Broncus Holding Corporation
堃博医疗控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2216)

(I) ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2022; AND (II) PROPOSED AMENDMENTS TO THE EXISTING MEMORANDUM AND ARTICLES OF ASSOCIATION AND ADOPTION OF THE NEW MEMORANDUM AND ARTICLES OF ASSOCIATION

The board (the "**Board**") of directors (the "**Directors**") of Broncus Holding Corporation (the "**Company**") is pleased to announce the audited consolidated results of the Company and its subsidiaries (collectively, the "**Group**", "**we**" or "**us**") for the year ended December 31, 2022 (the "**Reporting Period**"), together with the audited comparative figures for the year ended December 31, 2021.

FINANCIAL HIGHLIGHTS

	Year ended December 31, 2022 ***USD'000***	Year ended December 31, 2021 *USD'000*	Year-to-year change
Revenue	**9,413**	10,891	-13.57%
Revenue from sale of medical devices/consumables and others	**9,413**	8,739	
Revenue from licensing fees	**–**	2,152	
Gross Profit	**7,315**	8,742	-16.32%
Loss for the year	**(28,036)**	(236,178)	-88.13%
Add:			
Changes in fair value of convertible redeemable preferred shares	**–**	198,874	-100.00%
Share awards	**1,123**	9,011	-87.54%
Listing expenses	**–**	4,639	-100.00%
Non-IFRS adjusted net loss for the year[(1)]	**(26,913)**	(23,654)	13.78%

(1) Please refer to section headed "Non-IFRS Measures" in this results announcement for more details.

BUSINESS HIGHLIGHTS

The Board is pleased to announce that, from the commencement of the Reporting Period to the date of this announcement, we achieved significant progress with respect to our product pipelines and business operations, with some milestones summarised below:

(i) With respect to the market access and market share of our product, "Mist Fountain", a disposable nebulizing micro-catheter for endoscope, was officially approved for marketing in China in October 2022. BioStarNeedle, a disposable endoscope suction biopsy needle, was approved in the European Union in September 2022. In March 2023, our six products, namely LungPoint, Archimedes, Lungpoint Plus, and Arhchimedes Access Kit (Flexneedle, Sheath and Balloon), were officially approved for marketing by MD-15 regulations of the India authorities.

In 2022 financial year, our products were sold to over 33 countries and regions all over the world, including the United States, the United Kingdom, Germany, France, Japan, etc.

Our core product InterVapor® thermal vapor treatment system has been clinically applied in nearly 20 hospitals in more than 10 provinces/cities in China, after it was approved for marketing in China in March 2022, and the disposable thermal vapor treatment catheter has obtained the sunshine online procurement price in more than 14 provinces/cities.

According to the public information statistics by the Company, in 2022, our navigation products ranked first in China's installed market share.

(ii) With respect to our research and development, the registration clinical trial enrollment for RF-II was completed in December 2021. At present, the data collection of all the primary trial endpoints of the clinical study has been completed, and the clinical study results of the primary endpoints are under evaluation, the clinical trial report of which is expected to be completed in the second quarter of 2023.

For the Targeted Lung Denervation (TLD) Radiofrequency Ablation System, an innovative device for the treatment of acute exacerbation of COPD, the enrollment in the first-in-man (FIM) clinical trials was completed in July 2022, with 9 patients enrolled. The last subject follow-up visit is expected to be completed in the third quarter of 2023. In November 2022, the launch meeting of its multi-center pre-marketing clinical trial investigator program was successfully held, the program passed the review of the Ethics Committee of the leading researcher in February 2023, and the registration clinical trial will be launched in the first quarter of 2023.

In 2022, we participated in the 2022 "Leading Goose" (領雁) R&D project in Zhejiang Province to conduct research on new technologies for the diagnosis and treatment of respiratory diseases.

