Broncus Holding Corporation (2216 HK)

Pioneer in interventional pulmonology market

BUY (Initiation)

Target Price	**HK$23.77**
Up/Downside	**+120.05%**
Current Price	**HK$10.80**

As a pioneer in the field of interventional pulmonology, Broncus has China's first and only three-in-one in-house pulmonology platform with whole lung access navigation technology providing solutions throughout all stages of lung disease treatment. We are bullish on China interventional pulmonology market given the large pool of untapped patients and more physicians and hospitals eligible for performing lung treatment.

- **Pioneer in a large untapped and fast-growing interventional pulmonology market.** According to Frost & Sullivan (F&S), Broncus ranked first in China's interventional pulmonology navigation device market with a market share of 43.2% measured by sales volume and second with a market share of 37.5% measured by sales revenue during 2018 and 2020. F&S forecasts the interventional pulmonology navigation platform market in China to reach US$188.7mn by 2025E, mainly driven by 1) the improving penetration rate of bronchoscopy examination, 2) the increasing number of hospitals being able to perform lung treatment, and 3) large unmet medical needs for lung disease treatment.
- **Comprehensive portfolio of interventional diagnostic and therapeutic products.** Beyond the navigation platform, Broncus is developing an ablation system, InterVapor, the world's first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer. The Company is also developing RF-II, a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter, which is the only RFA system that specifically focuses on lung cancer treatment globally. Besides, Broncus has completed the first-in-man clinical trial of its Targeted Lung Denervation (TLD) radiofrequency ablation system in Sichuan to treat COPD.
- **Revenue to grow at a 133% CAGR in FY20-23E.** We expect total revenue to grow at 216%/ 85%/ 118% YoY in FY21E/ 22E/ 23E, mainly driven by the fast-growing sales from medical consumables. We forecast medical consumables sales to reach US$14mn in FY23E, contributing 34% of total revenue. We expect Broncus to turn profitable from FY24E, mainly thanks to the commercialization of InterVapor and RF-II.
- **Initiate at BUY with TP of HK$23.77**. Given that Broncus' major income will rely on future commercialization of consumables and pipeline products, we believe DCF is a proper method to value the Company. We derive TP of HK$23.77 based on a 10-year DCF model (WACC:10.4%, terminal growth rate: 2.0%).

Earnings Summary

(YE 31 Dec)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue (US$ mn)	8	3	10	19	41
YoY growth (%)	N/A	-60	216	85	118
Net income (US$ mn)	-32	-48	-27	-23	-13
EPS (US$)	N/A	N/A	-0.05	-0.04	-0.02
Consensus EPS (US$)	N/A	N/A	-0.11	-0.08	-0.07
P/S (x)	94	233	74	40	18
P/B (x)	N/A	N/A	15	28	57
ROE (%)	N/A	N/A	-55	-87	-102
Net gearing (%)	N/A	N/A	Net cash	Net cash	Net cash

Source: Company data, CMBIS estimates

China Healthcare Sector

Jill WU, CFA
(852) 3900 0842
jillwu@cmbi.com.hk

Jonathan ZHAO
(852) 6359 1614
jonathanzhao@cmbi.com.hk

Mkt. Cap. (HK$ mn)	5,677
Avg. 3mths t/o (HK$ mn)	N/A
52W High/Low (HK$)	18.00/10.12
Total Issued Shares (mn)	526

Source: Bloomberg

Shareholding Structure

Qiming Venture Partners	15.49%
Broncus Biomedical	8.32%
Lake Bleu Capital	5.15%
Others	71.04%

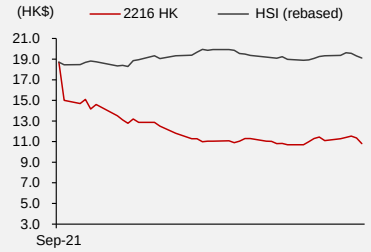
Source: HKEx, Bloomberg

Share performance

	Absolute	Relative
1-mth	-2.2%	1.6%
3-mth	N/A	N/A
6-mth	N/A	N/A

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: Ernst & Young

Web-site: https://www.broncus.com

SERIAL NUMBER

Contents

Investment Thesis

As a pioneer in the field of interventional pulmonology, Broncus has China's first and only three-in-one in-house pulmonology platform with whole lung access navigation technology providing solutions throughout all stages of lung disease treatment. The platform delivers the features of navigation, diagnostics and treatment with high accuracy, minimal side effects and lower costs, which has created high entry barriers to market followers and resulted in high switch cost for doctors or patients.

Pioneer of transforming the diagnosis and treatment paradigms of lung diseases

Broncus is a pioneer in real-time image lung navigation technologies and has developed the world's first and only real-time image whole lung access augmented reality navigation system. The Company's navigation platform consists of three marketed products, including LungPoint, LungPro (Archimedes) and LungPoint Plus (Archimedes Lite). Its proprietary Bronchoscopic Trans-Parenchymal Nodule Access ("BTPNA") technology supported by 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 the Company's lung navigation system, Broncus offers a comprehensive portfolio of industry-leading interventional diagnostic and therapeutic products. The 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.

Broncus is also developing RF Generator + RF Ablation Catheter ("RF-II"), a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter, which is the only RFA system that specifically focuses on lung cancer treatment globally.

Broncus' diagnostic solutions facilitate the early diagnosis and treatment of lung diseases, which could in turn help increase survival rates for patients. The Company's 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 its competitors.

Large market opportunity in interventional pulmonology market

In 2020, the interventional pulmonology navigation platform market in China reached US$6.9mn, growing at a CAGR of 68.9% from 2016 to 2020, and is expected to reach US$188.7mn by 2025E. In 2020, the sales of interventional pulmonology navigation platform in China reached 27 devices, growing at a CAGR of 73.2% during the period from 2016 to 2020, and is expected to reach 1,200 devices by 2025E.

There are four major players in China's interventional pulmonology navigation device market, including Broncus, which shares the entire interventional pulmonology navigation market in China. Broncus ranked first in China's interventional pulmonology navigation device market with a market share of 43.2% measured by sales volume and second with a market share of 37.5% measured by sales revenue during 2018 and 2020.

Broncus completed the first-in-man clinical trial of its Targeted Lung Denervation (TLD) radiofrequency ablation system, which is expected to benefit patients with chronic obstructive pulmonary disease ("COPD") worldwide. The clinical operation was completed by a team consisting of Professor Luo Fengming, Professor Liu Dan, Associate Professor Shen Yongchun and Dr. Zhu Hui of the Department of Respiratory and Critical Care Medicine, West China Hospital, Sichuan University.

F&S estimates that COPD-affected population was 219.2mn globally and 105.3mn in China in 2020, respectively, will increase to 258.4mn globally and 109.6mn in China by 2025E. In China, the number of new lung cancer patients will grow from 0.9mn in 2020 to more than 1mn in 2025E. 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.

Turn profitable from 2024E

We expect total revenue to grow at 216%/ 85%/ 118% YoY in FY21E/ 22E/ 23E, mainly driven by the fast-growing sales from medical consumables. We estimate medical consumables sales to be US$1mn/ US$4mn/ US$14mn, contributing 12%/ 20%/ 34% of total revenue in FY21E/ 22E/ 23E.

We estimate Broncus' net losses of US$27mn/ US$23mn/ US$13mn in FY21E/ 22E/ 23E. We estimate it will generate net profit of US$2mn in FY24E, mainly driven by the commercialization of InterVapor and RF-II which promoting sales of relevant medical consumables.

Initiate at BUY with TP of HK$23.77

As of 2017, Broncus commercialized its advanced navigation system, Lung pro, in China and its next future cash flow will rely on medical consumables of InterVapor and future commercialization of pipeline products. We believe DCF would be a reasonable valuation method to value the Company. We derive TP of HK$23.77 based on a 10-year DCF model (WACC:10.4%, terminal growth rate: 2.0%).

Investment risks

1) Future growth depends substantially on the success of product candidates;

2) Uncertain downward changing in price due to bidding process;

3) Uncertainty of medical insurance reimbursement;

4) Legislation may increase the difficulty and cost to obtain approval or CE certification;

5) Clinical product development with an uncertain outcome.

Leader in interventional pulmonology solution industry

Founded in 2012, Broncus Holding Corporation ("**Broncus**") is a pioneer in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Leveraging the Company's whole lung access navigation technology and encompassing navigation, diagnosis and treatment, the Company's integrated interventional pulmonology platform addresses the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases.

Figure 1: Major milestones of Broncus

Year	Event
2012	Broncus Medical was established in the US and acquired assets from Broncus Technology, Inc. pursuant to an asset purchase agreement.
2014	Archimedes was approved for marketing in the US.
2016	Broncus Hangzhou was established in the PRC to build a global R&D and operation center. Uptake Medical was established in the US. Through Uptake Medical, the Company acquired certain assets from Uptake Medical Corporation including InterVapor.
2018	InterVapor for COPD received CE Marking Certification.
2019	Empower RF Ablation catheter received both FDA and CE approval.
2020	InterVapor for COPD completed the NMPA's expert panel review. BioStarNeedle and Steerable sheath completed registration with the ZheJiang Medical Products Administration. First-in-Man trial of RF-II was completed. The West China Hospital trial of InterVapor for COPD was completed.
2021	Confirmatory clinical trial of RF-II was commenced. Clinical trial of H-marker was completed. Clinical data from VAPORIZE trial of BTVA for localized cancer lesions of the lung was published in Respiration.

Source: Company data, CMBIS

As China's leading interventional pulmonology medical device company, Broncus has built a portfolio of proprietary products providing interventional pulmonology diagnosis and treatment solutions, with complementary accessories.

Broncus is a pioneer in real-time image lung navigation technologies and has developed the world's first and only real-time image whole lung access augmented reality navigation system. The Company's navigation platform consists of three marketed products, including LungPoint, LungPro (Archimedes) and LungPoint Plus (Archimedes Lite).

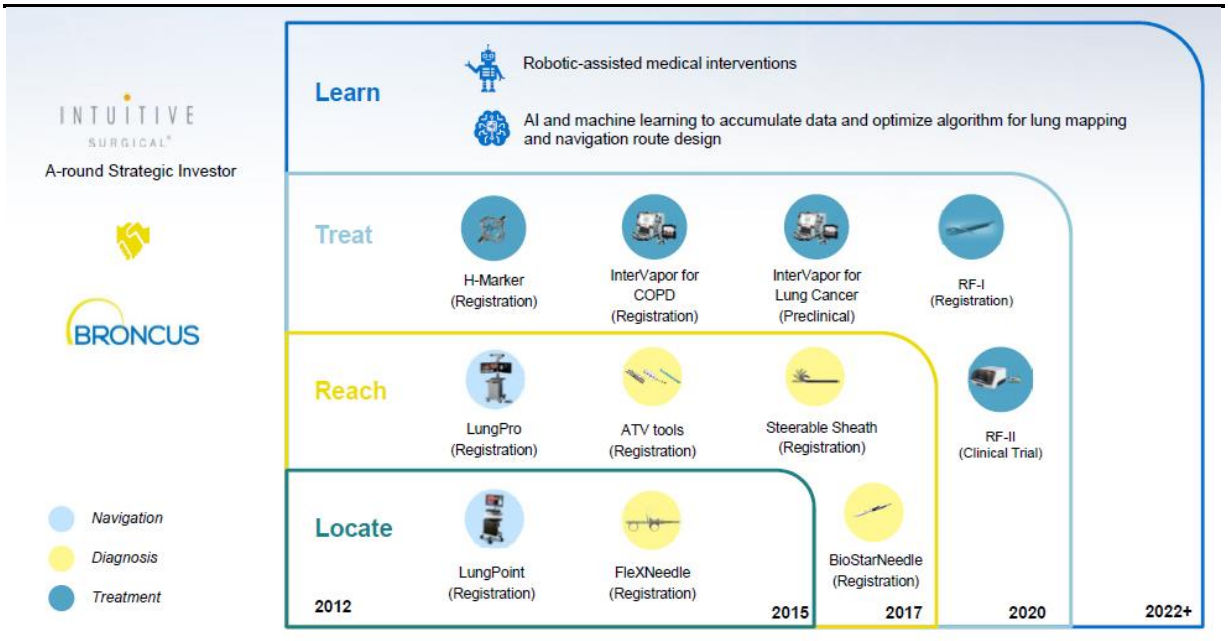
Extending its footprint to interventional pulmonology treatment, the Company has established the world's first thermal vapor energy ablation system, InterVapor, to treat lung diseases including chronic obstructive pulmonary disease ("**COPD**") and lung cancer. Its self-developed RF-II is the only catheter-based radiofrequency ablation system that specifically targets lung cancer. The Company has also developed H-Marker to locate lung nodules through the natural cavity of the human body.

Figure 2: Development status of Broncus' products

	Indication	Portfolio	Region	Preclinical	Clinical Trial	Registration
Treatment	COPD	InterVapor for COPD[2][8][9]	China	Clinical trial and expert review completed, technical review in process		2021.10
			US	FDA 510(K); registration application in preparation		2023.3
			EU			Launch for sale, EU (January, 2018)
			Others			Launch for sale, UK, Switzerland, Taiwan, Hong Kong, India, Australia
		TLD Ablation System[8]	China	Clinical trial starting from August 2021	2025.9	2026.12
	Lung Cancer/ Lung Nodules	InterVapor for Lung Cancer[3][8][9]	China	In design stage	2025.12	2027.3
			US/EU	In design stage		2023.6 for soft tissue
		RF-SEG Generator + RF-iCon Ablation Catheter (RF-II)[8]	China[4]	Clinical trial in process	2023.3	2024.3
			US/EU[5]	FDA 510(K)/CE; registration in process		2023.6 for soft tissue
		EMPOWER RF Ablation Catheter (RF-I)[8]	US			Launch for sale, US (February, 2019)
			EU			Launch for sale, EU (March, 2019)
		H-Marker[6][8]	China			Launch for sale (June, 2021)
		Percutaneous RFA probe[8]	China	In design stage	2022.8 2025.6	2026.12
Navigation	Navigation Platform[1]	LungPoint[8]	China			Launch for sale, China (December, 2014)
			US			Launch for sale, US (March, 2009)
			EU			Launch for sale, EU (June, 2010)
		LungPoint Plus/Archimedes Lite[8]	China			Launch for sale, China (December, 2020)
			US/EU			Launch for sale, US/EU (March, 2021)
		LungPro/Archimedes System[8]	China			Launch for sale, China (October, 2017)
			US			Launch for sale, US (February, 2014)
			EU			Launch for sale, EU (July, 2014)
		New-Generation Navigation Platform[8]	China	In design stage	2023.6 2025.12	2027.3
Diagnosis	Lung Cancer/ Lung Nodules	FleXNeedle[8]	China			Launch for sale, China (December, 2014)
			US			Launch for sale, US (April, 2009)
			EU			Launch for sale, EU (July, 2013)
		ATV FleXNeedle CN[7][8]	China			Launch for sale, China (November, 2019)
		BioStarNeedle[8]	China			Launch for sale, China (June, 2020)
		ATV Sheath[8]	China			Launch for sale, China (June, 2018)
			US			Launch for sale, US (October, 2013)
			EU			Launch for sale, EU (July, 2014)
		ATV Balloon[8]	China			Launch for sale, China (June, 2018)
			US			Launch for sale, US (October, 2013)
			EU			Launch for sale, EU (July, 2014)
		Steerable Sheath[8]	China			Launch for sale, China (July, 2020)

Source: Company data, CMBIS

Figure 3: Diagnosis and therapy area of lung diseases



Source: Company data, CMBIS

Broncus has a stable and dedicated management team with an average of over 20 years of experience in designing, developing and commercializing medical devices in China, US and Europe. Broncus is well positioned to capture the significant commercial opportunities in the large and fast-growing market for the lung disease treatment with a focus on COPD and lung cancer in China and globally.

