1,143	1,621
Taxes payable other than corporate income tax	157	144
Interest payable	93	190
	5,514	9,133

FINANCIAL INFORMATION

Our other payables and accruals increased from US\$5.5 million as of December 31, 2019 to US\$9.1 million as of December 31, 2020, which was primarily attributable to an upfront payment of US\$1.0 million with respect to our Series D financing, and an increase in accrued expenses of US\$1.7 million mainly due to the accrual of relevant fees associated with the [REDACTED].

LIQUIDITY AND CAPITAL RESOURCES

Overview

During the Track Record Period, we relied on capital contributions by our shareholders and bank loans as the major sources of liquidity. We also generate cash from our revenue from our sales of medical devices and consumables, including the LungPoint and the Archimedes System. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue of the medical devices and consumables and by launching new products, as a result of the broader market acceptance of our existing products and our continued efforts in marketing and expansion, improving cost control and operating efficiency and accelerating the turnover of trade receivables by tightening our credit policy.

With respect to cash management, our objective is to optimize liquidity to gain a better return for Shareholders in a risk-averse manner. Specifically, we have policies in place to monitor and manage the settlement of trade receivables. When determining the credit term of a customer or a distributor, we consider a number of factors, including its cash flow conditions and creditworthiness. To monitor the settlement of our trade receivables and avoid credit losses, we conduct annual review of each customer’s or distributor’s financial performance, which is primarily based on the amount and aging of the trade receivables due from such customer or distributor in the respective period. Pursuant to our distribution agreement, when our distributor fails to make a payment within the credit term, we may, at our discretion, refuse to take further orders, require payment in full before shipment, terminate the distribution arrangement or take certain other measures as appropriate.

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Cash Flows

The following table sets forth our cash flows for the periods indicated:

	For the year ended December 31,	
	2019	2020
	US\$'000	US\$'000
Cash flows from operating activities before movements in working capital	(15,173)	(17,411)
Net cash flows used in operating activities	(15,815)	(15,588)
Net cash flows used in investing activities	(268)	(1,089)
Net cash flows from financing activities	16,341	32,225
Net increase in cash and cash equivalents	258	15,548
Cash and cash equivalents at beginning of year	2,778	3,085
Effect of foreign exchange rate changes, net	49	155
Cash and cash equivalents at end of year	3,085	18,788

Net Cash Flows Used in Operating Activities

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs, selling and distribution expenses and administrative expenses.

For the year ended December 31, 2020, our net cash used in operating activities was US\$15.6 million, which was primarily attributable to changes in fair value of convertible redeemable preferred shares of US\$27.6 million, as the major positive non-cash adjustment to our net loss before tax of US\$48.8 million. The amount was then adjusted upward by changes in working capital, primarily including decrease in trade receivables of US\$1.0 million and increase in other payables and accruals of US\$2.3 million.

For the year ended December 31, 2019, our net cash used in operating activities was US\$15.8 million, which was primarily attributable to our net loss before tax of US\$32.6 million, adjusted for non-cash and non-operating items. Positive adjustments for non-cash and non-operating items primarily include changes in fair value of convertible redeemable preferred shares of US\$9.4 million and equity-settled share option expenses of US\$5.6 million. The amount was then adjusted downward by changes in working capital, primarily including decrease in other payables and accruals of US\$0.7 million and increase in finance lease receivables of US\$0.1 million.

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Net Cash Flows Used in Investing Activities

For the year ended December 31, 2020, our net cash used in investing activities was US\$1.1 million, mainly attributable to (i) purchases of items of property, plant and equipment of US\$1.1 million and (ii) loans to related parties of US\$0.3 million, which were partially offset by repayment of loans by related parties of US\$0.4 million.

For the year ended December 31, 2019, our net cash used in investing activities was US\$0.3 million, mainly attributable to (i) purchases of debt investment measured at fair value through profit or loss of US\$1.2 million, and (ii) purchases of items of property, plant and equipment of US\$0.4 million, which were partially offset by proceeds from disposal of debt investment measured at fair value through profit or loss of US\$1.2 million.

Net Cash Flows from Financing Activities

During the Track Record Period, we derived our cash inflows from financing activities primarily from proceeds from issue of convertible redeemable preferred shares and bank loans.

For the year ended December 31, 2020, we had US\$32.2 million of net cash flows from financing activities, primarily attributable to (i) proceeds from issue of convertible redeemable preferred shares of US\$37.6 million, (ii) new bank and other borrowings of US\$12.6 million, and (iii) loans from related parties of US\$4.6 million, which were partially offset by (i) repayment of bank and other borrowings of US\$14.9 million, and (ii) repayment of loans from related parties of US\$6.3 million.

For the year ended December 31, 2019, we had US\$16.3 million of net cash flows from financing activities, primarily attributable to (i) proceeds from issue of convertible redeemable preferred shares of US\$19.1 million, (ii) new bank and other borrowings of US\$7.6 million and (iii) loans from related parties of US\$6.1 million, which were partially offset by (i) repayment of bank and other borrowings of US\$10.8 million, and (ii) repayment of loans from related parties of US\$4.4 million.

WORKING CAPITAL

The Directors are of the opinion that, taking into account of the following financial resources available to us described below, we have sufficient working capital to cover at least 125% of our costs, including R&D costs, selling and distribution expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document:

- our future operating cash flows in respective periods;
- cash and cash equivalents;
- available equity financing and bank facilities; and
- the estimated net [REDACTED] from the [REDACTED].

FINANCIAL INFORMATION

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, which includes research and development expenses, and (ii) capital expenditures. We had bank balance and cash of US\$49.1 million as of March 31, 2021. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and 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. Assuming an average cash burn rate going forward of two times the level in 2020, we estimate that our cash and cash equivalents as of March 31, 2021 will be able to maintain our financial viability for [17.6] months or, if we take into account 10% of the estimated net [REDACTED] from the [REDACTED] (namely, the portion allocated for our working capital and other general corporate purposes), [29.2] months or, if we also take into account the estimated net [REDACTED] from the [REDACTED], [134.3] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the periods indicated:

	For the year ended December 31,	
	2019	2020
	US\$'000	US\$'000
R&D Costs⁽¹⁾		
R&D Costs for Core Products		
Clinical trial expenses	415	351
Staff costs	1,587	1,039
Raw material costs	515	634
Others ⁽²⁾	748	454
R&D Costs for Other Product Candidates		
Clinical trial expenses	122	106
Staff costs	2,630	2,722
Raw material costs	245	294
Others ⁽²⁾	1,672	1,135
Workforce Employment ⁽³⁾	6,832	7,111
Product Marketing Costs ⁽⁴⁾	3,024	2,286
Direct Production Costs ⁽⁵⁾	2,757	2,764
Other significant costs ⁽⁶⁾	3,936	2,126
Non-income taxes, royalties	28	17
Other governmental charges	—	—
Contingency allowances	—	—
	<u>24,511</u>	<u>21,037</u>

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Notes:

- (1) Our R&D burn rate, as the cash operating costs per month relating to R&D activities excluding depreciation and amortization expenses, was US\$7.9 million and US\$6.7 million during the years ended December 31, 2019 and 2020, respectively. Our burn rate decreased in the year ended December 31, 2020 compared to the year ended December 31, 2019, which was primarily because of cost saving measures adopted during the COVID-19 pandemic.
- (2) Others mainly consist of costs incurred for technical services, animal trials, registration, IP services and travels of R&D employees.
- (3) Workforce employment costs represent total non- R&D staff costs mainly including salaries, bonus and benefits.
- (4) Product marketing costs mainly consist of promotion expenses, business travel expenses and costs incurred for clinical education.
- (5) Direct production costs mainly consist of expenses incurred for purchase of components, raw materials, packaging materials and spare parts.
- (6) Other significant costs mainly consist of administrative expenses other than employee benefits expenses.

INDEBTEDNESS

The following table sets forth the breakdown of our financial indebtedness as of the dates indicated:

	As of December 31,		As of
	2019	2020	March 31,
	<i>US\$'000</i>	<i>US\$'000</i>	2021
			<i>US\$'000</i>
			(unaudited)
Interest-bearing bank and other borrowings	5,772	4,188	3,602
Lease liabilities	1,234	1,931	458
Total	7,006	6,119	4,060

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Interest-Bearing Bank and Other Borrowings

	Effective interest rate	Maturity	As of December 31,		As of March 31,
			2019	2020	2021
	(%)		US\$'000	US\$'000	US\$'000 (unaudited)
Current					
Bank loan-secured-RMB10,000,000	7.20	2020	1,433	–	–
Bank loans-secured-RMB30,000,000	5.66	2020	4,299	–	–
Bank loan-secured-RMB20,000,000	5.87	2021	–	3,065	3,044
Bank overdraft-secured	–	On demand	40	25	25
Bank loans-unsecured- current portion of long term loans of US\$1,098,000	1.00	2021	–	640	868
			5,772	3,730	3,937
Non-current					
Bank loans – unsecured – non-current portion of long term loans of US\$1,098,000	1.00	2022	–	458	230
Total			5,772	4,188	4,167
Analyzed into:					
Within one year or on demand			5,772	3,730	3,937
In the second year			–	458	230
			5,772	4,188	4,167

As of March 31, 2021, being the latest practicable date for the purpose of liquidity disclosure in this document, we did not incur new bank loans as compared to December 31, 2020.

As of December 31, 2020, we had in total US\$4.2 million outstanding bank loans, comprised of unsecured banking facilities in aggregate of US\$1.1 million from one commercial bank in the U.S. and secured banking facilities in aggregate of US\$3.1 million from one commercial bank in China, all of which will become due within two years. The US\$1.6 million decrease of bank loans as of December 31, 2020 compared to December 31, 2019 is due to the full repayment of the US\$5.7 million secured bank loan as of December 31, 2019 partially offset by the US\$1.1 million unsecured bank loan and the US\$3.1 million secured bank loan we obtained in 2020.

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Generally, the bank loan agreements contain covenants that impose certain restrictions or maintenance requirements on our Company, our subsidiaries and/or the guarantor, including:

- the guarantor and/or borrower, as applicable, may not change its business nature or corporate, asset and capital structure without the relevant bank’s consent;
- without the relevant bank’s consent, the guarantor and/or borrower, as applicable, may not create encumbrances on any part of its property or assets or provide any guarantee for other indebtedness; and
- the guarantor and/or borrower, as applicable, may not make any distribution or pay any dividend unless certain financial performance has been satisfied.

The bank loan agreements contain standard events of default such as the occurrence of a change of control, breach of any representation, warranty or covenant of the loan agreements, bankruptcy and an event that has a material adverse effect on our loan repayment capability such as material legal proceedings or business disruption. Our Directors confirm that we had no material defaults in payment of interest-bearing bank and other borrowings and had not breached any finance covenants thereunder during the Track Record Period and up to the Latest Practicable Date. Our Directors also confirm that we are not subject to other material covenants under any agreements with respect to any bank loans or other borrowings.

Lease Liabilities

The Group applies a single recognition and measurement approach for all leases, except for short-term leases. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets. The table below sets forth our lease liabilities for the period indicated:

	As of December 31,		As of
	2019	2020	March 31,
	US\$'000	US\$'000	2021
			US\$'000
			(unaudited)
Current	560	512	458
Non-current	674	1,419	1,271
Total	1,234	1,931	1,729

Our total lease liabilities increased from US\$1.2 million as of December 31, 2019 to US\$1.9 million as of December 31, 2020, primarily attributable to our additional leased properties and expanded office area to support our independent business operations which started to be carried out in 2020 on leased premises rather than within the office space provided by our incubator.

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Except as discussed above, we did not have any other material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of the Latest Practicable Date.

CAPITAL EXPENDITURES

We regularly make capital expenditures to expand our operations, upgrade our facilities and increase our operating efficiency. The table below sets forth our capital expenditures for the periods indicated:

	For the year ended December 31,	
	2019	2020
	US\$'000	US\$'000
Purchases of property, plant and equipment	361	1,101
Purchases of other intangible assets	10	73
Total	371	1,174

We expect to incur capital expenditures in 2021 primarily for production line expansion and equipment purchase. For details, see “Future Plans and Use of [REDACTED].” We expect to finance such capital expenditures through a combination of operating cash flows, net [REDACTED] from the [REDACTED] and bank and other borrowings. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

CONTRACTUAL OBLIGATIONS

Capital Commitments

As of December 31, 2019 and December 31, 2020, we had capital commitments of nil and US\$0.1 million, respectively, primarily in connection with our capital expenditure in respect of property, plant and equipment.

CONTINGENT LIABILITIES

As of December 31, 2019 and December 31, 2020, we did not have any contingent liabilities. We confirm that as of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

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OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

KEY FINANCIAL RATIOS

The table below sets forth the key financial ratios of our Group for the periods or as of the dates indicated:

	For the year ended/ As of December 31,	
	2019	2020
Gross margin ⁽¹⁾	74.1%	76.9%
Current ratio ⁽²⁾	64.0%	187.5%

Notes:

- (1) Gross margin equals gross profit divided by revenue for the year.
- (2) Current ratio equals current assets divided by current liabilities as of the end of the year.

Our gross margin remained stable for the year ended December 31, 2020 compared to that for the year ended December 31, 2019.

Our current ratio increased significantly from 64.0% for the year ended December 31, 2019 to 187.5% for the year ended December 31, 2020, mainly due to an increase in total current assets of US\$17.6 million as a result of increases in both inventories and cash and cash equivalents.

RELATED-PARTY TRANSACTIONS

The below table sets forth transactions between us and our related parties during the Track Record Period.

	For the year ended December 31,	
	2019	2020
	US\$'000	US\$'000
Rental fee to:		
Hangzhou Denuo	9	—
Management service from:		
Hangzhou Dinova	386	—

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	For the year ended December 31,	
	2019	2020
	US\$'000	US\$'000
Loans to:		
Aether Corporate Limited	85	—
Hangzhou Dinova	—	294
Loans from:		
Hangzhou Dinova	4,988	1,713
Hangzhou Nuomao	86	—
Hangzhou Denuo	3	—
Dinova Healthcare	1,000	2,880
Interests to:		
Hangzhou Dinova	84	44
Dinova Healthcare	19	56
Payment on behalf of our Group by:		
Shanghai Mingnuo	1,146	4,105
Payments on behalf of related parties for:		
Intuitive Surgical Operations, Inc	—	7
Shanghai Mingnuo	3,250	1,146

The below table sets forth outstanding balances with related parties as of the dates indicated.

	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Due from related parties:		
Intuitive Surgical Operations, Inc	—	7
Aether Corporate Limited	85	—
	<u>85</u>	<u>7</u>
Due to related parties:		
Hangzhou Dinova	1,629	—
Hangzhou Denuo	3	—
	<u>1,632</u>	<u>—</u>

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	As of December 31,	
	2019	2020
	US\$'000	US\$'000
Other payables and accruals:		
Hangzhou Dinoa	84	136
Dinoa Healthcare	—	41
	<u>84</u>	<u>177</u>
Trade Receivables:		
Intuitive Surgical Operations, Inc	<u>1,935</u>	<u>988</u>

Our Directors confirm that all material related party transactions during the Track Record Period were conducted on an arm’s length basis, and our Directors believe that it would not distort our results of operations over the Track Record Period or make our historical results over the Track Record Period not reflective of our expectations for our future performance. We expect to settle the outstanding balances with related parties before the [REDACTED]. Details of our transactions with related parties during the Track Record Period are set out in Note 32 to the Accountants’ Report included in Appendix I to this document.

MARKET RISK DISCLOSURE

We are exposed to a variety of financial risks, including foreign currency risk, credit risk and liquidity risk, as set out below.

Foreign Currency Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between U.S. dollars and other currencies in which we conduct business may affect our financial condition and results of operations. We seek to limit our exposure to foreign currency risk by minimizing our net foreign currency position. For further details, including relevant sensitivity analysis, please see Note 35 to the Accountants’ Report set out in Appendix I to this document.

Credit Risk

We are exposed to credit risk in relation to our cash and cash equivalents, pledged deposits, amounts due from related parties, an amount due from a director, trade receivables and financial assets included in prepayments, other receivables and other assets. The carrying amounts of each class of our financial assets represent our maximum exposure to credit risk in relation to financial assets. Our bank balances and pledged deposits are deposited with creditworthy banks with no recent history of default. For further details, see Note 35 to the Accountants’ Report set out in Appendix I to this document.

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Liquidity Risk

In the management of the liquidity risk, we monitor and maintains a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows. For further details, see Note 35 to the Accountants’ Report set out in Appendix I to this document.

DIVIDEND

No dividend has been paid or declared by us for the years ended December 31, 2019 and 2020, respectively. You should note that historical dividend distributions are not indicative of our future dividend distribution policy.

We are a holding company incorporated in the Cayman Islands. We may need dividends and other distributions on equity from our PRC subsidiary to satisfy our liquidity requirements. Current PRC regulations permit our PRC subsidiary to pay dividends to us only out of their accumulated profits, if any, determined in accordance with our Articles of Association and accounting standards and regulations in PRC. In addition, our PRC subsidiary is required to set aside at least 10% of their respective accumulated profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiary may also allocate a portion of its after-tax profits based on PRC accounting standards to employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiary incurs debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us. In addition, the PRC tax authorities may require us to adjust our taxable income under the contractual arrangements we currently have in place in a manner that would materially and adversely affect our PRC subsidiary’s ability to pay dividends and other distributions to us.

We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman counsel, under the Cayman Companies Act a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

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DISTRIBUTABLE RESERVES

As of December 31, 2020, we did not have any distributable reserves.

[REDACTED] EXPENSE INCURRED AND TO BE INCURRED

The total [REDACTED] expenses (including [REDACTED]) payable by our Company are estimated to be approximately HK\$[REDACTED] (or approximately US\$[REDACTED]) assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, [REDACTED] payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

As of December 31, 2020, the [REDACTED] expenses (excluding [REDACTED] and incentive fees) incurred by our Company in relation to the [REDACTED] were US\$[REDACTED]. In the year ended December 31, 2019, the [REDACTED] expenses charged to profit or loss were nil and the [REDACTED] expenses capitalized to deferred [REDACTED] expenses were nil. In the year ended December 31, 2020, the [REDACTED] expenses charged to profit or loss were US\$[REDACTED] (HK\$[REDACTED]) and the [REDACTED] expenses capitalized to deferred [REDACTED] expenses were US\$[REDACTED] (HK\$[REDACTED]). We estimate that additional [REDACTED] expenses of approximately HK\$ [REDACTED] (including [REDACTED]) will be incurred by our Company, approximately HK\$[REDACTED] of which is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] of which is expected to be capitalized.

The [REDACTED], the Hong Kong Stock Exchange trading fees and the SFC transaction levies, are expected to be HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED], respectively, assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]).

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[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that up to the date of this document, there has been no material adverse change in our financial, operational or trading positions or prospects since December 31, 2020, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, there were no circumstances that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

SHARE CAPITAL

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company immediately prior to and immediately following the completion of the [REDACTED].

As of the Latest Practicable Date, our authorized share capital was US\$50,000 divided into (i) 454,953,797 Shares with a nominal value of US\$0.0001 each; (ii) 14,652,475 Series A Preferred Shares; (iii) 13,134,352 Series B Preferred Shares; (iv) 11,191,242 Series C Preferred Shares; and (v) 6,068,134 Series D Preferred Shares.

As of the Latest Practicable Date, our issued share capital was approximately US\$9,602 divided into (i) 55,944,670 Shares with a nominal value of US\$0.0001 each; (ii) 14,652,475 Series A Preferred Shares; (iii) 9,563,448 Series B Preferred Shares; (iv) 9,791,147 Series C Preferred Shares; and (v) 6,068,134 Series D Preferred Shares.

SHARE CAPITAL IMMEDIATELY FOLLOWING COMPLETION OF THE [REDACTED]

Pursuant to the resolutions of the Shareholders on [●], subject to the [REDACTED] becoming unconditional and with effect immediately prior to the [REDACTED]:

1. each of the issued Preferred Shares be converted into one Share with a nominal value of US\$0.0001 each by re-designation and re-classification of each Preferred Share in issue as an ordinary share on a [one-for-one] basis and all the unissued and authorised Preferred Shares be re-designated and re-classified as ordinary shares with a nominal value of US\$0.0001 each (the “**Re-designation and Re-classification**”), such that the authorised share capital of the Company is US\$50,000 divided into 500,000,000 Shares with a nominal value of US\$0.0001 each, each with effect prior to the completion of the [REDACTED] on the [REDACTED], and
2. immediately after the Re-designation and Re-classification prior to the completion of the [REDACTED], each Share with a nominal value of US\$0.0001 each in the then authorised and issued share capital of the Company be sub-divided into four Shares of US\$0.000025 each (the “**Share Subdivision**”) such that immediately following the Share Subdivision, the authorised share capital of the Company is US\$50,000 divided into 2,000,000,000 Shares.

SHARE CAPITAL

Assuming the [REDACTED] is not exercised, the share capital of our Company immediately following completion of the [REDACTED] will be as follows:

<u>Description of Shares</u>	<u>Number of Shares</u>	<u>Approximate aggregate nominal value of Shares (US\$)</u>	<u>Approximate percentage of issued share capital (%)</u>
Shares in issue (including the Shares upon the Re-designation and Re-classification, and Share Subdivision)	384,079,496	9,601.99	[REDACTED]
Shares to be issued under the [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]	100.00

Assuming the [REDACTED] is exercised in full, the share capital of our Company upon completion of the [REDACTED] will be as follows:

<u>Description of Shares</u>	<u>Number of Shares</u>	<u>Approximate aggregate nominal value of Shares (US\$)</u>	<u>Approximate percentage of issued share capital (%)</u>
Shares in issue (including the Shares upon the Re-designation and Re-classification, and Share Subdivision)	384,079,496	9,601.99	[REDACTED]
Shares to be issued under the [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]	100.00

ASSUMPTIONS

The above tables assume that the [REDACTED] becomes unconditional, that Shares are issued pursuant to the [REDACTED], and that the Re-designation and Re-classification and the Share Subdivision take place as described above. The above tables do not take into account any additional Shares which may be issued pursuant to the Equity Incentive Plans.

SHARE CAPITAL

RANKING

The [REDACTED] are Shares in the share capital of our Company and rank equally with all Shares currently in issue or to be issued (including all Preferred Shares re-designated and re-classified into Shares upon completion of the [REDACTED]) and, in particular, will rank equally for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this document.

POTENTIAL CHANGES TO SHARE CAPITAL

Circumstances under which general meetings are required

Pursuant to the Cayman Companies Act and the terms of the Articles of Association, our Company may from time to time by ordinary resolution of Shareholders: (i) increase its share capital; (ii) consolidate and divide its share capital into Shares of larger amount; and (iii) cancel any Shares which have not been taken or agreed to be 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. See the section headed “Summary of the Constitution of our Company and Cayman Islands Companies Law – 2. Articles of Association – 2.5 Alteration of Capital” in Appendix III to this document for further details.

Equity Incentive Plans

We adopted the Equity Incentive Plans on [date], 2021. For further details, please see the section headed “Statutory and General Information – D. Equity Incentive Plans” in Appendix IV to 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 with a total nominal value of not more than the sum of:

1. 20% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED] (excluding any Shares to be issued pursuant to the exercise of the [REDACTED]); and
2. the aggregate nominal value of Shares repurchased by our Company (if any) under the authority referred to in the paragraph headed “General Mandate to Repurchase Shares” in this section.

SHARE CAPITAL

This general mandate to issue Shares will expire at the earliest of:

1. the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions; or
2. the expiration of the period within which our Company’s next annual general meeting is required by the Articles of Association or any other applicable laws to be held; or
3. the date on which it is varied or revoked by an ordinary resolution of our Shareholders in general meeting.

See the section headed “Statutory and General Information – A. Further Information about Our Group – 5. Resolutions of the Shareholders of our Company dated [●], 2021” in Appendix IV to this document for further details of this general mandate.]

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 our own securities with nominal value of up to 10% of the aggregate nominal value of our Shares in issue immediately following the completion of the [REDACTED] (excluding any Shares to be issued pursuant to the exercise of the [REDACTED]).

The repurchase mandate only relates to repurchases made on the Stock Exchange, or on any other stock exchange on which our Shares are [REDACTED] (and which are recognized by the SFC and the Stock Exchange for this purpose), and which are in accordance with 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 – 6. Repurchase of Our Shares” in Appendix IV to this document. This general mandate to repurchase Shares will expire at the earliest of:

1. the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions; or
2. the expiration of the period within which our Company’s next annual general meeting is required by the Articles of Association or any other applicable laws to be held; or
3. the date on which it is varied or revoked by an ordinary resolution of our Shareholders passed in a general meeting.

See the section headed “Statutory and General Information – A. Further Information about Our Group – 6. Repurchase of Our Shares” in Appendix IV to this document for further details of the Repurchase Mandate (as defined therein).]

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, QM12 and BBL, acting in concert, together with Mr. Zi and the Shareholders listed below (together with QM12 and BBL, our “**Controlling Shareholders**”), are collectively interested in [REDACTED]% of our total issued share capital, and will be collectively interested in [REDACTED]% of our total issued share capital immediately following the completion of the [REDACTED]. Details of the shareholding of our Controlling Shareholders are listed below:

Ultimate beneficial owner	Shareholder of our Company	Shareholding as of the Latest Practicable Date	Shareholding immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)
Mr. Zi ⁽¹⁾	QM12	21.20%	[REDACTED]%
	BBL	11.39%	[REDACTED]%
	Dinova Healthcare (Hong Kong) Co., Limited	8.62%	[REDACTED]%
	BRS Biomedical Limited	3.81%	[REDACTED]%
	Dinova Healthcare Delta Fund (USD) L.P.	3.35%	[REDACTED]%
	Xin Nuo Tong Investment Limited	1.36%	[REDACTED]%
	Dinova Venture Partners GP III, L.P.	0.90%	[REDACTED]%
	Dinova Venture Partners GP IV, L.P.	0.43%	[REDACTED]%
	Total interests of Mr. Zi	29.86%	[REDACTED]%
	Total interests of Our Controlling Shareholders	51.06%	[REDACTED]%

Notes:

- (1) For the purpose of the SFO, Mr. Zi is deemed to be interested in the Shares held by the Shareholders (except QM12) in the above table. See the notes in the section headed “Substantial Shareholders” in this document for details.

The above table does not take into account any Shares which may be issued pursuant to the Equity Incentive Plans. For the background of our Controlling Shareholders, please refer to the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments – 8. Information about our Shareholders” in this document.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

BBL is ultimately controlled by Mr. Zi and our Controlling Shareholders (other than QM12) are all close associates of Mr. Zi. During the Track Record Period, our Controlling Shareholders jointly effected their management and control of our Company as a unified group. QM12 and BBL entered into agreements to act in concert including the Concert Party Agreement. For details, please refer to the section headed “History, Reorganization and Corporate Structure – Reorganization – 3. Concert Party Agreements” in this document. Under the Concert Party Agreement, QM12 and BBL confirmed that they have been acting in concert since May 27, 2014 and have further agreed and undertaken to act in concert as Shareholders of our Company in authorizing or approving key matters of our Group where Shareholders’ approval is required.

INDEPENDENCE OF OUR BUSINESS

We believe that we are capable of carrying out our business independently of our Controlling Shareholders and their close associates after the [REDACTED] for the reasons set out below.

Management Independence

Upon the [REDACTED], our Board will consist of two executive Directors, three non-executive Directors and three INEDs, and our senior management team comprises four members.

Mr. Zhan, our executive Director and CEO, and Mr. Hong Xu, our executive Director and CTO, and the senior management team are responsible for the day-to-day management of our operations. The executive Directors and the members of our senior management team are independent of our Controlling Shareholders. Our Directors are of the view that our Company is able to function independently from our Controlling Shareholders for the following reasons:

- (i) Other than Mr. Zi, our non-executive Director, and Mr. Ao Zhang, our non-executive Director, all of the other Directors are independent of our Controlling Shareholders and decisions of the Board require the approval of a majority vote from the Board;
- (ii) we have appointed three INEDs, comprising almost half of the total members of our Board, who have sufficient knowledge, experience and competence to provide a balance of the potentially interested Directors with a view to promoting the interests of our Company and the Shareholders as a whole;
- (iii) our Company has established internal control mechanisms to identify connected transactions to ensure that our Shareholders or Directors with conflicting interests in a proposed transaction will abstain from voting on the relevant resolutions;
- (iv) in the event that there is a potential conflict of interest arising out of any contract or transaction to be entered into between our Company and our Directors, the interested Director is obliged to disclose his nature of interest in such contract or transaction; and

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (v) each of our Directors is aware of his or her fiduciary duties and responsibilities under the Listing Rules as a director, which require that he or she acts for the benefit and in the best interest of our Company and does not allow any conflict between his or her duties as a Director and his or her personal interests.

Based on the above, our Directors believe that our Board and senior management as a whole are able to play a managerial role in our Company independently from our Controlling Shareholders and their close associates after the [REDACTED].

Operational Independence

We have established our own organizational structure, with each department assigned to specific areas of responsibilities which have been in operation and are expected to continue to operate independently from our Controlling Shareholders and their close associates. We have independent access to suppliers and customers. We are also in possession of all relevant assets, licenses, trademarks and other intellectual properties necessary to carry on and operate our business and we have sufficient operational capacity in terms of capital and employees to operate independently.

Our Directors are of the view that there is no operational dependence by us on our Controlling Shareholders and our Group is able to operate independently from our Controlling Shareholders and their close associates after the [REDACTED].

Financial Independence

Our Group has its own independent financial, internal control and accounting systems. We make financial decisions and determine our use of funds according to our own business needs. We have opened accounts with banks independently and do not share any bank account with our Controlling Shareholders. We have made tax filings and paid tax independently of our Controlling Shareholders pursuant to applicable laws and regulations. We have established an independent finance department as well as implemented sound and independent audit, accounting and financial management systems. We have adequate internal resources to support our daily operation. We do not expect to rely on our Controlling Shareholders or any of their close associates for financing after the [REDACTED] as we expect that our working capital will be funded by, among others, the [REDACTED] Investments as well as the [REDACTED] from the [REDACTED].

As of the Latest Practicable Date, there was no outstanding loan extended by our Controlling Shareholders to us and no guarantee has been provided for our benefit by our Controlling Shareholders.

Based on the above, our Directors consider that there is no financial dependence on our Controlling Shareholders or their close associates.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

COMPETITION

As of the Latest Practicable Date, neither our Controlling Shareholders and their close associates nor any of our Directors is interested in any business, other than our Group, which competes or is likely to compete, either directly or indirectly, with our Group’s business and which requires disclosure pursuant to Rule 8.10 of the Listing Rules.

CORPORATE GOVERNANCE

Our Company will comply with the provisions of the Corporate Governance 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 have adopted the following corporate governance measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholders:

- (i) our Company has established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if our Group enters into connected transactions with our Controlling Shareholders or their close associates, our Company will comply with the applicable requirements under the Listing Rules;
- (ii) where a Shareholders’ meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their close associates has any material interest, our Controlling Shareholders and their close associates (as applicable) will not vote on the resolutions and shall not be counted in the quorum for the voting;
- (iii) our Board consists of a balanced composition of executive, non-executive and INEDs, with not less than one-third of INEDs 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 INEDs individually and collectively possess the requisite knowledge and experience to perform their duties. They will review whether there is any conflict of interests between our Group and provide impartial and professional advice to protect the interests of our minority Shareholders;
- (iv) where the advice from an independent professional, such as a financial or legal adviser, is reasonably requested by our Directors (including the INEDs), the appointment of such an independent professional will be made at our Company’s expenses; and

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (v) we have appointed Red Solar Capital Limited as our Compliance Adviser, who will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules including various requirements relating to Directors’ duties and corporate governance matters.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflict of interests between our Group and our Controlling Shareholders and to protect our minority Shareholders’ rights after the [REDACTED].

SUBSTANTIAL SHAREHOLDERS

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following completion of the [REDACTED], assuming the [REDACTED] is not exercised and no Shares are issued pursuant to the Equity Incentive Plans, the following persons will have interests 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 is, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company or any other member of our Group.