(iii) With regard to partnership, in May 2022, we officially launched the cooperation to introduce the ultrasound technology into the field of respiratory intervention treatment with Healium Medical Ltd., an Israeli company specializing in the R&D of ultrasound energy therapy and imaging monitoring;

In July 2022, we and Shanghai United Family Healthcare jointly established the "Multi-Disciplinary Diagnostics of Pulmonary Nodules", to jointly explore the new diagnosis and treatment service mode of respiratory intervention targeting groups with high-end medical demands;

In December 2022, we signed a strategic cooperation agreement on medical-engineering integration, with the Guangzhou Institute of Respiratory Health with regard to the lung radio frequency ablation system project & the adjustable and bendable bronchoscope sheath project.

Since December 2022, as the representative for cooperation in the respiratory intervention ecosystem, Broncus signed a partnership agreement for the digital medical innovation center with AstraZeneca.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2022

	Notes	**2022** ***USD'000***	2021 *USD'000*
REVENUE	*5*	**9,413**	10,891
Cost of sales		**(2,098)**	(2,149)
Gross profit		**7,315**	8,742
Other income and gains	*5*	**4,785**	3,129
Selling and distribution expenses		**(11,189)**	(12,706)
Administrative expenses		**(9,229)**	(18,546)
Impairment losses on financial assets, net		**(438)**	(584)
Research and development costs		**(19,167)**	(16,759)
Other expenses		**(12)**	(407)
Finance costs	*7*	**(98)**	(170)
Changes in fair value of convertible redeemable preferred shares		**–**	(198,874)
LOSS BEFORE TAX	*6*	**(28,033)**	(236,175)
Income tax expense	*8*	**(3)**	(3)
LOSS FOR THE YEAR		**(28,036)**	(236,178)
Attributable to:			
Owners of the parent		**(28,036)**	(235,784)
Non-controlling interests		**–**	(394)
		(28,036)	(236,178)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (USD)	*10*	**(0.06)**	(0.79)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2022

	2022 ***USD'000***	2021 *USD'000*
LOSS FOR THE YEAR	**(28,036)**	(236,178)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**(2,160)**	162
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	**(2,160)**	162
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	**(30,196)**	(236,016)
Attributable to:		
Owners of the parent	**(30,196)**	(235,625)
Non-controlling interests	**–**	(391)
	(30,196)	(236,016)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2022

	Notes	**2022**	2021
		USD'000	*USD'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**2,402**	2,729
Intangible assets		**5,910**	7,036
Right-of-use assets		**1,354**	1,907
Financial assets at fair value through profit or loss		**7,603**	–
Finance lease receivables		**67**	72
Trade receivables	*11*	**1,493**	1,681
Prepayments, other receivables and other assets		**247**	451
Pledged deposits		**–**	213
Total non-current assets		**19,076**	14,089
CURRENT ASSETS			
Inventories		**4,298**	4,192
Finance lease receivables		**25**	44
Trade and bills receivables	*11*	**8,598**	5,663
Prepayments, other receivables and other assets		**1,510**	1,586
Pledged deposits		**526**	25
Time deposits with original maturity over three months		**81,153**	–
Cash and cash equivalents		**106,756**	227,207
Total current assets		**202,866**	238,717
CURRENT LIABILITIES			
Trade payables	*12*	**321**	400
Lease liabilities		**652**	739
Other payables and accruals		**6,116**	7,438
Bank overdrafts		**29**	13
Contract liabilities		**299**	374
Total current liabilities		**7,417**	8,964
NET CURRENT ASSETS		**195,449**	229,753
TOTAL ASSETS LESS CURRENT LIABILITIES		**214,525**	243,842

	2022 *USD'000*	2021 *USD'000*
TOTAL ASSETS LESS CURRENT LIABILITIES	**214,525**	243,842
NON-CURRENT LIABILITIES		
Lease liabilities	**790**	1,196
Other payables and accruals	**175**	200
Contract liabilities	**102**	28
Total non-current liabilities	**1,067**	1,424
Net assets	**213,458**	242,418
EQUITY		
Equity attributable to owners of the parent		
Share capital	**12**	12
Reserves	**213,446**	242,406
Total equity	**213,458**	242,418

1. CORPORATE AND GROUP INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on 30 April 2012. The registered address of the Company is PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. The head office and principal place of business in China is located at No. 88 Jiangling Road, Xixing Street, Binjiang District, Hangzhou, Zhejiang Province, People's Republic of China (the "PRC").