Pioneer in a large untapped and fast-growing interventional pulmonology market

According to Frost & Sullivan ("**F&S**"), Broncus is the leading interventional pulmonology navigation platform player in China in terms of sales volume in 2020, with a comprehensive product portfolio covering lung navigation, diagnosis and ablation-based therapeutic products. According to F&S, Broncus had a 43.2% market share in China by sales volume and a 37.5% market share in China by sales revenue for interventional pulmonology navigation platforms during 2018 and 2020.

Facing the global prevalence of COPD and lung cancer that has been propelled by aging population, air pollution and smoking habit, the Company sees a huge market need for minimally invasive solutions to treat lung diseases. According to F&S, there was a COPD-affected population of 219.2mn globally and 105.3mn in China in 2020, respectively, and such population is expected to increase to 258.4mn globally and 109.6mn in China by 2025, respectively. According to F&S, 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. According to F&S, among the COPD-affected population in China, only around 28.6mn people were diagnosed in 2020 with a diagnostic yield as low as 27.2% and a control rate of 21.1%. In comparison, around 13.9mn people out of the 20.3mn COPD-affected population in the US were diagnosed in 2020, demonstrating a diagnostic yield as high as 68.6% and a control rate of 58.5%. The mortality rate of COPD in China was 72.9 deaths per 100,000 people in 2020. Although COPD cannot be cured, it can be effectively controlled. The actual number of deaths resulted from COPD in China is approximately 1mn, far exceeding those resulted from lung cancer. Therefore, there is a huge unmet clinical demand for COPD therapeutic solutions in China.

Global lung cancer incidence reached approximately 2.2mn people in 2020 and is expected to further increase to 2.5mn by 2025. China has the highest incidence of lung cancer in the world with a lung cancer population accounting for 41.9% 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 0.9mn in 2020 and is expected to further increase to more than 1mn by 2025. Among these patients, over half of them are diagnosed with the cancer already at late stages at first diagnosis. Average five-year survival rate is as low as 12.6% for stage III lung cancer patients and 2.9% for stage IV patients, according to F&S. However, the five-year survival rate is significantly higher at 56.6% if discovered at Stage I. Given that 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.

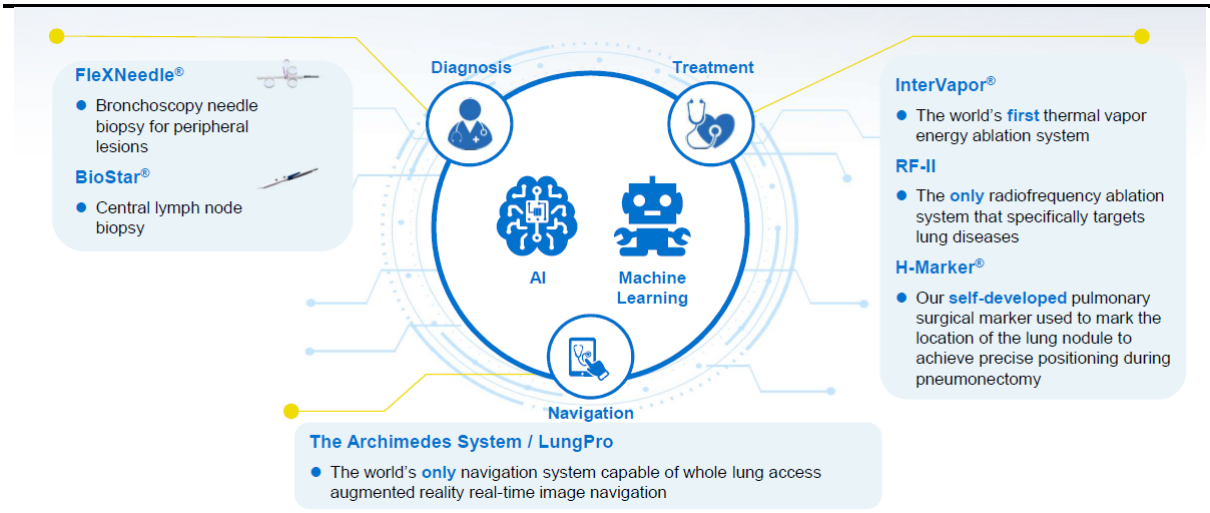
Increased awareness in application of bronchoscopic navigation, radiofrequency ablation and thermal vapor ablation through hospital adoption, doctor training and indication expansion has led to an increase in the number of hospitals providing navigation and ablation operations in China. A total of 96 navigation systems were adopted in China in 2020 while such number is expected to grow to 2,425 by 2025. However, in comparison with a total number of 1,101 navigation systems adopted in the US in 2020, which increased 7.4 times from 2016 and is expected to further grow to 4,430 by 2025, China's interventional pulmonology diagnostic and therapeutic product market remains largely untapped for Broncus to further penetrate into.

China's first and only three-in-one in-house pulmonology platform supported by real-time image whole lung access navigation technology

As a pioneer in the field of interventional pulmonology, the Company has 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. The platform delivers the features of navigation, diagnostics and treatment with high accuracy, minimal side effects and lower costs, which has created high entry barriers to market followers and resulted in high switch cost for doctors or patients.

Figure 4: Three-in-one in-house pulmonology platform supported by navigation technology



Source: Company data, CMBIS

Broncus has successfully developed the world's first and only real-time image whole lung access augmented reality navigation system, which enabled the Company to build an integrated product portfolio for lung disease diagnosis and treatment supported by the navigation system. The whole lung access navigation system enables access to any part of the entire lung, both inside and outside of the airways, based on which it is able to develop revolutionary medical devices and solutions to transform the diagnosis and treatment paradigms of lung diseases. The Company's LungPoint ATV System, also known as LungPro in mainland China or the Archimedes System outside mainland China (the "**Archimedes System**") is the world's only navigation system capable of whole lung access augmented reality real-time image navigation, according to F&S.

Its proprietary Bronchoscopic Trans-Parenchymal Nodule Access ("**BTPNA**") technology supported by 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.

To fully integrate with its lung navigation system, Broncus offers a comprehensive portfolio of industry-leading interventional diagnostic and therapeutic products. The InterVapor system ("**InterVapor**") is the world's first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer, according to F&S.

The Company is also developing RF Generator + RF Ablation Catheter ("**RF-II**"), a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter, which is the only radiofrequency ablation system that specifically targets lung cancer. The RF energy Broncus adopts 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.

Broncus has also developed a pulmonary surgery marker, H-Marker, 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.

Broncus also offers a variety of diagnostic medical consumables. The diagnostic solutions facilitate the early diagnosis and treatment of lung diseases, which could in turn help increase survival rates for patients.

Strong competitive advantages of Broncus' pulmonology platform

Whole lung access navigation with high accuracy. The proprietary navigation technology is capable of navigating inside and outside of the airway to achieve whole lung access. The patent-protected BTPNA technology supporting the Archimedes System is able to reach any part of the entire lung and lead directly to lesions away from or adjacent to an airway. Existing diagnostic methods are not satisfactory due to low diagnostic yield, imprecise positioning and complication to patients. About 74.3% of lung nodules are located at peripherals of the lung and for such nodules, the diagnostic yield of conventional bronchoscopy was only 37%. 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. The Archimedes System 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%.

LungPoint, the Company's 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. The Company's navigation technology supports simultaneous display of real-time image and virtual/simulated image with software-computed planned paths to precisely locate the target. As many doctors prefer using image-guided technology to find the best path to access and biopsy nodules, regardless of the size or location, Broncus' 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 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. The Company's navigation technology establishes a direct tunnel to nodules around the lungs which allows immediate biopsy and treatment. The 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. The 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, the Company's navigation technology utilizes harmless materials with proven safety profiles. In addition, the navigation technology is not contraindicated for medical electrical implants, which allows the Company to provide unique solutions for patients with pacemakers, scaffolds, or other existing implants.

Installation of equipment as an anchor. On one hand, the Company's 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 Broncus with an advantage in procurement tenders to hospitals. On the other hand, the installation of the equipment products at hospitals can serve as an anchor to further boost sales of consumables, deepen hospital penetration and enhance product loyalty from both patients and doctors.

Efficient R&D model with cost advantages

Broncus adopts a highly efficient R&D model that combines international technologies with local R&D cost advantages. Broncus leverages its software and hardware expertise, mature interventional pulmonology technology and proven medical device development experience in the US, and its global network with KOLs to promote products. Meanwhile, the Company leverages the cost advantages in China. Broncus' strong innovation capabilities and patent portfolio have been endorsed by Intuitive Surgical ("**ISRG US**") who strategically invested in the Company in 2018. As of April 30, 2021, Broncus owned (1) 87 issued patents (including pending announcements) and 248 patent applications in China and (2) 95 issued patents and 46 patent applications overseas.

Broncus collaborates with well-known pulmonologists and professionals from top hospitals and research institutions both in China and overseas, and also maintains close relationships with KOLs in the industry, which helps Broncus quickly map out the latest patent pipeline. In the product development process, Broncus collaborates with doctor consultants to conduct R&D activities from concept input, in vitro and animal testing to clinical trials. For instance, for the development of RF-II radiofrequency ablation system, Broncus 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. Dr. Felix JF Herth, Head of Department of Internal Medicine, Pulmonology and Critical Care of the Chest Hospital of Heidelberg University, serves as the R&D and medical advisor.

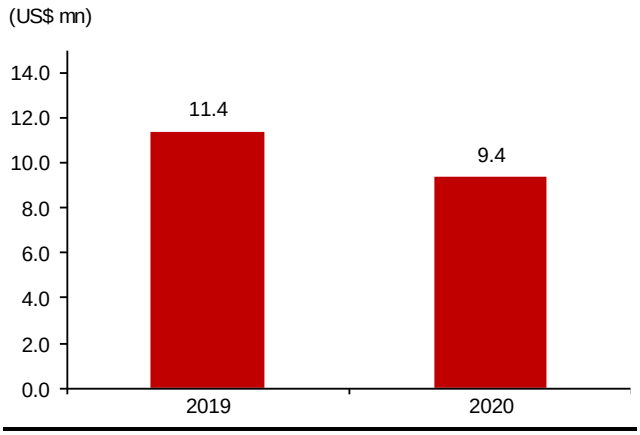
Furthermore, Broncus plans to increase spending on artificial intelligence and machine learning to accumulate large sets of clinical data and cases in the application of diagnosis and treatment procedures guided by the navigation systems, which will help optimize the algorithm for more precise and accurate lung mapping and navigation route design through augmented reality and virtual reality. The proprietary whole lung access navigation system is empowered by the algorithm constantly being optimized through imported and accumulated patient data generated from Virtual Bronchoscopic Navigation ("**VBN**") operations to continuously increase accuracy of procedure planning. The Company also plans to continuously optimize its algorithm and leverage its extensive first-hand real-world procedure experience for accurate prediction of lesion progressing and optimization of its therapeutic solutions. By doing so, the Company will further strengthen its leading position in lung navigation and the overall interventional pulmonology diagnosis and treatment fields.

Broncus has established a strong in-house R&D team of 80 people, with 73 team members based in China, 7 members based in the US as of April 30, 2021. 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. Besides, the clinical affairs team has significant experience in conducting clinical trials. As of April 30, 2021, the Company had 13 clinical staffs with 11 in China and two in the US.

Broncus' R&D cost in China is significantly lower than that of its global peers. According to F&S, R&D cost (including clinical research, animal experiments, R&D staff) in China is approximately 30% of that in the US on average. In addition, the cost per R&D staff in China can be approximately 20% to 30% to that in the US generally.

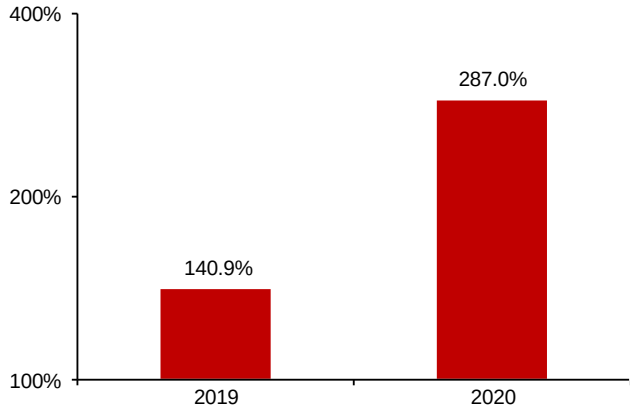
In 2019 and 2020, Broncus' total R&D costs amounted to US$11.4mn and US$9.4mn, accounting for 140.9% and 287.0% of its total revenue, respectively.

Figure 5: Total R&D expense (2019-2020)



Source: Company data, CMBIS

Figure 6: R&D expense to sales ratio (2019-2020)



Source: Company data, CMBIS

Global commercialization capabilities

Broncus' strong commercialization capability is attributed to its brand and expertise to increase market demand and commercialize its 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.