Name of Shareholder	Capacity/Nature of interest	Total number of Shares/underlying shares held as of the Latest Practicable Date ⁽¹⁾	Approximate percentage of interest in our Company as of the Latest Practicable Date	Approximate percentage of interest in our Company upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)
			(%)	(%)
QM12 ⁽²⁾	Beneficial interest	20,353,202	21.20	[REDACTED]
Qiming Venture Partners IV, L.P. ⁽²⁾	Interest in controlled corporation	20,353,202	21.20	[REDACTED]
Qiming GP IV, L.P. ⁽²⁾	Interest in controlled corporation	20,353,202	21.20	[REDACTED]
Qiming Corporate GP IV, Ltd ⁽²⁾	Interest in controlled corporation	20,353,202	21.20	[REDACTED]
Mr. Zi ⁽³⁾	Interest in controlled corporation	28,673,801	29.86	[REDACTED]
BBL ⁽⁴⁾	Beneficial interest	10,935,494	11.39	[REDACTED]
Dinova Healthcare Gamma Fund (USD) L.P. ⁽⁴⁾	Interest in controlled corporation	10,935,494	11.39	[REDACTED]
Dinova Venture Partners GP III, L.P. ⁽⁴⁾	Beneficial interest	865,002	0.90	[REDACTED]
	Interest in controlled corporation	10,935,494	11.39	[REDACTED]
Dinova Capital Limited ⁽⁴⁾	Interest in controlled corporation	11,800,496	12.29	[REDACTED]
Xin Nuo Tong Investment Limited ⁽⁵⁾	Beneficial interest	1,309,822	1.36	[REDACTED]
	Interest in controlled corporation	15,424,894	16.06	[REDACTED]
Dinova Healthcare (Hong Kong) Co., Limited ⁽⁶⁾	Beneficial interest	8,278,188	8.62	[REDACTED]

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Capacity/Nature of interest	Total number of Shares/underlying shares held as of the Latest Practicable Date ⁽¹⁾	Approximate percentage of interest in our Company as of the Latest Practicable Date	Approximate percentage of interest in our Company upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)
			(%)	(%)
Zhejiang Dinova ⁽⁶⁾	Interest in controlled corporation	8,278,188	8.62	[REDACTED]
Zhejiang Denuo Capital Management L.P. (浙江德諾資本管理合夥企業(有限合伙)) ⁽⁶⁾	Interest in controlled corporation	8,278,188	8.62	[REDACTED]
Hangzhou Denuo Commercial Information Consulting Co., Ltd. (杭州德諾商務資訊諮詢有限公司) ⁽⁶⁾	Interest in controlled corporation	8,278,188	8.62	[REDACTED]
Intuitive Surgical Operations, Inc. ⁽⁷⁾	Beneficial interest	5,834,473	6.08	[REDACTED]
Intuitive Surgical, Inc. ⁽⁷⁾	Interest in controlled corporation	5,834,473	6.08	[REDACTED]

Notes:

- (1) The number of Shares held assuming that all of the Preferred Shares have been converted into the Shares on an one:one basis.
- (2) For the purpose of the SFO, Qiming Venture Partners IV, L.P. (as a 96.94% shareholder of QM12), Qiming GP IV, L.P. (as the general partner of Qiming Venture Partners IV, L.P.) and Qiming Corporate GP IV, Ltd (as the general partner of Qiming GP IV, L.P.) are deemed to be interested in the Shares held by QM12.
- (3) For the purpose of the SFO, Mr. Zi is deemed to be interested in 28,673,801 Shares through the below entities he controls:
 - BBL (please see Note 4 below for details).
 - Dinova Healthcare (Hong Kong) Co., Limited (please see Note 6 below for details).
 - BRS Biomedical Limited, because it is wholly owned by Dinova Venture Partners LP II, L.P. whose general partner is Dinova Venture Partners GP II, L.P. Dinova Venture Partners Limited, the general partner of Dinova Venture Partners GP II, L.P., is owned by Mr. Zi as to one third. Hence, Mr. Zi is deemed to be interested in the Shares held by BRS Biomedical Limited.
 - Dinova Healthcare Delta Fund (USD) L.P., because Xin Nuo Tong Investment Limited is deemed to be interested in the Shares held by Dinova Healthcare Delta Fund (USD) L.P. (please see Note 5 below for details), and that Mr. Zi is the sole shareholder of Xin Nuo Tong Investment Limited. Hence, Mr. Zi is deemed to be interested in the Shares held by Dinova Healthcare Delta Fund (USD) L.P..
 - Xin Nuo Tong Investment Limited (please see Notes 4 and 5 below for details).

SUBSTANTIAL SHAREHOLDERS

- Dinova Venture Partners GP III, L.P. (please see Note 4 below for details).
 - Dinova Venture Partners GP IV, L.P., because Xin Nuo Tong Investment Limited is deemed to be interested in the Shares held by Dinova Venture Partners GP IV, L.P. (please see Note 5 below for details), and that Mr. Zi is the sole shareholder of Xin Nuo Tong Investment Limited. Hence, Mr. Zi is deemed to be interested in the Shares held by Dinova Venture Partners GP IV, L.P..
- (4) For the purpose of the SFO, Dinova Healthcare Gamma Fund (USD) L.P. (as the sole shareholder of BBL), Dinova Venture Partners GP III, L.P. (as the general partner of Dinova Healthcare Gamma Fund (USD) L.P.), Dinova Capital Limited (as the general partner of Dinova Venture Partners GP III, L.P.), Xin Nuo Tong Investment Limited (as the sole shareholder of Dinova Capital Limited) and Mr. Zi (as the sole shareholder of Xin Nuo Tong Investment Limited and as a limited partner holding approximately 33.33% interest in Dinova Venture Partners GP III, L.P.) are deemed to be interested in the Shares held by BBL. For the purpose of the SFO, Xin Nuo Tong Investment Limited and Dinova Capital Limited are deemed to be interested in the Shares held by Dinova Venture Partners GP III, L.P..
- (5) Xin Nuo Tong Investment Limited is a 40% shareholder of Dinova Venture Capital Limited, which is the general partner of Dinova Venture Partners GP IV L.P., and Dinova Venture Partners GP IV L.P. is the general partner of Dinova Healthcare Delta Fund (USD) L.P.. In addition, Xin Nuo Tong Investment Limited is also a limited partner holding 39.95% of Dinova Venture Partners GP IV L.P.. For the purpose of the SFO, Xin Nuo Tong Investment Limited is also deemed to be interested in the Shares held by Dinova Venture Partners GP IV L.P. and Dinova Healthcare Delta Fund (USD) L.P..
- (6) Dinova Healthcare (Hong Kong) Co., Limited, a company incorporated under the laws of Hong Kong and is wholly owned by Zhejiang Dinova. For the purpose of the SFO, Zhejiang Denuo Capital Management L.P. (浙江德諾資本管理合夥企業(有限合夥)) (as the general partner of Zhejiang Dinova), Hangzhou Denuo Commercial Information Consulting Co., Ltd. (杭州德諾商務資訊諮詢有限公司) (as the general partner of Zhejiang Denuo Capital Management L.P.), Mr. Zi (as a limited partner holding 39.60% interest of Zhejiang Denuo Capital Management L.P. and holds 40% interest in Hangzhou Denuo Commercial Information Consulting Co., Ltd.) are deemed to be interested in the Shares held by Dinova Healthcare (Hong Kong) Co., Limited.
- (7) Intuitive Surgical Operations, Inc. is a company incorporated in Delaware, United States. For the purpose of the SFO, Intuitive Surgical, Inc. (NASDAQ: ISRG) is deemed to be interested in the Shares held by Intuitive Surgical Operations, Inc..

DIRECTORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

As of the date of this document, our Board of Directors consists of eight Directors, comprising two executive Directors, three non-executive Directors and three INEDs.

The table below sets forth certain information in respect of the members of the Board of Directors of our Company:

Name	Age	Date of Joining our Group	Date of Appointment as Director	Position	Roles and Responsibilities
Guowei ZHAN (湛國威)	44	December 1, 2017	May 6, 2021	Executive Director and CEO	Overall strategic planning, business direction and operational management
Hong XU (徐宏)	34	February 22, 2018	May 6, 2021	Executive Director and CTO	Overall strategic planning, business direction and operational management
Michael Yi Wei ZHAO	55	April 30, 2012	April 30, 2012	Non-Executive Director, Chairman of the Board of Directors, chairman of the Nomination Committee and member of the Remuneration Committee	Participating in formulating our Company's corporate and business strategies
Zhenjun ZI (訾振軍)	50	February 18, 2014	February 18, 2014	Non-executive Director	Participating in formulating our Company's corporate and business strategies
Ao ZHANG (張奧)	36	April 29, 2021	April 29, 2021	Non-executive Director	Participating in formulating our Company's corporate and business strategies
Pok Man KAM (甘博文)	71	date of this document	date of this document	Independent non-executive Director, chairman of the Audit Committee and member of the Remuneration Committee	Supervising and providing independent judgement to our Board
Joseph Wan Yee LAU (劉允怡)	73	date of this document	date of this document	Independent non-executive Director, and member of the Audit Committee and the Nomination Committee	Supervising and providing independent judgement to our Board
Jian JI (計劍)	51	date of this document	date of this document	Independent non-executive Director, chairman of the Remuneration Committee and member of the Audit Committee and the Nomination Committee	Supervising and providing independent judgement to our Board

DIRECTORS AND SENIOR MANAGEMENT

Executive Directors

Mr. Guowei ZHAN (湛國威), aged 44, was appointed as an executive Director of our Company on May 6, 2021. He joined our Group as a General Manager and was also appointed as the CEO of our Company in December 2017. He is mainly involved in overall strategic planning, business direction and operational management.

Mr. Zhan has over 21 years of experience in the industry of medical devices. Prior to joining our Group, Mr. Zhan was the vice president of DiNovA Medtech Technology Co., Ltd. (杭州德諾科技有限公司), a specialized medical device business incubator in China, from August 2015 to June 2017. Prior to joining DiNova Medtech Technology Co., Ltd, Mr. Zhan served as a sales director and later as the Chief Marketing Officer at Lifetech Scientific Corporation (先健科技公司), a company listed on the Hong Kong Stock Exchange (stock code: 1302). Prior to that, he worked at Johnson & Johnson Medical (China) Ltd. (強生(中國)醫療器材有限公司) from July 1999 to June 2009 and held positions including national sales manager at Johnson & Johnson Biosense Webster. Mr. Zhan has been awarded as a yearly Top Sales Manager in 2007 at Johnson & Johnson Medical (China) Ltd. with outstanding sales performance.

Mr. Zhan graduated with a bachelor’s degree in international finance from Sun Yat-sen University, China in June 1999.

Mr. Hong XU (徐宏), aged 34, was appointed as an executive Director and CTO of our Company on May 6, 2021. He joined our Group as CTO of Broncus Hangzhou in February 2018, and is mainly involved in overall strategic planning, business direction and operational management.

Mr. Xu has over 10 years of industry experience. Prior to joining our Group, Mr. Xu served as the associate general manager at Shenzhen Chuangling Image Technology Co., Ltd. (深圳市創領圖像技術有限公司), a subsidiary of APT Medical Inc (深圳惠泰醫療器械股份有限公司), an electrophysiological and vascular interventional medical device company from September 2014 to February 2018 and held positions of manager of R&D, associate manager of R&D department and R&D engineer at APT Medical Inc. from July 2010 to March 2015.

Mr. Xu obtained a bachelor’s degree in polymer material and engineering from Sichuan University in Chengdu, China, in June 2010.

DIRECTORS AND SENIOR MANAGEMENT

Non-executive Directors

Mr. Michael Yi Wei ZHAO, aged 55, was appointed as a Director of our Company from April 30, 2012 to June 25, 2014, and was re-appointed as a Director on September 15, 2015. Mr. Zhao was re-appointed as a non-executive Director and chairman of the Board on May 6, 2021. Mr. Zhao is responsible for participating in formulating our Company’s corporate and business strategies.

Mr. Zhao has around 23 years of experience in medical devices, pharmaceuticals and health care areas. Prior to founding Broncus, Mr. Zhao served as the chief executive officer from April 2010 to March 2015 and the executive director with effect from October 2011 to March 2015 in Lifetech Scientific Corporation (先健科技公司) (stock code: 1302). From 1998 to 2006, Mr. Zhao worked at Johnson & Johnson Medical (China) Ltd. (強生(中國)醫療器材有限公司), a multinational corporation in the medical industry, in a number of senior management roles. Those roles include the Sales Representative of Ethicon Suture U.S., European Project Leader for Hepacoat Stents at Cordis European Office, Product Manager at Cordis Endovascular, Medical Australia, Group Marketing Manager of Cordis Franchise, Franchise Manager, Cordis, Medical China, Franchise Director and General Manager. Mr. Zhao received the Marketing Award in 2000 issued by Johnson & Johnson Medical in recognition of his outstanding performance and achievement.

Mr. Zhao obtained a bachelor’s degree in science from Huntington College in Huntington, the United States in May 1990 and earned his master’s degree in business administration from the University of Western Ontario in London, Canada in April 1998.

Mr. Zhao was the Secretary General of the Chinese Medical Association Arrhythmia Diagnosis and Treatment Committee.

Mr. Zhao currently holds directorship in the following major subsidiaries of our Group: Broncus Medical, Uptake Medical and Broncus Hangzhou.

Mr. Zhenjun ZI (訾振軍), aged 50, was appointed as a Director of our Company on February 18, 2014. He was re-designated as a non-executive Director on May 6, 2021. He is primarily responsible for participating in formulating our Company’s corporate and business strategies.

Mr. Zi has over 18 years of industry experience. Mr. Zi has been an executive director and the general manager of Venus Medtech (Hangzhou) Inc. (杭州啓明醫療器械股份有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 2500), since November 2012 was primarily responsible for the overall management, business strategies, regulatory approvals and commercial suitability of products. Prior to that, Mr. Zi worked at Lifetech Scientific Corporation (先健科技公司) (stock code: 1302) in roles including Technical Project Manager and Business Development and Strategic Planning Director from January 2003.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Zi received his master’s degree in science in applied chemistry from Hefei University of Technology in Hefei, China, in April 1998.

Mr. Zi currently holds directorship in major subsidiaries of our Group including Broncus Medical and Uptake Medical.

Mr. Ao ZHANG (張奧), aged 36, was appointed as a Director of our Company on April 29, 2021 and re-designated as a non-executive Director on May 6, 2021. He is primarily responsible for participating in formulating our Company’s corporate and business strategies.

Mr. Zhang has around 8 years of experience in healthcare investments. Mr. Zhang has worked at Suzhou Qiyuan Equity Investment Management Partnership Enterprise (Limited Partnership) since January 2015 and is currently a Principal. Mr. Zhang served as a vice president and was responsible for the healthcare investment area at WI Harper Group, a venture capital firm focusing on early to growth stage companies across the United States, Greater China, and Asia Pacific, from June 2013 to December 2014. Prior to that, he worked as an investment associate at CEC Capital Group (formerly known as China eCapital Corporation) (易凱資本有限公司), a investment bank with a core focus on the healthcare, consumer and technology, media and telecom sectors, from May 2010 to May 2013.

Mr. Zhang obtained a bachelor’s degree in biomedical engineering from Tsinghua University in Beijing, China in July 2007 and received his master of science degree in medical and radiological sciences from the University of Edinburgh in Edinburgh, the United Kingdom in December 2008 and a master of science degree in risk management and financial engineering from Imperial College London in London, the United Kingdom in November 2009.

Mr. Zhang currently holds directorship in major subsidiaries of our Group including Broncus Medical and Uptake Medical.

Independent Non-executive Directors

Dr. Pok Man KAM (甘博文), aged 71, has been appointed as an INED effective as of the date of this document. Dr. Kam is primarily responsible for supervising and providing independent judgement to our Board.

Dr. Kam is an expert in area of accounting and is familiar with roles of being an auditor, a regulator and an accountant in business. He worked as the chief executive officer of the Financial Reporting Council starting from April 2010 before his retirement in March 2013. Dr. Kam joined Jardine Matheson in April 1976 as a probationary local executive, and thereafter as the Group Financial Controller of Jardine Matheson until his retirement in March 2010. Dr. Kam worked at PricewaterhouseCoopers LLP (formerly known as Lowe Bingham & Matthews/Price Waterhouse & Co) as an auditing professional from April 1972 to March 1976.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Kam is currently the chairman of the Hospital Governing Committee of Queen Elizabeth Hospital since April 2016 and a convenor of Financial Reporting Review Panel since July 2016, a member of the Supervisory Committee of the Tracker Fund of Hong Kong since April 2016, the HKSAR Government Scholarship Fund (“GSF”) Steering Committee since May 2019, Investment Committees of GSF and the Self-financing Post-secondary Education Fund since May 2019, and Hong Kong Genome Institute Audit and Risk Committee since December 2020.

He was also the chairman of Hospital Authority Provident Fund Scheme from November 2015 to November 2020, a member of Hospital Authority from April 2013 to March 2019, a member of the Standards Advisory Council of the International Accounting Standards Board from December 2005 to December 2011 and the President of the Hong Kong Institute of Certified Public Accountants (formerly the Hong Kong Society of Accountants) from 1999 to 2001. He was a Professor of Practice in Accounting of the School of Accounting and Finance in The Hong Kong Polytechnic University from July 2015 to June 2019, an Adjunct Professor of Hong Kong Baptist University School of Business from January 2015 to August 2017, an Adjunct Associate Professor of the School Accountancy of The Chinese University of Hong Kong from March 2002 to July 2015, and an Adjunct Professor of The City University of Hong Kong from July 2008 to August 2014. In recognition of his distinguished and outstanding service to the community, he was awarded the Bronze Bauhinia Star in 2017.

Dr. Kam obtained a Doctor of Philosophy degree in Accounting from The University of the Sunshine Coast in Queensland, Australia in April 2008. He completed a Management Development Program at the Graduate School of Business Administration of Harvard University in Cambridge, the United States in November 1986. Prior to that, he obtained his master degree in business administration in The Chinese University of Hong Kong in Hong Kong in December 1983. He is also a fellow member of the Hong Kong Institute of Certified Public Accountants, the Institute of Chartered Accountants in England and Wales, a fellow associate of the Association of Chartered Certified Accountants, the Chartered Institute of Management Accountants and the Chartered Governance Institute. He is also a member of the Chartered Professional Accountants of British Columbia, Canada and honorary member of CPA Australia.

Professor Joseph Wan Yee LAU (劉允怡), aged 73, has been appointed as an INED effective as of the date of this document. Professor Lau is primarily responsible for supervising and providing independent judgement to our Board.

Professor Lau, an expert on hepato-pancreato-biliary surgery and an academician of the Chinese Academy of Sciences, is the Founding Master of Lee Woo Sing College and Research Professor at the Faculty of Medicine and Emeritus Professor at the Department of Surgery of The Chinese University of Hong Kong, current chairman of the Medical Council of Hong Kong, past president of the International Hepato-Pancreato-Biliary Association and Asian-Pacific Hepato-Pancreato-Biliary Association. Professor Lau has been an independent non-executive director of NISI (HK) Limited, a company that specializes in noninvasive surgical

DIRECTORS AND SENIOR MANAGEMENT

innovations, since February 2017. Professor Lau has also been an independent non-executive director of Venus Medtech (Hangzhou) Inc. (杭州啓明醫療器械股份有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 2500), since December 2019.

Professor Lau is active both at the international and local surgical scene and holds many key positions in government and professional organizations. He has been the chairman of the Medical Council of Hong Kong since March 2012. He was president of the International Hepato-Pancreato-Biliary Association from April 2002 to 2004. He was elected as an academician of the Chinese Academy of Sciences in 2003, and was awarded Honorary Fellow of Royal Australasian College of Surgeons in 2003. He was president of Asian-Pacific Hepato-Pancreato-Biliary Association from 2009 to 2011, and was awarded Honorary Fellow of College of Surgeons of Hong Kong in 2011.

Professor Lau was awarded the Wu Jieping Medical Prize in September 2012 for his momentous lifetime contributions to the global medical field and the Silver Bauhinia Star (SBS) in 2013 for his distinguished service to Hong Kong.

Professor Lau obtained bachelor’s degrees in medicine and surgery from the University of Hong Kong in Hong Kong in 1972 and was conferred a degree of doctor of medicine from the Chinese University of Hong Kong in Hong Kong in December 1995.

Dr. Jian JI (計劍), aged 51, has been appointed as an INED effective as of the date of this document. Dr. Ji is primarily responsible for supervising and providing independent judgement to our Board.

Dr. Ji is an expert in area of biomaterials and has over 23 years of industry experience. Dr. Ji currently serves as the director of Institute of Biomedical Macromolecule in Zhejiang University, and professor in Department of Polymer Science and Engineering, Zhejiang University since December 2004. Prior to that, he joined Department of Polymer Science and Engineering, Zhejiang University in December 1997 as a lecturer and became an associate professor in December 2000.

Dr. Ji is a fellow of the Royal Society of Chemistry and an associate editor for Journal of Materials Chemistry B. Dr. Ji was awarded as Chang Jiang Scholars by Ministry of Education. His research focuses on biomedical implant, tissue engineering and nanomedicine.

He obtained his bachelor’s degree in chemistry from Zhejiang University in Hangzhou, China in July 1992 and was conferred with a PhD degree in science from Zhejiang University in August 1997.

DIRECTORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The table below shows certain information in respect of the senior management of our Company:

Name	Age	Date of Joining our Group	Position	Roles and Responsibilities
Guowei ZHAN (湛國威)	44	December 2017	Executive Director and CEO	Overall strategic planning, business direction and operational management
Hong XU (徐宏)	34	February 2018	Executive Director and CTO	R&D of comprehensive product portfolio
Todd A. CORNELL	51	August 2017	President of Broncus Medical and Uptake Medical	Operations of our Group in the United States and Europe
Zhenhua LI (李振華)	37	January 2017	Head of Sales and Marketing and Clinical Education Affairs in Asia Region	Sales, marketing and clinical education team in Asia

Mr. Guowei ZHAN (湛國威), aged 44, is our executive Director and CEO. Please see his biography in the sub-section headed “Executive Directors” in this section.

Mr. Hong XU (徐宏), aged 34, is our executive Director and CTO. Please see his biography in the sub-section headed “Executive Directors” in this section.

Mr. Todd A. CORNELL, aged 51, joined our Group in August 2017 and was elected the president of Broncus Medical and Uptake Medical, our subsidiaries and is mainly responsible for the operations of our Group in the United States and Europe since March 15, 2019.

Mr. Cornell has 27 years of industry experience. Prior to joining our Group, Mr. Cornell served as vice president of sales at Sirtex Medical, Inc, a medical device company providing a radioactive treatment for inoperable liver cancer, from January 2017 to May 2017. From June 2009 to December 2016, he served as the vice president of sales at Pulmonx, Inc., a medical device company listed on NASDAQ (ticker symbol: LUNG) focusing in interventional pulmonology, planning tools, and treatments for obstructive lung disease.

Mr. Cornell obtained a bachelor’s degree in business administration from University of Tennessee in Knoxville, the United States in December 1991.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Zhenhua LI (李振華), aged 37, joined our Group in January 2017 and became the Head of Sales and Marketing and Clinical Education Affairs in Asia Region of Broncus Hangzhou responsible for sales, marketing and clinical education team in Asia in September 2019.

Mr. Li has around 11 years of industry experience. Prior to joining our Group, Mr. Li joined Lifetech Scientific (Shenzhen) Co., Ltd. (先健科技(深圳)有限公司) in April 2010 and served as the Director of Oversea Sales Department in 2016. Lifetech Scientific (Shenzhen) Co., Ltd. is a wholly-owned subsidiary of Lifetech Scientific Corporation (先健科技有限公司), a company listed on the Hong Kong Stock Exchange (stock code: 1302).

Mr. Li obtained a bachelor’s degree in biomedical engineering from University of Electronic Science and Technology of China in Chengdu, China, in July 2006.

DIRECTORS’ AND SENIOR MANAGEMENT’S INTERESTS

Save as disclosed above in this section, none of our Directors or senior management has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this document. Save as disclosed above in this section, 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 our 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. As of the Latest Practicable Date, save for the interests in the Shares of our Company held indirectly by Mr. Zhao and Mr. Zi, indirectly and directly by Mr. Zhan and directly by Mr. Hong Xu, which is disclosed in the section headed “Statutory and General Information – C. Further Information about Our Directors” in this document, none of our Directors held any interest in the securities within the meaning of Part XV of the SFO. Save as disclosed above in this section, as of the Latest Practicable Date, none of our Directors or senior management is related to other Directors or senior management of our Company.

JOINT COMPANY SECRETARIES

Mr. Wen Hao WANG (王文豪), aged 48, was appointed as a joint company secretary of our Company on May 6, 2021. Mr. Wang is primarily responsible for the overall company secretarial matters of our Group.

Mr. Wang has over 20 years of capital market experience covering both Asian and the U.S. financial markets. Mr. Wang worked at eHi Car Services Limited from September 2017 to April 2021 and last served as the vice president of finance and the board secretary. Prior to joining eHi Car Services Limited, Mr. Wang worked at the J.P. Morgan Securities (Asia Pacific) Ltd’s Shanghai representative office from November 2006 to August 2017, where he last served as

DIRECTORS AND SENIOR MANAGEMENT

an executive director. Prior to joining J.P. Morgan Securities (Asia Pacific) Ltd, Mr. Wang worked at J.P. Morgan Chase Bank N.A. from July 1998 to July 2005 in the United States and Hong Kong and last served as an assistant vice president.

Mr. Wang received his degree of bachelor of science from Saint John’s University in New York, the United States in May 1998.

Mr. Leong Yin LEE (李亮賢), aged 33, was appointed as a joint company secretary of our Company on May 6, 2021. Mr. Lee is primarily responsible for the overall company secretarial matters of our Group.

Mr. Lee has over ten years of experience in corporate secretarial field. He has started working at SWCS Corporate Services Group (Hong Kong) Limited since January 2015 and is currently serving as a manager of corporate Secretarial Department. He is responsible for providing listed and private companies with corporate secretarial services. Prior to that, he worked as a company secretarial trainee and was later promoted as company secretarial executive at Fair Wind Secretarial Services Limited from August 2010 to January 2015.

Mr. Lee received his bachelor’s degree in business administration in corporate administration from The Open University of Hong Kong in Hong Kong in August 2010. He was admitted as an associate member of The Hong Kong Institute of Chartered Secretaries and The Chartered Governance Institute in November 2018.

KEY TERMS OF EMPLOYMENT CONTRACTS

Employment Arrangements of Senior Management

We normally enter into (i) an employment contract, (ii) a confidentiality agreement and (iii) a non-compete agreement with our senior management members and other key personnel. Below sets forth the key terms of these contracts we normally enter into with our senior management and other key personnel.

- *Terms:* We normally enter into an employment contract with our senior management members and other key personnel with a term of three years.
- *No conflict:* During the term of the employment, without our consent, our senior management members and other key personnel shall not produce the same products as those of our Group, engage in the same businesses, nor hold any position (including shareholder, partner, director, supervisor, manager, employee, agent and consultant) in any entity that is in competition with our Group.

DIRECTORS AND SENIOR MANAGEMENT

Confidentiality

- *Confidential information:* It refers to the information that belongs to our Company including but not limited to non-patent technologies, designs, process flows, business strategies, business planning, business decisions, technical plans, technical indicators, computer software, database, network structure and environment, research and development records, technical reports, registration documents, product specifications, test reports, experimental data, test results, operation manuals, technical documents, relevant correspondence, financial information, personnel files, customer lists, sales plans, procurement information, pricing policies, purchase channels, meeting records, audio, video and other information.
- *Obligation and duration:* During the term of employment, the employees shall comply with our Group’s confidentiality rules and policies, and perform the confidentiality obligations corresponding to the job position. Except for performing job duties, the employees shall not, without our consent, divulge, publish, copy, impart, transfer or in any other way provide the known confidential information to a third party. In addition, the employee shall return any property of our Group including anything containing confidential information of our Group upon departure or request by our Group.

Intellectual Property Rights

- *Acknowledgement:* The employee agrees that, during the term of the employment, all inventions, creations, works, computer software, technical secrets or other trade secrets arising from the performance of duties or the use of the company’s resources belong to our Group. On request by our Group, the employee shall provide all necessary information and take all necessary actions to assist our Group in obtaining and exercising relevant intellectual property rights.

Non-competition

- *Non-competition obligation:* During the term of the employment and within two years after the departure, the employee shall not work as an employee of or provide any services to any other company which competes with our Group, and shall not develop or assist other people to develop competitive products and business.
- *Duration:* The non-competition obligations shall subsist throughout the employee’s term of employment and up to 24 months after termination of employment for whatever reason.

DIRECTORS AND SENIOR MANAGEMENT

REMUNERATION OF DIRECTORS AND SENIOR MANAGEMENT

Our Directors receive compensation in the form of salaries, bonuses, allowances, benefits in kind, pension scheme contributions and equity-settled share option expenses. We determine the compensation of our Directors based on each Director’s responsibilities, qualification, position and seniority. Each of our INEDs [has] signed an appointment letter with our Company for a term of [three] years effective upon the date of this document. For more information on the appointment letters, please refer to the section headed “Statutory and General Information – C. Further Information about Our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in this document.

For more information on the Directors’ remuneration during the Track Record Period as well as information on the highest paid individuals, please see Notes 8 and 9 of the Accountants’ Report set out in Appendix I to this document.

Save as disclosed above in this section and the sections headed “Financial Information”, “Accountants’ Report” and “Statutory and General Information” in this document, no other payments have been paid or are payable during the Track Record Period to our Directors by our Group.

CORPORATE GOVERNANCE

We [have] established the following committees in our Board of Directors: an Audit Committee, a Remuneration Committee and a Nomination Committee. The committees operate in accordance with terms of reference established by our Board of Directors.

Audit Committee

Our Company [has] established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code. The Audit Committee consists of three INEDs, namely, Dr. Pok Man Kam, Professor Joseph Wan Yee Lau and Dr. Jian Ji. Dr. Pok Man Kam, being the chairman of the Audit Committee, 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 of Directors by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Group, overseeing the audit process and performing other duties and responsibilities assigned by our Board of Directors.

DIRECTORS AND SENIOR MANAGEMENT

Remuneration Committee

Our Company [has] established the Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code. The Remuneration Committee consists of one non-executive Director, namely, Mr. Michael Yi Wei Zhao, and two INEDs, namely, Dr. Jian Ji and Dr. Pok Man Kam. Dr. Jian Ji is the chairman of the Remuneration Committee. The primary duties of the Remuneration Committee include, without limitation, making recommendations to the Board of Directors on our policy and structure for the remuneration of all Directors and senior management and on the establishment of a formal and transparent procedure for developing the policy on such remuneration, determining the specific remuneration packages of all Directors and senior management and reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by the Board of Directors from time to time.

Nomination Committee

Our Company [has] established the Nomination Committee with written terms of reference in compliance with the Corporate Governance Code. The Nomination Committee consists of one non-executive Director, namely, Mr. Michael Yi Wei Zhao, and two INEDs, namely, Professor Joseph Wan Yee Lau and Dr. Jian Ji. Mr. Michael Yi Wei Zhao is the chairman of the Nomination Committee. The primary duties of the Nomination Committee include, without limitation, reviewing the structure, size and composition of the Board of Directors, assessing the independence of the INEDs, making recommendations to the Board of Directors on matters relating to the appointment of Directors, developing, reviewing and assessing the adequacy of our Company’s policies and practices on corporate governance and reviewing our Company’s compliance with the Corporate Governance Code and disclosure in the corporate governance report.

Corporate Governance Code

Our Company aims to achieve high standards of corporate governance which are crucial to our development and safeguard the interests of our Shareholders. To accomplish this, we expect to comply with the Corporate Governance Code after the [REDACTED].

BOARD DIVERSITY POLICY

The Board will adopt a board diversity policy (the “**Board Diversity Policy**”) prior to the [REDACTED] in order to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Our Company recognizes and embraces the benefits of having a diverse Board. 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.

DIRECTORS AND SENIOR MANAGEMENT

Our Directors have a balanced mixed of knowledge and skills, including but not limited to business management, medical devices, biomaterials, pharmaceuticals, surgery, finance, investment and accounting. They obtained degrees in various majors including medicine, science, chemistry, applied chemistry, polymer chemistry, physics, engineering, risk management, financial engineering, business administration and international finance. Furthermore, our Board has a relatively wide range of ages, ranging from 34 years old to 73 years old. The Board of Directors is of the view that our Board satisfies the Board Diversity Policy.