The Company is an investment holding company. During the year, the Group was principally engaged in research and development, and the manufacture and commercialisation of medical devices and consumables.

The shares of the Company were listed on the Main Board of The Stock Exchange of Hong Kong Limited (the "Stock Exchange") on 24 September 2021.

2. BASIS OF PREPARATION

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs") issued by the International Accounting Standards Board ("IASB") and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for financial assets at fair value through profit or loss which have been measured at fair value. These consolidated financial statements are presented in USD and all values are rounded to the nearest thousand except when otherwise indicated.

3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following revised IFRSs for the first time for the current year's consolidated financial statements.

Amendments to IFRS 3	*Reference to the Conceptual Framework*
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*
Amendments to IAS 37	*Onerous Contracts – Cost of Fulfilling a Contract*
Annual Improvements to IFRS Standards 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

The nature and the impact of the revised IFRSs that are applicable to the Group are described below:

(a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* (the "Conceptual Framework") issued in March 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no business combinations during the year, the amendments did not have any impact on the financial position and performance of the Group.

(b) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items as determined by IAS 2 *Inventories*, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced prior to the property, plant and equipment being available for use, the amendments did not have any impact on the financial position or performance of the Group.

(c) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.

(d) *Annual Improvements to IFRS Standards 2018-2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:

- IFRS 9 *Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively from 1 January 2022. As there was no modification or exchange of the Group's financial liabilities during the year, the amendment did not have any impact on the financial position or performance of the Group.

4. OPERATING SEGMENT INFORMATION

For management purposes, the Group is not organised into business units based on their products and only has one reportable operating segment. Management monitors the operating results of the Group's operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment.

Geographical information

(a) Revenue from external customers

	2022	2021
	USD'000	*USD'000*
Mainland China	**5,813**	6,022
European Union	**2,016**	2,087
USA	**172**	718
Other countries/regions	**1,412**	2,064
	9,413	10,891

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	2022	2021
	USD'000	*USD'000*
USA	**6,104**	7,098
Mainland China	**3,626**	4,819
European Union	**27**	43
Other countries/regions	**4**	3
Total	**9,761**	11,963

The non-current asset information above is based on the locations of the assets and excludes financial instruments.

Information about major customers

Revenue from each major customer which accounted for 10% or more of the Group's revenue during the reporting period is set out below:

	2022	2021
	USD'000	*USD'000*
Customer A	**4,870**	2,250
Customer B	**N/A***	2,152

* The corresponding revenue of the customer is not disclosed as the revenue individually did not account for 10% or more of the Group's revenue during the reporting period.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2022	2021
	USD'000	*USD'000*
Revenue from contracts with customers		
Sale of medical devices and consumables	**8,929**	8,241
Licensing of intellectual property rights	**–**	2,152
Provision of services	**436**	488
Revenue from other sources		
Gross rental income	**48**	10
	9,413	10,891

Revenue from contracts with customers

(a) Disaggregated revenue information

	2022	2021
	USD'000	*USD'000*
Geographical markets		
Mainland China	**5,813**	6,022
European Union	**1,968**	2,087
USA	**172**	708
Other countries/regions	**1,412**	2,064
	9,365	10,881
Timing of revenue recognition		
Goods transferred at a point in time	**8,929**	10,393
Services transferred over time	**436**	488
	9,365	10,881

The following table shows the amounts of revenue recognised in the current reporting period that were included in the contract liabilities at the beginning of the reporting period:

	2022	2021
	USD'000	*USD'000*
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Sale of medical devices and consumables	**45**	260
Provision of services	**328**	231
	373	491

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sale of medical devices and consumables

Revenue from the sale of medical devices and consumables is recognised at the point in time when control of the asset is transferred to the customer.

Provision of services

Revenue from the product support services is recognised over the service period on a straight-line basis and revenue from research development support services is recognised over time using an input method to measure progress towards complete satisfaction of the service, because the customer simultaneously receives and consumes the benefits provided by the Group.