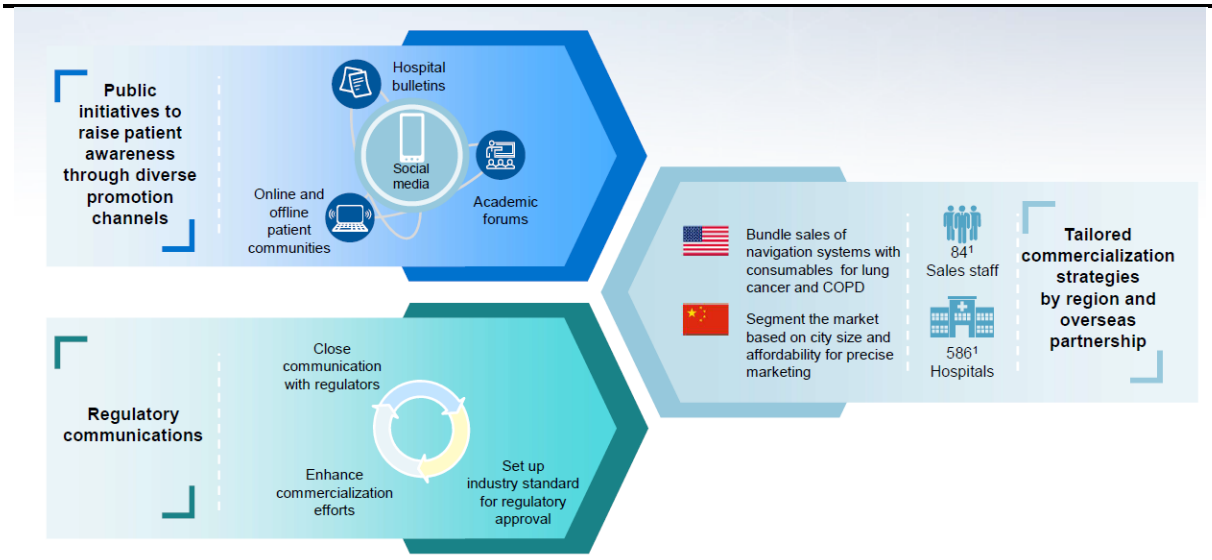
The Company engages in early market education when it is still in the stage of conducting clinical trials for product candidates to draw attention from hospitals, doctors and patients for faster access to commercialization when time ripens. Broncus maintains close and long-term relationships with KOLs and leading pulmonologists and hospitals in China and globally, such as The First Affiliated Hospital of Guangzhou Medical University and Thoraxklinik Heidelberg.

Broncus highly values the role that doctor education plays in promoting market awareness. Therefore, the Company has the education expertise and resources in related products and technologies to quickly replicate the successfully proven education model to accommodate newly introduced products and delivering quality training to doctors. For example, the First Affiliated Hospital of Guangzhou Medical University has been collaborating with the Company as a training center for education on navigation technology, COPD treatment technology and radiofrequency ablation ("**RFA**") technology and assists in training doctors at various local sites.

Clinical data are crucial to its sales and marketing process. Such clinical data provides solid scientific foundation for Broncus' commercial marketing efforts. Broncus is also carrying out post-market real-world studies for the products including the navigation system and diagnostic tools.

In addition, Broncus participates in public activities and promotes its 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, the Company cooperates with hospitals in setting up bulletins to conduct patient education on the technologies and products such as the augmented reality navigation systems and the BTPNA technology. Through these public initiatives, the Company delivers 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.

Figure 7: Broncus' strong branding and commercialization capability



Source: Company data, CMBIS

Furthermore, Broncus has tailored its commercialization strategies to different geographical locations and market segments. For instance, Broncus expands its footprint in US through in-house sales capabilities by promoting bundle sales of the navigation system with consumables for COPD and lung cancer. In China, the Company markets its products through distributor network and direct sales forces. Broncus has a dedicated in-house sales team which conducts academic marketing and clinical training driven by its extensive expertise and clinical resources. As of April 30, 2021, the sales team consisted of 84 members, including 63 members in China, 5 in India, 9 in North America and 7 in Europe, covering 586 hospitals in total. As the provider of the world's only real-time image whole lung access augmented reality navigation system, the Company products have contributed to the clinical experience of leading experts in China in setting up the guidelines for doctors conducting endoscopy procedures.

In addition, Broncus' production centers are based in China and US with an approximately 3,122 sq.m. facility in Hangzhou, China and an approximately 863 sq.m. leased facility in San Jose, US. The Company currently manufactures LungPoint, LungPoint Plus, the Archimedes System and InterVapor in US and most of the consumables in China. Over the years, Broncus has been gradually localizing the manufacturing process by moving it to China while maintaining quality production in manufacturing pulmonology diagnostic and therapeutic products, in order to form a solid basis for its long-term growth.

State-of-the-art lung navigation platform

Three marketed lung navigation products

Broncus currently has three marketed navigation products, including LungPoint, LungPoint Plus (known as Archimedes Lite outside Asia) and LungPro (known as Archimedes outside mainland 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 BTPNA.

Figure 8: Broncus' lung navigation products

Source: Company data, CMBIS

(1) LungPoint

LungPoint, or LungPoint Virtual Bronchoscopic Navigation ("**LungPoint VBN**"), 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. LungPoint was approved for marketing and commercial use in the US by the FDA in 2009, the EU by the BSI Group, The Netherlands B.V. ("**BSI**") in 2011, and the PRC by the NMPA in 2014. LungPoint is classified as a Class II medical device by the FDA, as a Class IIa medical device in the EU, and as a Class III medical device by the NMPA.

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.

(2) LungPoint Plus/Archimedes Lite

An advanced version of LungPoint, LungPoint Plus, also known as Archimedes Lite outside Asia, 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. LungPoint Plus has been commercialized internationally since late 2020. LungPoint Plus is classified as a Class II medical device by the FDA, as a Class IIa medical device in the EU, and as a Class III medical device by the NMPA.

LungPoint Plus 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.

(3) The Archimedes System

The LungPoint ATV System, also known as LungPro in mainland China or the Archimedes System outside mainland China, 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. The Archimedes System was approved for marketing and commercial use in the US 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 a Class II medical device by the FDA, as a Class IIa medical device in the EU, and as a Class III medical device by the NMPA.

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 an 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 suspicious lesion or 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.

Augmented reality whole lung access navigation technology

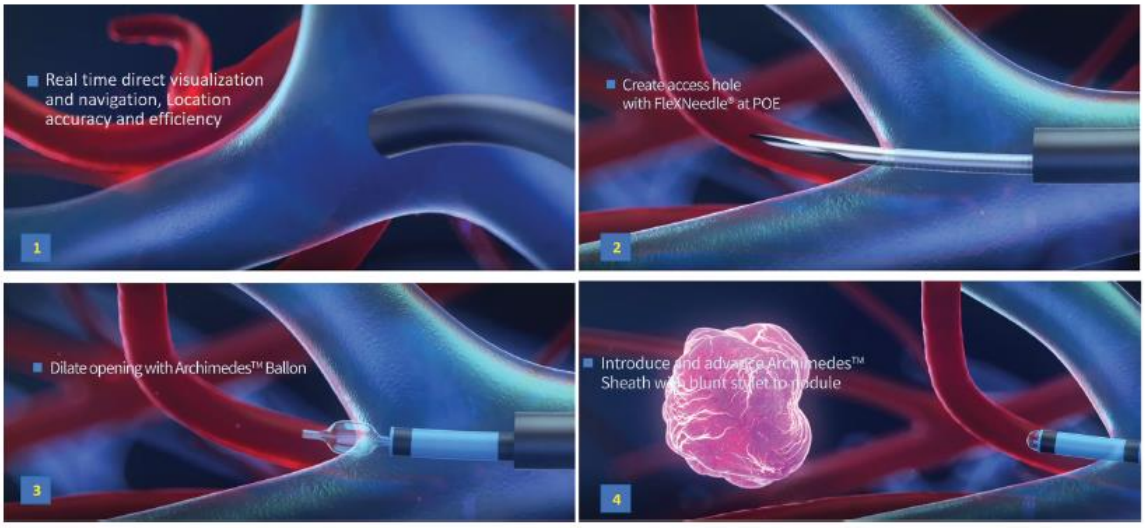
Broncus' Archimedes System is the world's only whole lung access augmented reality real-time image navigation systems, according to F&S. Employing image registration to guide bronchoscopic biopsies, its navigation platforms offer virtual bronchoscopic animations and a 3D airway tree enabling review and 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 VBN 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. The 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 Broncus' 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. The Company's Archimedes System is able to achieve navigation accuracy of within 3mm deviation from the exact location of the target.

Figure 9: Demonstration of augmented reality whole lung access navigation technology



Source: Company data, CMBIS

Product structure and operation procedure of lung navigation system

The Archimedes System consists 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 Broncus provides a username 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.

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 Bronch 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 the Company's navigation system and then use its 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.

Strong clinical evidence of Archimedes System

EAST 2 trial

Broncus has 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 US (six locations) and China (two locations in mainland China and one in Hong Kong) with one location in Germany. As of September 2020, 166 patients have provided written informed consent in the trial.

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.

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).

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.

Large opportunity in lung navigation market

The navigation systems have been used for virtual bronchoscopic navigation and lesion localization to access and sample pulmonary peripheral lesions. According to F&S, there is an accelerating population of lung cancer patients worldwide and in China. Globally, the number of lung cancer new cases increased from 2.0mn in 2016 to 2.2mn in 2020, and is expected to further increase to 2.5mn by 2025. In China, the number of lung cancer new cases increased from 813.4 thousand in 2016 to 924.1 thousand in 2020, and is expected to further increase to 1.1mn by 2025. 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 F&S. 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 F&S, in 2020, the number of bronchoscopy examinations in China reached 3.8mn examinations at a CAGR of 3.4% from a total of 3.4mn examinations in 2016. Such number is expected to reach 5.4mn by 2025. 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.

Currently, there are four major players in China's interventional pulmonology navigation device market, including Broncus, which shares 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 43.2% measured by sales volume and 37.5% measured by sales revenue during 2018 and 2020, with the other two market players sharing a market share of 35.8% and 18.5% 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 mainland China, is the world's only navigation system capable of whole lung access augmented reality real-time image navigation, according to F&S.

Figure 10: Overview of commercialized interventional pulmonary navigation platforms globally

Product Name	LungPro	superDimension™ Navigation System (Newest Generation)	Auris Robotic Endoscopy System	LungVision	SPiN Thoracic Navigation System	Monarch	Ion	ILLUMISITE	LungCare
Manufacturer	BRONCUS	Medtronic	AURIS	Body Vision	VERAN	Johnson & Johnson	Intuitive Surgical	Medtronic	
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[1] 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[2]	*No blood vessel reconstruction	No	No	No	No	No	*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: Company data, CMBIS

Note: 1 VBN: virtual bronchoscopic navigation. 2 BTPNA: Bronchoscopic Trans-Parenchymal Nodule Access

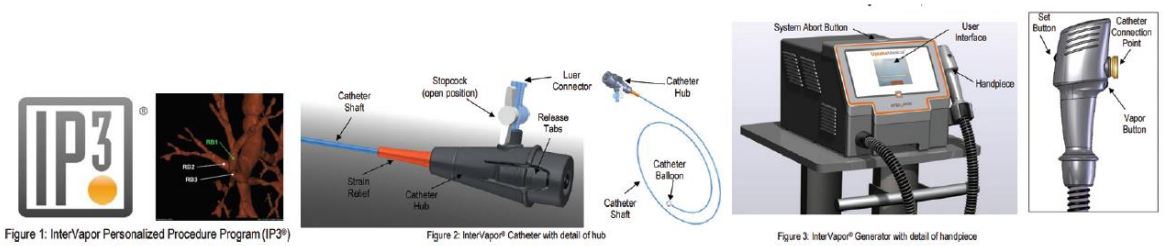
InterVapor for COPD and lung cancer

Through its acquisition of Uptake Medical Corporation's assets in July 2016, the Company was 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, the Company has 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. The Company expects NMPA to complete the technical review of InterVapor for COPD by the end of September 2021. The Company is 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.

InterVapor 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, 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 11: InterVapor system



Source: Company data, CMBIS

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 F&S. In 2018, an EC certificate (CE 678945) was issued by 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. Broncus has submitted the application for InterVapor for COPD to the NMPA and received the priority review of InterVapor for COPD by the NMPA.

Figure 12: Major global commercialized products for COPD-related interventional pulmonology therapeutic methods

Competing device	Manufacturer	Category	Key Technology	Indications	Marketed Region	Approval Time
InterVapor®	BRONCUS	Thermal vapor ablation	By installation 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, 2008
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: Company data, CMBIS

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.

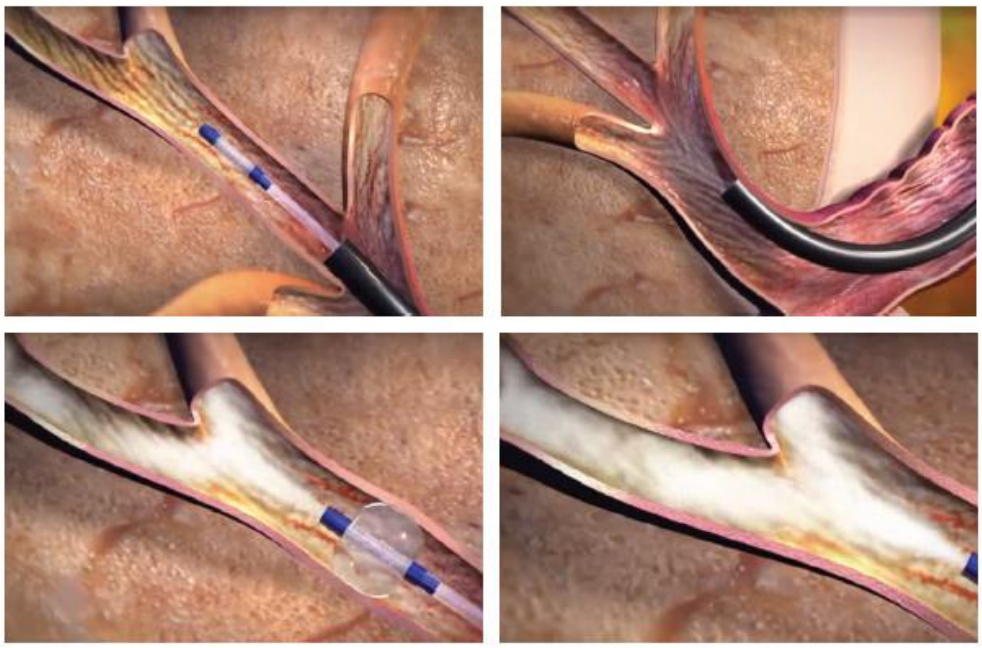
The InterVapor system can be used to complete the tissue ablation procedure as fast as 15 minutes which targets the most diseased lung segments with the healthier segments preserved to sustain pulmonary function and improve the living quality of emphysema patients. There have been several valve therapeutic 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.