The Nomination Committee is responsible for reviewing the diversity of the Board. Upon the [REDACTED], the Nomination Committee will from time to time review the Board Diversity Policy, develop and review measurable objectives for implementing the policy, and monitor the progress on achieving these measurable objectives in order to ensure that the policy remains effective. Our Company will (i) disclose the biographical details of each Director and (ii) report on the implementation of the Board Diversity Policy (including whether we have achieved board diversity) in its annual corporate governance report. In particular, our Company will take opportunities to increase the proportion of female members of the Board when selecting and recommending suitable candidates for Board appointments to help enhance gender diversity in accordance with stakeholder expectations and recommended best practices. Our Company also intends to promote gender diversity when recruiting staff at the mid to senior level so that our Company will have a pipeline of female senior management and potential successors to the Board. We plan to offer all-rounded trainings to female employees whom we consider to have the suitable experience, skills and knowledge of our operation and business, including but not limited to, business operation, management, accounting and finance, legal and compliance and research and development. We are of the view that such strategy will offer chances for our Board to identify capable female employees to be nominated as a member of the Board in future with an aim to providing our Board with a pipeline of female candidates to achieve gender diversity in our Board in the long run. The Nomination Committee will use its best endeavors and on suitable basis, to identify and recommend at least one female candidate to our Board for its consideration on appointment of a Director with the goal to have at least one female Director in our Board, subject to our Directors (i) being satisfied with the competence and experience of the relevant candidate based on reasonable criteria; and (ii) fulfilling their fiduciary duties to act in the best interests of our Company and our Shareholders as a whole when considering the appointment. We believe that such merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole.

DIRECTORS AND SENIOR MANAGEMENT

COMPLIANCE ADVISER

We have appointed Red Solar Capital Limited as our Compliance Adviser pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Adviser will advise our Company in certain circumstances including: (a) before the publication of any regulatory announcement, circular, or financial report; (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases; (c) where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; (d) where the Stock Exchange makes an inquiry to our Company under Rule 13.10 of the Listing Rules; and (e) where Stock Exchange or any other regulatory authorities make an inquiry regarding to company’s responsibilities or obligations as required by our Company under Listing Rules.

The term of appointment of our Compliance Adviser shall commence on the [REDACTED] and is expected to end on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

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.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are not members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which these non-executive Directors may hold directorships from time to time.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS

For a detailed description of our future plans, see “Business – Our Strategies.”

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and 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]% of net [REDACTED], or approximately HK\$[REDACTED] allocated to our Core Products as follows:
 - (i) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D and commercial launches of InterVapor including:
 - (a). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on clinical trials, including approximately HK\$[REDACTED] and HK\$[REDACTED] on clinical trials of InterVapor on lung cancer in China and U.S./EU, respectively, and approximately HK\$[REDACTED] on construction of research, development and testing facilities;
 - (b). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on post-market studies, including approximately HK\$[REDACTED], HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED] on the post-market studies in China, U.S., EU and other countries, respectively; and
 - (c). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on registration, including approximately HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED] on the registration in China, U.S. and other countries, respectively;
 - (ii) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D and commercial launches of RF-II, including:
 - (a). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on clinical trials, including approximately HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED] on clinical trials of RF-II in China, EU and U.S., respectively;

FUTURE PLANS AND USE OF [REDACTED]

- (b). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on commercialization in various jurisdictions, including approximately HK\$[REDACTED], HK\$[REDACTED] and HK\$[REDACTED] of the commercial launch of RF-II in China, EU and other countries, respectively, after receiving relevant marketing approval or CE Marking certification;
 - (c). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on product update; and
 - (d). [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] on registration, including approximately HK\$[REDACTED] and HK\$[REDACTED] on the registration in China and EU, respectively;
- [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED] allocated to our other products and product candidates as follows:
 - (i) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund the research and development of our navigation products, including the development of next-generation navigation systems;
 - (ii) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D, registration and commercialization of H-Marker;
 - (iii) [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund ongoing and planned R&D of other product candidates;
 - [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund our continued product line expansion of our manufacturing facilities;
 - [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], to fund our continued expansion of product portfolio through potential acquisition; and
 - [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for working capital and other general corporate purposes.

FUTURE PLANS AND USE OF [REDACTED]

The allocation of the [REDACTED] used for the above will be adjusted in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the estimated [REDACTED]. If the [REDACTED] is fixed at HK\$[REDACTED] per Share, being the high end of the stated [REDACTED], our net [REDACTED] will be (i) increased by approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised; or (ii) increased by approximately HK\$[REDACTED], assuming the [REDACTED] is exercised in full. In such circumstances, we currently intend to use such additional [REDACTED] to increase the net [REDACTED] applied for the same purposes as set out above on a pro rata basis. If the [REDACTED] is fixed at HK\$[REDACTED] per Share, being the low end of the stated [REDACTED], our net [REDACTED] will be (i) decreased by approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised; or (ii) decreased by approximately HK\$[REDACTED], assuming the [REDACTED] is exercised in full. In such circumstances, we currently intend to reduce the net [REDACTED] applied for the same purposes as set out above on a pro rata basis.

If the [REDACTED] is exercised in full, the additional net [REDACTED] that we will receive will be approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the proposed [REDACTED]. The Company may be required to issue up to an aggregate of [REDACTED] additional Shares pursuant to the [REDACTED].

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 may hold such funds in short-term deposits 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.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF BRONCUS HOLDING CORPORATION, GOLDMAN SACHS (ASIA) L.L.C AND HAITONG INTERNATIONAL CAPITAL LIMITED

Introduction

We report on the historical financial information of Broncus Holding Corporation (the “Company”) and its subsidiaries (together, the “Group”) set out on [pages I-4 to I-65], which comprises the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for the years ended 31 December 2019 and 2020 (the “Relevant Periods”), and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2019 and 2020 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-65] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ 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 accountants’ 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 accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance

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with the basis of preparation set out in note 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 accountants’ report, a true and fair view of the financial position of the Group and the Company as at 31 December 2019 and 2020 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange 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-3 have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

No historical financial statements for the Company

As at the date of this report, no statutory financial statements have been prepared for the Company since its date of incorporation.

Certified Public Accountants

Hong Kong

[Date]

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I HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

The Historical Financial Information is presented in United States dollar (“USD”) and all values are rounded to the nearest thousand (USD’000) except when otherwise indicated.

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CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

		Year ended 31 December	
		2019	2020
	Notes	USD’000	USD’000
REVENUE	5	8,072	3,259
Cost of sales		(2,094)	(753)
Gross profit		5,978	2,506
Other income and gains	5	304	1,074
Selling and distribution expenses		(8,609)	(6,352)
Administrative expenses		(8,855)	(7,722)
Impairment losses on financial assets, net	6	(20)	(214)
Research and development costs		(11,376)	(9,353)
Other expenses		(6)	(456)
Finance costs	7	(517)	(647)
Changes in fair value of convertible redeemable preferred shares	26	(9,448)	(27,620)
LOSS BEFORE TAX	6	(32,549)	(48,784)
Income tax expense	10	(2)	(2)
LOSS FOR THE YEAR		<u>(32,551)</u>	<u>(48,786)</u>
Attributable to:			
Owners of the parent		(31,929)	(48,237)
Non-controlling interests		<u>(622)</u>	<u>(549)</u>
		<u>(32,551)</u>	<u>(48,786)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (USD)	12	<u>(0.57)</u>	<u>(0.86)</u>

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended 31 December	
	2019	2020
	<i>USD’000</i>	<i>USD’000</i>
LOSS FOR THE YEAR	<u>(32,551)</u>	<u>(48,786)</u>
OTHER COMPREHENSIVE INCOME/(LOSS)		
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>35</u>	<u>(295)</u>
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	<u>35</u>	<u>(295)</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	<u><u>(32,516)</u></u>	<u><u>(49,081)</u></u>
Attributable to:		
Owners of the parent	(31,896)	(48,510)
Non-controlling interests	<u>(620)</u>	<u>(571)</u>
	<u><u>(32,516)</u></u>	<u><u>(49,081)</u></u>

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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		As at 31 December	
		2019	2020
	Notes	USD'000	USD'000
NON-CURRENT ASSETS			
Property, plant and equipment	13	816	2,473
Intangible assets	15	9,434	8,258
Right-of-use assets	14	1,216	1,984
Finance lease receivables	21	104	97
Trade receivables	17	935	–
Prepayments, other receivables and other assets	18	229	170
Pledged deposits	20	213	213
Total non-current assets		12,947	13,195
CURRENT ASSETS			
Inventories	16	1,828	3,051
Finance lease receivables	21	21	23
Trade receivables	17	3,189	2,936
Prepayments, other receivables and other assets	18	810	1,852
Due from a director	19	13	–
Due from related parties	32(c)	85	7
Pledged deposits	20	25	25
Cash and cash equivalents	20	3,085	18,788
Total current assets		9,056	26,682
CURRENT LIABILITIES			
Trade payables	22	246	357
Lease liabilities	14	560	512
Other payables and accruals	23	5,514	9,133
Due to related parties	32(c)	1,632	–
Interest-bearing bank and other borrowings	24	5,772	3,730
Contract liabilities	25	420	495
Total current liabilities		14,144	14,227
NET CURRENT (LIABILITIES)/ASSETS		(5,088)	12,455
TOTAL ASSETS LESS CURRENT LIABILITIES		7,859	25,650

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		As at 31 December	
		2019	2020
		USD’000	USD’000
	Notes		
NON-CURRENT LIABILITIES			
Lease liabilities	14	674	1,419
Contract liabilities	25	168	77
Interest-bearing bank and other borrowings	24	–	458
Convertible redeemable preferred shares	26	80,897	146,137
Total non-current liabilities		81,739	148,091
Net liabilities		(73,880)	(122,441)
EQUITY			
Equity attributable to owners of the parent			
Share capital	27	6	6
Reserves	28	(72,370)	(120,519)
Non-controlling interests		(72,364)	(120,513)
Total equity		(73,880)	(122,441)

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2019

	Attributable to owners of the parent					Non-controlling interests	Total equity
	Share capital	Other reserve*	Share option reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total	
	USD'000 (note 27)	USD'000 (note 28)	USD'000 (note 28)	USD'000 (note 28)	USD'000	USD'000	USD'000
At 1 January 2019	6	46,729	395	94	(92,774)	(45,550)	(1,272) (46,822)
Loss for the year	–	–	–	–	(31,929)	(31,929)	(622) (32,551)
Exchange differences on translation of foreign operations	–	–	–	33	–	33	2 35
Total comprehensive loss for the year	–	–	–	33	(31,929)	(31,896)	(620) (32,516)
Share dilution in subsidiaries due to capital injection from the Company	–	(80)	8	–	–	(72)	72 –
Equity-settled share option arrangements	–	–	5,354	–	–	5,354	304 5,658
Repurchase of shares of a subsidiary	–	(200)	–	–	–	(200)	– (200)
At 31 December 2019	<u>6</u>	<u>46,449</u>	<u>5,757</u>	<u>127</u>	<u>(124,703)</u>	<u>(72,364)</u>	<u>(1,516) (73,880)</u>

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Year ended 31 December 2020

	Attributable to owners of the parent					Non-controlling interests	Total equity
	Share capital	Other reserve*	Share option reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total	
	USD’000 (note 27)	USD’000 (note 28)	USD’000 (note 28)	USD’000 (note 28)	USD’000	USD’000	USD’000
At 31 December 2019	6	46,449	5,757	127	(124,703)	(72,364)	(73,880)
Loss for the year	–	–	–	–	(48,237)	(48,237)	(48,786)
Exchange differences on translation of foreign operations	–	–	–	(273)	–	(273)	(295)
Total comprehensive loss for the year	–	–	–	(273)	(48,237)	(48,510)	(571)
Share dilution in subsidiaries due to capital injection from the Company	–	(169)	30	–	–	(139)	139
Capital injection from the exercise of equity-settled share options in a subsidiary	–	–	–	–	–	–	7
Equity-settled share option arrangements	–	–	500	–	–	500	13
At 31 December 2020	<u>6</u>	<u>46,280</u>	<u>6,287</u>	<u>(146)</u>	<u>(172,940)</u>	<u>(120,513)</u>	<u>(1,928)</u>
	<u>6</u>	<u>46,280</u>	<u>6,287</u>	<u>(146)</u>	<u>(172,940)</u>	<u>(120,513)</u>	<u>(1,928)</u>

* These reserve accounts comprise the consolidated reserves of USD(72,370,000) and USD(120,519,000) in the consolidated statements of financial position as at 31 December 2019 and 2020, respectively.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

		Year ended 31 December	
		2019	2020
	Notes	USD'000	USD'000
CASH FLOWS FROM			
OPERATING ACTIVITIES			
Loss before tax		(32,549)	(48,784)
Adjustments for:			
Finance costs	7	517	647
Bank interest income	5	(17)	(11)
Interest income from non-current receivables	5	(102)	(65)
Investment income from debt investments measured at fair value through profit or loss	5	(3)	–
(Gain)/loss on disposal of items of property, plant and equipment	6	(122)	31
Loss on disposal of intangible assets		–	2
Depreciation of property, plant and equipment	13	248	287
Depreciation of right-of-use assets	14	576	658
Amortisation of intangible assets	15	1,249	1,247
Covid-19-related rent concessions from lessors	14	–	(15)
Gain on termination of a lease		–	(14)
Impairment of trade receivables	17	20	214
Write-down of inventories to net realisable value	6	–	11
Equity-settled share option expenses		5,597	509
Changes in fair value of convertible redeemable preferred shares	6	9,448	27,620
Foreign exchange differences, net	6	(35)	252
		(15,173)	(17,411)
Decrease/(increase) in inventories		81	(1,234)
(Increase)/decrease in trade receivables		(10)	1,018
(Increase)/decrease in finance lease receivables		(123)	23
Decrease/(increase) in prepayments, other receivables and other assets		15	(419)
(Increase)/decrease in an amount due from a director		(13)	13
Increase in an amount due from a related party		–	(7)
(Decrease)/increase in trade payables		(97)	111
(Decrease)/increase in other payables and accruals		(723)	2,325
Increase/(decrease) in contract liabilities		213	(16)
Cash used in operations		(15,830)	(15,597)
Interest received		17	11
Income tax paid		(2)	(2)
Net cash flows used in operating activities		(15,815)	(15,588)

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		Year ended 31 December	
		2019	2020
		USD’000	USD’000
Notes			
	CASH FLOWS FROM		
	INVESTING ACTIVITIES		
	Purchases of items of property, plant and equipment	(361)	(1,101)
	Proceeds from disposal of items of property, plant and equipment	185	–
	Purchases of intangible assets	(10)	(73)
	Purchases of debt investments measured at fair value through profit or loss	(1,188)	–
	Proceeds from disposal of debt investments measured at fair value through profit or loss	1,191	–
32(a)	Loans to related parties	(85)	(294)
	Repayment by related parties	–	379
	Net cash flows used in investing activities	(268)	(1,089)
	CASH FLOWS FROM		
	FINANCING ACTIVITIES		
	Proceeds from issue of convertible redeemable preferred shares	19,125	37,620
	New bank and other borrowings	7,637	12,628
	Repayment of bank and other borrowings	(10,832)	(14,882)
32(a)	Loans from related parties	6,077	4,593
	Repayment of loans from related parties	(4,445)	(6,265)
	Principal portion of lease payments	(528)	(703)
	Payment for deferred [REDACTED] expenses	–	(215)
	Capital injection from the exercise of equity-settled share options in a subsidiary	–	7
	Repurchase of shares of a subsidiary	(200)	–
	Interest paid	(493)	(558)
	Net cash flows from financing activities	16,341	32,225
	NET INCREASE IN CASH AND		
	CASH EQUIVALENTS	258	15,548
	Cash and cash equivalents at beginning of year	2,778	3,085
	Effect of foreign exchange rate changes, net	49	155
	CASH AND CASH EQUIVALENTS AT		
	END OF YEAR	20	3,085
			18,788
	ANALYSIS OF BALANCES OF CASH AND		
	CASH EQUIVALENTS		
	Cash and bank balances	20	3,085
			18,788

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STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December	
		2019	2020
	Notes	USD’000	USD’000
NON-CURRENT ASSETS			
Investments in subsidiaries		95,389	120,051
Total non-current assets		95,389	120,051
CURRENT ASSETS			
Due from a related party	32(c)	85	–
Due from subsidiaries	32(c)	7	122
Prepayments, other receivables and other assets	18	–	525
Cash and cash equivalents	20	241	13,270
Total current assets		333	13,917
CURRENT LIABILITIES			
Other payables and accruals	23	422	3,277
Total current liabilities		422	3,277
NET CURRENT (LIABILITIES)/ASSETS		(89)	10,640
TOTAL ASSETS LESS CURRENT LIABILITIES			
		95,300	130,691
NON-CURRENT LIABILITIES			
Convertible redeemable preferred shares	26	80,897	146,137
Total non-current liabilities		80,897	146,137
Net assets/(liabilities)		14,403	(15,446)
EQUITY			
Share capital	27	6	6
Reserves	28	14,397	(15,452)
Total equity		14,403	(15,446)

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II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on 30 April 2012. The registered address of the Company is PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

The Company is an investment holding company. During the Relevant Periods, the Company’s subsidiaries were principally engaged in research and development, and the manufacture and commercialisation of medical device and consumables.

As at the end of the Relevant Periods, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

Name	Place and date of incorporation/ registration and place of operations	Nominal value of issued ordinary/registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
Broncus Medical Inc. (“BMI”) (Note (a))	United States of America (“USA”) 7 May 2012	USD1	99.94%	–	Research development and commercialisation of medical devices and consumables
Broncus Medical (Australia) Pty Ltd (“BMA”) (Note (a))	Australia 15 October 2018	Australian dollar (“AUD”) 100	100%	–	Commercialisation of medical devices
Uptake Medical Technology Inc. (“UMT”) (Note (a))	USA 19 July 2016	USD1	100%	–	Research development and commercialisation of medical devices and consumables
Uptake Medical B.V. (Note (a))	Netherlands 17 August 2017	Euro (“EUR”) 10,000	–	100%	Commercialisation of medical devices
Broncus China Holding Corporation (“BCH”) (Note (a))	Cayman Islands 18 April 2013	USD1	93.02%	–	Commercialisation of medical devices
Broncus Medical (Hong Kong) Co., Limited (“BMHK”) (Note (b))	Hong Kong 19 June 2013	Hong Kong dollar (“HKD”) 10,000	–	93.02%	Commercialisation of medical devices
Hangzhou Broncus Medical Co., Ltd.* (“Hangzhou Broncus”) 杭州堃博生物科技 有限公司 (Note (c))	People Republic of China (“PRC”)/ Mainland China 24 February 2016	Renminbi (“RMB”) 150,000,000	–	93.02%	Research development and commercialisation of medical devices and consumables
Broncus Medical (China) Co., Ltd.* (“Shanghai Broncus”) 堃博生物科技(上海) 有限公司 (Note (a))	PRC/Mainland China 18 December 2012	RMB55,600,000	–	93.02%	Research development and commercialisation of medical devices and consumables
Hangzhou Kunpeng Medical Co., Ltd.* 杭州堃鹏生物科技 有限公司 (Note (a))	PRC/Mainland China 4 July 2018	RMB1,000,000	–	93.02%	No principle activity

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Notes:

- (a) No audited financial statements have been prepared for these entities for the years ended 31 December 2019 and 2020, as these entities were not subject to any statutory audit requirements under the relevant rules and regulations in their jurisdictions of incorporation.
- (b) The statutory financial statements of this entity for the year ended 31 December 2019 prepared under PRC General Accepted Accounting Principles (“PRC GAAP”) were audited by Shanghai Jiuyuan Certified Public Accountants (上海九源會計師事務所(特殊普通合夥)), certified public accountants registered in the PRC.
- (c) The statutory financial statements of this entity for the year ended 31 December 2019 prepared under PRC GAAP were audited by Pan-China Certified Public Accountants (天健會計師事務所(特殊普通合夥)), certified public accountants registered in the PRC.
- * The English names of these entities registered in Mainland China represent the best efforts made by the management of the Company to directly translate their Chinese names as they did not register any official English names.

2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board. All IFRSs effective for the accounting period commencing from 1 January 2020, as well as the amendment to IFRS 16 *Covid-19-Related Rent Concessions*, together with the relevant transitional provisions, have been consistently applied by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods.

The Historical Financial Information has been prepared under the historical cost convention, except for debt investments measured at fair value through profit or loss and convertible redeemable preferred shares which have been measured at fair value.

The Group had net deficit in assets of approximately USD122,441,000 as at 31 December 2020. Taking into account cash and cash equivalents on hand and operating and financing cash flows, the directors believe that the Group has sufficient cash flows in the foreseeable future to enable it to continue its operations and meet its liabilities as and when they fall due. Therefore, the Historical Financial Information has been prepared on a going concern basis.

Basis of consolidation

The Historical Financial Information includes the financial information of the Company and its subsidiaries (collectively referred to as the “Group”) for the Relevant Periods. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

The financial information of the subsidiaries is prepared for the same Relevant Periods as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in the statement of profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or accumulated losses, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

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2.2 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

Except for the amendment to IFRS 16, the Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to IFRS 3	<i>Reference to the Conceptual Framework²</i>
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	<i>Interest Rate Benchmark Reform – Phase 2¹</i>
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture⁴</i>
Amendments to IFRS 17	<i>Insurance Contracts^{3, 5}</i> <i>Insurance Contracts³</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current³</i>
Amendments to IAS 1	<i>Disclosure of Accounting Policies³</i>
Amendments to IAS 8	<i>Definition of Accounting Estimates³</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use²</i>
Amendments to IAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract²</i>
<i>Annual Improvements to IFRS 2018-2020</i>	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41 ²

¹ Effective for annual periods beginning on or after 1 January 2021

² Effective for annual periods beginning on or after 1 January 2022

³ Effective for annual periods beginning on or after 1 January 2023

⁴ No mandatory effective date yet determined but available for adoption

⁵ As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group considers that these new and revised IFRSs may result in changes in accounting policies but are unlikely to have a significant impact on the Group’s financial performance and financial position.

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures certain financial instruments at fair value at the end of each of the Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

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All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the Historical Financial Information on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories and financial assets), the asset’s recoverable amount is estimated. An asset’s recoverable amount is the higher of the asset’s or cash-generating unit’s value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person’s family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;
- or
- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);

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- (iii) the entity and the Group are joint ventures of the same third party;
- (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
- (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
- (vi) the entity is controlled or jointly controlled by a person identified in (a);
- (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
- (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The estimated useful lives of property, plant and equipment are as follows:

Machinery	5 to 10 years
Office equipment	3 to 7 years
Leasehold improvements	3 to 6 years

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation methods are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the statement of profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Intellectual property

Purchased intellectual property is stated at cost less any impairment losses and is amortised on the straight-line basis over its estimated useful life of 12 to 14 years, which is determined by considering the typical product effective life of the intellectual property.

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Software

Purchased software is stated at cost less any impairment losses and amortised on the straight-line basis over its estimated useful life of 3 to 10 years.

Research and development cost

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Office premises and warehouses	2 to 5 years
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If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

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(c) Short-term leases

The Group applies the short-term lease recognition exemption to its short-term leases of office premises (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option).

Lease payments on short-term leases are recognised as an expense on a straight-line basis over the lease term.

Group as a lessor

When the Group acts as a lessor, it classifies at lease inception (or when there is a lease modification) each of its leases as either an operating lease or a finance lease.

Leases in which the Group does not transfer substantially all the risks and rewards incidental to ownership of an asset are classified as operating leases. When a contract contains lease and non-lease components, the Group allocates the consideration in the contract to each component on a relative stand-alone selling price basis. Rental income is accounted for on a straight-line basis over the lease terms and is included in revenue in the statement of profit or loss due to its operating nature.

Leases that transfer substantially all the risks and rewards incidental to ownership of an underlying assets to the lessee are accounted for as finance leases. At the commencement date, the cost of the leased asset is capitalised at the present value of the lease payments and related payments (including the initial direct costs) and presented as a receivable at an amount equal to the net investment in the lease. The finance income on the net investment in the lease is recognised in the statement of profit or loss so as to provide a constant periodic rate of return over the lease terms.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially 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. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

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Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in the statement of profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in the statement of profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At the end of each of the Relevant Periods, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the end of each of the Relevant Periods with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

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The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and finance lease receivables which apply the simplified approach as detailed below.

Stage 1 –	Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
Stage 2 –	Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
Stage 3 –	Financial assets that are credit-impaired at the end of each of the Relevant Periods (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at the end of each of the Relevant Periods. The Group has established a provision matrix that is based on market historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

For trade receivables and finance lease receivables that contain a significant financing component and lease receivables, the Group chooses as its accounting policy to adopt the simplified approach in calculating ECLs with policies as described above.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as convertible redeemable preferred shares, loans and borrowings or payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade payables, other payables and accruals, amounts due to related parties, lease liabilities, interest-bearing bank and other borrowings and convertible redeemable preferred shares.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities designated upon initial recognition as at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. Gains or losses on liabilities designated at fair value through profit or loss are recognised in the statement of profit or loss, except for the gains or losses arising from the Group’s own credit risk which are presented in other comprehensive income with no subsequent reclassification to the statement of profit or loss. The net fair value gain or loss recognised in the statement of profit or loss does not include any interest charged on these financial liabilities.

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Financial liabilities at amortised cost (loans and borrowings and payables)

After initial recognition, interest-bearing bank and other borrowings and payables are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in the statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average basis and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired and form an integral part of the Group’s cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks which are not restricted as to use.

Provisions

A provision is recognised when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

When the effect of discounting is material, the amount recognised for a provision is the present value at the end of each of the Relevant Periods of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in the statement of profit or loss.

The Group provides for warranties in relation to the sale of certain products for general repairs of defects occurring during the warranty period. Provisions for these assurance-type warranties granted by the Group are recognised based on sales volume and past experience of the level of repairs and returns, discounted to their present values as appropriate.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

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Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and joint ventures, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to the statement of profit or loss by way of a reduced depreciation charge.

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Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sale of medical devices and consumables

Revenue from the sale of medical devices and consumables is recognised at the point in time when control of the asset is transferred to the customer.

(b) Provision of services

Revenue from the product support services is recognised over the service period on a straight-line basis and revenue from research development support services is recognised over time using an input method to measure progress towards complete satisfaction of the service, because the customer simultaneously receives and consumes the benefits provided by the Group.

Revenue from other sources

Rental income is recognised on a time proportion basis over the lease terms.

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Contract liabilities

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods or services. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related goods or services to the customer).

Share-based payments

The Company operates a share award plan for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“equity-settled transactions”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 29 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

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Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Other employee benefits

Pension scheme

The employees of the Group’s subsidiaries which operate in Mainland China and the United States are required to participate in a central pension scheme operated by the local government. The subsidiaries operating in Mainland China and the United States are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to the statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

Termination benefits

Termination benefits are recognised at the earlier of when the Group can no longer withdraw the offer of those benefits and when the Group recognises restructuring costs involving the payment of termination benefits.

Borrowing costs

All borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

Dividends

Final dividends are recognised as a liability when they are approved by the shareholders in a general meeting.

Foreign currencies

The Historical Financial Information is presented in USD, which is the Company’s functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on

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translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currencies of certain subsidiaries are currencies other than USD. As at the end of each of the Relevant Periods, the assets and liabilities of these entities are translated into USD at the exchange rates prevailing at the end of each of the Relevant Periods and their statements of profit or loss are translated into USD at the weighted average exchange rates for the year.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the statement of profit or loss.

For the purpose of the consolidated statement of cash flows, the cash flows of those subsidiaries are translated into USD at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into USD at the weighted average exchange rates for the year.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group’s accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the Historical Financial Information.

Research and development costs

Research and development costs are expensed in accordance with the accounting policy for research and development costs in note 2.3 to the Historical Financial Information. Determining the amounts to be capitalised or expensed requires management to make assumptions and judgements regarding to technical feasibility of completing the intangible asset, future economic benefits and so forth.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Provision for expected credit losses of trade receivables and finance lease receivables

The Group uses a provision matrix to calculate ECLs for trade receivables and finance lease receivables. The provision rates are based on ageing for groupings of various customer segments that have similar loss patterns (i.e., by customer type).

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The provision matrix is initially based on the historical observed default rates from listed companies in the same sector. The Group calibrates the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecast economic conditions (i.e., gross domestic product) are expected to deteriorate over the next year which can lead to an increased number of defaults in the medical industry sector, the historical default rates are adjusted. At the end of each of the Relevant Periods, the historical observed default rates are updated and changes in the forward-looking estimates are analysed.

The assessment of the correlation between historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and of forecast economic conditions. The Group’s historical credit loss experience and forecast of economic conditions may also not be representative of customers’ actual default in the future. The information about the ECLs on the Group’s trade receivables is disclosed in note 17 to the Historical Financial Information.

Useful lives of intangible assets

The Group’s finite life intangible assets primarily represent patents transferred from third parties. These intangible assets are amortised on a straight-line basis over their useful economic lives, which are estimated to be the patent life. Additional amortisation is recognised if the estimated useful lives of patents are different from the previous estimation. Useful lives are reviewed at the end of each of the Relevant Periods based on changes in circumstances.

Impairment of non-financial assets

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Relevant Periods. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Estimation of the fair value of financial liabilities

Certain financial liabilities are measured at fair value at the end of each of the Relevant Periods as disclosed in note 34 to the Historical Financial Information.

The convertible redeemable preferred shares issued by the Company are not traded in an active market and the respective fair value is determined by using valuation techniques. The Group applied the discounted cash flow method and back-solve method to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions such as the timing of the liquidation, redemption or the liquidation event as well as the probability of the various scenarios were based on the Group’s best estimates. Further details are included in note 26 to the Historical Financial Information.

Fair value measurement of share-based payments

The Group has set up the certain share plan and granted options to the Company’s directors and the Group’s employees. The fair value of the options is determined by a binomial model at the grant dates. Significant estimates on assumptions, including the expected volatility, risk-free interest rate and expected life of options, are made by the board of directors of the Company. Further details are included in note 29 to the Historical Financial Information.

4. OPERATING SEGMENT INFORMATION

For management purposes, the Group is not organised into business units based on their products and only has one reportable operating segment. Management monitors the operating results of the Group’s operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment.

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Geographical information

(a) Revenue from external customers

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Mainland China	3,600	1,267
European Union	2,241	749
USA	346	382
Other countries/regions	1,885	861
	<u>8,072</u>	<u>3,259</u>

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	As at 31 December	
	2019	2020
	USD’000	USD’000
USA	10,604	8,415
Mainland China	840	4,340
European Union	40	31
Other countries/regions	12	9
Total	<u>11,496</u>	<u>12,795</u>

The non-current asset information above is based on the locations of the assets and excluded financial instruments.

Information about major customers

Revenue from each major customer which accounted for 10% or more of the Group’s revenue during the Relevant Periods is set out below:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Customer A	2,045	N/A*
Customer B	N/A*	565
Customer C	N/A*	449

* The corresponding revenue of the customer is not disclosed as the revenue individually did not account for 10% or more of the Group’s revenue during the Relevant Periods.

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5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
<i>Revenue from contracts with customers</i>		
Sale of medical devices and consumables	7,606	2,788
Provision of services	461	428
<i>Revenue from other sources</i>		
Gross rental income	5	43
	<u>8,072</u>	<u>3,259</u>

Revenue from contracts with customers

(a) Disaggregated revenue information

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Geographical markets		
Mainland China	3,600	1,267
European Union	2,236	749
USA	346	339
Other countries/regions	1,885	861
	<u>8,067</u>	<u>3,216</u>
Timing of revenue recognition		
Goods transferred at a point in time	7,606	2,788
Services transferred over time	461	428
	<u>8,067</u>	<u>3,216</u>

The following table shows the amounts of revenue recognised during the Relevant Periods that were included in the contract liabilities at the beginning of the Relevant Periods and recognised from performance obligations satisfied in previous periods:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Revenue recognised that was included in contract liabilities at the beginning of the year:		
Sale of medical devices and consumables	190	27
Provision of services	155	266
	<u>345</u>	<u>293</u>

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(b) *Performance obligations*

Information about the Group’s performance obligations is summarised below:

Sale of medical devices and consumables

Revenue from the sale of medical devices and consumables is recognised at the point in time when control of the asset is transferred to the customer.

Provision of services

Revenue from the product support services is recognised over the service period on a straight-line basis and revenue from research development support services is recognised over time using an input method to measure progress towards complete satisfaction of the service, because the customer simultaneously receives and consumes the benefits provided by the Group.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at the end of each of the Relevant Periods are as follows:

	As at 31 December	
	2019	2020
	<i>USD’000</i>	<i>USD’000</i>
Amounts expected to be recognised as revenue:		
Within one year	797	675
After one year	168	77
	<u>965</u>	<u>752</u>

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue after one year relate to provision of services, of which the performance obligations are to be satisfied within two years.

An analysis of other income and gains is as follows:

	Year ended 31 December	
	2019	2020
	<i>USD’000</i>	<i>USD’000</i>
<u>Other income</u>		
Government grants (<i>note (a)</i>)	25	352
Compensation from termination of a distribution agreement	–	632
Bank interest income	17	11
Interest income from non-current receivables	102	65
Investment income from debt investments measured at fair value through profit or loss	3	–
	<u>147</u>	<u>1,060</u>
<u>Gains</u>		
Gain on disposal of items of property, plant and equipment	122	–
Gain on termination of a lease	–	14
Foreign exchange gains, net	35	–
	<u>157</u>	<u>14</u>
	<u>304</u>	<u>1,074</u>

Note:

- (a) The government grants mainly represent incentives received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new product development and expenditure incurred on certain projects.