Licensing of intellectual property rights

Revenue from the licensing of intellectual property rights is recognised at the point in time when the licensee is granted with a right to use the intellectual property rights.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follows:

	2022	2021
	USD'000	*USD'000*
Amounts expected to be recognised as revenue:		
Within one year	**471**	381
After one year	**102**	28
	573	409

The amounts of transaction prices allocated to the remaining performance obligations which are expected to be recognised as revenue after one year relate to provision of services, of which the performance obligations are to be satisfied within two years. All the other amounts of transaction prices allocated to the remaining performance obligations are expected to be recognised as revenue within one year.

An analysis of other income and gains is as follows:

	2022	2021
	USD'000	*USD'000*
Other income		
Government grants *(note a)*	**497**	1,840
Compensation from a licence agreement	**–**	1,000
Bank interest income	**2,558**	117
Interest income from non-current receivables	**70**	44
Others	**106**	14
	3,231	3,015
Gains		
Foreign exchange gains, net	**691**	–
Fair value gains, net:		
Financial assets at fair value through profit or loss	**863**	–
Gain on disposal of items of property, plant and equipment	**–**	96
Gain on termination of leases	**–**	18
	1,554	114
	4,785	3,129

Note:

(a) The government grants for the year ended 31 December 2022 mainly represent incentives received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new product development and compensation for expenditure incurred on certain projects.

6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	2022	2021
	USD'000	*USD'000*
Cost of inventories sold	**2,098**	1,825
Cost of services provided	**–**	64
Cost of licensing of intellectual property rights	**–**	250
Research and development costs	**19,167**	16,759
Loss/(gain) on disposal of items of property, plant and equipment	**5**	(96)
Changes in fair value of convertible redeemable preferred shares	**–**	198,874

7. FINANCE COSTS

An analysis of finance costs is as follows:

	2022	2021
	USD'000	*USD'000*
Interest on bank borrowings	**–**	51
Interest on lease liabilities	**98**	119
	98	170

8. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

PRC

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), the subsidiaries which operate in Mainland China were entitled to a preferential income tax rate of 2.5% (2021: 2.5%) for small and micro enterprises except that Hangzhou Broncus Medical Co., Ltd. was subject to CIT at a rate of 15% (2021: 15%) for a High and New Technology Enterprise on the taxable income.

USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of up to 21% (2021: 21%) on the taxable income arising in the USA during the year.

Netherlands

The subsidiary incorporated in Netherlands was subject to income tax at the rate of 15% (2021: 15%) on the estimated assessable profits arising in Netherlands during the year.

Australia

The subsidiary incorporated in Australia was subject to income tax at the rate of 27.5% (2021: 27.5%) on the estimated assessable profits arising in Australia during the year.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong

The subsidiary incorporated in Hong Kong was subject to income tax at the rate of 16.5% (2021: 16.5%) on the estimated assessable profits arising in Hong Kong during the year.

The income tax expense of the Group during the year is analysed as follows:

	2022	2021
	USD'000	*USD'000*
Current – USA		
Charge for the year	**3**	3

9. DIVIDEND

No dividend has been paid or declared by the Company during the year (2021: Nil). The Board has resolved not to recommend the payment of a final dividend for the year ended 31 December 2022 (2021: Nil).

10. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 487,749,376 (2021: 298,960,470) in issue during the year. The number of shares for the current period has been arrived at after eliminating the shares of the Company held under the restricted stock unit scheme.

The calculation of basic loss per share is based on:

	2022	2021
	USD'000	*USD'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(28,036)**	(235,784)

	Number of shares	
	2022	2021
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**487,749,376**	298,960,470

As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2022 and 2021 in respect of a dilution as the impact of the equity-settled share award arrangements had an anti-dilutive effect on the basic loss per share amounts presented.