Operation procedure of InterVapor for COPD

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.

Figure 13: Ablation operation using InterVapor for COPD



Source: Company data, CMBIS

Multiple clinical trials for InterVapor

Broncus has completed a number of clinical trials to evaluate the performance, safety and efficacy of InterVapor. The clinical history of InterVapor 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 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. The STEP-UP trial was initiated and sponsored by Uptake Medical Corporation, whose assets were acquired by Broncus in 2016. 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.

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 was 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.

The primary efficacy endpoints of the trial are the between group differences in forced expiratory volume in one second ("**FEV1**") or the St. George's Respiratory Questionnaire for COPD ("**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 was 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.

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, the Company 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 who 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 June 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 SGRQ-C information will be obtained. Information regarding adverse events, serious adverse events, and major medical complications will also be collected at each visit.

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.

A total of 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 September 2021.

VAPORIZE trial

Subsequent to the STEP-UP Trial, Broncus commenced the VAPORIZE trial in December 2018 to explore the use of InterVapor to a new indication (lung cancer). The trial demonstrates the Company's ongoing R&D and clinical work after obtained the CE Marking certification in the EU.

The objective of this trial was 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 were 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 included 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.

Six patients were enrolled in the trial and 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

The Company has 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 was 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 was 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.

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 conclusion, 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, Broncus initiated the BTVA Registry Study in April 2018 and has 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.

From the commencement of the BTVA Registry study to June 2020, Broncus has 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. The Company expects to complete the patient enrollment by the end of 2021.

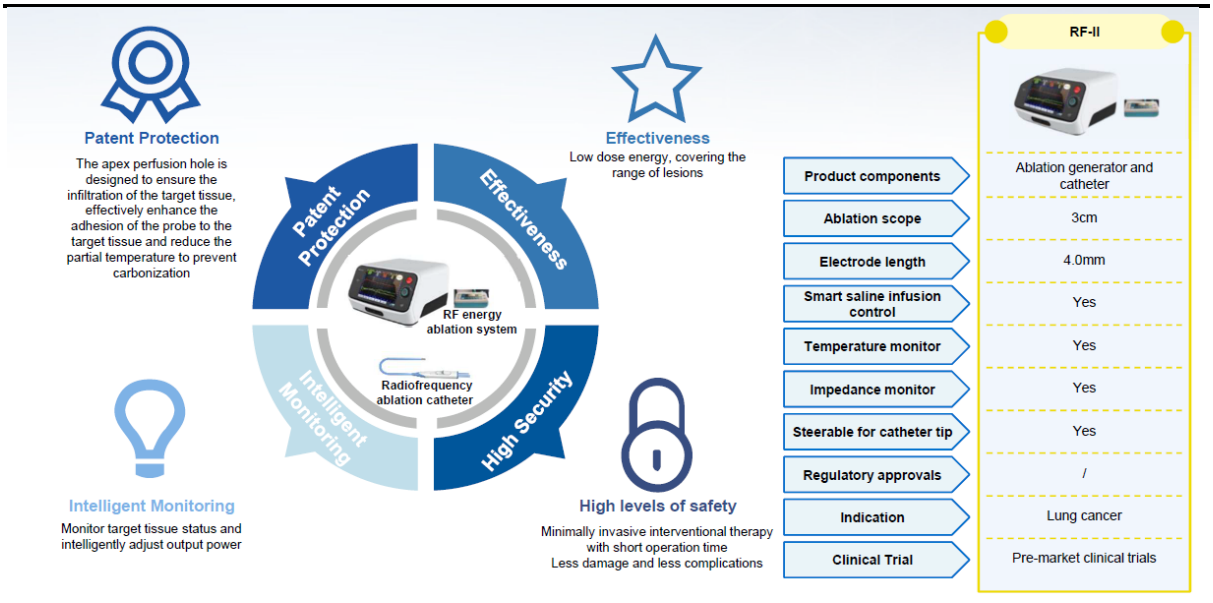
RF generator + RF ablation catheter (RF-II)

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 F&S. Broncus has 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. Broncus expects to leverage clinical data collected in China to apply for registrations of RF-II in the US and EU and also plans to initiate clinical trials in the US and EU if further required by relevant regulatory authorities.

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.

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 F&S, 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.

Figure 14: RF Ablation Catheter (RF-II) system



Source: Company data, CMBIS

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.

Summary of clinical trial data

First-in-Man trial

Broncus has 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 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.

Confirmatory clinical trial

Broncus is 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 non-small-cell lung carcinoma ("**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.

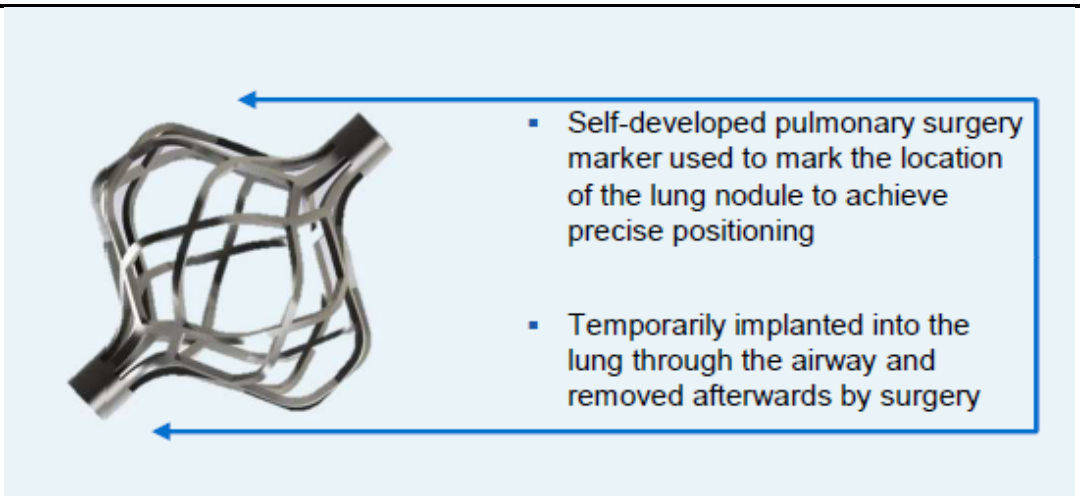
17 study centers had been initiated and continued to actively enroll patients. 63 patients had been enrolled and underwent RFA followed with scheduled follow-up visits per protocol. Preliminary data indicate the safety and effectiveness of RF-II with good procedure tolerance.

Other consumable products for lung nodules

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.

Figure 15: H marker



Source: Company data, CMBIS

As a single-use pulmonary surgery marker, H-Marker has the following advantages:

(1) 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;

(2) 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;

(3) 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;

(4) 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.

Broncus has received the designation of H-Marker as a Class II innovative medical device, which is eligible for expedited approval, by Zhejiang MPA (浙江省药品监督管理局) in October 2020 and obtained the Zhejiang MPA approval in June 2021.

Interventional diagnosis products

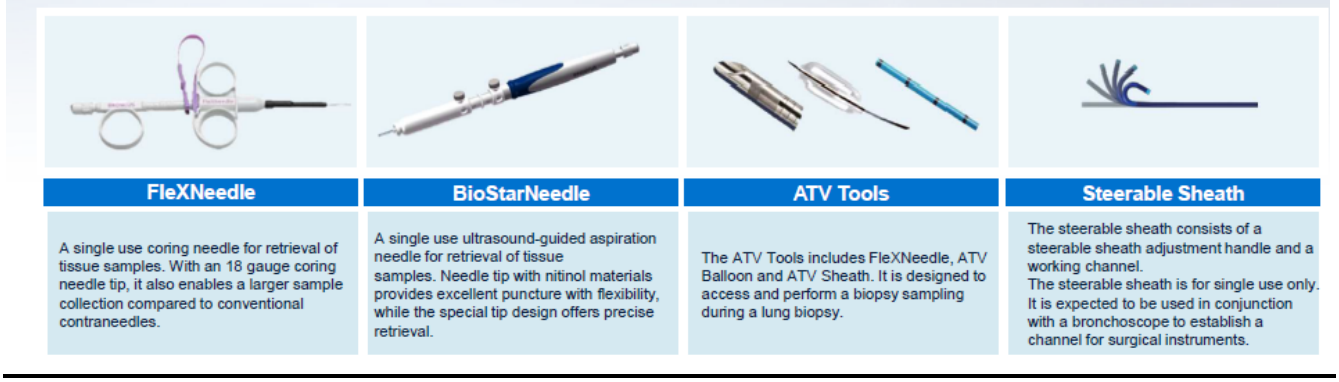
FleXNeedle is a single-use coring needle for retrieval of tissue samples. It is placed through a flexible bronchoscope. When used together with the navigation systems, the needle can be guided to a targeted area within the respiratory organs. With an 18-gauge coring needle tip, it also enables a larger sample collection compared to conventional contra needles.

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.

The ATV Tools includes FleXNeedle, ATV Balloon and ATV Sheath. It is designed to access lesions and perform a biopsy sampling during BTPNA. 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 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.

Figure 16: Interventional diagnosis products for lung nodules



Source: Company data, CMBIS

Overview of pulmonary diseases, diagnosis and treatment

Large prevelance of pulmonary diseases

The lung has a complex structure with the bronchial tree consisting of bronchi, bronchioles, and alveoli and the width of the bronchus within the bronchial tree will reduce when the number of bifurcations increase. After 10 bifurcations, the diameter of the bronchus is expected to be around 1.08mm. Such a feature has made the lung a very delicate and complicated organ for diagnosis and treatment, according to F&S. Pulmonary diseases affect the lungs and other parts of the respiratory system. Pulmonary diseases may be caused by infection, smoking tobacco, or breathing in second hand tobacco smoke, radon, asbestos, or other forms of air pollution. Pulmonary diseases typically include diseases such as lung cancer, COPD, pneumonia, pulmonary tuberculosis and asthma. Among these, COPD and lung cancer are two of the most prevalent lung diseases with 2.2mn global new cases of lung cancers in 2020 and 219.2mn global COPD patients in total in 2020, according to F&S.

Multiple growth drivers for China's interventional pulmonology device market:

1) Accelerating 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 190.6mn in 2020, which accounted for 13.5% of the total population. The population aged above 65 years old will 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 will 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.

2) 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 with total number increased at a CAGR of 11.5% from 14,518 in 2015 to 22,424 in 2019. The development of downstream healthcare institutions drives the growing demand in the medical devices in China.

3) Strong government policy support. 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" was issued by the NMPA, which specified the criteria of innovative medical devices and the application process and supporting documents for the prioritized review procedure. Many interventional pulmonology devices, especially lung navigation systems, fit the criteria of innovative medical devices, thus they are eligible for fast review procedures compared with regular medical devices. These policies will stimulate the innovation of the medical device industry in China in the long term.

4) 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.

5) Increasing public awareness. With the increasing awareness of pulmonary diseases, demand for pulmonology medical services has been growing 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.

6) Abundant training resources and improving 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, 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.

7) Lower R&D cost in China. The cost of conducting clinical research in China is approximately 30% of that in the US on average. The cost of conducting animal experiments in China is also around 30% of that in the US. In addition, the cost per R&D staff in China can be approximately 20% to 30% of that in the US 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.

Overview of lung cancer

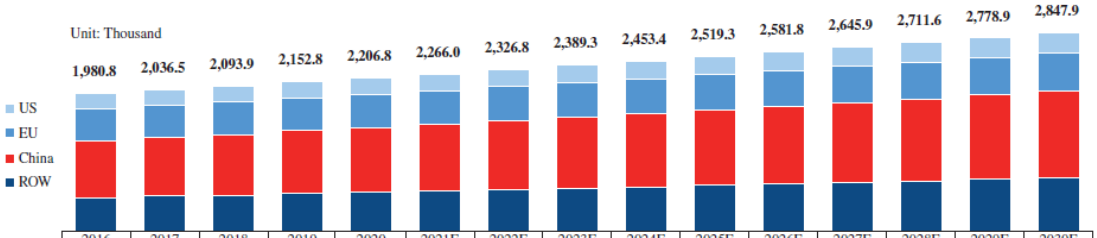
Lung cancer is a type of cancer caused by abnormal and harmful cell growth in tissues of the lung. The main types of lung cancer are small-cell lung carcinoma ("**SCLC**"), also called oat cell cancer, which accounted for approximately 15% of the total incidence of lung cancer around the world, and NSCLC, which accounted for approximately 85% of the total incidence of lung cancer as of 2019, according to the F&S. 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.

High lung cancer incidence worldwide

Lung cancer has the world's largest cancer patient pool, of which approximately 85% is NSCLC. Global lung cancer incidence reached 2.2mn in 2020, growing from 2.0mn in 2016 at a CAGR of 2.7%, and is expected to further increase to 2.9mn by 2030, according to F&S.

Figure 17: Breakdown of new cases of lung cancer by region, 2016-2030E

Period	CAGR				
	Global	US	EU	China	ROW
2016-2020	2.7%	1.0%	1.5%	3.2%	3.8%
2020-2025E	2.7%	2.4%	1.1%	3.2%	3.3%
2025E-2030E	2.5%	1.9%	1.0%	2.8%	3.2%



	2016	2017	2018	2019	2020	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Global	1,980.8	2,036.5	2,093.9	2,152.8	2,206.8	2,266.0	2,326.8	2,389.3	2,453.4	2,519.3	2,581.8	2,645.9	2,711.6	2,778.9	2,847.9
US	224.4	222.5	234.0	228.2	233.9	239.8	245.4	251.1	256.9	262.9	268.0	273.1	278.3	283.7	289.1
EU	455.6	462.8	470.0	476.5	483.0	488.8	493.9	499.1	504.2	509.4	514.5	519.7	524.9	530.1	535.3
China	813.4	840.2	867.5	895.3	924.1	953.8	984.5	1,016.1	1,048.8	1,082.6	1,113.1	1,144.4	1,176.6	1,209.8	1,243.9
ROW	487.4	511.1	522.3	552.9	565.8	583.6	603.0	623.0	643.5	664.5	686.3	708.7	731.7	755.3	779.6

Source: NCCR, F&S, CMBIS

In terms of new cases of lung cancer, the US had over 233.9 thousand cases in 2020, which grew at a CAGR of 1.0% from 2016 whereas China had over 924.1 thousand cases during the same period, which grew at a CAGR of 3.2% from 2016. Lung cancer was the most prevalent cancer in China in 2020. The lung cancer incidence in the US is expected to further increase to 262.9 thousand by 2025, and to reach 289.1 thousand by 2030. In China, the lung cancer incidence is expected to further increase to 1,082.6 thousand by 2025, representing a CAGR of 3.2% from 2020. Given that the unhealthy lifestyle and smoking habits of the Chinese population in general, it is estimated that the lung cancer incidence in China would reach 1,243.9 thousand by 2030, representing a CAGR of 2.8% from 2025 to 2030.