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6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	<i>Notes</i>	Year ended 31 December	
		2019	2020
		<i>USD’000</i>	<i>USD’000</i>
Cost of inventories sales		1,895	647
Cost of services provided		199	95
Research and development costs*		11,376	9,353
Depreciation of property, plant and equipment**	13	248	287
Depreciation of right-of-use assets***	14(a)	576	658
Amortisation of intangible assets****	15	1,249	1,247
Impairment of trade receivables, net	17	20	214
Write-down of inventories to net realisable value*****		–	11
Government grants	5	(25)	(352)
Interest income from non-current receivables	5	(102)	(65)
Bank interest income	5	(17)	(11)
Investment income from debt instruments measured at fair value through profit or loss	5	(3)	–
Compensation from termination of a distribution agreement	5	–	(632)
(Gain)/loss on disposal of items of property, plant and equipment		(122)	31
Changes in fair value of convertible redeemable preferred shares	26	9,448	27,620
Lease payments not included in the measurement of lease liabilities	14(c)	243	158
Foreign exchange differences, net		(35)	252
Auditor’s remuneration		94	22
[REDACTED] expenses		–	1,599
Employee benefit expense (excluding directors’ and chief executive’s remuneration (note 8)):			
Wages and salaries		9,122	9,109
Pension scheme contributions		556	339
Staff welfare expenses		1,371	1,577
Equity-settled share option expenses		4,750	509
		<u>15,799</u>	<u>11,534</u>

* The research and development costs include USD5,588,000 and USD4,270,000 relating to employee benefit expense for the Relevant Periods.

** The depreciation of property, plant and equipment for the Relevant Periods is included in “Selling and distribution expenses”, “Administrative expenses” and “Research and development costs” in the consolidated statements of profit or loss.

*** The depreciation of right-of-use assets for the Relevant Periods is included in “Administrative expenses” and “Research and development costs” in the consolidated statements of profit or loss.

**** The amortisation of intangible assets for the Relevant Periods is included in “Research and development costs” in the consolidated statements of profit or loss.

***** The write-down of inventories to net realisable value for the Relevant Periods is included in “Cost of sales” in the consolidated statements of profit or loss.

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7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Interest on bank and other borrowings	359	465
Interest on lease liabilities	55	82
Interest on other loans from related parties	103	100
	<u>517</u>	<u>647</u>

8. DIRECTORS’ AND CHIEF EXECUTIVE’S REMUNERATION

Mr. Michael Yi Wei Zhao, Mr. Zhenjun Zi and Mr. Ao Zhang were appointed as non-executive directors of the Company on 6 May 2021. Mr. Guowei Zhan and Mr. Hong Xu were appointed as executive directors of the Company on 6 May 2021.

Dr. Pok Man KAM, Professor Joseph Wan Yee LAU and Dr. Jian JI were appointed as independent non-executive directors on [●].

Certain directors received remuneration from the Company and its subsidiaries for their appointment as directors of these subsidiaries. The remuneration of each of these directors as recorded in the financial statements of the Company and its subsidiaries is set out below:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Fees	–	–
Other emoluments:		
Salaries, bonuses, allowances and benefits in kind	341	341
Pension scheme contributions	3	–
Equity-settled share option expenses	847	–
	<u>1,191</u>	<u>341</u>

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Independent non-executive directors

There were no fees and other emoluments payable to the independent non-executive directors during the Relevant Periods.

Directors

	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Equity- settled share option expenses	Total remuneration
	USD’000	USD’000	USD’000	USD’000
Year ended 31 December 2019				
Mr. Guowei Zhan (chief executive)	149	3	847	999
Mr. Michael Yi Wei Zhao	192	–	–	192
	<u>341</u>	<u>3</u>	<u>847</u>	<u>1,191</u>

Year ended 31 December 2020

Mr. Guowei Zhan (chief executive)	149	–	–	149
Mr. Michael Yi Wei Zhao	192	–	–	192
	<u>341</u>	<u>–</u>	<u>–</u>	<u>341</u>

During the Relevant Periods, Mr. Guowei Zhan was granted share options in respect of his services to the Group, further details of which are included in the disclosures in note 29 to the Historical Financial Information. The fair value of such options, which has been recognised in the statement of profit or loss over the vesting period, was determined as at the date of grant and the amounts included in the Historical Financial Information for the Relevant Periods are included in the above directors’ remuneration disclosures.

There was no arrangement under which a director or the chief executive waived or agreed to waive any remuneration during the Relevant Periods. During the Relevant Periods, no remuneration was paid by the Group to the directors as an inducement to join or upon joining the Group or as compensation for loss of office.

9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods included one and nil director, respectively, details of whose remuneration are set out in note 8 above. Details of the remuneration for the remaining four and five highest paid employees who are neither a director nor chief executive of the Company during the Relevant Periods are as follows:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Salaries, bonuses, allowances and benefits in kind	560	1,068
Pension scheme contributions	21	26
Equity-settled share option expenses	2,097	392
	<u>2,678</u>	<u>1,486</u>

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The numbers of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands are as follows:

	Number of employees	
	Year ended 31 December	
	2019	2020
	USD’000	USD’000
HKD1,000,000 to HKD2,000,000	–	4
HKD3,000,000 to HKD4,000,000	1	–
HKD4,000,000 to HKD5,000,000	1	1
HKD5,000,000 to HKD6,000,000	1	–
HKD7,000,000 to HKD8,000,000	1	–
	4	5

During the Relevant Periods, share options were granted to certain non-director and non-chief executive highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in note 29 to the Historical Financial Information. The fair value of such options, which has been recognised in the statement of profit or loss over the vesting period, was determined as at the date of grant and the amounts included in the Historical Financial Information for the Relevant Periods are included in the above non-director and non-chief executive highest paid employees’ remuneration disclosures.

10. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

PRC

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China were entitled to a preferential income tax rate of 20% for small and micro enterprises during the Relevant Periods except that Hangzhou Broncus was subject to CIT at a rate of 25% on the taxable income for the year ended 31 December 2020.

USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of up to 21% on the taxable income arising in the USA during the Relevant Periods.

Netherlands

The subsidiary incorporated in Netherlands was subject to income tax at the rates of 19% and 16.5% on the estimated assessable profits arising in Netherlands during the years ended 31 December 2019 and 2020, respectively.

Australia

The subsidiary incorporated in Australia was subject to income tax at the rate of 27.5% on the estimated assessable profits arising in Australia during the Relevant Periods.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

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Hong Kong

The subsidiary incorporated in Hong Kong was subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong during the Relevant Periods.

The income tax expense of the Group during the Relevant Periods is analysed as follows:

	Year ended 31 December	
	2019	2020
	USD'000	USD'000
Current – USA		
Charge for the year	2	2

A reconciliation of the tax expense applicable to loss before tax at the statutory rate to the tax expense at the effective tax rate is as follows:

	Year ended 31 December	
	2019	2020
	USD'000	USD'000
Loss before tax	(32,549)	(48,784)
Tax at the statutory tax rate	(5,010)	(4,513)
Expenses not deductible for tax	1,161	185
Additional deductible allowance for research and development costs	(221)	(470)
Temporary differences and tax losses not recognised	4,072	4,800
Tax charge at the Group’s effective tax rate	2	2

Deferred tax assets have not been recognised in respect of the following items:

	As at 31 December	
	2019	2020
	USD'000	USD'000
Tax losses	86,190	104,199
Deductible temporary differences	1,619	1,794
	87,809	105,993

The Group had tax losses arising in Mainland China of RMB130,022,000 (equivalent to USD18,632,000) and RMB149,340,000 (equivalent to USD26,148,000) as at 31 December 2019 and 2020, that will expire in one to five years for offsetting against taxable profits, respectively.

The Group had tax losses arising in USA of USD37,454,000 and USD37,454,000 as at 31 December 2019 and 2020, that will expire in twelve to seventeen years for offsetting against taxable profits, respectively. The Group had tax losses arising in USA of USD28,956,000 and USD38,908,000 as at 31 December 2019 and 2020 for offsetting against taxable profits indefinitely, respectively.

The Group had tax losses arising in Netherlands of USD1,049,000 and USD1,574,000 as at 31 December 2019 and 2020, that will expire in three to six years for offsetting against taxable profits, respectively.

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The Group had tax losses arising in Australia of USD99,000 and USD115,000 as at 31 December 2019 and 2020 for offsetting against taxable profits indefinitely, respectively.

Deferred tax assets have not been recognised in respect of these losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

11. DIVIDEND

No dividend has been paid or declared by the Company since its date of incorporation and up to the end of the Relevant Periods.

12. LOSS SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss for the years ended 31 December 2019 and 2020 attributable to ordinary equity holders of the parent, and the numbers of ordinary shares of 55,944,670 and 55,944,670, respectively. No adjustment has been made to the basic loss per share amounts presented for the Relevant Periods in respect of a dilution as the impact of the convertible redeemable preferred shares had an anti-dilutive effect on the basic loss per share amounts presented.

13. PROPERTY, PLANT AND EQUIPMENT

	Leasehold improvements	Machinery	Office equipment	Construction in progress	Total
	USD'000	USD'000	USD'000	USD'000	USD'000
31 December 2019					
At 1 January 2019:					
Cost	382	633	370	–	1,385
Accumulated depreciation	(176)	(254)	(166)	–	(596)
Net carrying amount	206	379	204	–	789
At 1 January 2019, net of accumulated depreciation	206	379	204	–	789
Additions	72	226	46	–	344
Disposals	–	(62)	(1)	–	(63)
Depreciation provided during the year (<i>note</i> <i>6</i>)	(88)	(106)	(54)	–	(248)
Exchange realignment	(1)	(5)	–	–	(6)
At 31 December 2019, net of accumulated depreciation	189	432	195	–	816
At 31 December 2019:					
Cost	452	768	408	–	1,628
Accumulated depreciation	(263)	(336)	(213)	–	(812)
Net carrying amount	189	432	195	–	816

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	Leasehold improvements <i>USD’000</i>	Machinery <i>USD’000</i>	Office equipment <i>USD’000</i>	Construction in progress <i>USD’000</i>	Total <i>USD’000</i>
31 December 2020					
At 1 January 2020:					
Cost	452	768	408	–	1,628
Accumulated depreciation	(263)	(336)	(213)	–	(812)
Net carrying amount	189	432	195	–	816
At 1 January 2020, net of accumulated depreciation	189	432	195	–	816
Additions	–	154	155	1,629	1,938
Disposal	(6)	(22)	(3)	–	(31)
Depreciation provided during the year (<i>note</i> <i>6</i>)	(97)	(120)	(70)	–	(287)
Exchange realignment	3	27	7	–	37
At 31 December 2020, net of accumulated depreciation	89	471	284	1,629	2,473
At 31 December 2020:					
Cost	450	779	537	1,629	3,395
Accumulated depreciation	(361)	(308)	(253)	–	(922)
Net carrying amount	89	471	284	1,629	2,473

14. LEASES

The Group as a lessee

The Group has lease contracts for warehouses and office premises used in its operations. Leases of warehouses and office premises generally have lease terms between 2 and 5 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group. There are no lease contracts that include extension and termination options and variable lease payments.

(a) *Right-of-use assets*

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Year ended 31 December	
	2019 <i>USD’000</i>	2020 <i>USD’000</i>
As at 1 January	1,317	1,216
Additions	474	1,917
Reduction as a result of lease termination	–	(501)
Depreciation charge	(576)	(658)
Exchange realignment	1	10
As at the end of year	1,216	1,984

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(b) Lease liabilities

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Carrying amount at 1 January	1,288	1,234
New leases	474	1,900
Accretion of interest recognised during the year	55	82
Reduction as a result of lease termination	–	(515)
Covid-19-related rent concession from lessors	–	(15)
Exchange realignment	–	30
Payments	(583)	(785)
	<u>1,234</u>	<u>1,931</u>
Carrying amount at the end of year	<u>1,234</u>	<u>1,931</u>
Analysed into:		
Current portion	560	512
Non-current portion	<u>674</u>	<u>1,419</u>

The maturity analysis of lease liabilities is disclosed in note 35 to the Historical Financial Information.

(c) The amounts recognised in the consolidated statements of profit or loss in relation to leases are as follows:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Interest on lease liabilities	55	82
Depreciation charge of right-of-use assets	576	658
Covid-19-related rent concessions from lessors	–	(15)
Gain on termination of a lease	–	(14)
Expense relating to short-term leases (included in administrative expenses and research and development costs) (note 6)	<u>243</u>	<u>158</u>
Total amount recognised in profit or loss	<u>874</u>	<u>869</u>

(d) The total cash outflow for leases is disclosed in note 31(c) to the Historical Financial Information.

The Group as a lessor

The Group leases its medical devices in European Union and USA under operating lease arrangements and financing lease arrangements with leases negotiated for terms within one year and within eight years, respectively. Rental income recognised by the Group during the years ended 31 December 2019 and 2020 was USD5,000 and USD43,000, respectively, details of which are included in note 5 to the Historical Financial Information.

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15. INTANGIBLE ASSETS

	Software	Intellectual property	Total
	USD’000	USD’000	USD’000
31 December 2019			
At 1 January 2019:			
Cost	48	16,340	16,388
Accumulated amortisation	(27)	(5,688)	(5,715)
Net carrying amount	21	10,652	10,673
Cost at 1 January 2019, net of accumulated amortisation	21	10,652	10,673
Additions	10	–	10
Amortisation provided during the year (<i>note 6</i>)	(13)	(1,236)	(1,249)
At 31 December 2019, net of accumulated amortisation	18	9,416	9,434
At 31 December 2019:			
Cost	58	16,340	16,398
Accumulated amortisation	(40)	(6,924)	(6,964)
Net carrying amount	18	9,416	9,434
31 December 2020			
At 1 January 2020:			
Cost	58	16,340	16,398
Accumulated amortisation	(40)	(6,924)	(6,964)
Net carrying amount	18	9,416	9,434
Cost at 1 January 2020, net of accumulated amortisation	18	9,416	9,434
Additions	73	–	73
Disposal	(2)	–	(2)
Amortisation provided during the year (<i>note 6</i>)	(11)	(1,236)	(1,247)
At 31 December 2020, net of accumulated amortisation	78	8,180	8,258
At 31 December 2020:			
Cost	113	16,340	16,453
Accumulated amortisation	(35)	(8,160)	(8,195)
Net carrying amount	78	8,180	8,258

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16. INVENTORIES

	As at 31 December	
	2019	2020
	USD’000	USD’000
Raw materials	756	1,459
Work in progress	289	439
Finished goods	783	1,153
	1,828	3,051

17. TRADE RECEIVABLES

	As at 31 December	
	2019	2020
	USD’000	USD’000
Trade receivables		
Current	3,224	3,193
Non-current	936	–
	4,160	3,193
Impairment	(36)	(257)
	4,124	2,936

Certain of the Group’s trading terms with its customers are on credit. The credit period is generally three to six months. Each customer has a maximum credit limit. The Group seeks to maintain strict control over its outstanding receivables. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

Included in the Group’s trade receivables were amounts due from the Group’s related parties of USD1,935,000 and USD988,000 as at 31 December 2019 and 2020, respectively.

An ageing analysis of the trade receivables of the Group as at the end of each of the Relevant Periods (based on the invoice date and net of loss allowance) is as follows:

	As at 31 December	
	2019	2020
	USD’000	USD’000
Within 3 months	2,023	1,360
3 to 6 months	66	58
6 to 12 months	100	14
1 to 2 years	–	516
2 to 3 years	1,935	–
Over 3 years	–	988
	4,124	2,936

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The movements in the loss allowance for impairment of trade receivables are as follows:

	As at 31 December	
	2019	2020
	USD’000	USD’000
At beginning of year	16	36
Impairment losses, net (<i>note 6</i>)	20	214
Exchange realignment	–	7
At end of year	36	257

An impairment analysis is performed at the end of each of the Relevant Periods using a provision matrix to measure expected credit losses. The provision rates are based on ageing for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the end of each of the Relevant Periods about past events, current conditions and forecasts of future economic conditions.

Set out below is the information about the credit risk exposure on the Group’s trade receivables using a provision matrix:

As at 31 December 2019

	Gross carrying amount	Expected credit loss rate	Expected credit loss
	USD’000	%	USD’000
Individually assessed:			
Trade receivables from licence	1,936	0.05%	1
Collectively assessed:			
Less than 1 year	2,224	1.57%	35
	4,160		36

As at 31 December 2020

	Gross carrying amount	Expected credit loss rate	Expected credit loss
	USD’000	%	USD’000
Individually assessed:			
Trade receivables from licence	989	0.05%	1
Collectively assessed:			
Less than 1 year	1,463	2.12%	31
1 to 2 years	741	30.36%	225
	3,193		257

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18. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

Group

	As at 31 December	
	2019	2020
	USD’000	USD’000
Current		
Prepayments	286	613
Prepaid [REDACTED] expenses	–	525
Deposits and other receivables	266	91
Value-added tax recoverable	258	514
Other assets	–	109
	<u>810</u>	<u>1,852</u>
Non-current		
Advance payments for property, plant and equipment	30	80
Deposits	<u>199</u>	<u>90</u>
	<u>229</u>	<u>170</u>
	<u>1,039</u>	<u>2,022</u>

Company

	As at 31 December	
	2019	2020
	USD’000	USD’000
Current		
Prepaid [REDACTED] expenses	<u>–</u>	<u>525</u>

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As at the end of each of the Relevant Periods, the loss allowance was assessed to be minimal.

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19. DUE FROM A DIRECTOR

Amounts due from a director, disclosed pursuant to section 383(1)(d) of the Hong Kong Companies Ordinance and Part 3 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, are as follows:

Name	At 31 December 2020 <i>USD’000</i>	Maximum amount outstanding during the year <i>USD’000</i>	At 31 December 2019 and 1 January 2020 <i>USD’000</i>	Maximum amount outstanding during the year <i>USD’000</i>	At 1 January 2019 <i>USD’000</i>	Security held
Mr. Michael Yi Wei Zhao	–	13	13	26	–	None

The payments on behalf of Mr. Michael Yi Wei Zhao for the years ended 31 December 2019 and 2020 were unsecured, non-interest-bearing and repayable on demand.

20. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS

Group

	As at 31 December	
	2019 <i>USD’000</i>	2020 <i>USD’000</i>
Total cash and bank balances, including pledged deposits	3,323	19,026
Less: Pledged deposits:		
Pledged for bank overdraft facilities	(25)	(25)
Pledged for rent deposits	(213)	(213)
Cash and cash equivalents	3,085	18,788
Denominated in:		
USD	1,829	17,883
RMB	1,168	662
AUD	41	41
EUR	46	192
HKD	–	3
Swiss Franc (“CHF”)	1	7
Total cash and cash equivalents	3,085	18,788

Company

	As at 31 December	
	2019 <i>USD’000</i>	2020 <i>USD’000</i>
Cash and cash equivalents	241	13,270
Denominated in USD	241	13,270

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The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances and pledged deposits are deposited with creditworthy banks with no recent history of default.

21. FINANCE LEASE RECEIVABLES

	As at 31 December	
	2019	2020
	USD’000	USD’000
Finance lease receivables	147	138
Unrealised finance income	(22)	(18)
	<u>125</u>	<u>120</u>
Finance lease receivables, net	<u>125</u>	<u>120</u>
Analysed into:		
Current portion	21	23
Non-current portion	104	97
	<u>125</u>	<u>120</u>

An ageing analysis of the finance lease receivables of the Group as at the end of each of the Relevant Periods (based on the lease commencement date) is as follows:

	As at 31 December	
	2019	2020
	USD’000	USD’000
Within 1 years	125	–
1 to 2 years	–	120
	<u>125</u>	<u>120</u>

At the end of each of the Relevant Periods, the total undiscounted lease payments receivable by the Group in future periods under finance leases with its tenant are as follows:

	As at 31 December	
	2019	2020
	USD’000	USD’000
Within one year	21	23
After one year but within two years	21	23
After two years but within three years	21	23
After three years but within four years	21	23
After four years but within five years	21	23
After five years	42	23
	<u>147</u>	<u>138</u>
Unrealised finance income	(22)	(18)
	<u>125</u>	<u>120</u>

There was no unguaranteed residual value in connection with finance lease arrangements or contingent lease arrangements of the Group that need to be recorded as at the end of each of the Relevant Periods.

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22. TRADE PAYABLES

	As at 31 December	
	2019	2020
	USD’000	USD’000
Trade payables	246	357

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December	
	2019	2020
	USD’000	USD’000
Within 3 months	228	346
3 to 6 months	4	3
6 to 12 months	8	2
Over 1 year	6	6
	246	357

Trade payables are non-interest-bearing and are normally settled on terms of 30 days.

23. OTHER PAYABLES AND ACCRUALS

Group

	As at 31 December	
	2019	2020
	USD’000	USD’000
Other payables	2,221	3,566
Accrued expenses	1,900	3,612
Accrued payroll	1,143	1,621
Taxes payable other than corporate income tax	157	144
Interest payable	93	190
	5,514	9,133

Other payables are non-interest-bearing and repayable on demand.

Included in the Group’s other payables and accruals were amounts due to the Group’s related parties of USD84,000 and USD177,000 as at 31 December 2019 and 2020, respectively.

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Company

	As at 31 December	
	2019	2020
	USD’000	USD’000
Other payables	314	1,629
Accrued expenses	44	1,648
Accrued payroll	64	–
	422	3,277

Other payables are non-interest-bearing and repayable on demand.

24. INTEREST-BEARING BANK AND OTHER BORROWINGS

	Effective interest rate (%)	Maturity	Notes	As at 31 December	
				2019	2020
				USD’000	USD’000
Current					
Bank loan – secured					
– RMB10,000,000	7.20	2020	(a)	1,433	–
Bank loans – secured					
– RMB30,000,000	5.66	2020	(b)	4,299	–
Bank loan – secured					
– RMB20,000,000	5.87	2021	(c)	–	3,065
Bank overdraft – secured	–	On demand	(d)	40	25
Bank loans – unsecured					
– current portion of long term loans of USD1,098,000	1.00	2021	(e)	–	640
				5,772	3,730
Non-current					
Bank loans – unsecured					
– non-current portion of long term loans of USD1,098,000	1.00	2022	(e)	–	458
				5,772	4,188
Analysed into:					
Within one year or on demand				5,772	3,730
In the second year				–	458
				5,772	4,188

Notes:

- (a) The subsidiary of the Group, Shanghai Broncus, has guaranteed certain of the Group’s bank loans amounting to RMB10,000,000.

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- (b) A director of the Group, Mr. Michael Yi Wei Zhao, has guaranteed certain of the Group’s bank loans amounting to RMB30,000,000.
- (c) The subsidiary of the Group and a director of the Group, namely Hangzhou Broncus and Mr. Michael Yi Wei Zhao, have guaranteed certain of the Group’s bank loans amounting to RMB20,000,000 and RMB20,000,000, respectively.
- (d) At 31 December 2019 and 2020, the Group’s overdraft facilities amounting to USD80,000 and USD80,000, of which USD40,000 and USD25,000 had been utilised as at the end of the year, respectively, were secured by the pledge of certain of the Group’s time deposits amounting to USD25,000 and USD25,000, respectively (note 20).
- (e) In April 2020, the Group’s two subsidiaries in the United States received loans of total USD1,098,000 under the PPP administered by the Small Business Administration (“SBA”). The PPP is a part of the *Coronavirus Aid, Relief, and Economic Security Act* enacted by the United States Congress on 27 March 2020 in response to the Covid-19 pandemic. The repayment of these loans, including interest, will be forgiven if the above mentioned received loans comply with the forgiveness requirement of the PPP loan program, which should be approved by SBA. The Group submitted applications for the forgiveness of the PPP loans in December 2020 and they are pending for approvals as of 31 December 2020.

25. CONTRACT LIABILITIES

The Group recognised the following revenue-related contract liabilities:

	As at 31 December	
	2019	2020
	USD’000	USD’000
Current		
Sale of medical devices and consumables	154	264
Service fee	266	231
	420	495
Non-current		
Service fee	168	77
Total contract liabilities	588	572

26. CONVERTIBLE REDEEMABLE PREFERRED SHARES

Group and Company

Convertible redeemable preferred shares (the “Preferred Shares”) issued by the Company are redeemable upon occurrence of certain future events. These instruments can also be converted into ordinary shares of the Company at any time at the option of the holders, or automatically upon occurrence of an initial public offering of the Company’s shares, or when agreed by the majority of the holders of each class of the Preferred Shares.

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Since the date of incorporation, the Company has completed several rounds of financing arrangements by issuing preferred shares, details of which are as follows:

Preferred Shares	Date of issuance	Purchase price (USD/Share)	Number of Preferred Shares	Total consideration (USD)
Series A1	2 March 2018	2.57	5,834,473	15,000,000
Series A2	2 March 2018	0.83 ^(a)	8,818,002	7,318,943
Series B1	20 April 2018	3.05	3,283,588	10,000,003
Series B2	10 April 2019	3.05	3,283,587	10,000,000
Series B3	6 May 2019	3.05	2,996,273	9,125,000
Series C1	27 August 2020	3.84	5,986,013	23,000,000
Series C2	25 September 2020	3.84	3,805,134	14,620,430

Notes:

- (a) Pursuant to the Company’s shareholders’ resolution passed on 2 March 2018, in the best interests of the Company and its shareholders, the Company approved to convert the previously issued convertible bonds directly into Series A2 Preferred Shares by conversion of the outstanding principal amount and all unpaid and accrued interest at the conversion price of USD0.83 per share.
- (b) Series A Preferred Shares include Series A1 Preferred Shares and Series A2 Preferred Shares; Series B Preferred Shares include Series B1 Preferred Shares, Series B2 Preferred Shares and Series B3 Preferred Shares; and Series C Preferred Shares include Series C1 Preferred Shares and Series C2 Preferred Shares.

The key terms of all series of the Preferred Shares are summarised as follows:

Conversion rights

The Preferred Shares shall be convertible, at the option of the holder thereof, at any time after the issue date of Preferred Shares into such number of fully paid and non-assessable ordinary shares or automatically be converted, based on the then-effective conversion price, without the payment of any additional consideration, into fully-paid and non-assessable ordinary shares upon the earlier of (i) the closing of a Qualified IPO (see definition below), and (ii) the date specified by written consent or agreement of the holders of the majority of the holders of each series preferred.

Qualified IPO is defined as a firm commitment underwritten registered public offering by the Company of its shares (or other vehicle to be established for the purpose of the IPO) on the Hong Kong Stock Exchange, NASDAQ, the New York Stock Exchange, the Shanghai Stock Exchange or another internationally recognised exchange as may be agreed among the shareholders, at an offering price to the public which implies a gross pre-offering equity valuation of the Company (or the Group, as the case may be) of at a pre-determined amount and which results in aggregate proceeds to the Company (or the Group, as the case may be) (net of underwriters’ discounts and commissions) of at a pre-determined amount (or any cash proceeds of other currency of equivalent value).

Dividend rights

No dividend or distribution, whether in cash, in property, or in any other shares of the Company, shall be declared, paid, set aside or made with respect to the ordinary shares at any time unless a dividend or distribution is likewise declared, paid, set aside or made, respectively, at the same time with respect to each outstanding Preferred Share such that the dividend or distribution declared, paid, set aside or made to the holder thereof shall be equal to the dividend or distribution that such holder would have received if such Preferred Shares had been converted into ordinary shares immediately prior to the record date for such dividend or distribution, or if no such record date is established, the date such dividend or distribution is made, and if such share then participated in and the holder thereof received such dividend or distribution.

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Liquidation preferences

In the event of any liquidation, dissolution or winding up of the Company (the “Liquidation Event”), whether voluntary or involuntary, all assets and funds of the Company legally available for distribution to the members (after satisfaction of all creditors’ claims and claims that may be preferred by law) shall be distributed to the members of the Company, and in the event of a Deemed Liquidation Event (see definition below), the holders of ordinary shares and Preferred Shares then outstanding shall be entitled to be paid out of the consideration payable to the members in such Deemed Liquidation Event together with any other assets of the Company legally available for distribution to the Members, as follows:

- A. The holders of each series of Series C Preferred Shares shall be entitled to receive, on parity with each other and prior and in preference to any distribution of any of the assets or funds of the Company to the holders of the Series B Preferred Shares, Series A Preferred Shares and the ordinary shares by reason of their ownership of such shares, an amount per Series C Preferred Share equal to 100% of the Series C issue price, plus all declared but unpaid dividends on such Series C Preferred Share (the amount payable pursuant to this sentence, the “Series C Liquidation Preference Amount”). If the assets and funds thus distributed among the holders of the Series C Preferred Shares shall be insufficient to permit the payment to such holders of the full Series C Liquidation Preference Amount, then the entire assets and funds of the Company legally available for distribution to the Series C Preferred Shares shall be distributed rateably among the holders of the Series C Preferred Shares in proportion to the aggregate Series C Liquidation Preference Amount each such holder is otherwise entitled to receive pursuant to this paragraph A.
- B. If there are any assets or funds remaining after the aggregate Series C Liquidation Preference Amount has been distributed or paid in full to the applicable holders of Series C Preferred Shares pursuant to paragraph A above, the holders of each series of Series B Preferred Shares and Series A Preferred Shares shall be entitled to receive, on parity with each other and prior and in preference to any distribution of any of the assets or funds of the Company to the holders of the ordinary shares by reason of their ownership of such shares, an amount per Series B Preferred Share or per Series A Preferred Share equal to 100% of the Series B issue price or the Series A issue price, as applicable, plus all declared but unpaid dividends on such Series B Preferred Share or Series A Preferred Share, as applicable (collectively, the “Series B Liquidation Preference Amount” with respect to Series A Preferred Share, and the “Series A Liquidation Preference Amount” with respect to Series B Preferred Share). If the assets and funds thus distributed among the holders of the Series B Preferred Shares and Series A Preferred Shares shall be insufficient to permit the payment to such holders of the full Series B Liquidation Preference Amount and Series A Liquidation Preference Amount, then the entire assets and funds of the Company legally available for distribution to the Series B Preferred Shares and Series A Preferred Shares shall be distributed rateably among the holders of the Series B Preferred Shares and Series A Preferred Shares in proportion to the aggregate Series B Liquidation Preference Amount and Series A Liquidation Preference Amount each such holder is otherwise entitled to receive pursuant to this paragraph B.
- C. If there are any assets or funds remaining after the aggregate Series C Liquidation Preference Amount, Series B Liquidation Preference Amount and Series A Liquidation Preference Amount have been distributed or paid in full to the applicable holders of Preferred Shares pursuant to paragraphs A and B above, the remaining assets and funds of the Company available for distribution to the Members shall be distributed rateably among holders of ordinary shares then held by each holder on an as-converted basis, excluding the holders of the Preferred Shares.
- D. Notwithstanding the above, for purposes of determining the amount each holder of Preferred Shares is entitled to receive with respect to a Liquidation Event, each such holder of Preferred Shares shall be deemed to have converted (regardless of whether such holder actually converted) such holder’s Preferred Shares of such series into ordinary shares immediately prior to the Liquidation Event if, as a result of an actual conversion, such holder would receive, in the aggregate, an amount greater than the amount that would be distributed to such holder if such holder did not convert such Preferred Shares into ordinary shares. If any such holder shall be deemed to have converted Preferred Shares into ordinary shares pursuant to this paragraph, then such holder shall not be entitled to receive any distribution that would otherwise be made to holders of Preferred Shares that have not converted (or have not been deemed to have converted) into ordinary shares.

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“Deemed Liquidation Event” is defined as: (1) any consolidation, amalgamation, scheme of arrangement or merger of any company with the Group with or into any other person or other reorganisation in which the members or shareholders of such company immediately prior to such consolidation, amalgamation, merger, scheme of arrangement or reorganisation own less than fifty percent (50%) of such company’s voting power in the aggregate immediately after such consolidation, merger, amalgamation, scheme of arrangement or reorganisation, or any transaction or series of related transactions to which such company is a party in which in excess of fifty percent (50%) of such company’s voting power is transferred; (2) a sale, transfer, lease or other disposition of all or substantially all of the assets of any company (or any series of related transactions resulting in such sale, transfer, lease or other disposition of all or substantially all of the assets of such company) or (3) the exclusive licensing of all or substantially all of any company’s intellectual property to a third party or parties.