11. TRADE AND BILLS RECEIVABLES

	2022	2021
	USD'000	*USD'000*
Current		
Trade receivables	**9,837**	5,996
Bills receivable	**–**	514
	9,837	6,510
Non-current		
Trade receivables	**1,494**	1,682
	11,331	8,192
Impairment	**(1,240)**	(848)
	10,091	7,344

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	2022	2021
	USD'000	*USD'000*
Within 3 months	**5,511**	4,194
3 to 6 months	**67**	1,951
6 to 12 months	**1,914**	667
1 to 2 years	**2,599**	18
	10,091	6,830

12. TRADE PAYABLES

	2022	2021
	USD'000	*USD'000*
Trade payables	**321**	400

An ageing analysis of the trade payables as at the end of the reporting period, based on the invoice date, is as follows:

	2022	2021
	USD'000	*USD'000*
Within 3 months	**308**	397
3 to 6 months	**11**	1
6 to 12 months	**1**	2
Over 1 year	**1**	–
	321	400

The trade payables are non-interest-bearing and are normally settled on 30-day terms.

MANAGEMENT DISCUSSION AND ANALYSIS

MARKET REVIEW

Facing the global prevalence of COPD and lung cancer that has been propelled by aging population, air pollution and smoking habit, we see a huge market need for minimally invasive solutions to treat lung diseases. According to Frost & Sullivan, in 2022, there were 233.6 million cases of chronic obstructive pulmonary disease in the world and 107 million cases in China, which are expected to increase to 258.4 million and 109.6 million in by 2025, respectively. On November 16, 2022, China COPD Care Conference was held in Beijing, which published the Annual Report of the National Center for Respiratory Medicine on COPD and information on the major COPD-affected areas in 2022. In terms of incidence, the prevalence rate of people over 40 years old reached 13.7%, and that of people over 70 years old reached as high as 30%. According to Frost & Sullivan, among the COPD patients, 27.0% are at severe or extreme severe stages in China, who would face a mortality rate of 54.0% within five years without proper treatment. Therefore, the whole population of COPD patients, especially patients in severe and extremely severe conditions, is in great need of effective COPD therapeutic solutions.

Global lung cancer incidence reached approximately 2.26 million people in 2020 and is expected to further increase to 2.5 million 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 0.9 million in 2020 and is expected to further increase to more than 1.0 million by 2025. Among these patients, over half of them are diagnosed with the cancer already at late stages at first diagnosis with a five-year survival rate as low as 12.6% for stage III patients and 2.9% for stage IV patients, according to Frost & Sullivan. Early diagnosis and treatment is an effective way to improve the overall survival rate of lung cancer patients. Patients can effectively receive an early diagnosis, and safe and effective treatment solutions at an early stage to achieve a higher survival rate.