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 F&S, 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 US, 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, according to F&S, 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 F&S, the latest five-year survival rate of lung cancer (calculated for the period between 2012 and 2015) is 19.7% in China.

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.

Overview of COPD

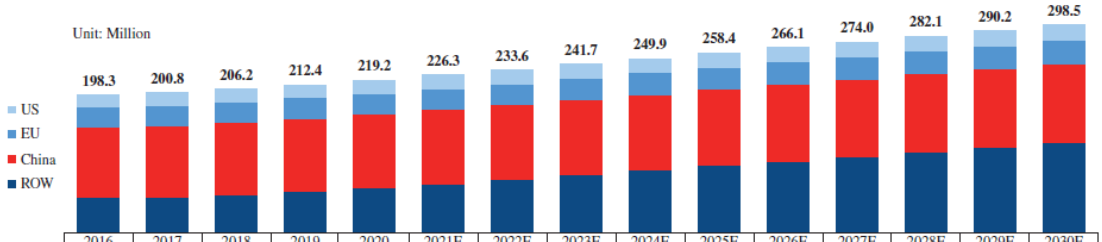
COPD is a common disease characterized by persistent respiratory symptoms and airflow restrictions, including chronic cough, sputum production and progressive dyspnea. The diagnosis of COPD is predicated upon the recognition of its two major forms: emphysema and chronic bronchitis. These two forms represent 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 F&S, in 2020, the COPD prevalence reached 219.2mn globally at a CAGR of 2.5% from 2016 to 2020, and is expected to grow at a higher CAGR of 3.3% from 2020 to 2025 to reach 258.4mn by 2025 and reach 298.5mn by 2030, representing a CAGR of 2.9% from 2025 to 2030.

Figure 18: Breakdown of prevalence of COPD by region, 2016-2030E

Period	CAGR				
	Global	US	EU	China	ROW
2016-2020	2.5%	1.7%	1.3%	0.9%	6.7%
2020-2025E	3.3%	1.5%	1.2%	0.8%	8.3%
2025E-2030E	2.9%	1.5%	1.1%	0.7%	6.1%

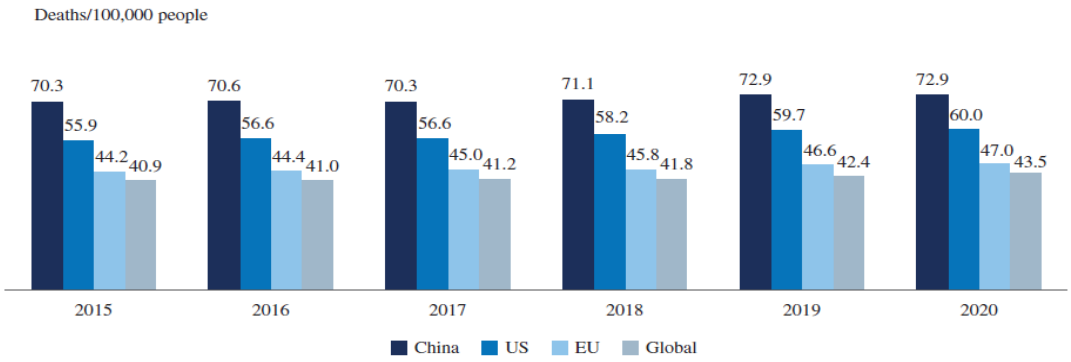


	2016	2017	2018	2019	2020	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Global	198.3	200.8	206.2	212.4	219.2	226.3	233.6	241.7	249.9	258.4	266.1	274.0	282.1	290.2	298.5
US	19.0	19.3	19.7	20.1	20.3	20.7	21.0	21.3	21.6	21.9	22.3	22.6	22.9	23.3	23.6
EU	28.3	28.6	29.0	29.5	29.8	30.2	30.5	30.9	31.2	31.6	32.0	32.3	32.7	33.1	33.4
China	101.7	102.7	103.5	104.4	105.3	106.2	107.0	107.8	108.7	109.6	110.4	111.1	111.8	112.6	113.3
ROW	49.3	50.2	53.9	58.3	63.8	69.4	75.1	81.7	88.4	95.2	101.5	108.0	114.6	121.3	128.1

Source: Literature research, the GDB study, F&S, CMBIS

In the US, the prevalence of COPD reached 20.3mn people in 2020, and is expected to grow at a CAGR of 1.5% from 2020 to 2025 to reach 21.9mn people by 2025 and reach 23.6mn people by 2030, representing a CAGR of 1.5% from 2025 to 2030. In China, the prevalence of COPD reached 105.3mn people in 2020 and is expected to reach 109.6mn people by 2025 with a CAGR of 0.8% from 2020 to 2025 and reach 113.3mn people by 2030, representing a CAGR of 0.7% from 2025 to 2030. The mortality rate of COPD is higher in China as compared to the US and EU, leading at 72.9 deaths/100,000 people, which shows unmet market need for diagnosis and 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 US 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 US, according to F&S.

Figure 19: Mortality rate of COPD by region, 2015-2020



Source: the GDB study, F&S, CMBIS

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 US, according to F&S. 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 β2 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 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

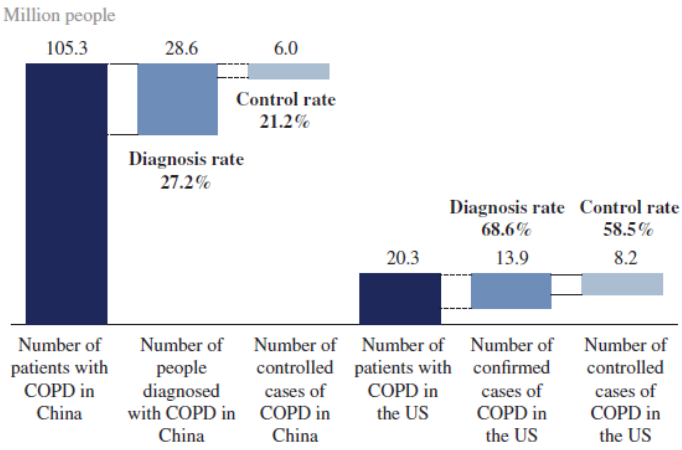
Current pulmonology diagnosis and treatment paradigm

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 7.5%. The number of COPD patients in China is 105.3mn compared against a 20.3mn COPD patient population in the US in 2020. 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 27.2% as compared to a diagnosis rate of 68.6% in the US. There has been material difference in the control rate of COPD between China and US with only 21.1% in China compared against 58.5% in the US.

Figure 20: Current status of COPD diagnosis and treatment in China and US, 2020



Source: F&S, CMBIS

(1) 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.

(2) 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.

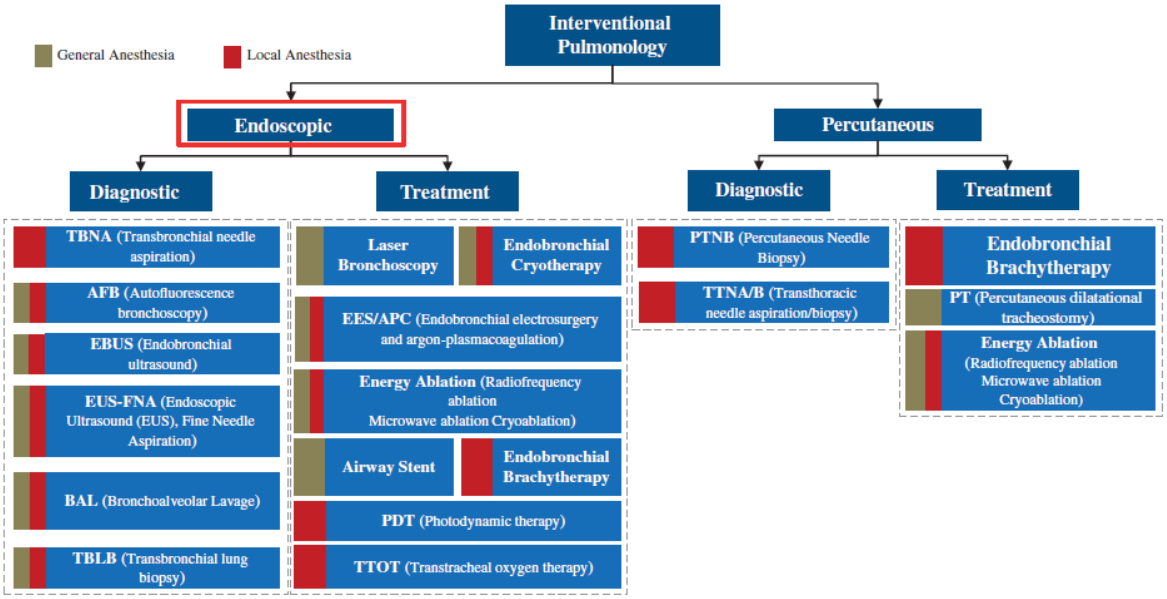
(3) Current treatment options are limited. Traditional pharmaceutical treatment options for COPD are mainly designed to slow down the exacerbation of patients' conditions or enhance prevention. However, these traditional pharmaceutical treatment options are proven to have low effectiveness for late stage 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.

Figure 21: Breakdown of interventional pulmonology

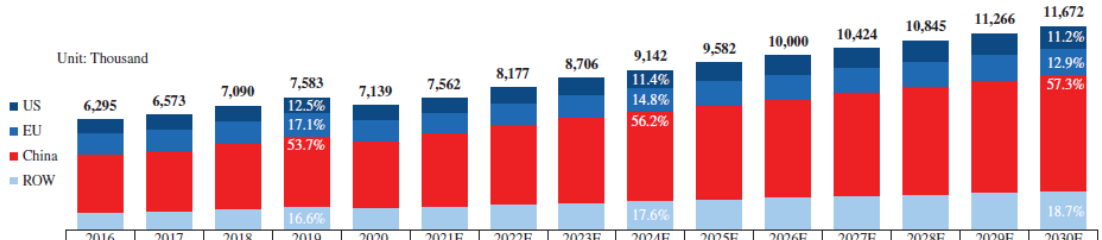


Source: the GDB study, F&S, CMBIS

Interventional pulmonology therapy with minimally invasive methods has been increasingly used in the treatment of pulmonary diseases such as COPD and lung cancer. In 2020, the number of bronchoscopy examination procedures conducted globally reached 7.1mn units at a CAGR of 3.2% from 2016 to 2020. Such number is expected to reach 9.6mn units by 2025 and 11.7mn units by 2030. In 2020, the number of bronchoscopy examination procedures conducted in China reached 3.8mn units at a CAGR of 3.4% from 2016 to 2020 and such number is expected to reach 5.4mn units by 2025 and 6.7mn units by 2030.

Figure 22: Breakdown of bronchoscopy examination procedure number by region, 2016-2030E

Period	CAGR				
	Global	U.S.	EU	China	ROW
2016-2020	3.2%	2.1%	0.5%	3.4%	6.5%
2020-2025E	6.1%	4.1%	2.8%	7.0%	7.4%
2025E-2030E	4.0%	3.7%	1.6%	4.4%	5.0%



	2016	2017	2018	2019	2020	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Global	6,295	6,573	7,090	7,583	7,139	7,562	8,177	8,706	9,142	9,582	10,000	10,424	10,845	11,266	11,672
US	818	848	900	947	887	870	944	995	1,042	10,87	1,131	1,175	1,218	1,261	1,302
EU	1,187	1,229	1,260	1,299	1,210	1,195	1,257	1,309	1,351	1,388	1,417	1,442	1,465	1,485	1,501
China	3,358	3,516	3,802	4,076	3,844	4,201	4,563	4,888	5,143	5,398	5,654	5,910	6,164	6,424	6,684
ROW	932	980	1,127	1,261	1,198	1,297	1,412	1,513	1,606	1,708	1,798	1,898	1,997	2,095	2,184

Source: F&S, CMBIS

Entry barriers of interventional pulmonology market

(1) 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

its numerous branches, high quality and highly accurate interventional pulmonology navigation devices are required 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.

(2) 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.

(3) Professional barriers. Highly skilled laborers 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 laborers 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.

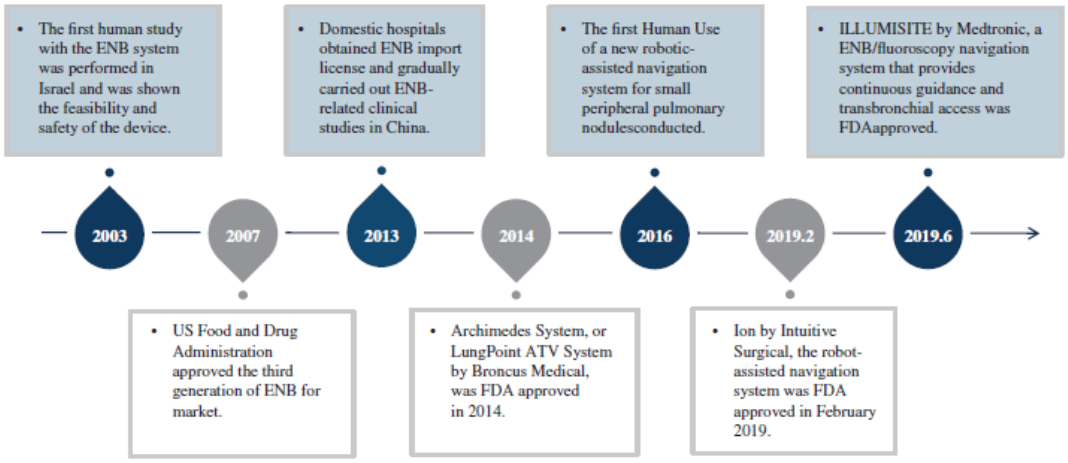
(4) Underserved public education on interventional pulmonology medical devices. There is still ample room to raise awareness of interventional pulmonology medical devices due to a lack of profound understanding of this field currently from both the doctors and patients in China. It is important for companies 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 are highly dependent on how the companies manage their commercialization and promotion.