Redemption rights

In the event that the Company has not consummated a Qualified IPO on or prior to 31 December 2022, any holder(s) of Series C Preferred Shares (the “Initiating Redeeming Party(ies)”) may, upon written request to the Company (the “Redemption Request”), require the Company to redeem all or any portion of the Series C Preferred Shares held by such Initiating Redeeming Party(ies). If a Redemption Request is made by an Initiating Redeeming Party, the Company shall (1) redeem such Series C Preferred Shares held by the Initiating Redeeming Party as the Initiating Redeeming Party has set out in the Redemption Request and (2) unless at least 60% of Series C Preferred Shareholders agree otherwise, not submit its first filing unless and until the redemption closing has been fully consummated in accordance with these provisions.

The redemption price for each Series C Preferred Share (the “Redemption Price”) redeemed shall be an amount in cash equal to the sum of (a) the Series C issue price, (b) an amount which would result in each holder of a Series C Preferred Share being deemed receiving an Internal Rate of Return of ten percent (10%) in respect of each Series C Preferred Share per annum, accruing daily from the applicable Series C Issue Date and compounded annually until the related Series C Preferred Shares are redeemed in full by the Company, plus (c) any declared but unpaid dividends on such Series C Preferred Shares.

The Group does not bifurcate any embedded derivatives from the host instruments and has designated the entire instruments as financial liabilities at fair value through profit or loss. Any directly attributable transaction costs are recognised as finance costs in profit or loss. Subsequent to initial recognition, the fair value change of the Preferred Shares is recognised in profit or loss except for the portion attributable to credit risk change which shall be recognised in other comprehensive income, if any. The directors of the Company considered that there is no material credit risk change during the Relevant Periods.

The convertible redeemable preferred shares were classified as non-current liabilities unless the preferred shareholders demand the Company to redeem the preferred shares within 12 months after the end of the Relevant Periods.

The movements of the Preferred Shares are set out below:

	Series A	Series B	Series C	Total
	USD’000	USD’000	USD’000	USD’000
As at 31 December 2018	42,324	10,000	–	52,324
Issue of Preferred Shares	–	19,125	–	19,125
Changes in fair value	5,825	3,623	–	9,448
As at 31 December 2019	48,149	32,748	–	80,897
Issue of Preferred Shares	–	–	37,620	37,620
Changes in fair value	12,564	7,760	7,296	27,620
As at 31 December 2020	60,713	40,508	44,916	146,137

The Group applied the discount cash flow method and back-solve method to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the Preferred Shares.

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Set out below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as at the end of each of the Relevant Periods.

Significant unobservable inputs

	As at 31 December	
	2019	2020
Discount rate	19%	N/A
Risk-free interest rate	1.62%	0.12%
Discount for lack of marketability (“DLOM”)	16%	17%
Equity volatility	40.43%	56.39%

The discount rate was estimated by the weighted average cost of capital as of the valuation date. The Group estimated the risk-free interest rate based on the yield of the US Government Bond as of each of the valuation date with a maturity life equal to the period from the respective valuation dates to the expected liquidation dates. The lack of marketability discount was estimated based on the option-pricing method. Under the option-pricing method, the cost of a put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the discount for lack of marketability. The volatility was estimated based on implied volatility of comparable companies as of the valuation dates. Probability weight under each of the redemption feature and liquidation preferences were based on the Group’s best estimates. In addition to the assumptions adopted above, the Company’s projections of future performance were also factored into the determination of the fair value of the Preferred Shares on the valuation dates.

Management considered that fair value changes of the Preferred Shares that are attributable to changes of credit risk of these instruments are not material.

Quantitative sensitivity analysis

	As at 31 December	
	2019	2020
1% increase in risk-free rate	(618)	(333)
1% decrease in risk-free rate	595	444
10% increase in equity volatility	1,557	1,399
10% decrease in equity volatility	(2,212)	(1,897)
5% increase in DLOM	(4,662)	(8,670)
5% decrease in DLOM	4,662	8,670

27. SHARE CAPITAL

The Company was incorporated in the Cayman Islands on 30 April 2012 with an initial authorised share capital of USD50,000 with a par value of USD1 each. On 22 May 2014, the authorised share capital was sub-divided into 500,000,000 shares with a par value of USD0.0001 each.

	As at 31 December	
	2019	2020
	USD’000	USD’000
Issued and fully paid:		
55,944,670 ordinary shares of USD0.0001 each	6	6

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28. RESERVES

Group

The amounts of the Group’s reserves and the movements therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

Other reserve

The Group’s other reserve includes:

- (1) The capital reserve of the Group represents the paid-up capital and share premium of the companies comprising the Group, details of the movements in the capital reserve are set out in the consolidated statements of changes in equity, and
- (2) The excess of consideration for purchasing the shares of its subsidiary held by a non-controlling shareholder over the proportion of the carrying amounts of the subsidiary’s net assets acquired.

Share option reserve

Share option reserve of the Group represent share-based compensation reserve due to equity-settled share award.

Exchange fluctuation reserve

The exchange fluctuation reserve is used to record exchange differences arising from the translation of the financial statements of entities of which the functional currencies are not USD.

Company

	Capital reserve	Accumulated losses	Total
	<i>USD’000</i>	<i>USD’000</i>	<i>USD’000</i>
At 1 January 2019	46,728	(21,703)	25,025
Total comprehensive loss for the year	–	(10,628)	(10,628)
At 31 December 2019 and 1 January 2020	46,728	(32,331)	14,397
Total comprehensive loss for the year	–	(29,849)	(29,849)
At 31 December 2020	<u>46,728</u>	<u>(62,180)</u>	<u>(15,452)</u>

29. SHARE-BASED PAYMENTS

The subsidiaries, BMI, UMT and BCH, operates share-based payment schemes (the “Schemes”) for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Eligible participants of the Schemes include the Company’s directors and the Group’s employees.

The share options have vesting terms (share options shall vest in equal monthly instalments) in schedule from the grant date and there is no performance target required except that the eligible participant remains in service for the Group during the vesting period. The exercise price of the share options is various with each person and share plan.

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The share options granted by the Group during the Relevant Periods are as follows:

<u>Date of grant</u>	<u>Name of grantor</u>	<u>Number of options</u>	<u>Vesting period</u> (months)	<u>Exercise price</u> (USD)
March 2019	UMT	242,354	0-27	0.90
March 2019	BCH	3,631,764	0-48	0.16
April 2019	BMI	562,300	0-20	0.45
April 2019	BMI	258,354	0-24	1.34
April 2019	BMI	531,906	0-16	0.45
April 2019	BMI	1,250,759	0-48	1.34
April 2019	UMT	699,176	48	0.90
July 2019	UMT	127,096	48	0.90

Movements in the number of share options granted and their related weighted average exercise price are as below:

	<u>2019</u>		<u>2020</u>	
	<u>Weighted average exercise price</u> USD/share	<u>Number of options</u>	<u>Weighted average exercise price</u> USD/share	<u>Number of options</u>
Outstanding as at 1 January	0.51	1,697,242	0.54	8,655,765
Granted during the year	0.55	7,303,709	—	—
Exercised during the year	0.45	(109,290)	1.34	(5,000)
Forfeited during the year	0.68	(235,896)	0.59	(905,893)
Outstanding as at end of the year	0.54	<u>8,655,765</u>	0.54	<u>7,744,872</u>

During the years ended 31 December 2019 and 2020, share-based expenses of USD5,597,000 and USD509,000 were charged to the statement of profit or loss, respectively.

The fair value of equity-settled share options granted was estimated as at the date of grant using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the key assumptions that the model used.

	<u>As at 31 December 2019</u>
Expected volatility (%)	39.23 – 53.93
Risk-free interest rate (%)	2.35 – 2.67
Expected life of options (year)	3.3 – 10.0
Weighted average share price (USD)	0.407 – 1.146

30. COMMITMENTS

The Group had the following capital commitments at the end of each of the Relevant Periods:

	<u>As at 31 December</u>	
	<u>2019</u>	<u>2020</u>
	USD’000	USD’000
Contracted, but not provided for:		
Leasehold improvements	—	100

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31. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the years ended 31 December 2019 and 2020, the Group had non-cash additions to right-of-use assets of USD474,000 and USD1,900,000, respectively, and lease liabilities of USD474,000 and USD1,900,000, respectively, in respect of lease arrangements for warehouses and office premises.

(b) Changes in liabilities arising from financing activities

	Amount due to related parties	Interest payable	Lease liabilities	Interest- bearing bank and other borrowings	Convertible redeemable preferred shares
	USD'000	USD'000	USD'000	USD'000	USD'000
At 1 January 2019	–	69	1,288	9,055	52,324
Changes from financing cash flows	1,632	(438)	(583)	(3,195)	19,125
Interest expense	–	462	55	–	–
New leases	–	–	474	–	–
Changes in fair value of convertible redeemable preferred shares	–	–	–	–	9,448
Foreign exchange difference	–	–	–	(88)	–
At 31 December 2019	<u>1,632</u>	<u>93</u>	<u>1,234</u>	<u>5,772</u>	<u>80,897</u>

	Amount due to related parties	Interest payable	Lease liabilities	Interest- bearing bank and other borrowings	Convertible redeemable preferred shares
	USD'000	USD'000	USD'000	USD'000	USD'000
At 1 January 2020	1,632	93	1,234	5,772	80,897
Changes from financing cash flows	(1,672)	(476)	(785)	(3,352)	37,620
Interest expense	–	557	82	–	–
New leases	–	–	1,900	–	–
Covid-19-related rent concession from lessors	–	–	(15)	–	–
Reduction as a result of lease termination	–	–	(515)	–	–
Changes in fair value of convertible redeemable preferred shares	–	–	–	–	27,620
Foreign exchange difference	40	8	30	670	–
At 31 December 2020	<u>–</u>	<u>182</u>	<u>1,931</u>	<u>3,090</u>	<u>146,137</u>

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(c) Total cash outflow for leases

The total cash outflow for leases included in the statements of cash flows is as follows:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Within operating activities	243	158
Within financing activities	583	785
	826	943

32. RELATED PARTY TRANSACTIONS

Name	Relationship
Intuitive Surgical Operations, Inc. (“Intuitive Surgical”)	Shareholder
Aether Corporate Limited	Shareholder
BC Mars L.P.	Shareholder
CNCB CAPITAL VALUE SPC-CNCB Capital Energy Investment Fund SP (“CNCB CAPITAL”)	Shareholder
Dinova Healthcare Holding Corporation (“Dinova Healthcare”)	An entity controlled by a director
Hangzhou Denuo Technology Co., Ltd. (“Hangzhou Denuo”)	An entity controlled by a director
Hangzhou Dinova Medical Technology Co., Ltd. (“Hangzhou Dinova”)	An entity controlled by a director
Hangzhou Nuomao Medical Technology Co., Ltd. (“Hangzhou Nuomao”)	An entity controlled by a director
Shanghai Mingnuo Medical Technology Co., Ltd. (“Shanghai Mingnuo”)	An entity controlled by a director

- (a) In addition to the transactions detailed elsewhere in the Historical Financial Information, the Group had the following transactions with related parties during the Relevant Periods:

Group

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Rental fee to:		
Hangzhou Denuo	9	–
Management service from:		
Hangzhou Dinova	386	–
Loans to:		
Aether Corporate Limited	85	–
Hangzhou Dinova	–	294
	85	294
Loans from:		
Hangzhou Dinova*	4,988	1,713
Hangzhou Nuomao	86	–
Hangzhou Denuo	3	–
Dinova Healthcare*	1,000	2,880
	6,077	4,593

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	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Interests to:		
Hangzhou Dinova*	84	44
Dinova Healthcare*	19	56
	<u>103</u>	<u>100</u>
Payment on behalf of the Group by:		
Shanghai Mingnuo	<u>1,146</u>	<u>4,105</u>
Payments on behalf of related parties for:		
Intuitive Surgical	–	7
Shanghai Mingnuo	<u>3,250</u>	<u>1,146</u>
	<u>3,250</u>	<u>1,153</u>

* The loans from Hangzhou Dinova and Dinova Healthcare are unsecured and bear interest at interest rates of 5.3% and 8% per annum, respectively.

Company

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Loan to:		
Aether Corporate Limited	<u>85</u>	<u>–</u>

(b) Other transactions with related parties:

A director of the Group, Mr. Michael Yi Wei Zhao, has guaranteed certain of the Group’s bank loans up to RMB30,000,000 and RMB50,000,0000 during the years ended 31 December 2019 and 2020, respectively.

(c) Outstanding balances with related parties:

Group

	As at 31 December	
	2019	2020
	USD’000	USD’000
Due from related parties*:		
Intuitive Surgical	–	7
Aether Corporate Limited	<u>85</u>	<u>–</u>
	<u>85</u>	<u>7</u>

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ACCOUNTANTS’ REPORT

	As at 31 December	
	2019	2020
	USD'000	USD'000
Due to related parties*:		
Hangzhou Dinova	1,629	–
Hangzhou Denuo	3	–
	<u>1,632</u>	<u>–</u>
Other payables and accruals*:		
Hangzhou Dinova	84	136
Dinova Healthcare	–	41
	<u>84</u>	<u>177</u>
Trade receivables**:		
Intuitive Surgical	<u>1,935</u>	<u>988</u>

On 6 April 2017, a subsidiary of the Group entered into a license agreement with Intuitive Surgical and an exclusive license would be granted to Intuitive Surgical by payments at USD1,000,000 per year for a period of five years.

* The balances are non-trade in nature.

** The balances are trade in nature.

Company

	As at 31 December	
	2019	2020
	USD'000	USD'000
Due from a related party:		
Aether Corporate Limited	<u>85</u>	<u>–</u>
Due from subsidiaries:		
BMA	7	7
BMHK	–	75
BCH	–	40
	<u>7</u>	<u>122</u>

The balances with related parties are unsecured, interest-free and repayable on demand except for:

- (a) transactions detailed elsewhere in notes 17 and 23; and
- (b) loans from Dinova Healthcare and Hangzhou Dinova as stated in note 32(a) and the amount due to Hangzhou Dinova will be payable on or before 30 September 2020 as at 31 December 2019.

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ACCOUNTANTS’ REPORT

(d) Compensation of key management personnel of the Group:

	Year ended 31 December	
	2019	2020
	USD’000	USD’000
Salaries, bonuses, allowances and benefit in kind	622	709
Pension scheme contributions	16	1
Equity-settled share option expenses	2,304	134
Total compensation paid to key management personnel	2,942	844

Further details of directors’ remuneration are included in note 8 to the Historical Financial Information.

33. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

Group

Financial assets – at amortised cost

	As at 31 December	
	2019	2020
	USD’000	USD’000
Trade receivables	4,124	2,936
Finance lease receivables	125	120
Financial assets included in prepayments other receivables and other assets	465	181
Due from a director	13	–
Due from related parties	85	7
Pledged deposits	238	238
Cash and cash equivalents	3,085	18,788
	8,135	22,270

Financial liabilities

As at 31 December 2019

	Financial liabilities at amortised cost	Financial liabilities at fair value through profit or loss	Total
	USD’000	USD’000	USD’000
Trade payables	246	–	246
Financial liabilities included in other payables and accruals	2,314	–	2,314
Interest-bearing bank and other borrowings	5,772	–	5,772
Convertible redeemable preferred shares	–	80,897	80,897
Lease liabilities	1,234	–	1,234
Due to related parties	1,632	–	1,632
	11,198	80,897	92,095

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As at 31 December 2020

	Financial liabilities at amortised cost	Financial liabilities at fair value through profit or loss	Total
	USD’000	USD’000	USD’000
Trade payables	357	–	357
Financial liabilities included in other payables and accruals	3,756	–	3,756
Interest-bearing bank and other borrowings	4,188	–	4,188
Convertible redeemable preferred shares	–	146,137	146,137
Lease liabilities	1,931	–	1,931
	<u>10,232</u>	<u>146,137</u>	<u>156,369</u>

Company

Financial assets – at amortised cost

	As at 31 December	
	2019	2020
	USD’000	USD’000
Due from a related party	85	–
Due from subsidiaries	7	122
Cash and cash equivalents	241	13,270
	<u>333</u>	<u>13,392</u>

Financial liabilities

As at 31 December 2019

	Financial liabilities at amortised cost	Financial liabilities at fair value through profit or loss	Total
	USD’000	USD’000	USD’000
Financial liabilities included in other payables and accruals	314	–	314
Convertible redeemable preferred shares	–	80,897	80,897
	<u>314</u>	<u>80,897</u>	<u>81,211</u>

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As at 31 December 2020

	Financial liabilities at amortised cost	Financial liabilities at fair value through profit or loss	Total
	USD’000	USD’000	USD’000
Financial liabilities included in other payables and accruals	1,629	–	1,629
Convertible redeemable preferred shares	–	146,137	146,137
	<u>1,629</u>	<u>146,137</u>	<u>147,766</u>

34. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of cash and cash equivalents, pledged deposits, financial assets included in prepayments, other receivables and other assets, amounts due from related parties and a director, trade receivables, trade payables, interest-bearing bank and other borrowings, financial liabilities included in other payables and accruals and amounts due to related parties approximate to their carrying amounts largely due to the short-term maturities of these instruments. All the carrying amounts of the Group’s non-current financial assets and financial liabilities approximate to their fair value.

The Group’s finance department headed by the chief financial officer is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the chief financial officer. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the finance controller. The valuation process and results are discussed with the directors of the Company periodically for financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair values of the pledged deposits, trade receivables, finance lease receivables, financial assets included in prepayments, other receivables and other assets and interest-bearing bank and other borrowings have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities. The fair value of convertible redeemable preferred shares is estimated by the option-pricing method and equity allocation model.

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Liabilities measured at fair value:

As at 31 December 2019

	Fair value measurement using			
	Quoted prices in active markets	Significant observable inputs	Significant unobservable inputs	Total
	(Level 1)	(Level 2)	(Level 3)	
	USD’000	USD’000	USD’000	USD’000
Convertible redeemable preferred shares	–	–	80,897	80,897

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As at 31 December 2020

	Fair value measurement using			Total
	Quoted	Significant	Significant	
	prices in	observable	unobservable	
	active	inputs	inputs	
	markets			
	(Level 1)	(Level 2)	(Level 3)	
	USD'000	USD'000	USD'000	USD'000
Convertible redeemable preferred shares	—	—	146,137	146,137

The changes in Level 3 instruments of convertible redeemable preferred shares and a summary of significant unobservable inputs to the valuation of these financial instruments together with a quantitative sensitivity analysis for the years ended 31 December 2019 and 2020 are presented in note 26 to the Historical Financial Information.

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

35. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise interest-bearing bank and other borrowings and cash and cash equivalents. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as trade and other receivables and trade and other payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

Foreign currency risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between USD and other currencies in which the Group conducts business may affect the Group’s financial condition and results of operations. The Group seeks to limit its exposure to foreign currency risk by minimising its net foreign currency position.

The following table demonstrates the sensitivity as at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rates, with all other variables held constant, of the Group’s loss before tax (due to translation of monetary assets and liabilities) and the Group’s equity.

	Increase/ (decrease) in rate of foreign currency	Increase/ (decrease) in loss before tax	Increase/ (decrease) in equity
	%	USD’000	USD’000
31 December 2019			
If USD weakens against RMB	5	(3)	(10)
If USD strengthens against RMB	(5)	3	10
If USD weakens against CHF	5	(1)	(1)
If USD strengthens against CHF	(5)	1	1
If USD weakens against GBP	5	(2)	(2)
If USD strengthens against GBP	(5)	2	2
If USD weakens against AUD	5	–	–
If USD strengthens against AUD	(5)	–	–
If USD weakens against EUR	5	(15)	(15)
If USD strengthens against EUR	(5)	15	15

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	Increase/ (decrease) in rate of foreign currency	Increase/ (decrease) in loss before tax	Increase/ (decrease) in equity
	%	USD’000	USD’000
31 December 2020			
If USD weakens against RMB	5	165	172
If USD strengthens against RMB	(5)	(165)	(172)
If USD weakens against HKD	5	–	–
If USD strengthens against HKD	(5)	–	–
If USD weakens against CHF	5	–	–
If USD strengthens against CHF	(5)	–	–
If USD weakens against GBP	5	–	–
If USD strengthens against GBP	(5)	–	–
If USD weakens against AUD	5	–	–
If USD strengthens against AUD	(5)	–	–
If USD weakens against EUR	5	(18)	(18)
If USD strengthens against EUR	(5)	18	18

Credit risk

The Group is exposed to credit risk in relation to its cash and cash equivalents, pledged deposits, amounts due from related parties, an amount due from a director, trade receivables and financial assets included in prepayments, other receivables and other assets. The carrying amounts of each class of the above financial assets represent the Group’s maximum exposure to credit risk in relation to financial assets.

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on ageing information unless other information is available without undue cost or effort, and year-end staging classification. The amounts presented are gross carrying amounts for financial assets.

Group

As at 31 December 2019

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Trade receivables*	–	–	–	4,160	4,160
Finance lease receivables	–	–	–	125	125
Financial assets included in prepayments, other receivables and other assets					
– Normal**	465	–	–	–	465
Due from a director					
– Normal**	13	–	–	–	13
Due from related parties					
– Normal**	85	–	–	–	85
Pledged deposits					
– Not yet past due	238	–	–	–	238
Cash and cash equivalents					
– Not yet past due	3,085	–	–	–	3,085
	<u>3,886</u>	<u>–</u>	<u>–</u>	<u>4,285</u>	<u>8,171</u>

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As at 31 December 2020

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Trade receivables*	–	–	–	3,193	3,193
Finance lease receivables	–	–	–	120	120
Financial assets included in prepayments, other receivables and other assets					
– Normal**	181	–	–	–	181
Due from related parties					
– Normal**	7	–	–	–	7
Pledged deposits					
– Not yet past due	238	–	–	–	238
Cash and cash equivalents					
– Not yet past due	18,788	–	–	–	18,788
	19,214	–	–	3,313	22,527

Company

As at 31 December 2019

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Due from a related party					
– Normal**	85	–	–	–	85
Due from subsidiaries					
– Normal**	7	–	–	–	7
Cash and cash equivalents					
– Not yet past due	241	–	–	–	241
	333	–	–	–	333

As at 31 December 2020

	12-month ECLs	Lifetime ECLs			
	Stage 1	Stage 2	Stage 3	Simplified approach	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Due from subsidiaries					
– Normal**	122	–	–	–	122
Cash and cash equivalents					
– Not yet past due	13,270	–	–	–	13,270
	13,392	–	–	–	13,392

* For trade receivables to which the Group applies the simplified approach for impairment, information based on the provision matrix is disclosed in note 17 to the Historical Financial Information.

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- ** The credit quality of the financial assets included in prepayments, other receivables and other assets and amounts due from a director and related parties is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

Further quantitative data in respect of the Group’s exposure to credit risk arising from trade receivables are disclosed in note 17 to the Historical Financial Information.

Since the Group trades only with recognised and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty and by geographical region. As at 31 December 2019, the Group had certain concentrations of credit risk as 46.5% and 71.3% of the Group’s trade receivables were due from the Group’s largest debtor and five largest debtors, respectively. As at 31 December 2020, the Group had certain concentrations of credit risk as 31.0% and 76.5% of the Group’s trade receivables were due from the Group’s largest debtor and five largest debtors, respectively.

Liquidity risk

In the management of the liquidity risk, the Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

Group

As at 31 December 2019					
	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Trade payables	77	169	–	–	246
Financial liabilities included in other payables and accruals	1,531	755	7	21	2,314
Lease liabilities	19	180	406	701	1,306
Due to related parties	–	–	1,632	–	1,632
Interest-bearing bank and other borrowings	–	40	5,902	–	5,942
	<u>1,627</u>	<u>1,144</u>	<u>7,947</u>	<u>722</u>	<u>11,440</u>

As at 31 December 2020					
	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Trade payables	57	300	–	–	357
Financial liabilities included in other payables and accruals	3,505	174	31	46	3,756
Lease liabilities	–	170	461	1,566	2,197
Interest-bearing bank and other borrowings	111	153	3,542	461	4,267
	<u>3,673</u>	<u>797</u>	<u>4,034</u>	<u>2,073</u>	<u>10,577</u>

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Company

	As at 31 December 2019				
	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Financial liabilities included in other payables and accruals	314	–	–	–	314

	As at 31 December 2020				
	On demand	Less than 3 months	3 to 12 months	1 to 5 years	Total
	USD’000	USD’000	USD’000	USD’000	USD’000
Financial liabilities included in other payables and accruals	1,629	–	–	–	1,629

Details of the description of convertible redeemable preferred shares are included in note 26 to the Historical Financial Information.

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group monitors capital (including share capital and preferred shares on an as-converted basis) by regularly reviewing the capital structure. As a part of this review, the Group considers the cost of capital and the risks associated with the issued share capital. The Group may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or repurchase the Company’s shares.

36. EVENT AFTER THE RELEVANT PERIODS

On 25 January 2021, the Company entered into the Series D Preferred Shares purchase agreement with certain investors, pursuant to which, the investors agreed to subscribe for and purchase, and the Company agreed to issue and sell to such investors, the number of 6,068,134 Series D Preferred Shares for the aggregate purchase price of approximately USD40,000,000 as consideration.

As part of the reorganisation steps, the Company made a series of flip-up of options and minority shares at subsidiaries, which was fully completed on [●]. As a result, UMT, BMI and BCH cancelled all the share options in each of these subsidiaries in exchange for options in the Company, and each of BMI and BCH became a wholly-owned subsidiary of the Company.

On [●] 2021, the Company’s shareholders resolved that each share of USD0.0001 in the then authorised and issued share capital of the Company be sub-divided into four ordinary shares of USD0.000025 each (the “Share Subdivision”) such that immediately following the Share Subdivision, (i) the authorised share capital of the Company is USD50,000 divided into 2,000,000,000 ordinary shares of USD0.000025 each; and (ii) the issued share capital of the Company shall consist of 384,079,496 ordinary shares of USD0.000025 each.

37. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of its subsidiaries in respect of any period subsequent to 31 December 2020.

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX III

**SUMMARY OF THE CONSTITUTION OF OUR COMPANY
AND CAYMAN ISLANDS COMPANIES LAW**

**SUMMARY OF THE CONSTITUTION OF OUR COMPANY AND CAYMAN
COMPANIES LAW**

1 Memorandum of Association

The Memorandum of Association of the Company was conditionally adopted on [●], 2021 and states, inter alia, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by the Cayman Companies Act or any other law of the Cayman Islands.

The Memorandum of Association is available for inspection at the address specified in Appendix V in the section headed “Documents available for inspection”.

2 Articles of Association

The Articles of Association of the Company were conditionally adopted on [●] and include provisions to the following effect:

2.1 *Classes of Shares*

The share capital of the Company consists of ordinary shares. The capital of the Company at the date of adoption of the Articles is US\$[50,000] divided into [2,000,000,000] shares of US\$[0.000025] each.

2.2 *Directors*

(a) *Power to allot and issue Shares*

Subject to the provisions of the Cayman Companies Act and the Memorandum and Articles of Association, the unissued shares in the Company (whether forming part of its original or any increased capital) shall be at the disposal of the Directors, who may offer, allot, grant options over or otherwise dispose of them to such persons, at such times and for such consideration, and upon such terms, as the Directors shall determine.

Subject to the provisions of the Articles of Association and to any direction that may be given by the Company in general meeting and without prejudice to any special rights conferred on the holders of any existing shares or attaching to any class of shares, any share may be issued with or have attached thereto such preferred, deferred, qualified or other special rights or restrictions, whether in regard to dividend, voting, return of capital or otherwise, and to such persons at such times and for such consideration as the Directors may determine. Subject to the Cayman Companies Act and to any special rights conferred

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on any shareholders or attaching to any class of shares, any share may, with the sanction of a special resolution, be issued on terms that it is, or at the option of the Company or the holder thereof, liable to be redeemed.

(b) Power to dispose of the assets of the Company or any subsidiary

The management of the business of the Company shall be vested in the Directors who, in addition to the powers and authorities by the Articles of Association expressly conferred upon them, may exercise all such powers and do all such acts and things as may be exercised or done or approved by the Company and are not by the Articles of Association or the Cayman Companies Act expressly directed or required to be exercised or done by the Company in general meeting, but subject nevertheless to the provisions of the Cayman Companies Act and of the Articles of Association and to any regulation from time to time made by the Company in general meeting not being inconsistent with such provisions or the Articles of Association, provided that no regulation so made shall invalidate any prior act of the Directors which would have been valid if such regulation had not been made.

(c) Compensation or payment for loss of office

Payment 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 first be approved by the Company in general meeting.

(d) Loans to Directors

There are provisions in the Articles of Association prohibiting the making of loans to Directors or their respective close associates which are equivalent to the restrictions imposed by the Companies Ordinance.

(e) Financial assistance to purchase Shares

Subject to all applicable laws, the Company may give financial assistance to Directors and employees of the Company, its subsidiaries or any holding company or any subsidiary of such holding company in order that they may buy shares in the Company or any such subsidiary or holding company. Further, subject to all applicable laws, the Company may give financial assistance to a trustee for the acquisition of shares in the Company or shares in any such subsidiary or holding company to be held for the benefit of employees of the Company, its subsidiaries, any holding company of the Company or any subsidiary of any such holding company (including salaried Directors).

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(f) Disclosure of interest in contracts with the Company or any of its subsidiaries

No Director or proposed Director shall be disqualified by his office from contracting with the Company either as vendor, purchaser or otherwise nor shall any such contract or any contract or arrangement entered into by or on behalf of the Company with any person, company or partnership of or in which any Director shall be a member or otherwise interested be capable on that account of being avoided, nor shall any Director so contracting or being any member or so interested be liable to account to the Company for any profit so realised by any such contract or arrangement by reason only of such Director holding that office or the fiduciary relationship thereby established, provided that such Director shall, if his interest in such contract or arrangement is material, declare the nature of his interest at the earliest meeting of the board of Directors at which it is practicable for him to do so, either specifically or by way of a general notice stating that, by reason of the facts specified in the notice, he is to be regarded as interested in any contracts of a specified description which may be made by the Company.

A Director shall not be entitled to vote on (nor shall be counted in the quorum in relation to) any resolution of the Directors in respect of any contract or arrangement or any other proposal in which the Director or any of his close associates (or, if required by the Listing Rules, his other associates) has any material interest, and if he shall do so his vote shall not be counted (nor is he to be counted in the quorum for the resolution), but this prohibition shall not apply to any of the following matters, namely:

- (i) the giving to such Director or any of his close associates of any security or indemnity 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;
- (ii) the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or any of his close associates 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;
- (iii) any proposal concerning an offer of shares, 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 any of his close associates is/are or is/are to be interested as a participant in the underwriting or sub-underwriting of the offer;

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- (iv) any proposal or arrangement concerning the benefit of employees of the Company or any of its subsidiaries including:
 - (A) the adoption, modification or operation of any employees' share scheme or any share incentive scheme or share option scheme under which the Director or any of his close associates may benefit; or
 - (B) the adoption, modification or operation of a pension or provident fund or retirement, death or disability benefits scheme which relates both to Directors, their close associates and employees of the Company or any of its subsidiaries and does not provide in respect of any Director or any of his close associates, as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates; and
- (v) any contract or arrangement in which the Director or any of his close associates 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.

(g) Remuneration

The Directors shall be entitled to receive by way of remuneration for their services such sum as shall from time to time be determined by the Directors, or the Company in general meeting, as the case may be, such sum (unless otherwise directed by the resolution by which it is determined) to be divided amongst the Directors in such proportions and in such manner as they may agree, or failing agreement, equally, except that in such event any Director holding office for less than the whole of the relevant period in respect of which the remuneration is paid shall only rank in such division in proportion to the time during such period for which he has held office. Such remuneration shall be in addition to any other remuneration to which a Director who holds any salaried employment or office in the Company may be entitled by reason of such employment or office.

The Directors shall also be entitled to be paid all expenses, including travel expenses, reasonably incurred by them in or in connection with the performance of their duties as Directors including their expenses of travelling to and from board meetings, committee meetings or general meetings or otherwise incurred whilst engaged on the business of the Company or in the discharge of their duties as Directors.

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The Directors may grant special remuneration to any Director who shall perform any special or extra services at the request of the Company. Such special remuneration may be made payable to such Director in addition to or in substitution for his ordinary remuneration as a Director, and may be made payable by way of salary, commission or participation in profits or otherwise as may be agreed.

The remuneration of an executive Director or a Director appointed to any other office in the management of the Company shall from time to time be fixed by the Directors and may be by way of salary, commission or participation in profits or otherwise or by all or any of those modes and with such other benefits (including share option and/or pension and/or gratuity and/or other benefits on retirement) and allowances as the Directors may from time to time decide. Such remuneration shall be in addition to such remuneration as the recipient may be entitled to receive as a Director.

(h) Retirement, appointment and removal

The Directors shall have power at any time and from time to time to appoint any person to be a Director, either to fill a casual vacancy or as an addition to the existing Directors. Any Director so appointed shall hold office only until the next general meeting of the Company and shall then be eligible for re-election at that meeting, but shall not be taken into account in determining the number of Directors and which Directors are to retire by rotation at such meeting.

The Company may by ordinary resolution remove any Director (including a Managing Director or other executive Director) before the expiration of his period of office notwithstanding anything in the Articles of Association or in any agreement between the Company and such Director (but without prejudice to any claim for compensation or damages payable to him in respect of the termination of his appointment as Director or of any other appointment of office as a result of the termination of this appointment as Director). The Company may also by ordinary resolution appoint another person in his place. Any Director so appointed shall hold office during such time only as the Director in whose place he is appointed would have held the same if he had not been removed.

The Company may also by ordinary resolution elect any person to be a Director, either to fill a casual vacancy or as an addition to the existing Directors. No person shall, unless recommended by the Directors, be eligible for election to the office of Director at any general meeting unless, during the period, which shall be at least seven days, commencing no earlier than the day after the despatch of the notice of the meeting appointed for such election and ending no later than seven days prior to the date of such meeting, there has been given to the Secretary of the Company notice in writing by a

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member of the Company (not being the person to be proposed) entitled to attend and vote at the meeting for which such notice is given of his intention to propose such person for election and also notice in writing signed by the person to be proposed of his willingness to be elected.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

The office of a Director shall be vacated:

- (i) if he resigns his office by notice in writing to the Company at its registered office or its principal office in Hong Kong;
- (ii) if an order is made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs and the Directors resolve that his office be vacated;
- (iii) if, without leave, he is absent from meetings of the Directors (unless an alternate Director appointed by him attends) for 12 consecutive months, and the Directors resolve that his office be vacated;
- (iv) if he becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors generally;
- (v) if he ceases to be or is prohibited from being a Director by law or by virtue of any provision in the Articles of Association;
- (vi) if he is removed from office by notice in writing served upon him signed by not less than three-fourths in number (or, if that is not a round number, the nearest lower round number) of the Directors (including himself) for the time being then in office; or
- (vii) if he shall be removed from office by an ordinary resolution of the members of the Company under the Articles of Association.

At every annual general meeting of the Company one-third of the Directors for the time being, or, if their number is not three or 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 (including those appointed for a specific term) shall be subject to retirement by rotation at least once every three years. A retiring Director shall retain office until the close of the meeting at which he retires and shall be eligible for re-election thereat. The Company at any annual general meeting at which any Directors retire may fill the vacated office by electing a like number of persons to be Directors.

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(i) Borrowing powers

The Directors may from time to time at their discretion exercise all the powers of the Company to raise or borrow or to secure the payment of any sum or sums of money for the purposes of the Company and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof.

(j) Proceedings of the Board

The Directors may meet together for the despatch of business, adjourn and otherwise regulate their meetings and proceedings as they think fit in any part of the world. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairperson of the meeting shall have a second or casting vote.

2.3 Alteration to constitutional documents

No alteration or amendment to the Memorandum or Articles of Association may be made except by special resolution.

2.4 Variation of rights of existing shares or classes of shares

If at any time the share capital of the Company is divided into different classes of shares, all or any of the rights attached to any class of shares for the time being issued (unless otherwise provided for in the terms of issue of the shares of that class) may, subject to the provisions of the Cayman Companies Act, be varied 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 meeting of the holders of the shares of that class. To every such separate meeting all the provisions of the Articles of Association relating to general meetings shall *mutatis mutandis* apply, but so that the quorum for the purposes of any such separate meeting and of any adjournment thereof shall be a person or persons together holding (or representing by proxy or duly authorised representative) at the date of the relevant meeting not less than one-third in nominal value of the issued shares of that class.

The special rights conferred upon the holders of shares of any class shall not, unless otherwise expressly provided in the rights attaching to or the terms of issue of such shares, be deemed to be varied by the creation or issue of further shares ranking *pari passu* therewith.

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2.5 Alteration of capital

The Company may, from time to time, whether or not all the shares for the time being authorised shall have been issued and whether or not all the shares for the time being issued shall have been fully paid up, by ordinary resolution, increase its share capital by the creation of new shares, such new capital to be of such amount and to be divided into shares of such respective amounts as the resolution shall prescribe.

The Company may from time to time by ordinary resolution:

- (a) consolidate and divide all or any of its share capital into shares of a larger amount than its existing shares. On any consolidation of fully paid shares and division into shares of larger amount, the Directors may settle any difficulty which may arise as they think expedient and in particular (but without prejudice to the generality of the foregoing) may as between the holders of shares to be consolidated determine which particular shares are to be consolidated into each consolidated share, and if it shall happen that any person shall become entitled to fractions of a consolidated share or shares, such fractions may be sold by some person appointed by the Directors for that purpose and the person so appointed may transfer the shares so sold to the purchaser thereof and the validity of such transfer shall not be questioned, and so that the net proceeds of such sale (after deduction of the expenses of such sale) may either be distributed among the persons who would otherwise be entitled to a fraction or fractions of a consolidated share or shares rateably in accordance with their rights and interests or may be paid to the Company for the Company's benefit;
- (b) cancel any shares which at the date of the passing of the resolution have not been taken or agreed to be taken by any person, and diminish the amount of its share capital by the amount of the shares so cancelled subject to the provisions of the Cayman Companies Act; and
- (c) sub-divide its shares or any of them into shares of smaller amount than is fixed by the Memorandum of Association, subject nevertheless to the provisions of the Cayman Companies Act, and so that the resolution whereby any share is sub-divided may determine that, as between the holders of the shares resulting from such sub-division, one or more of the shares may have any such preferred or other special rights, over, or may have such deferred rights or be subject to any such restrictions as compared with the others as the Company has power to attach to unissued or new shares.

The Company may by special resolution reduce its share capital or any capital redemption reserve in any manner authorised and subject to any conditions prescribed by the Cayman Companies Act.

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2.6 Special resolution – majority required

A “special resolution” is defined in the Articles of Association to have the meaning ascribed thereto in the Cayman Companies Act, for which purpose, the requisite majority shall be not less than three-fourths 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 specifying the intention to propose the resolution as a special resolution has been duly given and includes a special resolution approved in writing by all of the members of the Company entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of such members, and the effective date of the special resolution so adopted shall be the date on which the instrument or the last of such instruments (if more than one) is executed.

In contrast, an “ordinary resolution” is defined in the Articles of Association 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 held in accordance with the Articles of Association and includes an ordinary resolution approved in writing by all the members of the Company aforesaid.

2.7 Voting rights

Subject to any special rights, privileges or restrictions as to voting for the time being attached to any class or classes of shares, at any general meeting on a poll every member present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote for each share registered in his name in the register of members of the Company.

Where any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

In the case of joint registered holders of any share, any one of such persons may vote at any meeting, either personally or by proxy, in respect of such share as if he were solely entitled thereto; but if more than one of such joint holders be present at any meeting personally or by proxy, that one of the said persons so present being the most or, as the case may be, the more senior shall alone be entitled to vote in respect of the relevant joint holding and, for this purpose, seniority shall be determined by reference to the order in which the names of the joint holders stand on the register in respect of the relevant joint holding.

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A member of the Company in respect of whom an order has been made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs may vote by any person authorised in such circumstances to do so and such person may vote by proxy.

Save as expressly provided in the Articles of Association or as otherwise determined by the Directors, no person other than a member of the Company duly registered and who shall have paid all sums for the time being due from him payable to the Company in respect of his shares shall be entitled to be present or to vote (save as proxy for another member of the Company), or to be reckoned in a quorum, either personally or by proxy at any general meeting.

At any general meeting a resolution put to the vote of the meeting shall be decided by way of a poll save that the chairperson of the meeting may allow a resolution which relates purely to a procedural or administrative matter as prescribed under the Listing Rules to be voted on by a show of hands.

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 proxy(ies) or representative(s) at any general meeting of the Company or at any general 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 entitled to exercise the same rights and powers on behalf of the recognised clearing house (or its nominee(s)) which he represents as that recognised clearing house (or its nominee(s)) could exercise as if it were an individual member of the Company holding the number and class of shares specified in such authorisation, including, where a show of hands is allowed, the right to vote individually on a show of hands.

2.8 Annual general meetings and extraordinary general meetings

The Company shall hold a general meeting as its annual general meeting each year, within a period of not more than 15 months after the holding of the last preceding annual general meeting (or such longer period as the Stock Exchange may authorise). The annual general meeting shall be specified as such in the notices calling it.

The board of Directors may, whenever it thinks fit, convene an extraordinary general meeting. General meetings shall also be convened on the written requisition of any one or more members holding together, as at the date of deposit of the requisition, shares representing not less than one-tenth of the paid up capital of the Company which carry the right of voting at general meetings of the Company. The written requisition shall be deposited at the principal office of the Company in Hong Kong or, in the event the Company ceases to have such a principal office, the registered office of the Company, specifying the objects of the meeting and the resolutions to be added to the meeting agenda, and signed by the requisitionist(s). If the

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Directors do not within 21 days from the date of deposit of the requisition proceed duly to convene the meeting to be held within a further 21 days, the requisitionist(s) themselves or any of them representing more than one-half of the total voting rights of all of them, may convene the general meeting in the same manner, as nearly as possible, as that in which meetings may be convened by the Directors provided that any meeting so convened shall not be held after the expiration of three months from the date of deposit of the requisition, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the Directors shall be reimbursed to them by the Company.

2.9 Accounts and audit

The Directors shall cause to be kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to show and explain its transactions and otherwise in accordance with the Cayman Companies Act.

The Directors shall from time to time determine whether, and to what extent, and at what times and places and under what conditions or regulations, the accounts and books of the Company, or any of them, shall be open to inspection by members of the Company (other than officers of the Company) and no such member shall have any right of inspecting any accounts or books or documents of the Company except as conferred by the Cayman Companies Act or any other relevant law or regulation or as authorised by the Directors or by the Company in general meeting.

The Directors shall, commencing with the first annual general meeting, cause to be prepared and to be laid before the members of the Company at every annual general meeting a profit and loss account for the period, in the case of the first account, since the incorporation of the Company and, in any other case, since the preceding account, together with a balance sheet as at the date to which the profit and loss account is made up and a Director's report with respect to the profit or loss of the Company for the period covered by the profit and loss account and the state of the Company's affairs as at the end of such period, an auditor's report on such accounts and such other reports and accounts as may be required by law. Copies of those documents to be laid before the members of the Company at an annual general meeting shall not less than 21 days before the date of the meeting, be sent in the manner in which notices may be served by the Company as provided in the Articles of Association to every member of the Company and every holder of debentures of the Company provided that the Company shall not be required to send copies of those documents to any person of whose address the Company is not aware or to more than one of the joint holders of any shares or debentures.

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2.10 Auditors

The Company shall at every annual general meeting appoint an auditor or auditors of the Company who shall hold office until the next annual general meeting. The removal of an auditor before the expiration of his period of office shall require the approval of an ordinary resolution of the members in general meeting. The remuneration of the auditors shall be fixed by the Company at the annual general meeting at which they are appointed provided that in respect of any particular year the Company in general meeting may delegate the fixing of such remuneration to the Directors.

2.11 Notice of meetings and business to be conducted thereat

An annual general meeting shall be called by not less than 21 days' notice in writing and any extraordinary general meeting shall be called by not less than 14 days' notice in writing. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and shall specify the time, place and agenda of the meeting, particulars of the resolutions and the general nature of the business to be considered at the meeting. The notice convening an annual general meeting shall specify the meeting as such, and the notice convening a meeting to pass a special resolution shall specify the intention to propose the resolution as a special resolution. Notice of every general meeting shall be given to the auditors and all members of the Company (other than those who, under the provisions of the Articles of Association or the terms of issue of the shares they hold, are not entitled to receive such notice from the Company).

Notwithstanding that a meeting of the Company is called by shorter notice than that mentioned above, it shall be deemed to have been duly called if it is so agreed:

- (a) in the case of a meeting called as an annual general meeting, by all members of the Company entitled to attend and vote thereat or their proxies; and
- (b) in the case of any other meeting, by a majority in number of the members having a right to attend and vote at the meeting, being a majority together holding not less than 95% in nominal value of the shares giving that right.

If, after the notice of a general meeting has been sent but before the meeting is held, or after the adjournment of a general meeting but before the adjourned meeting is held (whether or not notice of the adjourned meeting is required), the Directors, in their absolute discretion, consider that it is impractical or unreasonable for any reason to hold a general meeting on the date or at the time and place specified in the notice calling such meeting, it may change or postpone the meeting to another date, time and place.

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The Directors also have the power to provide in every notice calling a general meeting that in the event of a gale warning or a black rainstorm warning is in force at any time on the day of the general meeting (unless such warning is cancelled at least a minimum period of time prior to the general meeting as the Directors may specify in the relevant notice), the meeting shall be postponed without further notice to be reconvened on a later date.

Where a general meeting is postponed:

- (a) the Company shall endeavour to cause a notice of such postponement, which shall set out the reason for the postponement in accordance with the Listing Rules, to be placed on the Company's website and published on the Stock Exchange's website as soon as practicable, but failure to place or publish such notice shall not affect the automatic postponement of a general meeting due to a gale warning or black rainstorm warning being in force on the day of the general meeting;
- (b) the Directors shall fix the date, time and place for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting; and such notice shall specify the date, time and place at which the postponed meeting will be reconvened and the date and time by which proxies shall be submitted in order to be valid at such reconvened meeting (provided that any proxy submitted for the original meeting shall continue to be valid for the reconvened meeting unless revoked or replaced by a new proxy); and
- (c) only the business set out in the notice of the original meeting shall be transacted at the reconvened meeting, and notice given for the reconvened meeting does not need to specify the business to be transacted at the reconvened meeting, nor shall any accompanying documents be required to be recirculated. Where new business is to be transacted at such reconvened meeting, the Company shall give a fresh notice for such reconvened meeting in accordance with the Articles of Association.

2.12 Transfer of shares

Transfers of shares may be effected by an instrument of transfer in the usual common form or in such other form as the Directors may approve which is consistent with the standard form of transfer as prescribed by the Stock Exchange.

The instrument of transfer shall be executed by or on behalf of the transferor and, unless the Directors otherwise determine, the transferee, and 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 of the Company in respect thereof. All instruments of transfer shall be retained by the Company.

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The Directors may refuse to register any transfer of any share which is not fully paid up or on which the Company has a lien. The Directors may also decline to register any transfer of any shares unless:

- (a) the instrument of transfer is lodged with the Company accompanied by the certificate for the shares to which it relates (which shall upon the registration of the transfer be cancelled) and such other evidence as the Directors may reasonably require to show the right of the transferor to make the transfer;
- (b) the instrument of transfer is in respect of only one class of shares;
- (c) the instrument of transfer is properly stamped (in circumstances where stamping is required);
- (d) in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred does not exceed four;
- (e) the shares concerned are free of any lien in favour of the Company; and
- (f) a fee of such amount not exceeding the maximum amount as the Stock Exchange may from time to time determine to be payable (or such lesser sum as the Directors may from time to time require) is paid to the Company in respect thereof.

If the Directors refuse to register a transfer of any share they shall, within two months after the date on which the transfer was lodged with the Company, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on 10 business days' notice (or on 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, be suspended and the register of members of the Company closed at such times for such periods as the Directors may from time to time determine, provided that the registration of transfers shall not be suspended or the register closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine provided that such period shall not be extended beyond 60 days in any year).

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2.13 Power of the Company to purchase its own shares

The Company is empowered by the Cayman Companies Act and the Articles of Association to purchase its own shares subject to certain restrictions and the Directors may only exercise this power on behalf of the Company subject to the authority of its members in general meeting as to the manner in which they do so and to any applicable requirements imposed from time to time by the Stock Exchange and the Securities and Futures Commission of Hong Kong. Shares which have been repurchased will be treated as cancelled upon the repurchase.

2.14 Power of any subsidiary of the Company to own shares

There are no provisions in the Articles of Association relating to the ownership of shares by a subsidiary.

2.15 Dividends and other methods of distribution

Subject to the Cayman Companies Act and the Articles of Association, the Company in general meeting may declare dividends in any currency but no dividends shall exceed the amount recommended by the Directors. No dividend may be declared or paid other than out of profits and reserves of the Company lawfully available for distribution, including share premium.

Unless and to the extent that the rights attached to any shares or the terms of issue thereof otherwise provide, all dividends shall (as regards any shares not fully paid throughout the period in respect of which the dividend is paid) be apportioned and paid pro rata according to the amounts paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. For these purposes no amount paid up on a share in advance of calls shall be treated as paid up on the share.

The Directors may from time to time pay to the members of the Company such interim dividends as appear to the Directors to be justified by the profits of the Company. The Directors may also pay half-yearly or at other intervals to be selected by them any dividend which may be payable at a fixed rate if they are of the opinion that the profits available for distribution justify the payment.

The Directors may retain any dividends or other monies payable on or in respect of a share upon which the Company has a lien, and may apply the same in or towards satisfaction of the debts, liabilities or engagements in respect of which the lien exists. The Directors may also deduct from any dividend or other monies payable to any member of the Company all sums of money (if any) presently payable by him to the Company on account of calls, instalments or otherwise.

No dividend shall carry interest against the Company.

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Whenever the Directors or the Company in general meeting have resolved that a dividend be paid or declared on the share capital of the Company, the Directors may further resolve: (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up on the basis that the shares so allotted are to be of the same class as the class already held by the allottee, provided that the members of the Company entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment; or (b) that the members of the Company 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 Directors may think fit on the basis that the shares so allotted are to be of the same class as the class already held by the allottee. The Company may upon the recommendation of the Directors by ordinary resolution resolve in respect of any one particular dividend of the Company that notwithstanding the foregoing a dividend may be satisfied wholly in the form of an allotment of shares credited as fully paid without offering any right to members of the Company to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other sum payable in cash to a holder of shares may be paid by cheque or warrant sent through the post addressed to the registered address of the member of the Company entitled, or in the case of joint holders, to the registered address of the person whose name stands first in the register of members of the Company in respect of the joint holding or to such person and to such address as the holder or joint holders may in writing direct. Every cheque or warrant so sent shall 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 of members of the Company in respect of such shares, and shall be sent at his or their risk and the payment of any such cheque or warrant by the bank on which it is drawn shall operate as a good discharge to the Company in respect of the dividend and/or bonus represented thereby, notwithstanding that it may subsequently appear that the same has been stolen or that any endorsement thereon has been forged. The Company may cease sending such cheques for dividend entitlements or dividend warrants by post if such cheques or warrants have been left uncashed on two consecutive occasions. However, the Company may exercise its power to cease sending cheques for dividend entitlements or dividend warrants after the first occasion on which such a cheque or warrant is returned undelivered. Any one of two or more joint holders may give effectual receipts for any dividends or other monies payable or property distributable in respect of the shares held by such joint holders.

Any dividend unclaimed for six years from the date of declaration of such dividend may be forfeited by the Directors and shall revert to the Company.

The Directors may, with the sanction of the members of the Company in general meeting, direct that any dividend be satisfied wholly or in part by the distribution of specific assets of any kind, and in particular of paid up shares, debentures or warrants to subscribe securities of any other company, and where any difficulty arises in regard to such distribution the Directors may settle it as they think expedient, and in particular may disregard fractional entitlements, round the same up or down or provide that the same shall accrue to the benefit of the Company, and may fix the value for distribution of such specific assets and may determine that cash payments shall be made to any members of the Company upon the footing of the value so fixed in order to adjust the rights of all parties, and may vest any such specific assets in trustees as may seem expedient to the Directors.

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2.16 Proxies

Any member of the Company entitled to attend and vote at a meeting of the Company shall be entitled to appoint another person who must be an individual as his proxy to attend and vote instead of him and a proxy so appointed shall have the same right as the member to speak at the meeting. A proxy need not be a member of the Company.

Instruments of proxy shall be in common form or in such other form as the Directors may from time to time approve provided that it shall enable a member to instruct his proxy to vote in favour of or against (or in default of instructions or in the event of conflicting instructions, to exercise his discretion in respect of) each resolution to be proposed at the meeting to which the form of proxy relates. The instrument of proxy shall be deemed to confer authority to vote on any amendment of a resolution put to the meeting for which it is given as the proxy thinks fit. The instrument of proxy shall, unless the contrary is stated therein, be valid as well for any adjournment of the meeting as for the meeting to which it relates provided that the meeting was originally held within 12 months from such date.

The instrument appointing a proxy shall be in writing under the hand of the appointor or his attorney authorised in writing or if the appointor is a corporation either under its seal or under the hand of an officer, attorney or other person authorised to sign the same.

The instrument appointing a proxy and (if required by the Directors) the power of attorney or other authority (if any) under which it is signed, or a notarially certified copy of such power or authority, shall be delivered at the registered office of the Company (or at such other place as may be specified in the notice convening the meeting or in any notice of any adjournment or, in either case, in any document sent therewith) not less than 48 hours before the time appointed for holding the meeting or adjourned meeting at which the person named in the instrument proposes to vote or, in the case of a poll taken subsequently to the date of a meeting or adjourned meeting, not less than 48 hours before the time appointed for the taking of the poll and in default the instrument of proxy shall not be treated as valid. No instrument appointing a proxy shall be valid after the expiration of 12 months from the date named in it as the date of its execution. Delivery of any instrument appointing a proxy shall not preclude a member of the Company from attending and voting in person at the meeting or poll concerned and, in such event, the instrument appointing a proxy shall be deemed to be revoked.

2.17 Calls on shares and forfeiture of shares

The Directors may from time to time make calls upon the members of the Company in respect of any monies unpaid on their shares (whether on account of the nominal amount of the shares or by way of premium or otherwise) and not by the conditions of allotment thereof made payable at fixed times and each member of the Company shall (subject to the Company serving upon him at least 14 days' notice specifying the time and place of payment and to whom such payment shall be made) pay to the person at the time and place so specified the amount called on his shares. A call may be revoked or postponed as the Directors may determine. A person upon whom a call is made shall remain liable on such call notwithstanding the subsequent transfer of the shares in respect of which the call was made.

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A call may be made payable either in one sum or by instalments and shall be deemed to have been made at the time when the resolution of the Directors authorising the call was passed. The joint holders of a share shall be jointly and severally liable to pay all calls and instalments due in respect of such share or other monies due in respect thereof.

If a sum called in respect of a share shall not be paid before or on the day appointed for payment thereof, the person from whom the sum is due shall pay interest on the sum from the day appointed for payment thereof to the time of actual payment at such rate, not exceeding 15% per annum, as the Directors may determine, but the Directors shall be at liberty to waive payment of such interest wholly or in part.

If any call or instalment of a call remains unpaid on any share after the day appointed for payment thereof, the Directors may at any time during such time as any part thereof remains unpaid serve a notice on the holder of such shares requiring payment of so much of the call or instalment as is unpaid together with any interest which may be accrued and which may still accrue up to the date of actual payment.

The notice shall name a further day (not being less than 14 days from the date of service of the notice) on or before which, and the place where, the payment required by the notice is to be made, and shall state that in the event of non-payment at or before the time and at the place appointed, the shares in respect of which such call was made or instalment is unpaid will be liable to be forfeited.

If the requirements of such notice are not complied with, any share in respect of which such notice has been given may at any time thereafter, before payment of all calls or instalments and interest due in respect thereof has been made, be forfeited by a resolution of the Directors to that effect. Such forfeiture shall include all dividends and bonuses declared in respect of the forfeited shares and not actually paid before the forfeiture. A forfeited share shall be deemed to be the property of the Company and may be re-allotted, sold or otherwise disposed of.

A person whose shares have been forfeited shall cease to be a member of the Company in respect of the forfeited shares but shall, notwithstanding the forfeiture, 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 Directors shall in their discretion so require) interest thereon at such rate not exceeding 15% per annum as the Directors may prescribe from the date of forfeiture until payment, and the Directors may enforce payment thereof without being under any obligation to make any allowance for the value of the shares forfeited, at the date of forfeiture.

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2.18 Inspection of register of members

The register of members of the Company shall be kept in such manner as to show at all times the members of the Company for the time being and the shares respectively held by them. The register may, on 10 business days' notice (or on 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, be closed at such times and for such periods as the Directors may from time to time determine either generally or in respect of any class of shares, provided that the register shall not be closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine provided that such period shall not be extended beyond 60 days in any year).

Any register of members kept in Hong Kong shall during normal business hours (subject to such reasonable restrictions as the Directors may impose) be open to inspection by any member of the Company without charge and by any other person on payment of a fee of such amount not exceeding the maximum amount as may from time to time be permitted under the Listing Rules as the Directors may determine for each inspection.

2.19 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, choice or election of a chairperson which shall not be treated as part of the business of the meeting.

Two members of the Company present in person or by proxy shall be a quorum provided always that if the Company has only one member of record the quorum shall be that one member present in person or by proxy.

A corporation being a member of the Company shall be deemed for the purpose of the Articles of Association to be present in person if represented by its duly authorised representative being the person appointed by resolution of the directors or other governing body of such corporation or by power of attorney to act as its representative at the relevant general meeting of the Company or at any relevant general meeting of any class of members of the Company.

The quorum for a separate general meeting of the holders of a separate class of shares of the Company is described in paragraph 2.4 above.

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2.20 Rights of minorities in relation to fraud or oppression

There are no provisions in the Articles of Association concerning the rights of minority shareholders in relation to fraud or oppression.

2.21 Procedure on liquidation

If the Company shall be wound up, and the assets available for distribution amongst the members of the Company 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 of the Company 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 in a winding up 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 amongst the members of the Company in proportion to the capital paid up at the commencement of the winding up on the shares held by them respectively. The foregoing is without prejudice to the rights of the holders of shares issued upon special terms and conditions.

If the Company shall be wound up, the liquidator may with the sanction of a special resolution of the Company and any other sanction required by the Cayman Companies Act, divide amongst the members of the Company in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose, set such value as he deems fair upon any 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 of the Company. The liquidator may, with the like sanction, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the members of the Company as the liquidator, with the like sanction and subject to the Cayman Companies Act, shall think fit, but so that no member of the Company shall be compelled to accept any assets, shares or other securities in respect of which there is a liability.

2.22 Untraceable members

The Company shall be entitled to sell any shares of a member of the Company or the shares to which a person is entitled by virtue of transmission on death or bankruptcy or operation of law if: (a) all cheques or warrants, not being less than three in number, for any sums payable in cash to the holder of such shares have remained uncashed for a period of 12 years; (b) the Company has not during that time or before the expiry of the three month period referred to in (d) below received any indication of the whereabouts or existence of the member; (c) during the 12 year period, at least three dividends in respect of the shares in question have become payable and no dividend during that period has been claimed by the member; and (d) upon expiry of the 12 year period, the Company has caused an advertisement to be published in the newspapers or subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles

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of Association, giving notice of its intention to sell such shares and a period of three months has elapsed since such advertisement and the Stock Exchange has been notified of such intention. The net proceeds of any such sale shall belong to the Company and upon receipt by the Company of such net proceeds it shall become indebted to the former member for an amount equal to such net proceeds.

SUMMARY OF CAYMAN ISLANDS COMPANY LAW AND TAXATION

3 Introduction

The Cayman Companies Act is derived, to a large extent, from the older Companies Acts of England, although there are significant differences between the Cayman Companies Act and the current Companies Act of England. Set out below is a summary of certain provisions of the Cayman Companies Act, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of corporate law and taxation which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

4 Incorporation

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 30 April 2012 under the Cayman Companies Act. As such, its 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 size of its authorised share capital.

5 Share Capital

The Cayman Companies Act permits a company to issue ordinary shares, preference shares, redeemable shares or any combination thereof.

The Cayman 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 premia on those shares shall be transferred to an account called the "share premium account". At the option of a company, these provisions may not apply to premia 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 Cayman Companies Act provides that the share premium account may be applied by a company, subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation:

- (a) paying distributions or dividends to members;

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- (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;
- (c) in the redemption and repurchase of shares (subject to the provisions of section 37 of the Cayman Companies Act);
- (d) writing-off the preliminary expenses of the company;
- (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company; and
- (f) providing for the premium payable on redemption or purchase of any 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 Cayman Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands, 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.

Subject to the detailed provisions of the Cayman Companies Act, 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. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. The manner of such a purchase must be authorised either by the articles of association or by an ordinary resolution of the company. The articles of association may provide that the manner of purchase may be determined by the directors 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 member of the company holding 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.

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There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company 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 to act 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.

6 Dividends and Distributions

With the exception of section 34 of the Cayman Companies Act, there are no statutory provisions relating to the payment of dividends. Based upon English case law which is likely to be persuasive in the Cayman Islands in this area, dividends may be paid only out of profits. In addition, section 34 of the Cayman 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 (see paragraph 5 above for details).

7 Shareholders' Suits

The Cayman Islands courts can be expected to follow English case law precedents. The rule in *Foss v. Harbottle* (and the exceptions thereto which permit a minority shareholder to commence a class 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 where the wrongdoers are themselves in control of the company, and (c) an action which requires a resolution with a qualified (or special) majority which has not been obtained) has been applied and followed by the courts in the Cayman Islands.

8 Protection of Minorities

In the case of a company (not being a bank) having a share capital divided into shares, the Grand Court of the Cayman Islands 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 Grand Court shall direct.

Any shareholder of a company may petition the Grand Court of the Cayman Islands 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.

Claims against a company by its shareholders must, as a general rule, 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.

The English common law rule that the majority will not be permitted to commit a fraud on the minority has been applied and followed by the courts of the Cayman Islands.

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9 Disposal of Assets

The Cayman Companies Act contains no specific restrictions on the powers of directors to dispose of assets of a company. As a matter of general law, in the exercise of those powers, the directors must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the company.

10 Accounting and Auditing Requirements

The Cayman Companies Act requires that a company shall cause to be kept proper books of account with respect to:

- (a) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place;
- (b) all sales and purchases of goods by the company; and
- (c) 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.

11 Register of Members

An exempted company may, subject to the provisions of its articles of association, maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as its directors may from time to time think fit. There is no requirement under the Cayman 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.

12 Inspection of Books and Records

Members of a company will have no general right under the Cayman 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 of association.

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13 Special Resolutions

The Cayman Companies Act provides that a resolution is a special resolution when it has been passed by a majority of at least two-thirds of such members as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given, except that a company may in its articles of association specify that the required majority shall be a number greater than two-thirds, and may additionally so provide that such majority (being not less than two-thirds) may differ as between matters required to be approved by a special resolution. Written resolutions signed by all the members entitled to vote for the time being of the company may take effect as special resolutions if this is authorised by the articles of association of the company.

14 Subsidiary Owning Shares in Parent

The Cayman Companies Act does not prohibit a Cayman Islands company acquiring and holding shares in its parent company provided its objects so permit. The directors of any subsidiary making such acquisition must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the subsidiary.

15 Mergers and Consolidations

The Cayman Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (b) "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorised by (a) a special resolution of each constituent company and (b) such other authorisation, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

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16 Reconstructions

There are statutory provisions which facilitate reconstructions and amalgamations approved by a majority in number representing 75% in value of shareholders or creditors, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. Whilst a dissenting shareholder would have the right to express to the Grand Court his view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Grand 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 and if the transaction were approved and consummated the dissenting shareholder would have no rights comparable to the appraisal rights (i.e. the right to receive payment in cash for the judicially determined value of his shares) ordinarily available, for example, to dissenting shareholders of United States corporations.

17 Take-overs

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90% of the shares which are the subject of the offer accept, the offeror may at any time within two months after the expiration of the said four months, by notice require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Grand Court of the Cayman Islands within one month of the notice objecting to the transfer. The burden is on the dissenting shareholder to show that the Grand 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.

18 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 Cayman Islands courts to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

19 Liquidation

A company may be placed in liquidation compulsorily by an order of the court, or voluntarily (a) by a special resolution of its members if the company is solvent, or (b) by an ordinary resolution of its members if the company is insolvent. The liquidator's duties are to collect the assets of the company (including the amount (if any) due from the contributories (shareholders)), settle the list of creditors and discharge the company's liability to them, rateably if insufficient assets exist to discharge the liabilities in full, and to settle the list of contributories and divide the surplus assets (if any) amongst them in accordance with the rights attaching to the shares.

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20 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.

21 Taxation

Pursuant to section 6 of the Tax Concessions Act (As Revised) of the Cayman Islands, the Company may obtain an undertaking from the Financial Secretary of the Cayman Islands:

- (a) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to the Company or its operations; and
- (b) in addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable:
 - (i) on or in respect of the shares, debentures or other obligations of the Company; or
 - (ii) by way of the withholding in whole or in part of any relevant payment as defined in section 6(3) of the Tax Concessions Act (As Revised).