Lung navigation

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. 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.

Figure 23: International players in interventional pulmonology medical device industry



Source: F&S, CMBIS

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

Figure 24: Commercialized interventional pulmonary navigation platforms globally

Product Name	LungPro/ Archimedes	superDimension™ Navigation System (Newest Generation)	LungVision	IG4 Image Guided System	Monarch	Ion	ILLUMISITE	LungCare
Manufacturer	Broncus	Medtronic, USA	Body Vision Medical	Olympus/Veran Medical	Johnson & Johnson AURIS, USA	Intuitive Surgical, USA	Medtronic, USA	LungCare Medicals, China
Classification	Optical 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	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(1)	Yes by CrossCountry™(2) *No blood vessel reconstruction	No	Yes by TTNA(3)	No	No	Yes by CrossCountry™ *No blood vessel reconstruction	No
FDA Approval Time	2014.02	2015.01	2017.04	2017.05	2018.03	2019.02	2019.08	N/A
NMPA Approval Time	2017.10	2017.04	N/A	2017.05	N/A	N/A	N/A	2016.05

Source: F&S, CMBIS

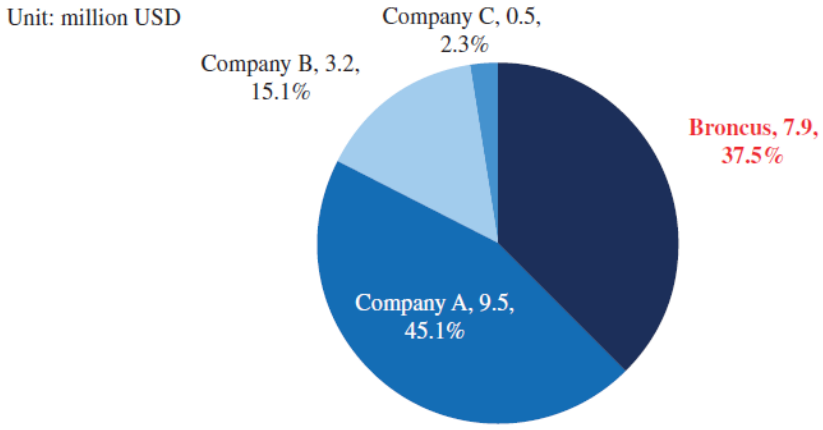
The average ex-factory prices of lung navigation systems marketed in China have stayed relatively stable in the past few years and the major raw materials used for manufacturing the systems have also stayed relatively stable and is expected to remain so. A wider market acceptance of advanced navigation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

Market size of China's interventional pulmonology navigation device market

In 2020, the interventional pulmonology navigation platform market in China reached US$6.9mn with a high CAGR of 68.9% from 2016 to 2020, and is expected to reach US$188.7mn by 2025. In 2020, the sales of interventional pulmonology navigation platform in China reached 27 devices at a CAGR of 73.2% during the period from 2016 to 2020, and is expected to reach 1,200 devices by 2025.

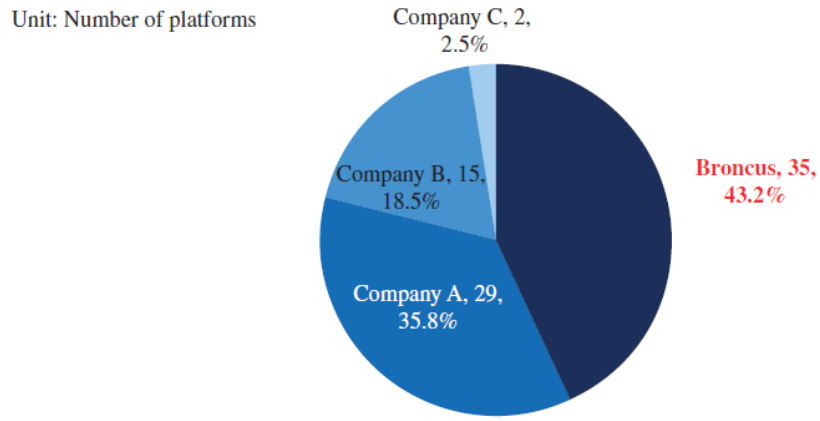
There are four major players in China's interventional pulmonology navigation device market, including Broncus, which shares the entire market of interventional pulmonology navigation platform sales. Broncus ranked first in China's interventional pulmonology navigation device market with a market share of 43.2% measured by sales volume and second with a market share of 37.5% measured by sales revenue during 2018 and 2020**.** Company A ranked second with a market share of 35.8% measured by sales volume and first with a market share of 45.1% measured by sales revenue during 2018 and 2020. Company B ranked third with a market share of 18.5% measured by sales volume and 15.1% measured by sales revenue during 2018 and 2020. Company C ranked last with a market share of 2.5% measured by sales volume and 2.3% measured by sales revenue during 2018 and 2020.

Figure 25: Breakdown of China interventional pulmonology navigation platform sales revenue by manufacturers, 2018-2020



Source: F&S, CMBIS

Figure 26: Breakdown of China interventional pulmonology navigation platform sales volume by manufacturers, 2018-2020



Source: F&S, CMBIS

Pulmonary Disease Diagnosis

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 is inserted through a small hole between the ribs to check the area to be biopsied. As for interventional pulmonology diagnosis, endoscopy and other tools are used 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.

Figure 27: Different diagnosis options for lung cancer

	Radiological scanning	Interventional Pulmonology		Open lung biopsy
		Endoscopic Diagnosis	Percutaneous diagnosis	
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, LungCare Medical, Body Vision Medical, Medtronic	Medtronic, 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 a 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 (COPD, heart failure, etc.) may not be possible to use invasive procedures for diagnosis and staging. It can sometimes cause pneumonia, pneumothorax, self-limited minor bleeding, an inadvertent puncture of the adjacent structure, and etc.	It can cause pneumonia, pneumothorax, self-limited minor bleeding, an inadvertent puncture of the adjacent structure, and etc. 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: F&S, CMBIS

Interventional pulmonology diagnostic methods can generally be 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.

Figure 28: Major interventional pulmonology diagnostic methods

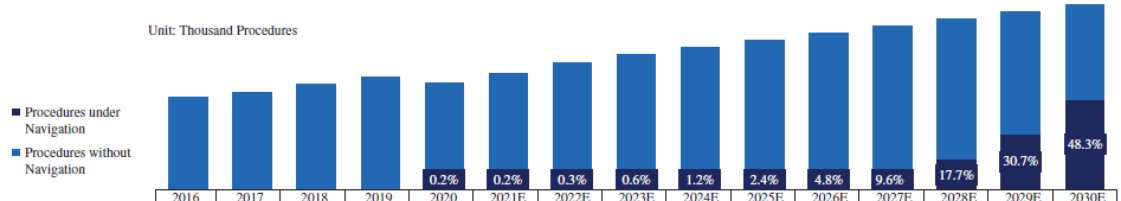
Name	Approach	Reach lesions outside airways	Accuracy	Application	Complications
Transbronchial Needle Aspiration (TBNA)	One of the most basic approaches using a flexible bronchoscope to obtain cellular material with a needle that is passed through the bronchial wall.	Yes	Increase the diagnostic yield 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: F&S, CMBIS

Based on F&S's analysis, in 2020, the number of bronchoscopy examination procedures performed under navigation platform guidance in China reached 6.4 thousand units at a CAGR of 151.7% from 2016 to 2020, and is expected to reach 130.1 thousand units by 2025 at a CAGR of 82.7% from 2020 to 2025, accounting for 2.4% 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 2020, the market size of interventional pulmonology diagnostic consumables in China reached US$26.3mn at a CAGR of 25.6% from 2016 to 2020, and is expected to reach US$137.7mn by 2025.

Figure 29: Number of bronchoscopy examination procedures performed under navigation platform guidance in China, 2016-2030E

Period	CAGR
2016-2020	151.7%
2020-2025E	82.7%
2025E-2030E	90.1%



	2016	2017	2018	2019	2020	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Total Procedures in China	3,358.2	3,516.0	3,802.1	4,075.6	3,844.3	4,200.6	4,562.6	4,888.4	5,142.6	5,398.3	5,653.9	5,909.6	6,164.2	6,423.7	6,684.4
Procedures without Navigation	3,358.0	3,515.6	3,801.1	4,074.1	3,837.9	4,191.2	4,547.3	4,859.0	5,082.7	5,268.2	5,380.5	5,344.3	5,075.0	4,452.3	3,458.1
Procedures under Navigation	0.2	0.4	1.0	1.5	6.4	9.4	15.3	29.4	59.9	130.1	273.3	565.3	1,089.3	1,971.4	3,226.3

Source: F&S, CMBIS

Figure 30: 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: F&S, CMBIS

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 RFA, thermal vapor ablation, and microwave ablation. Energy ablation system heats the tumor and thereby 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 F&S.

According to F&S, RFA, as the first commercially viable ablation device, is currently available and widely adopted with the following advantages:

(1) Cost effective. It is relatively cost effective compared with other newer devices, such as microwave ablation and high-intensity–focused ultrasound scan.

(2) Safety. Using small electrode size (14-17 gauge), it gently burns with a better safety profile than that of microwave ablation and cryoablation.

(3) 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.

(4) 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 (1) a 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 (2) 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.

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

Figure 31: Major global commercialized RFA systems for interventional pulmonary treatment

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	Partial or complete coagulation and ablation of soft tissue	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	Thermal coagulation necrosis of soft tissues	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: F&S, CMBIS

RF II can effectively compete with products developed by major international brands with the unique and proprietary technologies it employs: RF-II enters lungs through the bronchus by interventional methods, enabling minimally invasive treatment; the radiofrequency ablation energy that RF-II adopts is a safe technology for lung cancer treatment, in the same way as its application in tachycardia treatment for many years.

InterVapor can effectively compete with products developed by international brands as it is the world's first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung

cancer.

Figure 32: Major global commercialized products for COPD-related interventional pulmonology therapeutic methods

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: F&S, CMBIS

Financial analysis

Revenue to deliver 133% CAGR in FY21-23E

We expect total revenue to grow 216%/ 85%/ 118% YoY to US$10mn/ US$19mn/ US$41mn in FY21E/22E/23E, mainly driven by the fast-growing in medical consumables and new product approvals.

Before 2023E, we expect the navigator system (Lung point and Lung pro) will contribute the most revenue to the Company. We estimate medical devices will account for 84%/ 78%/ 64% of FY21E/22E/23E total revenue.

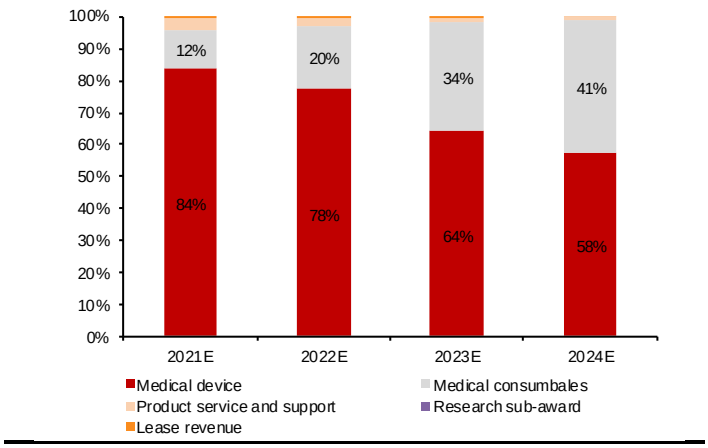
We forecast InterVapor will receive approval from NMPA in 2022E and RF-II will receive approval from NMPA in 2024E. As InterVapor formally commercializes in China by 2022E, we foresee rapid growth in medical consumables that associated with InterVapor. We forecast the revenue of medical consumables to grow 213%/ 280%/ 100% YoY to US$4mn/ US$14mn/ US$29mn, accounting for 20%/ 34%/ 41% of the total revenue in FY22E/ 23E/ 24E. After 2025E, we expect a secondary wave of rapid growth in medical consumables thanks to commercialization of RF-II and relevant consumables.

Figure 33: Revenue forecasts (2021E-2024E)

(US$ mn)	2020	2021E	2022E	2023E	2024E
Sales of medical devices and consumables	**2.8**	**9.9**	**18.5**	**40.8**	**68.3**
YoY	*-63%*	*253%*	*88%*	*121%*	*67%*
Medical device		8.7	14.8	26.6	39.8
YoY			*71%*	*80%*	*50%*
Medical consumables		1.2	3.8	14.3	28.5
YoY			*213%*	*280%*	*100%*
Product service and support	**0.3**	**0.4**	**0.5**	**0.6**	**0.7**
YoY	*27%*	*20%*	*20%*	*20%*	*20%*
Research sub-award	**0.1**	**0.0**	**0.0**	**0.0**	**0.0**
YoY	*-52%*	*-100%*	*N/A*	*N/A*	*N/A*
Lease revenue	**0.0**	**0.0**	**0.1**	**0.1**	**0.1**
YoY	*760%*	*10%*	*10%*	*10%*	*10%*
Total revenue	**3.3**	**10.3**	**19.0**	**41.4**	**69.1**
YoY	*-60%*	*216%*	*85%*	*118%*	*67%*

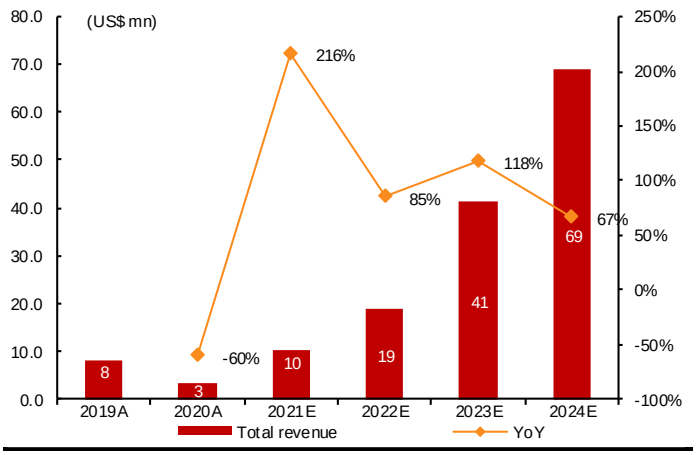
Source: Company data, CMBIS estimates

Figure 34: Revenue breakdown



Source: Company data, CMBIS estimates

Figure 35: Total revenue and growth forecasts



Source: Company data, CMBIS estimates

Turn profitable from 2024E

Broncus recorded net losses of US$32mn/ US$48mn in FY19A/20A. We expect it to continue incur

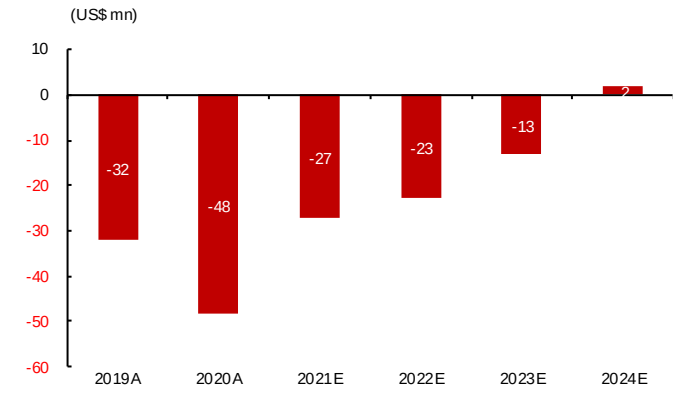
net loss of US$27mn/ US$23mn/ US$13mn in FY21E/FY22E/FY23E and generate net profit of US$2mn in FY24E.