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 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 not party to any double tax treaties that are applicable to any payments made by or to the Company.

22 Exchange Control

There are no exchange control regulations or currency restrictions in the Cayman Islands.

23 General

Maples and Calder (Hong Kong) LLP, the Company's legal advisers on Cayman Islands law, have sent to the Company a letter of advice summarising aspects of Cayman Islands company law. This letter, together with a copy of the Cayman Companies Act, is available for inspection as referred to in the section headed "Documents available for inspection" in Appendix V. 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/she is more familiar is recommended to seek independent legal advice.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Cayman Companies Act on April 30, 2012. Our registered office address is at the offices of PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. As our Company is incorporated in the Cayman Islands, our operation is subject to the relevant laws and regulations of the Cayman Islands, the Articles and the Memorandum. A summary of the relevant laws and regulations of the Cayman Islands and of our constitution is set out in the section headed “Summary of the Constitution of our Company and Cayman Islands Companies Law” in this document.

Our Company [was] registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on 40th Floor, Dah Sing Financial Centre, No. 248 Queen’s Road East, Wanchai, Hong Kong and has been registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on [●], 2021. Mr. Leong Yin Lee (李亮賢) has been appointed as the authorized representative of our Company for the acceptance of service of process and notices in Hong Kong whose correspondence address is the same as our place of business.

As of the date of this document, our Company’s head office is located at [Room 317, 3/F, Building 2, No. 88 Jiangling Rd, Xixing Street, Binjiang District, Hangzhou, China].

2. Changes in the Share Capital of Our Company

As of the date of incorporation of our Company, our authorized share capital was US\$50,000.00 divided into 50,000 Shares with an initial par value of US\$1.00 each.

The following sets out the changes in the share capital of our Company during the two years immediately preceding the date of this document

- (a) On August 17, 2020, our shareholders passed a special resolution to re-designate 11,191,242 unissued Shares of par value US\$0.0001 each into 11,191,242 Series C Preferred Shares of par value US\$0.0001 each. On August 17, 2020 and September 25, 2020, 9,791,147 Series C Preferred Shares out of 11,191,242 Series C Preferred Shares were issued and allotted to below shareholders in the following manner:
 - (1) 4,684,706 Series C Preferred Shares to LBC Sunshine Healthcare Fund L.P.;
 - (2) 1,301,307 Series C Preferred Shares to ACM 01 Limited;
 - (3) 2,342,353 Series C Preferred Shares to BC Mars L.P., Silver Pearl Limited;
 - (4) 161,474 Series C Preferred Shares to Silver Pearl Limited; and

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- (5) 1,301,307 Series C Preferred Shares to CNCB CAPITAL VALUE SPC-CNCB Capital Energy Investment Fund SP.
- (b) On January 23, 2021, our shareholders passed a special resolution to re-designate 6,068,134 unissued Shares of par value US\$0.0001 each into 6,068,134 Series D Preferred Shares of par value US\$0.0001 each. On January 25, 2021, 6,068,134 Series D Preferred Shares were all allotted to below shareholders in the following manner:
 - (1) 5,309,619 Series D Preferred Shares to Elegant Holding Limited;
 - (2) 303,406 Series D Preferred Shares to Strong Leap Holdings Limited;
 - (3) 303,406 Series D Preferred Shares to Valliance Emerging Opportunities Limited Partnership Fund; and
 - (4) 151,703 Series D Preferred Shares to Emerging Markets Healthcare Partners LLC.
- (c) Share Subdivision.

For details of our Company’s authorized and issued share capital and consideration relating to the allotment of the Preferred Shares and Share Subdivision above, please refer to the sections headed “Share Capital – Authorized and Issued Share Capital”, “History, Reorganization and Corporate Structure – [REDACTED] Investments” and “History, Reorganization and Corporate Structure – Reorganization – 5. Share Subdivision” in this document.

Save as disclosed above, there has been no alternation in our share capital within the two years immediately preceding the date of this document.

3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report set out in Appendix I to this document.

The following sets out the changes in the share capital of our major subsidiaries within the two years immediately preceding the date of this document

Broncus Hangzhou

On May 20, 2019, the registered capital of Broncus Hangzhou increased from RMB20 million to RMB50 million.

On July 17, 2020, the registered capital of Broncus Hangzhou further increased from RMB50 million to RMB100 million.

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On September 10, 2020, the registered capital of Broncus Hangzhou further increased from RMB100 million to RMB150 million.

On December 29, 2020, the registered capital of Broncus Hangzhou further increased from RMB150 million to RMB250 million.

Uptake Medical

On March 11, 2021, the registered capital of Uptake Medical increased from US\$30,500 to US\$100,000.

Broncus Medical

On March 11, 2021, the number of the authorized shares of Broncus Medical increased from 60,000,000 to 100,000,000.

Save as disclosed above, there has been no alteration in the share capital of any major subsidiaries of our Company within the two years immediately preceding the date of this document.

Save for the subsidiaries mentioned in the Accountants’ Report set out in Appendix I to this document, our Company has no other subsidiaries.

4. Corporate Reorganization

Our Company has gone through the corporate reorganization. For details of the history and development of our Company, see “History, Reorganization and Corporate Structure” in this document.

5. Resolutions of the Shareholders of Our Company dated [●]

Written resolutions of our Shareholders were passed on [●] pursuant to which, among others:

- (a) conditional on (i) the Listing Committee granting the [REDACTED] of, and permission to deal in, the Shares in issue and to be issued as to be stated in this document and such [REDACTED] and permission not subsequently having been revoked prior to the commencement of dealing in the Shares on the Stock Exchange; (ii) the [REDACTED] having been determined; (iii) the obligations of the [REDACTED] under the [REDACTED] becoming unconditional and not being terminated in accordance with the terms of the [REDACTED] or otherwise, in each case on or before such dates as may be specified in the [REDACTED]; and (iv) the [REDACTED] having been duly executed by the [REDACTED] and our Company:
 - (1) the [REDACTED] (including the [REDACTED]) was approved, and the proposed allotment and issue of the [REDACTED] under the [REDACTED] were approved, and the Directors were authorized to determine the [REDACTED] for, and to allot and issue the [REDACTED];

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- (2) a general unconditional mandate was given to our Directors to exercise all powers of our Company to allot, issue and deal with Shares or securities convertible into Shares and to make or grant offers, agreements or options (including any warrants, bonds, notes and debentures conferring any rights to subscribe for or otherwise receive Shares) which might require Shares to be allotted and issued or dealt with 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, otherwise than by way of the [REDACTED], rights issue or pursuant to the exercise of any subscription rights attaching to any warrants which may be allotted and issued by the Company from time to time or, pursuant to the exercise of any options which may be granted under the Share Option Plan or allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles of Association on a specific authority granted by our Shareholders in general meeting, shall not exceed 20% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED], excluding any Shares which may fall to be issued pursuant to the exercise of the [REDACTED];
 - (3) a general unconditional mandate (the “**Repurchase Mandate**”) was given to our Directors to exercise all powers of our Company to repurchase on the Stock Exchange or on any other stock exchange on which the securities of our Company may be listed and which is recognized by the SFC and the Stock Exchange for this purpose, such number of Shares as will represent 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 issued pursuant to the exercise of the [REDACTED];
 - (4) the general unconditional mandate as mentioned in paragraph (2) above was 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 purchase Shares referred to in paragraph (3) 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 issued pursuant to the exercise of the [REDACTED];
 - (5) the acknowledgement by all the Preferred Shareholders of the agreed conversion number as applicable and the resolution not to exercise the right to further adjustment of conversion ratio;
- (b) the Share Subdivision was approved with effect immediately before [REDACTED] on the [REDACTED];

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- (c) the terms of the Share Option Plan was approved and adopted with effect from [REDACTED]; and
- (d) the Memorandum and the Articles were conditionally approved and adopted with effect from the [REDACTED].

Each of the general mandates referred to in paragraphs (a)(2), (a)(3) and (a)(4) above will remain in effect until whichever is the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles of Association; or
- the time when such mandate is revoked or varied by an ordinary resolution of the Shareholders in a general meeting.

6. Repurchase of Our Shares

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this document concerning the repurchase of our own securities.

(a) Provision of the Listing Rules

The Listing Rules permit companies with a primary listing on the Stock Exchange to repurchase their own securities on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(i) Shareholders' Approval

All proposed repurchases of securities (which must be fully paid up in the case of shares) by a company with a primary listing on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders in general meeting, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to a resolution passed by our Shareholders on [●], the Repurchase Mandate was given to our Directors authorizing them to exercise all powers of our Company to repurchase Shares on the Stock Exchange, or on any other stock exchange on which the securities of our Company may be [REDACTED] and which is recognized by the SFC and the Stock Exchange for this purpose, with a total nominal value up to 10% of the aggregate nominal value of our Shares in issue immediately following completion of the [REDACTED] (excluding any Shares which may be issued under the [REDACTED]), with such mandate to expire at the earliest of (i) the conclusion of the next annual general

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meeting of our Company (unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions), (ii) the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held, and (iii) the date when it is varied or revoked by an ordinary resolution of our Shareholders in general meeting.

(ii) Source of Funds

Purchases must be funded out of funds legally available for the purpose in accordance with the Memorandum and the Articles and the applicable laws and regulations of Hong Kong and the Cayman Islands. A listed company may not purchase its own securities on the Stock Exchange 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. As a matter of Cayman Islands law, any purchases by the Company may be made out of profits or out of the proceeds of a new issue of shares made for the purpose of the purchase or from sums standing to the credit of our share premium account or out of capital, if so authorized by the Articles of Association and subject to the Cayman Companies Act. Any premium payable on the purchase over the par value of the shares to be purchased must have been provided for out of profits or from sums standing to the credit of our share premium account or out of capital, if so authorized by the Articles of Association and subject to the Cayman Companies Act.

(iii) Trading Restrictions

The total number of shares which a listed company may repurchase on the Stock Exchange is the number of shares representing up to 10% of the aggregate number of shares in issue. A company may not issue or announce a proposed issue of new securities for a period of 30 days immediately following a repurchase (other than an issue of securities pursuant to an exercise of warrants, share options or similar instruments requiring the company to issue securities which were outstanding prior to such repurchase) without the prior approval of the Stock Exchange. In addition, a listed company is prohibited from repurchasing its shares on the Stock Exchange if the purchase price is 5% or more than the average closing market price for the five preceding trading days on which its shares were traded on the Stock Exchange. The Listing Rules also prohibit a listed company from repurchasing its securities if the repurchase would result in the number of listed securities which are in the hands of the public falling below the relevant prescribed minimum percentage as required by the Stock Exchange. A company is required to procure that the broker appointed by it to effect a repurchase of securities discloses to the Stock Exchange such information with respect to the repurchase as the Stock Exchange may require.

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(iv) Status of Repurchased Shares

The listing of all purchased securities (whether on the Stock Exchange or otherwise) is automatically cancelled and the relevant certificates must be cancelled and destroyed. Under the laws of the Cayman Islands, unless the Directors resolve to hold the shares purchased by our Company as treasury shares prior to the purchase, shares purchased by our Company shall be treated as cancelled and the amount of our Company’s issued share capital shall be diminished by the nominal value of those shares. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital under Cayman Islands law.

(v) Suspension of Repurchase

A listed company may not make any repurchase of securities after a price sensitive development has occurred or has been the subject of a decision until such time as the price sensitive information has been made publicly available. In particular, during the period of one month immediately preceding the earlier of (a) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of a listed company’s results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules) and (b) the deadline for publication of an announcement of a listed company’s results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), the listed company may not repurchase its shares on the Stock Exchange other than in exceptional circumstances. In addition, the Stock Exchange may prohibit a repurchase of securities on the Stock Exchange if a listed company has breached the Listing Rules.

(vi) Reporting Requirements

Certain information relating to repurchases of securities on the Stock Exchange or otherwise must be reported to the Stock Exchange not later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following Business Day. In addition, a listed company’s annual report is required to disclose details regarding repurchases of securities made during the year, including a monthly analysis of the number of securities repurchased, the purchase price per share or the highest and lowest price paid for all such repurchases, where relevant, and the aggregate prices paid.

(vii) Core Connected Persons

The Listing Rules prohibit a company from knowingly purchasing securities on the Stock Exchange from a “core connected person”, that is, a director, chief executive or substantial shareholder of the company or any of its subsidiaries or a close associate of any of them (as defined in the Listing Rules) and a core connected person shall not knowingly sell its securities to the company.

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(b) Reasons for Repurchases

Our Directors believe that it is in the best interests of our Company and Shareholders for our Directors to have a general authority from the Shareholders to enable our Company 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 our Company and Shareholders.

(c) Funding of Repurchases

Repurchase of the Shares must be funded out of funds legally available for such purpose in accordance with the Articles of Association and the applicable laws of the Cayman Islands. Our Directors may not repurchase the Shares on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange. Subject to the foregoing, our Directors may make repurchases with profits of our Company or out of a new issuance of shares made for the purpose of the repurchase or, if authorized by the Articles of Association and subject to the Cayman Companies Act, out of capital and, in the case of any premium payable on the repurchase, out of profits of our Company or from sums standing to the credit of the share premium account of our Company or, if authorized by the Articles of Association and subject to Cayman Companies Act, out of capital.

[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 the working capital requirements of our Company or its gearing levels which, in the opinion of the Directors, are from time to time appropriate for our Company.]

(d) General

The exercise in full of the Repurchase Mandate, on the basis of [REDACTED] Shares in issue immediately following completion of the [REDACTED], but assuming the [REDACTED] is not exercised, could accordingly result in up to approximately [REDACTED] Shares being repurchased by our Company during the period prior to the earliest of:

- The conclusion of the next annual general meeting of our Company unless renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions;
- the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held; or
- the date when it is varied or revoked by an ordinary resolution of the Shareholders in general meeting.

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None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their close associates currently intends to sell any Shares to our Company.

Our Directors have undertaken to the Stock Exchange that, so far as the same may be applicable, they will exercise the Repurchase Mandate in accordance with the Listing Rules and the applicable laws in the Cayman Islands.

If, as a result of any repurchase of Shares, a Shareholder’s proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purposes of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of our Company 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.

Any repurchase of Shares that results in the number of Shares held by the public being reduced to less than 25% of the Shares then in issue could only be implemented if the Stock Exchange agreed to waive the Listing Rules requirements regarding the public shareholding referred to above. It is believed that a waiver of this provision would not normally be given other than in exceptional circumstances.

No core connected person of our Company has notified our Company that he or she has a present intention to sell Shares to our Company, or has undertaken not to do so, if the Repurchase Mandate is exercised.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contracts

The following contracts (not being contracts entered into in the ordinary course of business) were entered into by members of our Group within the two years immediately preceding the date of this document which are or may be material:

- (a) the series C preferred share purchase agreement dated August 17, 2020 entered into among our Company, investors including LBC Sunshine Healthcare Fund L.P., ACM 01 Limited, Silver Pearl Limited, BC Mars L.P., and CNCB CAPITAL VALUE SPC-CNCB Capital Energy Investment Fund SP, and major subsidiaries including Broncus Medical, Uptake Medical, Broncus Shanghai and Broncus Hangzhou in relation to the sale and purchase of 9,791,147 Series C Preferred Shares for an aggregate consideration of US\$37,620,430.00;
- (b) the series D preferred share purchase agreement dated January 25, 2021 entered into among our Company, investors including Elegant Holding Limited, Strong Leap Holdings Limited, Valliance Emerging Opportunities Limited Partnership Fund, Emerging Markets Healthcare Partners LLC, and major subsidiaries including

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Broncus China Holding, Broncus Medical, Uptake Medical and Broncus Hangzhou, in relation to the sale and purchase of 6,068,134 Series D Preferred Shares for an aggregate consideration of US\$39,999,986.41;

- (c) [a [REDACTED] agreement dated [●] among the Company, [●], and [●], pursuant to which [●] agreed to subscribe for our shares in the amount of USD [●] million (excluding brokerage, SFC transaction levy and Hong Kong Stock Exchange trading fee);]
- (d) [●]; and
- (e) the [REDACTED].

2. Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be material to our Group’s business:






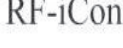

No.	Trademark	Owner	Place of Registration
1.	H-Marker	Broncus Hangzhou	PRC
2.	H+Marker	Broncus Hangzhou	PRC
3.	Uptake	Broncus Hangzhou	PRC
4.		Broncus Hangzhou	PRC
5.	爱普可	Broncus Hangzhou	PRC
6.	Uptake	Broncus Hangzhou	PRC
7.		Broncus Hangzhou	PRC
8.		Broncus Hangzhou	PRC
9.	爱普可	Broncus Hangzhou	PRC
10.		Broncus Hangzhou	PRC
11.	爱普可	Broncus Hangzhou	PRC
12.		Broncus Hangzhou	PRC

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No.	Trademark	Owner	Place of Registration
13.	Uptake	Broncus Hangzhou	PRC
14.	堃博	Broncus Hangzhou	PRC
15.		Broncus Hangzhou	PRC
16.		Broncus Hangzhou	PRC
17.	堃博	Broncus Hangzhou	PRC
18.	堃博	Broncus Hangzhou	PRC
19.	BRNCUS	Broncus Hangzhou	PRC
20.	BRNCUS	Broncus Hangzhou	PRC
21.	BRNCUS	Broncus Hangzhou	PRC
22.	堃博	Broncus Hangzhou	PRC
23.	堃博	Broncus Hangzhou	PRC
24.	堃博	Broncus Hangzhou	PRC
25.	BRNCUS	Broncus Hangzhou	PRC
26.	BRNCUS	Broncus Hangzhou	PRC
27.	BRNCUS	Broncus Hangzhou	PRC
28.	BRNCUS	Broncus Hangzhou	PRC
29.	BRNCUS	Broncus Hangzhou	PRC
30.	BRNCUS	Broncus Hangzhou	PRC

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As of the Latest Practicable Date, we had applied for the registration of the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Registration Number	Class	Application Date	Applicant	Intended Place of Registration
1.		305455431	9, 10, 42	2020-11-20	Broncus Hangzhou	Hong Kong
2.	堃博	49091749	42	2020-08-20	Broncus Hangzhou	PRC
3.		46407865	09	2020-05-18	Broncus Hangzhou	PRC
4.		46412220	11	2020-05-18	Broncus Hangzhou	PRC
5.		46407627	10	2020-05-18	Broncus Hangzhou	PRC
6.		46415220	09	2020-05-18	Broncus Hangzhou	PRC
7.		46417526	11	2020-05-18	Broncus Hangzhou	PRC
8.		46401305	10	2020-05-18	Broncus Hangzhou	PRC
9.		46401736	09	2020-05-18	Broncus Hangzhou	PRC
10.		46420888	11	2020-05-18	Broncus Hangzhou	PRC
11.		46392472	10	2020-05-18	Broncus Hangzhou	PRC
12.		46400816	10	2020-05-18	Broncus Hangzhou	PRC
13.		46396354	10	2020-05-18	Broncus Hangzhou	PRC
14.		46407618	10	2020-05-18	Broncus Hangzhou	PRC

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No.	Trademark	Registration Number	Class	Application Date	Applicant	Intended Place of Registration
15.		46396303	10	2020-05-18	Broncus Hangzhou	PRC
16.		46386927	11	2020-05-18	Broncus Hangzhou	PRC
17.	堃博	44443302	35	2020-03-09	Broncus Hangzhou	PRC
18.	堃博	44450136	11	2020-03-09	Broncus Hangzhou	PRC
19.	堃博	44465974	42	2020-03-09	Broncus Hangzhou	PRC
20.		44037970	09	2020-02-11	Broncus Hangzhou	PRC
21.		52462720	10	2020-12-24	Broncus Hangzhou	PRC
22.	堃博	52443905	10	2020-12-24	Broncus Hangzhou	PRC
23.		52024514	09	2020-12-09	Broncus Hangzhou	PRC
24.		52875744	10	2021-01-11	Broncus Hangzhou	PRC
25.		52900842	10	2021-01-11	Broncus Hangzhou	PRC
26.	Uptake	52900868	10	2021-01-11	Broncus Hangzhou	PRC
27.	BRONCUS	52610946	10	2020-12-30	Broncus Hangzhou	PRC
28.		51420490	42	2020-11-19	Broncus Hangzhou	PRC

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(b) *Patents*

For a discussion of the details of the patents and patent applications of our Core Products, please refer to the section headed “Business – Intellectual Property Rights” in this document.

(c) *Copyright*

As of the Latest Practicable date, we had the following copyright which we consider to be or may be material to our business:

<u>No.</u>	<u>Copyright Name</u>	<u>Copyright Number</u>	<u>Registration Date</u>	<u>Issue Date</u>	<u>Owner</u>	<u>Place of Registration</u>
1.	Logo-Flex knight	11-2020-F-16461	2020-08-28	N/A	Broncus Hangzhou	PRC
2.	MR Lung Navigation System V1.0	2019SR0398629	2019-04-26	N/A	Broncus Shanghai	PRC

(d) *Domain Name*

As of the Latest Practicable Date, the following was the key domain names of our Group:

<u>No.</u>	<u>Domain Name</u>	<u>Registered Owner</u>	<u>Expiry Date</u>
1.	Broncus.com	Broncus Medical	2021-08-30
2.	Uptakemedicaltechnology.com	Uptake Medical	2022-08-23
3.	Uptakemed.com	Uptake Medical	2022-08-23
4.	Uptakemedtechnology.com	Uptake Medical	2022-08-23
5.	Uptakemedtech.com	Uptake Medical	2022-08-23

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 Group’s business.

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C. FURTHER INFORMATION ABOUT OUR DIRECTORS

1. Particulars of Directors’ Service Contracts and Appointment Letters

(a) *Executive Directors and non-executive Directors*

Each of the executive Directors and non-executive Directors has entered into a service agreement with our Company under which the initial term of their service agreement shall commence from the date of their appointment until terminated in accordance with the terms and conditions of the service agreement or by either party giving to the other not less than [●] month[s]’ prior notice.

Pursuant to the service agreements entered into with our Company, the executive Director and non-executive Directors will receive [●] and [●] for financial years ended December 31, [●] and December 31, [●] as director’s fees.

(b) *INEDs*

Each of our INEDs has entered into an appointment letter with our Company effective from the [REDACTED]. The initial term of their appointment letters shall commence from the date of their appointment for a period of [three years] [or until [●]], whichever is earlier (subject always to re-election as and when required under the Articles of Association) until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other not less than [●] month[s]’ prior notice in writing. Under these appointment letters, each of Dr. Jian Ji, Professor Joseph Wan Yee Lau and Dr. Pok Man Kam as our independent non-executive Directors will receive an annual director’s fee of [HK\$400,000] commencing on the effective date of their appointment.

Details of our Company’s remuneration policy is described in the section headed “Directors and Senior Management – Remuneration of Directors and Senior Management” in this document.

2. Remuneration of Directors

Save as disclosed in “Directors and Senior Management” and “Appendix I – Accountants’ Report – Note 8. Directors’ and Chief Executive’s Remuneration” for financial years ended December 31, 2019 and December 31, 2020, none of our Directors received other remunerations of benefits in kind from us.

Under the arrangements currently in force at the date of this document, our Directors will be entitled to receive remuneration fees, social welfare and benefits (excluding share-based compensation, which may be paid to any Directors) which, for the year ending December 31, 2021, is expected to be approximately US\$600,000 in aggregate.

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3. Disclosure of Interests

(a) *Interests and short positions of our Directors in the share capital of our Company and its associated corporations following completion of the [REDACTED]*

Immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), the interests and/or short positions (as applicable) of our Directors and chief executive in the Shares, underlying shares and debentures of our Company and its associated corporations, within the meaning of Part XV of the SFO, which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and/or short positions (as applicable) which they are taken or deemed to have taken under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules (“**Model Code**”), will be as follows:

Name of Director or chief executive	Nature of interest	Number and class of securities immediately following completion of the [REDACTED] ⁽¹⁾	Approximate percentage of interest in our Company immediately following completion of the [REDACTED] ⁽¹⁾
			(%)
Mr. Zhan ⁽²⁾	Interest in controlled corporation	[REDACTED] Shares	[REDACTED]
Mr. Zhao ⁽³⁾	Interest in controlled corporation	[REDACTED] Shares	[REDACTED]
Mr. Zi ⁽⁴⁾	Interest in controlled corporation	[REDACTED] Shares	[REDACTED]

Notes:

- (1) The calculation is based on the total number of [REDACTED] Shares in issue immediately following completion of the Share Subdivision and the [REDACTED] (assuming the [REDACTED] is not exercised and no Shares are issued pursuant to the Equity Incentive Plans).
- (2) Mr. Zhan holds approximately 63.37% interest in Wise Seed Limited, which will beneficially hold [REDACTED] Shares immediately following completion of the [REDACTED]. Accordingly, Mr. Zhan is deemed to be interested in the Shares held by Wise Seed Limited.
- (3) St. Christopher Investment Limited is wholly owned by Mr. Zhao. Dinova Healthcare Holding Corporation is owned as to approximately 83.54% by St. Christopher Investment Limited, which is wholly owned by Mr. Zhao. Accordingly, Mr. Zhao is deemed to be interested in the total number of Shares held by each of St. Christopher Investment Limited and Dinova Healthcare Holding Corporation, which will beneficially hold [REDACTED] and [REDACTED] Shares respectively immediately following completion of the [REDACTED].

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- (4) Mr. Zi is deemed to be interested in the total number of Shares held by each of BBL, Dinova Healthcare (Hong Kong) Co., Limited, BRS Biomedical Limited, Dinova Healthcare Delta Fund (USD) L.P., Xin Nuo Tong Investment Limited, Dinova Venture Partners GP III, L.P. and Dinova Venture Partners GP IV, L.P., which will beneficially hold [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [REDACTED] Shares respectively immediately following completion of the [REDACTED]. See the section headed “Substantial Shareholders” in this document for details.

(b) Interests and short positions discloseable under Divisions 2 and 3 of Part XV of the SFO

For information on the persons who will, immediately following completion of the Share Subdivision and the [REDACTED], having or be deemed or taken to have beneficial interests or short position in our Shares or underlying shares which would fall to be disclosed to our Company under the provisions of Divisions 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Group, please see the section headed “Substantial Shareholders” in this document.

Save as set out above, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following completion of the Share Subdivision and the [REDACTED], be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group or had option in respect of such share capital.

4. Disclaimers

Save as disclosed in the sections headed “Directors and Senior Management”, “Financial Information”, “[REDACTED]”, “Substantial Shareholders” and “Statutory and General Information – C. Further Information about Our Directors” in Appendix IV to this document:

- (i) there are no existing or proposed service contracts (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation)) between the Directors and any member of the Group;
- (ii) none of the Directors or the experts named in the sub-section headed “E. Other Information – Consents of Experts” in this section below has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to any member of the Group, or are proposed to be acquired or disposed of by or leased to any member of the Group;

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- (iii) no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any Shares in or debentures of our Company within the two years ended on the date of this document;
- (iv) none of the Directors is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of the Group taken as a whole;
- (v) taking no account of any Shares which may be taken up under the [REDACTED], so far as is known to any Director or chief executive of our Company, no other person (other than a Director or chief executive of our Company) will, immediately following completion of the [REDACTED], have interests or short positions in the Shares or underlying shares which would fall to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or (not being a member of the Group), be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of the Group; and
- (vi) save as disclosed in the section headed “Directors and Senior Management” in this document, none of the Directors or chief executive of our Company has any interests or short positions in the Shares, underlying shares or debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is 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 into the register referred to therein, or will be required, pursuant to the Model Code, to be notified to the Company and the Stock Exchange.

D. EQUITY INCENTIVE PLANS

The following is a summary of the principal terms of our Company’s Equity Incentive Plans which consists of the Share Option Plan and the RSU Scheme. The Share Option Plan and the RSU Scheme were adopted and approved by resolutions in writing by the Board on [●], 2021.

1. Share Option Plan

(a) Summary of terms

Duration. Unless terminated sooner by the Board, the Share Option Plan will automatically terminate on the expiration of the 10 year period measured from the date the Share Option Plan is adopted by the Board. After which no options under the Share Option Plan may be granted.

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Administration. The Share Option Plan shall be subject to the administration of the Board or one or more committees appointed by the Board (the “**Administrator**”). The Administrator shall have the right (i) to interpret and construe the provisions of the Share Option Plan and awards in good faith; (ii) to determine the which eligible persons receive awards under the Share Option Plan, grant awards, determine the number of securities to be offered or awarded, and to determine the specific terms and conditions of awards consistent with the conditions and limitations of the Share Option Plan; (iii) to prescribe, amend, rescind rules and regulations relating to the administration of the Share Option Plan of the awards made thereto; (iv) to accelerate or extend the vesting or exercisability or extend the term of any or all outstanding awards in such circumstances as the Administrator may deem appropriate; (v) to establish, amend and repeal such rules and regulations as it may deem appropriate for proper administration of the Share Option Plan and awards and to make such determinations under, and issue such interpretations of, the Share Option Plan and any outstanding awards agreements as it may deem necessary or advisable to promote the best interests of the Corporation; and (vi) may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Share Option Plan or any award as it deems necessary or appropriate to administer the Share Option Plan and any awards.

Notwithstanding the foregoing, the Board may delegate any of its powers, authorities and discretions in relation to the Share Option Plan to any committee or one or more officers, and any such delegation may be made on such terms and subject to such conditions as the Board may think fit and the Board may annul or vary any such delegation.

The Board or a committee may delegate some or all of administrative powers reflected in written resolution complying with the provisions of the Share Option Plan periodically. The Board may retain the authority to concurrently administer the Share Option Plan with a committee and/or an Officers and may revest in the Board its powers previously delegated at any time. If the administration of the Share Option Plan is delegated to an officer, the officer will have, in connection with the administration of the Share Option Plan, the powers theretofore possessed by the Board that have been delegated to him, provided that (i) he shall not delegate to another person any of the administrative powers he is authorized to exercise; (ii) he shall not be delegated with any power to determine any matter in connection with the options of him or his affiliates; and (iii) only the Board or a committee may determine the fair market value of the shares.

Option Agreement and Notice of Grant. Each option granted under the Share Option Plan shall be evidenced by an option agreement and a notice of grant in the specified form between our Company and a participant. Subject to the terms of the Share Option Plan and the terms of the form option agreement attached in the Share Option Plan, each option may contain additional terms and conditions as the Board deems appropriate.

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Grant

An option will be allocated and granted subject to the performance criteria as set forth at the sole discretion of the Board and the provisions in the Share Option Plan. Each option may contain additional terms and conditions as the Board deems appropriate subject to the terms of the Share Option Plan. Each option shall be exercisable at such time or times, during such period and for such number of Shares as shall be determined by the Board, subject to the special requirements of the Share Option Plan, and set forth in the documents evidencing the option.

Payment

The exercise price shall become immediately due upon exercise of the option under the Share Option Plan. Subject to the provisions of award agreement, any rules or procedures adopted by the Company and applicable laws, the exercise price of an option must be paid by: (1) cash, wire transfer of immediately available funds or by check payable to the order of the Company; (2) if there is a public market for Shares at the time of exercise, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator; (3) delivery (either by actual delivery or attestation) of Shares owned by the participant valued at their fair market value as agreed by the Administrator; (4) to the extent permitted by the Administrator, surrendering shares then issuable upon the option's exercise valued at their fair market value on the exercise date; (5) delivery of a promissory note or any other property that the Administrator accepts and determines is good and valuable consideration; or (6) to the extent permitted by the Company, any combination of the above payment forms approved by the Administrator.

Transferability of Awards and Shares

Unless the Administrator may determine, options may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law. During the life of a participant, options will be exercisable only by the participant. Any sale, transfer, assignment, pledge, encumbrance or other disposition made in contravention of this provision shall be null and void.

[Until the completion of the [REDACTED], a participant shall not sell, transfer, assign, pledge, encumber or otherwise dispose of any shares issued under the Share Option Plan. Any sale, transfer, assignment, pledge encumbrance or other disposition made in contravention of this provision shall be null and void.]

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Maximum number of Shares

Pursuant to the Share Option Plan, the total number of Shares shall not exceed 3,170,566 Shares (subject to any adjustment for share subdivisions or other dilutive issuances).

Right of Repurchase

Should a participant cease service while holding vested Shares, the Company shall have the discretion to repurchase vested Shares at fair market value.

The terms upon which such repurchase right shall be exercisable (including the period and procedure for exercise and the appropriate vesting schedule for the purchased shares) shall be established by the Board and set forth in the document evidencing such repurchase right. The Company’s right to repurchase vested Shares upon a participant’s termination of service shall cease upon the completion of the [REDACTED].

Capitalization Adjustments

In the event of changes in the outstanding Shares or in the capital structure of the Company by reason of any share or extraordinary cash dividend, share split, reverse share split, share subdivision, an extraordinary corporate transaction such as any recapitalization, reorganization, merger, consolidation, combination, exchange, or other relevant change in capitalization occurring after the grant date of any award, awards granted under the Share Option Plan and any award agreements, the exercise price of options, and the overall share limit will be equitably adjusted or substituted, as to the number, price or kind of a share or other consideration subject to such awards to the extent necessary to preserve the economic intent of such award.

(b) Options to be granted

We have applied for[, and have been granted] (i) a waiver from the Stock Exchange from strict compliance with the disclosure requirements under Rule 17.02(1)(b) of an paragraph 27 of Appendix 1A to the Listing Rules and (ii) an exemption from the SFC 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 in connection with the information of the options granted under the Share Option Plan. For further details, please refer to the section headed “Waivers from Strict Compliance with the Listing Rules and Exemptions from Compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance – Waiver and Exemption in relation to the Share Option Plan” in this document.

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The options will be granted based on the performance and significance of the grantees who have made important contributions to and are important to the long-term growth and success of our Group. The grantees include [one] member of our senior management team and [30] other employees (including former employees) of our Group. Details of the options to be granted under the Share Option Plan are set out below:

Name of grantee	Position held with our Group	Address	Exercise Price	Number of Shares subject to the options granted ⁽¹⁾	Date of Grant	Vesting Period	Approximate percentage of shareholding immediately following completion of the [REDACTED] ⁽²⁾ (%)
Member of our senior management team							
Todd A. Cornell	President of Broncus Medical and Uptake Medical	520 Heron Run Court Alpharetta GA 30004	US\$[●]	[●]	[●]	[●]	[REDACTED]
Grantees with options under the Share Option Plan representing the right to acquire more than [●] Shares							
30 other employees (including former employees) of our Group	–	–	US\$[●]	[●]	[●]	[●]	[REDACTED]

Notes:

1. Subject to any adjustment for the Share Subdivision
2. Assuming that the [REDACTED] is not exercised.

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Assuming full exercise of options under the Share Option Plan, the shareholding of our Shareholders immediately following the [REDACTED] will be diluted by approximately [REDACTED]%, if calculated on the basis of [REDACTED] Shares in issue immediately following completion of the Share Subdivision and the [REDACTED], excluding any additional Shares which may fall to be allotted and issued upon the exercise of the [REDACTED] or under the Share Option Plan. The consequent impact on the earnings per ordinary share for the years ended December 31, 2019 and 2020 is nil and nil respectively, being the incremental impact to diluted earnings per share, since the options would not be included in the calculation of diluted earnings per share due to anti-dilution. As of the Latest Practicable Date, no share option has been granted under the Share Option Plan.

2. RSU Scheme

(a) Purpose

This RSU Scheme is established to reward employees or consultants for their past contribution to the success of the Company, and to provide incentives to them to further contribute to the Company.

(b) Conditions

This RSU Scheme shall take effect upon the passing of a resolution by the Board to approve the RSU Scheme.

(c) Duration and Administration

- 1.1. The RSU Scheme shall be valid and effective for a period of 10 years commencing on the date on which the RSU Scheme become unconditional (the “**Effective Date**”), after which period no further award of restricted share units (“**RSUs**”) granted to an eligible participant (“**Award**”) will be granted by the provisions of the RSU Scheme, but the provisions of this RSU Scheme shall remain in full force and effect to the extent necessary to give effect to the vesting of any Awards granted prior thereto or otherwise as may be required in accordance with the provisions of the RSU Scheme.
- 1.2. The RSU Scheme shall be subject to the administration of the Board who may delegate all or part of such administration to a committee or any other authorised agent. Save as otherwise provided in this RSU Scheme, for any matters concerning the interpretation or application of this RSU Scheme, the decision of the Board or persons to whom the Board has delegated relevant powers shall be final and binding on all parties.

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- 1.3. Without prejudice to the Board’s general power of administration, the Company may also from time to time appoint one or more trustees to hold the Shares underlying the Awards on trust and to assist with the administration and vesting of RSUs granted pursuant to the RSU Scheme. The trustee to be appointed by the Company (the “**Trustee**”) shall administer the RSU Scheme in accordance with the decisions and directions of the Board.
- 1.4. Subject to any applicable laws, regulations and rules, the powers and obligations of the Trustee will be limited as set forth in the trust deed between the Company and the Trustee (the “**Trust Deed**”). The Trustee will hold the trust fund in accordance with the terms of the Trust Deed.
- 1.5. No individual acting as a director, officer, other employee or agent of the Company or any its subsidiary will be liable to any person who satisfies the eligibility requirements (“**Eligible Participant**”), former Eligible Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the RSU Scheme or any Award, and such individual will not be personally liable with respect to the RSU Scheme because of any contract or other instrument executed in his or her capacity as the director, officer, other employee or agent of the Company or any its subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any its subsidiary that has been or will be granted or delegated any duty or power relating to the RSU Scheme’s administration or interpretation, against any cost or expense (including attorneys’ fees) or liability (including any sum paid in settlement of a claim with the Board’s approval) arising from any act or omission concerning this RSU Scheme unless arising from such person’s own fraud or bad faith.

(d) Determination of Eligibility

- 1.6. Persons eligible to receive the Awards under this RSU Scheme are any employee or officer of the Company or any its subsidiary including (without limitation) any executive or non-executive director in the employment of or holding office in the Company or any its subsidiary (the “**Employee**”) or consultants and other independent advisors who provide bona fide services to the Company or any its subsidiary.
- 1.7. The Board will determine how an authorized leave of absence or any other change or purported change in an Eligible Participant’s service provider status (such as a transfer of employment or death) affects an Award and the Eligible Participant’s continued eligibility under the RSU Scheme, and the extent to which, and the period during which the Eligible Participant, his or her legal representative, conservator, guardian or designated beneficiary, may exercise rights under the Award, if applicable.

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(e) Grant of Awards

1.8. On and subject to the terms of the RSU Scheme, the Board has the power but not the obligation, at any time and from time to time before and including the 10th anniversary of the Effective Date, to offer to grant to any Eligible Participant as the Board may in its sole and absolute discretion select an Award for such number of RSUs representing the corresponding number of underlying Shares (being in a board lot or an integral multiple thereof) as the Board may determine. The Board may in its absolute discretion specify such event, time limit or conditions (if any) as it thinks fit when making such offer to the Eligible Participant, including, without limitation, any minimum period for which an Award must be held, or conditions as to performance criteria to be satisfied by the Eligible Participant and/or the Company and/or the Group which must be satisfied before an Award can be vested.

1.9. Upon the completion of the Company's [REDACTED], no Award shall be offered or granted:

- (a) to any Eligible Participant after a price sensitive event has occurred or a price sensitive matter has been the subject of a decision, until the relevant price sensitive or inside information has been announced in accordance with the applicable provisions of law or the Listing Rules;
- (b) to any Eligible Participant during the period commencing one month immediately before the following (whichever is earlier):
 - (i) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules);
 - (ii) the deadline for the Company to publish an announcement of its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules);

and ending on the date of the results announcement. No Award shall be granted during any period of delay in the publication of a results announcement.

- (c) to any director of the Company on any day on which the Company's financial results are published and during the period of:
 - (i) 60 days immediately preceding the publication of the annual results of the Company or, if shorter, the period from the end of the relevant financial year up to the publication of the results; or

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- (ii) 30 days immediately preceding the publication of the quarterly (if any) or half-yearly results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication of the results.
 - (d) if the requisite approvals for that grant from any applicable regulatory authorities have not been granted;
 - (e) the securities laws or regulations require that a document or other [REDACTED] documents be issued in respect of the grant of the Awards or in respect of the RSU Scheme, unless the Board determines otherwise;
 - (f) while granting the Award would result in a breach by the Company, its Subsidiaries or any of their respective directors of any applicable securities or other laws, rules or regulations;
 - (g) where such grant of Award would result in a breach of the 10% limit specified in the paragraph “Maximum Number of Shares Underlying the RSUs” below, or the 25% minimum public float requirement as required under the Listing Rules, or would otherwise cause the Company to issue Shares in excess of the permitted amount in the mandate approved by the Shareholders; or
 - (h) if the Board so determines in its sole and absolute discretion.
- 1.10. An offer of the grant of an Award shall be made to any Eligible Participant by notice (the “**Notice of Grant**”) a specified form specifying the number of Shares underlying the RSUs granted to them, the vesting schedule as determined by the Board in its sole discretion, the date by which the grant must be accepted being a date not more than 28 days after the date of the letter by which an Award is offered to an Eligible Participant (the “**Offer Date**”) (provided such offer shall be open for acceptance after the effective period of the RSU Scheme) (the “**Offer Period**”) and further requiring the Eligible Participant to hold the Award on the terms on which it is to be granted and to be bound by the provisions of the RSU Scheme. The Notice of Grant shall also state that the offer of an Award shall be personal to the Eligible Participant concerned and the Shares underlying the RSUs shall not be transferable. The inadvertent non-compliance with the requirements of this paragraph shall not render the grant of an Award invalid if the Board so determines and makes such remedial action, if any, as it deems appropriate in its absolute discretion.
- 1.11. An Award shall be deemed to have been granted and accepted and to have taken effect when the duplicate letter comprising acceptance of the offer of the grant of the Award duly signed by the Eligible Participant who accepts the offer or grant of an Award (the “**Grantee**”) thereof, together with a remittance in favor of the Company of such amount (if any) as may be determined by the Board and set out in the Offer

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by way of consideration for the grant thereof, is received by the Company within the time period specified in the offer of the grant of the Award. Such payment shall in no circumstances be refundable.

- 1.12. Any offer of the grant of an Award may be accepted or deemed to have been accepted in respect of any number of Shares underlying the RSUs up to the number in respect of which the Award is offered provided that it is accepted in respect of a board lot or an integral multiple thereof. To the extent that the offer of the grant of an Award is not accepted within 28 days after the Offer Date, it will be deemed to have been irrevocably declined and will lapse, unless the Board in its absolute discretion determines otherwise.
- 1.13. The price to be paid as consideration for the grant of any RSU shall, subject to any adjustments made, be such amount in such form as may be determined by the Board from time to time and as set out in the Notice of Grant.

(f) Term of the RSU Scheme

- 1.14. Subject to any early termination as may be determined by the Board pursuant to the paragraph "Alteration of the Scheme" below, the RSU Scheme shall be valid and effective for a period of 10 years commencing the Effective Date, after which no Awards will be granted, but the provisions of the RSU Scheme shall in all respects remain in full force and effect and the Awards granted during the term of this RSU Scheme may continue to be valid and exercisable in accordance with their terms of grant.

(g) Vesting of Awards

- 1.15. An Award shall be personal to the Grantee and shall not be assignable and no Grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest in favour of any third party over or in relation to any RSU. Any breach of the foregoing by the Grantee shall entitle the Company to cancel any outstanding entitlement of such Grantee. This does not prejudice the operation of any general provision of law regarding the appointment and capacity of a nominee, attorney, trustee or other personal representative.
- 1.16. Subject to the terms of the RSU Scheme and the specific terms and conditions applicable to each Award which may be determined at the sole and absolute discretion of the Board from time to time, the RSUs granted to a Grantee in an Award shall be vested subject to such vesting schedule as set out in the relevant Notice of Grant, and within reasonable time after the vesting criteria and conditions have been fulfilled, satisfied or waived, the Board will send a vesting notice to each of the relevant Grantee. The vesting notice will confirm the extent to which the vesting criteria and conditions have been fulfilled, satisfied or waived, and the

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number of Shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those Shares) or the amount of cash the Grantee will receive.

1.17. Subject as provided in the RSU Scheme and any conditions specified by the Board, the RSUs granted in an Award shall be vested subject to the following vesting conditions:

- (a) the Grantee has not violated any provision of the Articles or other constitutional documents of the relevant member of the Group, or otherwise impaired the interests of the Group;
- (b) in the event of the Grantee ceasing to be an employee by reason of death, the legal personal representative(s) of the Grantee shall be entitled within a period of 12 months from the date of death (or such longer period as the Board may determine) to receive the entitlement in full;
- (c) if a general or partial offer (whether by way of take-over offer, share repurchase offer or otherwise in like manner other than by way of a scheme of arrangement) is made to all the holders of Shares (or all such holders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or in concert with the offeror) the Company shall use its best endeavours to procure that such offer is extended to all the Grantees (on the same terms *mutatis mutandis*, and assuming that they will become, by receiving in full of the Awards granted to them, shareholders of the Company). If such offer becomes or is declared unconditional, the Grantee (or his legal personal representative(s)) shall be entitled to receive his outstanding entitlement in full at any time within 14 days after the date on which such general offer becomes or is declared unconditional;
- (d) in the event of an effective resolution being passed for the voluntary winding-up of the Company or an order of the court being made for the winding-up of the Company, notice thereof shall be given by the Company to Grantees with Awards outstanding in full or in part at such date. If a Grantee immediately prior to such event had any outstanding entitlement, the Grantee (or his legal personal representative(s)) may by notice in writing to the Company within 21 days after the date of such resolution elect to be treated as if the entitlement had been claimed immediately before the passing of such resolution either to its full extent or to the extent specified in the notice, whereupon the Grantee shall be duly issued and allotted with the relevant Shares underlying the RSUs (or treated as such by the Company) and entitled to receive out of the assets available in the liquidation *pari passu* with the holders of Shares such sum as would have been received in respect of the Shares that are the subject of such election;

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- (e) if a compromise or arrangement of any nature between the Company and its members or creditors is proposed for the purposes of or in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies, the Company shall give notice thereof to all Grantees (together with a notice of the existence of the relevant provisions) on the same date as it despatches to each member or creditor of the Company a notice summoning the meeting to consider such scheme, and thereupon the all or any of the Award(s) of each Grantee shall be vested in whole or in part within the time or period stipulated by the Board for this purpose, the end of which period being in any event not less than 14 days before the date appointed for the hearing of the Court for the purposes of considering and if thought fit sanctioning such scheme. Upon the scheme becoming effective (whether on the terms presented to the Court or on any other terms as may be approved by such Court), all outstanding entitlements shall lapse and terminate. The Board shall endeavour to procure that any Shares issued as a result of the vesting of Awards shall for the purposes of such scheme form part of the issued share capital of the Company on the effective date thereof and that such Shares shall in all respects be subject to and bound by such scheme. If for any reason the scheme is not approved by the Court, the rights of Grantees to claim their respective entitlements shall with effect from the date of the making of the order by the Court be restored in full and shall thereupon become exercisable (but subject to the other terms of the RSU Scheme) as if the scheme had not been proposed by the Company and no claim shall lie against the Company or any of its officers for any loss or damage sustained by any Grantee as a result of the aforesaid process;
 - (f) in the event of an Grantee, having been an Eligible Participant at the time of the grant of the Award, subsequently ceases to be an Eligible Participant, any outstanding RSUs held by such Grantee shall terminate and be cancelled; and
 - (g) any such other conditions as the Board or its delegate(s) may set out in its/their sole discretion in the Notice of Grant that must be fulfilled before any RSU can be vested.
- 1.18. The Shares underlying the RSUs in respect of an Award will be subject to all the provisions of the Articles of the Company for the time being in force and will rank pari passu with the fully paid Shares in issue and accordingly will entitle the holders to participate in all dividends and other distributions paid or made on or after the date of the Shares are transferred to the Grantee (or its designee).
- 1.19. Shares underlying the RSUs in respect of an Award granted pursuant to the RSU Scheme shall not carry voting rights unless and until the Award has vested and such Shares are actually transferred to the Grantee (or its designee), subject to the registration of the Grantee (or such other person as may be designated by the Grantee) as the holder thereof. If under the terms of a resolution passed or an

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announcement made by the Company a dividend is to be or is proposed to be paid to holders of Shares on the register on a date prior to the date when an Award is effectively vested under the terms of this RSU Scheme, the Shares to be issued upon such vesting will not rank for such dividend.

- 1.20. The Trustee will hold Shares underlying the Awards granted to Grantees pending the vesting of the Awards.

None of the directors of the Company has any direct or indirect interests in the Trustee.

- 1.21. Subject to the Eligible Participant executing all documents that the Board considers necessary for vesting (which may include, without limitation, a certification to the Company or its relevant subsidiary that he has complied with all the terms and conditions set out in the rules of the RSU Scheme and the grant letter of the Award), the Board may decide in its absolute discretion to direct and procure the Trustee to, either, transfer the Shares underlying the RSUs in respect of the Award, or the Trustee to pay in cash an amount which is the entitlement corresponding to the Shares to the Grantee (or its designee). If a Grantee fails to execute the required documents in accordance with the vesting notice, the Award of the Grantee will lapse.

(h) Lapse of Award

Any Award shall lapse and be automatically cancelled and not be vested in the Grantee on the earliest of:

- (a) the expiry of the Offer Period;
- (b) the expiry of any of the periods referred to in paragraph (g);
- (c) subject to paragraph (g), the date of the commencement of the winding-up of the Company;
- (d) the date on which the Grantee ceases to be an Eligible Participant (as determined by the Board or its delegate(s)) by reason of such Grantee's termination of employment with or service to the Company or any its subsidiary;
- (e) the date on which the Grantee commits a breach of the first section under paragraph (g);
- (f) the occurrence or non-occurrence of any event, expiry of any period, or non-satisfaction of any condition, as specified under this RSU Scheme and in the letter containing the offer or grant of the relevant Award;

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- (g) subject to the last section under paragraph (g), the failure of the Grantee to execute required documents in accordance with the vesting notice;
- (h) the date on which the Grantee has any other circumstances in which the Board deems it inappropriate to vest the Award, or
- (i) the date on which the Grantee expressly waives his or her Award by submitting a written declaration to the Company,

provided that in each case above mentioned the Board or its delegate(s) in its absolute discretion may decide that such Award shall not so lapse or shall be subject to such conditions or limitations as it may decide and any of such decision shall be conclusive and binding on the Grantee.

(i) Maximum Number of Shares Underlying the RSUs

1.22. The maximum number of Shares in respect of which RSUs may be granted under the RSU Scheme when aggregated with the maximum number of Shares in respect of which options or awards may be granted under any other share-based incentive scheme shall not exceed [●]% of the issued capital of the same class of the Company as of the Effective Date of the RSU Scheme (or of the refreshment of the [●]% limit). Such limit may be refreshed subject to the shareholders’ approval, but in any event, the total number that may underlie the RSUs granted following the date of approval by the shareholders of the refreshed limit (the “**New Approval Date**”) under the limit as refreshed must not exceed 10% of the Shares in issue as at the New Approval Date. Awards lapsed in accordance with the terms of the RSU Scheme shall not be counted for the purpose of calculating the 10% limit. Within the aforesaid 10% limit (or alternatively subject to the approval of shareholders of the Company in general meeting), the maximum number of Shares underlying the RSUs to be issued upon vesting of all outstanding Awards under this RSU Scheme may be increased by increments as determined by the Board, provided that the total number of Shares underlying the RSUs to be issued upon vesting of all outstanding Awards under the RSU Scheme and options or awards under all other schemes of the Company granted and yet to be vested does not exceed 30% of all the Shares of the same class in issue from time to time. No Award may be granted under the RSU Scheme if this will result in the aforesaid limit being exceeded.

1.23. Upon the completion of the Company’s [REDACTED], except with the approval of shareholders in general meeting, no Award may be granted to any one person such that the total number of Shares underlying the RSUs issued and to be issued upon vesting of Awards and any other option or awards over the underlying Shares (including exercised, cancelled and outstanding options or awards) granted and to be granted to such person in any 12-month period up to the date of the latest grant exceeds 1% of the Shares in issue from time to time.

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- 1.24. The maximum number of Shares referred to in this paragraph shall be adjusted, in such manner as the auditors of the Company (the “**Auditors**”) shall certify in writing to the Board to be fair and reasonable, in the event of any alteration in the capital structure of the Company whether by way of capitalisation of profits or reserves, rights issue, consolidation, subdivision or reduction of the share capital of the Company provided that no such adjustment shall be made in the event of an issue of Shares as consideration in respect of a transaction to which the Company is a party.
- 1.25. To the extent that the Company may, during the Relevant Period (defined below), grant Awards pursuant to the RSU Scheme (to non-connected persons) which may be satisfied by the Company allotting and issuing new Shares upon the vesting of the Awards, the Company shall at its annual general meeting propose for the shareholders to consider and, if thought fit, pass an ordinary resolution approving a mandate specifying:
- (a) the maximum number of new Shares that may underlie Awards granted pursuant to the RSU Scheme during the Relevant Period; and
 - (b) that the Board has the power to allot and issue Shares, procure the transfer of Shares and otherwise deal with Shares pursuant to the vesting of any Awards that are granted pursuant to the RSU Scheme during the Relevant Period as and when the Awards vest.

The above mandate shall remain in effect during the period from the passing of the ordinary resolution granting the mandate until the earliest of:

- (A) the conclusion of the next annual general meeting of the Company;
- (B) the expiration of the period within which the next annual general meeting of the Company is required by the Articles of the Company or any applicable law to be held; and
- (C) the expiration of the period within which the authority set out in such resolution is revoked or varied by an ordinary resolution of the shareholders in general meeting,

(the “**Relevant Period**”).

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(j) Grant of Awards to Connected Persons

1.26. Upon the completion of the Company's [REDACTED], if the grant of any Award involves the allotment of new Shares to any director, chief executive or substantial shareholder of the Company or any of their respective associates, the approval of independent non-executive directors of the Company (excluding any independent non-executive director of the Company who is intended to be a Grantee) will be required for such grant of Award and the Company will be required to comply with the applicable announcement, circular and independent shareholder approval requirements (if any).

1.27. Upon the completion of the Company's [REDACTED], if a grant of Award(s) to a substantial shareholder or an independent non-executive director of the Company or their respective associates will result in the total number of Shares underlying the RSUs issued and to be issued upon exercise of all the options or awards granted and to be granted (including options or awards exercised, cancelled and outstanding) to such person under the RSU Scheme and any other scheme in the 12-month period up to and including the date of such grant:

- (a) representing in aggregate over 0.1% of the Shares in issue from time to time; and
- (b) having an aggregate value, based on the closing price of the Shares as stated in the Stock Exchange's daily quotations sheet at the date of each grant, in excess of HK\$5 million,

such further grant of Award(s) must be approved by the shareholders of the Company, voting by way of poll. In this case, the Board shall procure that all the requirements of the Listing Rules relating to sending a circular to shareholders are complied with. All connected persons of the Company shall abstain from voting in favour of the resolution at such general meeting.

(k) Reorganisation of Capital Structure

1.28. In the event of any alteration in the capital structure of the Company whilst any Award remains exercisable, whether by way of capitalisation of profits or reserves, rights issue, consolidation, subdivision or reduction of the share capital of the Company in accordance with applicable laws and regulatory requirements (other than an issue of Shares as consideration in respect of a transaction to which the Company is a party), such corresponding adjustments (if any) shall be made to:

- (a) the number or nominal amount of Shares, the subject matter of the Award (insofar as it is unvested); and/or

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- (b) the aggregate number of Shares underlying the RSUs subject to outstanding Awards; and/or
- (c) the amount of the equivalent value of the Shares underlying the RSUs; and/or
- (d) the method of vesting of the Award,

as the Auditors shall certify in writing to the Board to be in their opinion fair and reasonable, provided that any adjustment shall be made on the basis that the proportion of the issued share capital of the Company to which a Grantee is entitled after such adjustment shall remain the same, or as nearly as possible the same as that to which he was entitled to subscribe had he exercised all the Awards held by him immediately before such adjustment, but so that no such adjustment shall be made the effect of which would be to enable any Share to be issued at less than its nominal value, or to alter any terms of the relevant Award to the advantage of the Grantee without the approval of the shareholders of the Company. The capacity of the Auditors in this paragraph is that of experts and not of arbitrators and their certification shall be final and binding on the Company and the Grantees. The costs of the Auditors shall be borne by the Company.

- 1.29. If there has been any alteration in the capital structure of the Company, the Company shall, within 14 days of such alteration, inform the Grantee of such alteration and shall either inform the Grantee of the adjustment to be made pursuant to the certificate of the Auditors obtained by the Company for such purpose, or if no such certificate has yet been obtained, inform the Grantee of such fact and instruct the Auditors to issue a certificate in that regard.

(l) Share Capital

- 13.1 The vesting of any Award shall be subject to the members of the Company in general meeting approving any necessary increase in the authorised share capital of the Company. Subject thereto, the Board shall make available sufficient authorised but unissued share capital of the Company to meet subsisting requirements on the vesting of Awards.

(m) Disputes

The decision of the Board (or persons to whom the Board has delegated relevant powers) shall be final and binding on all parties regarding the interpretation or application of the RSU Scheme. The Board may, in its sole discretion, refer any dispute arising in connection with the RSU Scheme (whether as to the number of Shares underlying the RSUs, the subject of an Award or otherwise) to the decision of the Auditors who shall act as experts and not as arbitrator. In such a case the Auditors' decision shall be final and binding on all parties.

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(n) Alteration of the RSU Scheme

- 1.30. The Board shall have complete and exclusive power and authority to amend or modify the RSU Scheme in any and all respects. However, except as otherwise expressly provided in the RSU Scheme, no such amendment or modification shall adversely affect the rights and obligations of a Grantee under an outstanding Award unless the applicable Grantee consents to such amendment or modification. Notwithstanding the foregoing, a Grantee’s rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that (i) the amendment, taken as a whole, does not materially impair the Grantee’s rights, or (ii) subject to the limitations of applicable laws, if any, and without the affected Grantee’s consent, the Board may amend the terms of any one or more Award(s) hereunder if necessary to comply with any applicable laws.
- 1.31. Any alterations to the terms and conditions of the RSU Scheme which are of a material nature shall be subject to the approval of the shareholders of the Company in general meeting, except where the alterations or changes take effect automatically under the existing terms of the RSU Scheme. The Board’s determination shall be conclusive as to whether any proposed alteration to the terms and conditions of the RSU Scheme is material. Unless the Grantee of the relevant Award is a substantial shareholder or an independent non-executive director of the Company, the requirement of this paragraph shall not affect any alterations that take effect automatically under the existing terms of the RSU Scheme.
- 1.32. The powers and authority of the Board in relation to the alteration of any terms of the RSU Scheme shall not be changed except with prior sanction of a resolution of the Company in general meeting.

(o) Termination and Cancellation

- 1.33. The Company by resolution in general meeting or the Board may at any time terminate the operation of the RSU Scheme before the termination date and in such event no further Awards will be offered but the provisions of the RSU Scheme shall remain in full force in all other respects. All Awards granted prior to such termination shall continue to be valid and exercisable in accordance with the terms of the RSU Scheme. In the event of termination, the Company or its relevant subsidiaries shall notify the Trustee and all Grantees of such termination and of how property held by the Trustee on trust for the Grantees (including, but not limited to, any Shares held) and the outstanding Awards shall be dealt with.

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Below is a list of grantees of the RSUs to be granted under the RSU Scheme. As of the Latest Practicable Date, no RSUs of our Company have been allotted and issued to the Trustee under the RSU Scheme.

<u>Name of Grantee</u>	<u>Grant date, vesting commencement date and duration of the RSUs</u>	<u>Number of outstanding Shares underlying RSUs granted</u>	<u>Approximate percentage of issued Shares immediately after completion of the [REDACTED] (assuming the [REDACTED] is not exercised)</u>
Directors			
Mr. Zhao	Between [●] and [●]	[●]	[REDACTED]%
Mr. Zi	Between [●] and [●]	[●]	[REDACTED]%
Mr. Zhan	Between [●] and [●]	[●]	[REDACTED]%
Hong Xu	Between [●] and [●]	[●]	[REDACTED]%
Senior Management			
Zenhua Li	Between [●] and [●]	[●]	[REDACTED]%
Total		[●]	[REDACTED]%

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

Save as disclosed in the section headed “Risk Factors” in this document and so far as our Directors are aware, no litigation or claim of material importance is pending or threatened against any member of our Group.

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3. Joint Sponsors

The Joint Sponsors have made an application on our behalf to the Listing Committee for the [REDACTED] of, and permission to deal in, the Shares in issue (including the Shares or conversion of Preferred Shares) and to be issued pursuant to (i) the [REDACTED] and (ii) the [REDACTED].

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules. Each of the Joint Sponsors will receive a fee of US\$0.5 million for acting as a sponsor for the [REDACTED].

4. Qualifications and Consents of Experts

The following experts have each given and have not withdrawn their respective written consents to the issue of this document with copies of their reports, letters, opinions or summaries of opinions (as the case may be) and the references to their names included herein in the form and context in which they are respectively included.

Name	Qualification
Goldman Sachs (Asia) L.L.C.	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities under the SFO
Haitong International Capital Limited	A licensed corporation to conduct Type 6 (advising on corporate finance) regulated activities as defined under the CFO
Ernst & Young	Certified Public Accountants and Registered Public Interest Entity Auditor
King & Wood Mallesons	Legal adviser to our Company as to PRC law
Maples and Calder (Hong Kong) LLP	Legal adviser to our Company as to Cayman Islands law
Frost & Sullivan International Limited	Industry Consultant

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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.

5. Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all 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.

6. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Documents from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

7. Preliminary expenses

Our Company did not incur any material preliminary expenses.

8. Other Disclaimers

- (a) Save as disclosed in this document, within the two years immediately preceding the date of this document:
 - (i) no share or loan capital or debenture of our Company or any of our subsidiaries has been issued or agreed to be issued or is proposed to be issued for cash or as fully or partly paid other than in cash or otherwise;
 - (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option; and
 - (iii) no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries.
- (b) Save as disclosed in the sections headed “Financial Information”, “[REDACTED]” and “Risk Factors” in this document:
 - (i) there are no founder, management or deferred shares nor any debentures in our Company or any of our subsidiaries;

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- (ii) no share or loan capital or debenture of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option; and
 - (iii) no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of its subsidiaries by our Company for subscribing or agreeing to subscribe, or procuring or agreeing to procure subscriptions, for any shares in or debentures of our Company or any of our subsidiaries.
- (c) We do not have any promoters. No cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters in connection with the [REDACTED] and the related transactions described in this document within the two years immediately preceding the date of this document.
- (d) There is no restriction affecting the remittance of profits or repatriation of capital of our Company into Hong Kong from outside Hong Kong.
- (e) Our Directors confirm that:
 - (i) there is no arrangement under which future dividends are waived or agreed to be waived or is agreed conditionally or unconditionally to be put under option; and
 - (ii) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document.
- (f) Saved as disclosed in this document, our Company has no outstanding convertible debt securities or debentures.

APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE FOR INSPECTION

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were: (i) a copy of the [REDACTED]; (ii) the written consents referred to in the section headed “Consents of Experts” in Appendix IV to this document; and (iii) copies of each of the material contracts referred to in the section headed “Summary of Material Contracts” in Appendix IV to this document.

DOCUMENTS AVAILABLE FOR INSPECTION

Copies of the following documents will be available for inspection at the office of Davis Polk & Wardwell, Hong Kong Solicitors, at The Hong Kong Club Building, 3A Chater Road, Central, Hong Kong, during normal business hours up to and including the date which is 14 days from the date of this document:

- (a) the Memorandum of Association and the Articles of the Company;
- (b) the Cayman Companies Act;
- (c) the Accountants’ Report and the report on the [REDACTED] prepared by Ernst & Young, the texts of which are set out in Appendices I and II to this document;
- (d) the audited consolidated financial statements of our Group for the years ended December 31, 2019 and 2020;
- (e) the PRC legal opinions issued by King & Wood Mallesons, our PRC legal adviser in respect of certain general corporate matters and property interests of our Group;
- (f) the letter of advice prepared by Maples and Calder (Hong Kong) LLP, our legal adviser on Cayman Islands law, summarizing certain aspects of the Cayman Islands companies law referred to in this document;
- (g) the industry report prepared by Frost & Sullivan referred to in the section headed “Industry Overview” in this document;
- (h) the material contracts referred to in the section headed “Statutory and General Information – B. Further Information about Our Business – Summary of Material Contracts” in Appendix IV to this document;
- (i) the service agreements and the appointment letters with our Directors referred to in the section headed “Statutory and General Information – C. Further Information about our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in Appendix IV to this document;

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF
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- (j) the written consents referred to in the paragraph headed “Statutory and General Information – E. Other Information – 4. Consents of Experts” in Appendix IV to this document;
- (k) the terms of the Equity Incentive Plans;
- (l) the list of grantees under the Share Option Plans referred to in the subsection headed “Waivers from Strict Compliance with the Listing Rules and Exemptions from Compliance with the Companies (Winding Up And Miscellaneous Provisions) Ordinance – Waiver and Exemption in relation to the Share Option Plan” in this document.