Figure 36: P&L forecasts

(YE 31 Dec) (US$ mn)	2019	2020	2021E	2022E	2023E	2024E
Revenue	**8**	**3**	**10**	**19**	**41**	**69**
YoY		*-59.6%*	*216.0%*	*84.8%*	*117.7%*	*66.7%*
Cost of sales	-2	-1	-2	-4	-9	-15
% of revenue	*-25.9%*	*-23.1%*	*-22.7%*	*-22.4%*	*-22.0%*	*-21.7%*
Gross profit	**6**	**3**	**8**	**15**	**32**	**54**
GPM	*74.1%*	*76.9%*	*77.3%*	*77.6%*	*78.0%*	*78.3%*
Selling and distribution expenses	-9	-6	-9	-13	-19	-21
% of revenue	*-106.7%*	*-194.9%*	*-90.0%*	*-70.0%*	*-45.0%*	*-30.0%*
Administrative expenses	-9	-8	-14	-12	-15	-19
% of revenue	*-109.7%*	*-236.9%*	*-136.0%*	*-63.1%*	*-36.2%*	*-28.0%*
R&D expenses	-11	-9	-14	-15	-15	-15
% of revenue	*-141%*	*-287%*	*-136%*	*-79%*	*-36%*	*-21%*
Other income and gains	0	1	0	0	0	0
% of revenue	*3.8%*	*33.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Impairment losses on financial assets, net	-0	-0	0	0	0	0
% of revenue	*1.0%*	*28.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Other expenses	-0	-0	0	0	0	0
% of revenue	*-0.1%*	*-14.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating profit	**-23**	**-21**	**-29**	**-26**	**-16**	**-1**
% of revenue	*-279.8%*	*-629.5%*	*-284.7%*	*-134.3%*	*-39.4%*	*-0.9%*
Finance costs - net	-1	-1	2	2	3	2
% of revenue	*-6.4%*	*-19.9%*	*17.2%*	*11.2%*	*6.6%*	*3.5%*
Changes in FV of convertible redeemable preferred shares	-9	-28	0	0	0	0
% of revenue	*-117.0%*	*-847.5%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Profit before tax	**-33**	**-49**	**-28**	**-23**	**-14**	**2**
PBT margin	*-403.2%*	*-1496.9%*	*-267.5%*	*-123.1%*	*-32.7%*	*2.6%*
Income tax expense	0	0	0	0	0	0
% tax rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
Total net profit	**-33**	**-49**	**-28**	**-23**	**-14**	**2**
Minority Interests	-1	-1	-1	-1	-1	-1
Net profit attributable to shareholders	**-32**	**-48**	**-27**	**-23**	**-13**	**2**

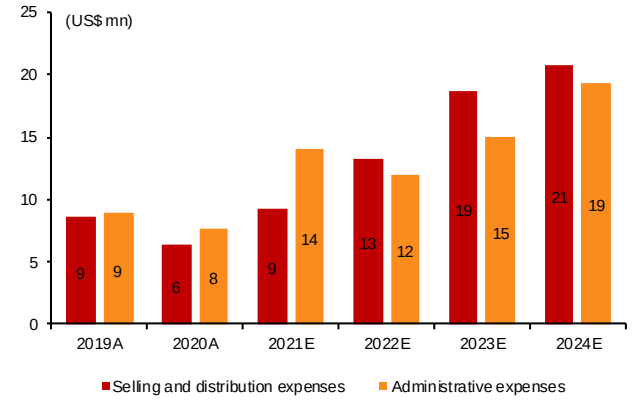
Source: Company data, CMBIS estimates

Figure 37: Net profit forecasts



Source: Company data, CMBIS estimates

Figure 38: SG&A expenses forecasts

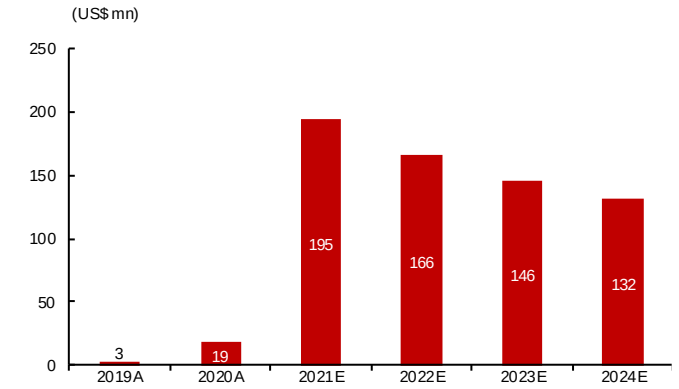


Source: Company data, CMBIS estimates

SG&A spending to increase. Selling expenses were US$9mn/ US$6mn in FY19A/20A and we forecast selling expenses to increase to US$9mn/ US$13mn/ US$19mnmn in FY21E/22E/23E, representing selling expenses ratios of 90%/ 70%/ 45%. Admin expenses were US$9mn/ US$8mn in FY19A/20A and we expect admin expenses to be US$14mn/ US$12mn/ US$15mn in FY21E/22E/23E.

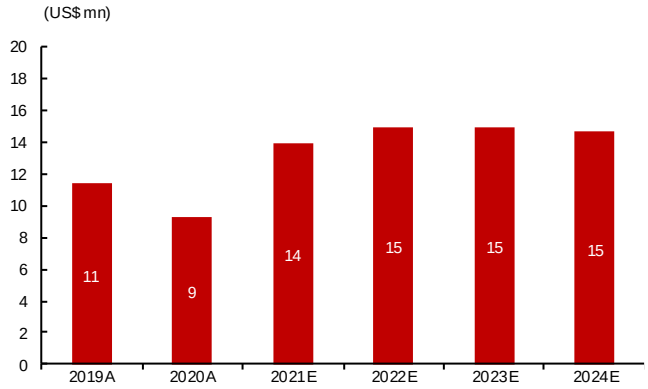
R&D spending to remain stable. We forecast R&D cost to increase from US$11mn/ US$9mn in FY19A/ 20A to US$14mn/ US$15mn/ US$15mn in FY21E/ 22E/ 23E.

Figure 39: Cash and cash equivalent forecasts



Source: Company data, CMBIS estimates

Figure 40: R&D expenses forecasts



Source: Company data, CMBIS estimates

Financial Statements

Income statement

YE 31 Dec (US$ mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue	**8**	**3**	**10**	**19**	**41**
Medical devices and consumables	8	3	10	19	41
Product service and support	0	0	0	0	1
Research sub-award	0	0	0	0	0
Lease revenue	0	0	0	0	0
Cost of sales	-2	-1	-2	-4	-9
Gross profit	**6**	**3**	**8**	**15**	**32**
R&D expenses	-11	-9	-14	-15	-15
Selling and distribution expenses	-9	-6	-9	-13	-19
Administrative expenses	-9	-8	-14	-12	-15
Net impairment losses on financial assets	-0	-0	0	0	0
Other income and gains	0	1	0	0	0
Operating profit	**-23**	**-21**	**-29**	**-26**	**-16**
Finance costs - net	-1	-1	2	2	3
Changes in fair value of convertible redeemable preferred shares	-9	-28	0	0	0
Profit before tax	**-33**	**-49**	**-28**	**-23**	**-14**
Income tax expense	-0	-0	0	0	0
Total net profit	**-33**	**-49**	**-28**	**-23**	**-14**
Minority Interests	-1	-1	-1	-1	-1
Profit attributable to shareholders	**-32**	**-48**	**-27**	**-23**	**-13**

Cash flow summary

YE 31 Dec (US$ mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Profit before tax	**-33**	**-49**	**-28**	**-23**	**-14**
Depreciation for plant and equipment	0	0	1	1	1
Depreciation of right-of-use assets	1	1	0	0	0
Change in working capital	-1	2	5	-4	-3
Others	16	30	1	1	1
Finance costs - net	1	1	-2	-2	-3
Net cash from operating	**-16**	**-16**	**-22**	**-27**	**-17**
Capex	-0	-1	-2	-2	-4
Addition of intangible assets	-0	-0	-2	-2	-2
Other investing activities	0	0	0	0	0
Net cash from investing	**-0**	**-1**	**-4**	**-4**	**-6**
Net proceeds from issue of shares	0	0	200	0	0
Bank borrowing	-3	-2	0	0	0
Other financing activities	20	34	2	2	3
Net cash from financing	**16**	**32**	**202**	**2**	**3**
Net change in cash	0	16	176	-29	-20
Cash at the beginning of the year	3	3	19	195	166
Cash at the end of the year	**3**	**19**	**195**	**166**	**146**

Balance sheet

YE 31 Dec (US$ mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Non-current assets	**13**	**13**	**15**	**17**	**20**
Property, plant and equipment	1	2	4	5	8
Right-of-use assets	1	2	2	2	2
Intangible assets	9	8	9	10	11
Pledged deposits	0	0	0	0	0
Finance lease receivables	0	0	0	0	0
Trade receivables	1	0	0	0	0
Prepayments	0	0	0	0	0
Current assets	**9**	**27**	**198**	**173**	**159**
Trade receivables	3	3	2	4	8
Prepayments	1	2	1	2	3
Due from related parties	0	0	0	0	0
Inventories	2	3	1	2	2
Due from a director	0	0	0	0	0
Pledged deposits	0	0	0	0	0
Finance lease receivables	0	0	0	0	0
Cash and cash equivalents	3	19	195	166	146
Current liabilities	**14**	**14**	**15**	**15**	**18**
Trade payables	0	0	1	1	2
Other payables and accruals	6	9	9	9	9
Due to related parties	2	0	0	0	0
Contract liabilities	0	0	1	1	2
Borrowings	6	4	4	4	4
Lease liabilities	1	1	1	1	1
Non-current liabilities	**82**	**148**	**148**	**148**	**148**
Borrowings	0	0	0	0	0
Contract liabilities	0	0	0	0	0
Lease liabilities	1	1	1	1	1
Convertible redeemable preferred	81	146	146	146	146
Total net assets	**-74**	**-122**	**50**	**27**	**13**
Minority interest	-2	-2	-2	-3	-3
Shareholders' equity	**-74**	**-122**	**50**	**27**	**13**

Key ratios

YE 31 Dec	FY19A	FY20A	FY21E	FY22E	FY23E
Sales mix (%)					
Sales of medical devices	94.2	85.5	95.7	97.2	98.5
Product service and support	3.2	10.2	3.9	2.5	1.4
Research sub-award	2.5	2.9	0.0	0.0	0.0
Lease revenue	0.1	1.3	0.5	0.3	0.1
Total	100.0	100.0	100.0	100.0	100.0
Profit & loss ratios (%)					
Gross margin	74	77	77	78	78
EBITDA margin	-371	-1,410	-266	-122	-33
Pre-tax margin	-403	-1,497	-267	-123	-33
Net margin	-396	-1,480	-263	-120	-32
Effective tax rate	-0	-0	0	0	0
Balance sheet ratios					
Current ratio (x)	1	2	14	11	9
Inventory days	245	546	350	250	180
Trade receivables turnover	185	390	180	150	150
Trade payables turnover	39	68	80	80	80
Net debt to total equity ratio (%)	N/A	N/A	Net	Net	Net
Returns (%)					
ROE	N/A	N/A	-54.7	-87.1	-101.7
ROA	-147.9	-122.3	-12.9	-12.3	-7.6
Per share value					
EPS (RMB)	N/A	N/A	-0.05	-0.04	-0.02
DPS (RMB)	N/A	N/A	0.00	0.00	0.00
BVP (RMB)	N/A	N/A	0.10	0.05	0.03

Source: Company data, CMBIS estimates

Valuation

TP of HK$23.77 based on DCF model

In 2017, Broncus commercialized its advance navigation system, Lung pro, in China and its future cash flows will rely on commercialization of pipeline products. We believe DCF would be a reasonable valuation method to value the Company. We derive TP of HK$23.77 based on a 10-year DCF valuation (WACC: 10.4%, terminal growth rate: 2.0%).

Figure 41: Base case valuation on DCF valuation

DCF Valuation (in US$ mn)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	-29	-26	-16	-1	17	51	120	208	348	548
Tax rate	0.0%	0.0%	0.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%	15.0%
EBIT*(1-tax rate)	-29	-26	-16	-1	14	43	102	177	296	466
+ D&A	2	2	3	3	4	4	4	4	4	4
- Change in working capital	5	-4	-3	-12	-12	-35	-50	-81	-127	-191
- Capx	-2	-2	-4	-4	-3	-3	-3	-3	-3	-3
FCFF	**-24**	**-29**	**-21**	**-14**	**3**	**9**	**53**	**97**	**170**	**276**
Terminal value										**3,347**

Terminal value (US$ mn)	1,242
Total PV (US$ mn)	1,421
Net debt (US$ mn)	-189
Minority interest (US$ mn)	-2
Equity value (US$ mn)	**1,612**
Equity value (HK$ mn)	**12,492**
# of shares outstanding (mn)	526
Price per share (HK$)	**23.77**

Terminal growth rate	**2.0%**
WACC	**10.4%**
Cost of Equity	13.1%
Cost of Debt	5.0%
Equity Beta	0.9
Risk Free Rate	4.0%
Market Risk Premium	10.1%
Target Debt to Asset ratio	30.0%
Effective Corporate Tax Rate	15.0%

Source: CMBIS estimates

Figure 42: Sensitivity analysis (HK$)

	WACC				
Terminal growth rate	9.4%	9.9%	**10.4%**	10.9%	11.4%
1.0%	25.60	23.51	21.66	20.03	18.58
1.5%	26.96	24.66	22.66	20.89	19.32
2.0%	28.50	25.97	**23.77**	21.84	20.15
2.5%	30.26	27.45	25.02	22.91	21.06
3.0%	32.30	29.14	26.44	24.11	22.09

Source: Company data, CMBIS estimates

Investment Risks

Future growth depends substantially on the success of product candidates

Broncus' business substantially depends on the successful development, regulatory approval or CE Marking certification and commercialization of the Company's 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 Broncus may develop in the future. The Company has invested a significant portion of its efforts and financial resources in the development of its existing product candidates. Broncus incurred net losses for the years ended December 31, 2019 and 2020 and for the four months ended April 30, 2020 and 2021, because the expenses the Company incurred exceeded the gross profit generated from the sales of its current products, primarily the LungPoint and the Archimedes System and consumables, with R&D costs alone amounted to 140.9%, 287.0%, 577.1% and 270.6% of its total revenue for the same periods. Whether the Company can generate profit from its operating activities largely depends on the successful commercialization of product candidates.

Uncertain downward changing in price due to bidding process

As of the April 30, 2021, there was generally no tender or bidding process or price guidance set on its 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 Boncus' increasing efforts to promote bronchoscopic navigation and ablation procedures and its navigation and interventional pulmonology therapeutic products in the market, awareness of bronchoscopic navigation and ablation procedures and the Company's 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 Broncus' navigation equipment and interventional pulmonology therapeutic products, it may negatively affect the price of the Company's products and therefore have a material adverse effect on the its business and results of operations.

Uncertainty of medical insurance reimbursement

The governmental insurance coverage or reimbursement level in China for new procedures such as BTPNA and/or navigation-guided 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 results of operations may be adversely affected.

Future legislation may increase the difficulty and cost to obtain approval or CE certification

In China, the US 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 the Company's product candidates, restrict or regulate post-approval or post-CE Marking certification activities and affect its ability to profitably sell Broncus' products and any product candidates for which the Company obtains 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 the Company receives 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 the Company from being able to generate revenue, attain profitability, or commercialize its products.

Clinical product development with an uncertain outcome

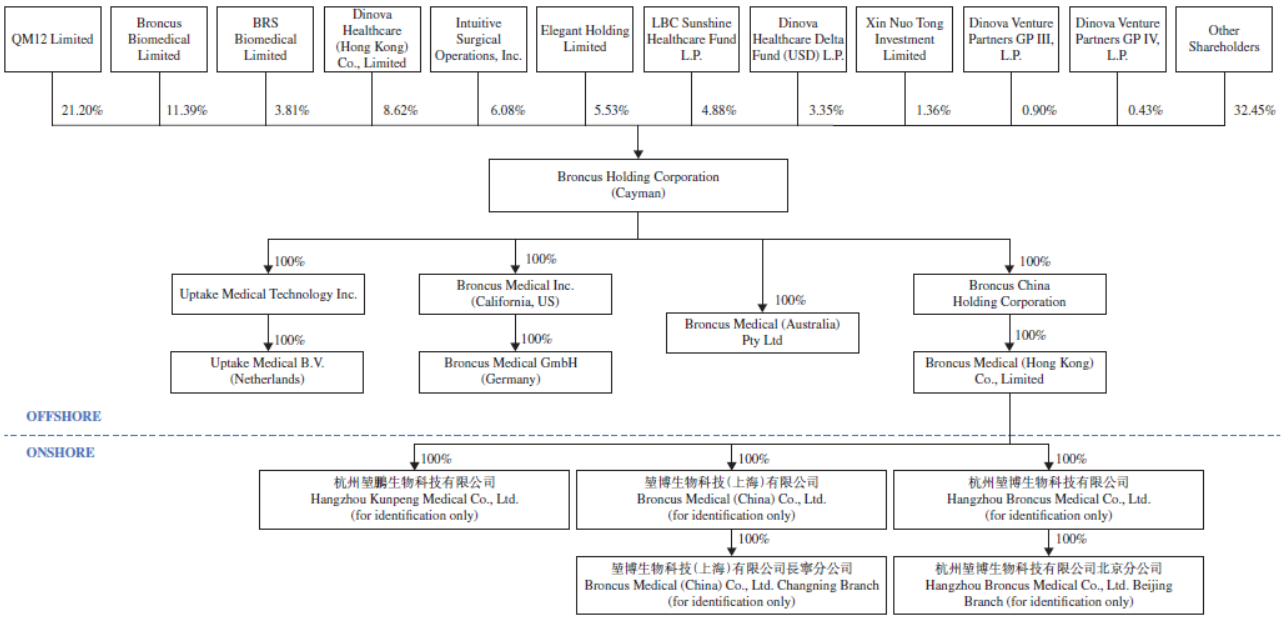
Clinical testing is expensive and can take multiple years to complete, and its outcome is inherently uncertain. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Clinical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

The results of preclinical studies and early clinical trials of its 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 the case of any trials Broncus conducts, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials.

Broncus' future clinical trial results may not be favourable. Even if the Company's future clinical trial results show favourable efficacy, not all patients may benefit. For its 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.

Appendix: Company Profile

Figure 43: Shareholder structure (Pre-IPO)



Source: Company data, CMBIS

Figure 44: Management profile

Name	Age	Date of Joining	Date of Appointment	Position	Roles and Responsibilities
Guowei ZHAN (湛国威)	44	2017/12/01	2021/05/06	Executive Director and CEO	Overall strategic planning, business direction and operational management.
Hong XU (徐宏)	34	2018/02/22	2021/05/06	Executive Director and CTO	Overall strategic planning, business direction and operational management.
Michael Yi Wei ZHAO (赵亦伟)	55	2012/04/30	2012/04/30	Non-executive Director, Chairman of the Board of Directors, chairman of the Nomination Committee and member of the Remuneration Committee	Participating in formulating Company's corporate and business strategies.
Zhenjun ZI (訾振军)	50	2014/02/18	2014/02/18	Non-executive Director	Participating in formulating Company's corporate and business strategies.
Ao ZHANG (张奥)	36	2021/04/29	2021/04/29	Non-executive Director	Participating in formulating Company's corporate and business strategies.
Pok Man KAM (甘博文)	71	2021/04/30	2021/04/30	Independent non-executive Director, chairman of the Audit Committee and member of the Remuneration Committee	Supervising and providing independent judgement to Board.

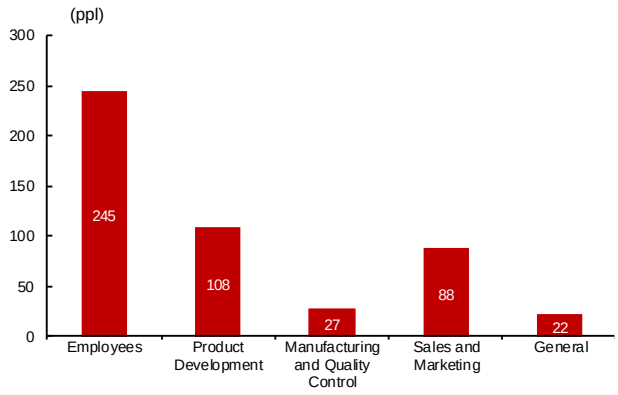
Source: Company data

Figure 45: Employee structure

Function	# of staff	% of Total
Product Development	108	44%
Manufacturing and Quality Control	27	11%
Sales and Marketing	88	36%
General	22	9%
Total	**245**	**100%**

Source: Company data (as of 30 Jun 2021)

Figure 46: Employee number breakdown



Source: Company data (as of 30 Jun 2021)

Disclosures & Disclaimers

Analyst Certification

The research analyst who is primary responsible for the content of this research report, in whole or in part, certifies that with respect to the securities or issuer that the analyst covered in this report: (1) all of the views expressed accurately reflect his or her personal views about the subject securities or issuer; and (2) no part of his or her compensation was, is, or will be, directly or indirectly, related to the specific views expressed by that analyst in this report.
Besides, the analyst confirms that neither the analyst nor his/her associates (as defined in the code of conduct issued by The Hong Kong Securities and Futures Commission) (1) have dealt in or traded in the stock(s) covered in this research report within 30 calendar days prior to the date of issue of this report; (2) will deal in or trade in the stock(s) covered in this research report 3 business days after the date of issue of this report; (3) serve as an officer of any of the Hong Kong listed companies covered in this report; and (4) have any financial interests in the Hong Kong listed companies covered in this report.

CMBIS or its affiliate(s) have investment banking relationship with the issuers covered in this report currently / in preceding 12 months.

CMBIS Ratings

BUY	: Stock with potential return of over 15% over next 12 months
HOLD	: Stock with potential return of +15% to -10% over next 12 months
SELL	: Stock with potential loss of over 10% over next 12 months
NOT RATED	: Stock is not rated by CMBIS
OUTPERFORM	: Industry expected to outperform the relevant broad market benchmark over next 12 months
MARKET-PERFORM	: Industry expected to perform in-line with the relevant broad market benchmark over next 12 months
UNDERPERFORM	: Industry expected to underperform the relevant broad market benchmark over next 12 months

CMB International Securities Limited

Address: 45/F, Champion Tower, 3 Garden Road, Hong Kong, Tel: (852) 3900 0888 Fax: (852) 3900 0800

CMB International Securities Limited ("CMBIS") is a wholly owned subsidiary of CMB International Capital Corporation Limited (a wholly owned subsidiary of China Merchants Bank)

Important Disclosures

There are risks involved in transacting in any securities. The information contained in this report may not be suitable for the purposes of all investors. CMBIS does not provide individually tailored investment advice. This report has been prepared without regard to the individual investment objectives, financial position or special requirements. Past performance has no indication of future performance, and actual events may differ materially from that which is contained in the report. The value of, and returns from, any investments are uncertain and are not guaranteed and may fluctuate as a result of their dependence on the performance of underlying assets or other variable market factors. CMBIS recommends that investors should independently evaluate particular investments and strategies, and encourages investors to consult with a professional financial advisor in order to make their own investment decisions.
This report or any information contained herein, have been prepared by the CMBIS, solely for the purpose of supplying information to the clients of CMBIS or its affiliate(s) to whom it is distributed. This report is not and should not be construed as an offer or solicitation to buy or sell any security or any interest in securities or enter into any transaction. Neither CMBIS nor any of its affiliates, shareholders, agents, consultants, directors, officers or employees shall be liable for any loss, damage or expense whatsoever, whether direct or consequential, incurred in relying on the information contained in this report. Anyone making use of the information contained in this report does so entirely at their own risk.
The information and contents contained in this report are based on the analyses and interpretations of information believed to be publicly available and reliable. CMBIS has exerted every effort in its capacity to ensure, but not to guarantee, their accuracy, completeness, timeliness or correctness. CMBIS provides the information, advices and forecasts on an "AS IS" basis. The information and contents are subject to change without notice. CMBIS may issue other publications having information and/ or conclusions different from this report. These publications reflect different assumption, point-of-view and analytical methods when compiling. CMBIS may make investment decisions or take proprietary positions that are inconsistent with the recommendations or views in this report.
CMBIS may have a position, make markets or act as principal or engage in transactions in securities of companies referred to in this report for itself and/or on behalf of its clients from time to time. Investors should assume that CMBIS does or seeks to have investment banking or other business relationships with the companies in this report. As a result, recipients should be aware that CMBIS may have a conflict of interest that could affect the objectivity of this report and CMBIS will not assume any responsibility in respect thereof. This report is for the use of intended recipients only and this publication, may not be reproduced, reprinted, sold, redistributed or published in whole or in part for any purpose without prior written consent of CMBIS.
Additional information on recommended securities is available upon request.

For recipients of this document in the United Kingdom
This report has been provided only to persons (I)falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended from time to time) ("The Order") or (II) are persons falling within Article 49(2) (a) to (d) ("High Net Worth Companies, Unincorporated Associations, etc.,) of the Order, and may not be provided to any other person without the prior written consent of CMBIS.

For recipients of this document in the United States
CMBIS is not a registered broker-dealer in the United States. As a result, CMBIS is not subject to U.S. rules regarding the preparation of research reports and the independence of research analysts. The research analyst who is primary responsible for the content of this research report is not registered or qualified as a research analyst with the Financial Industry Regulatory Authority ("FINRA"). The analyst is not subject to applicable restrictions under FINRA Rules intended to ensure that the analyst is not affected by potential conflicts of interest that could bear upon the reliability of the research report. This report is intended for distribution in the United States solely to "major US institutional investors", as defined in Rule 15a-6 under the US, Securities Exchange Act of 1934, as amended, and may not be furnished to any other person in the United States. Each major US institutional investor that receives a copy of this report by its acceptance hereof represents and agrees that it shall not distribute or provide this report to any other person. Any U.S. recipient of this report wishing to effect any transaction to buy or sell securities based on the information provided in this report should do so only through a U.S.-registered broker-dealer.

For recipients of this document in Singapore
This report is distributed in Singapore by CMBI (Singapore) Pte. Limited (CMBISG) (Company Regn. No. 201731928D), an Exempt Financial Adviser as defined in the Financial Advisers Act (Cap. 110) of Singapore and regulated by the Monetary Authority of Singapore. CMBISG may distribute reports produced by its respective foreign entities, affiliates or other foreign research houses pursuant to an arrangement under Regulation 32C of the Financial Advisers Regulations. Where the report is distributed in Singapore to a person who is not an Accredited Investor, Expert Investor or an Institutional Investor, as defined in the Securities and Futures Act (Cap. 289) of Singapore, CMBISG accepts legal responsibility for the contents of the report to such persons only to the extent required by law. Singapore recipients should contact CMBISG at +65 6350 4400 for matters arising from, or in connection with the report.