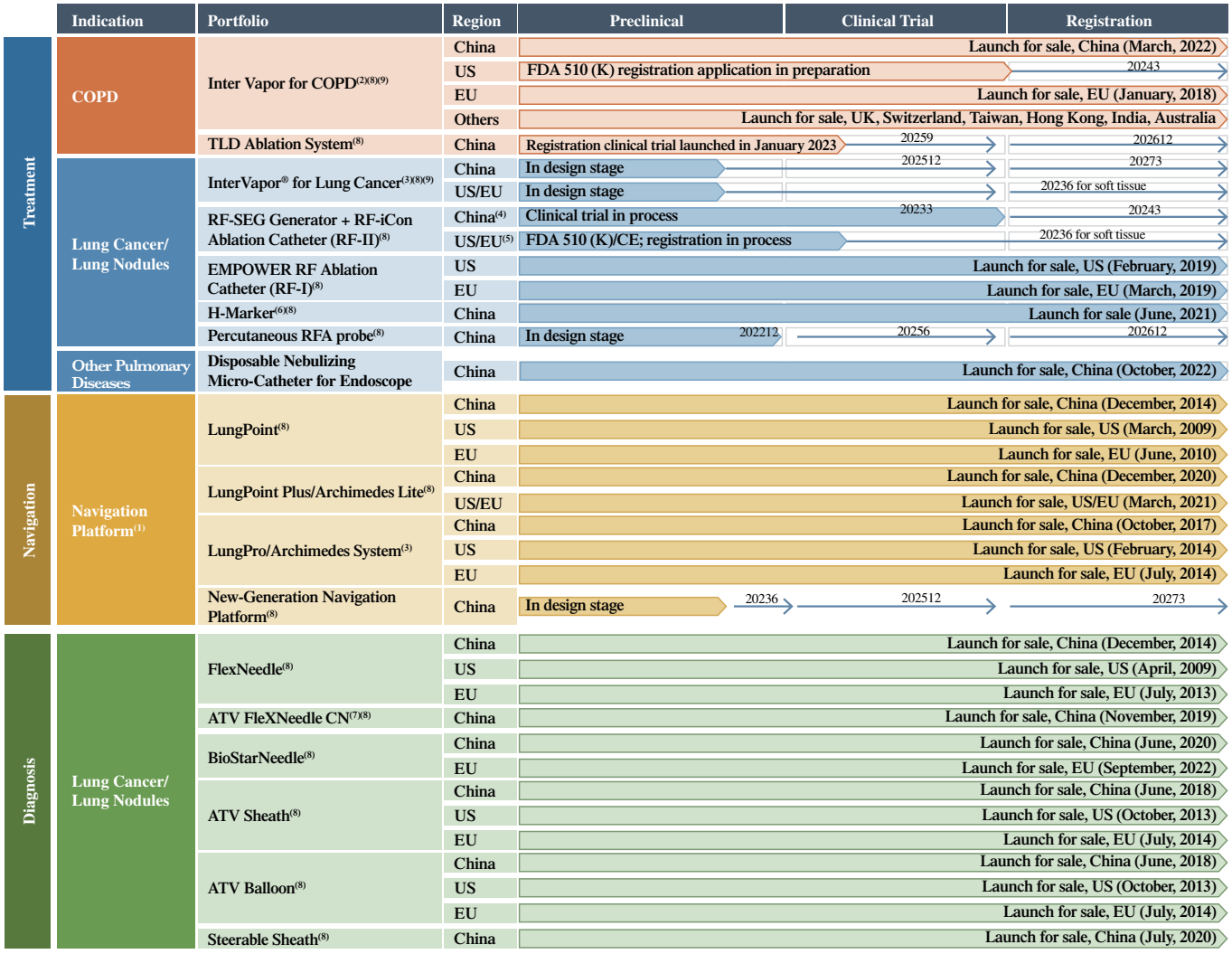
BUSINESS REVIEW

Founded in 2012, we are a pioneer medical device company in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Based on the proprietary whole lung access navigation technology, we have developed an integrated interventional pulmonology platform including navigation, diagnosis and treatment, and improved the diagnosis and treatment effect of lung cancer and COPD through a series of lung disease diagnosis and treatment product lines, thus addressing the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases.

As of December 31, 2022, we had 18 products and major product candidates under various stages. Our core products are the InterVapor® and RF-II. InterVapor® is the world's first and only Thermal Vapor Treatment System to treat lung diseases including COPD and lung cancer. RF-II is a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer.

Our products and product pipeline

Set out below are the development status of our products and major product candidates on our three-in-one pulmonology platform as at the date of this results announcement:



Notes:

1. Our navigation systems have been approved for marketing in the U.S., EU and PRC. Post-market study (EAST 2 Trial) for the Archimedes System has been completed.

2. In March 2022, the Company's InterVapor® has been granted approval for marketing by the NMPA.

3. The clinical study report of R&D clinical trial (VAPORIZE trial) was completed in July 2021.

4. The Company has completed the enrollment of all subjects for the clinical trial.

5. Expect to leverage clinical data collected in China to apply for registrations in the U.S. and EU.

6. The clinical trial has been completed and the registration in the PRC was approved in June 2021.

7. The version of FleXNeedle manufactured in China.

8. Our in-house developed products refer to products that we have developed as the sponsor of their clinical trials.

9. Subsequent to the acquisition of InterVapor® from Uptake Medical Corp, we continue to improve InterVapor® by sponsoring clinical trials in China and overseas to obtain approvals from local authorities.

Business highlights

The Board is pleased to announce that, from the commencement of the Reporting Period to the date of this announcement, we achieved significant progress with respect to our product pipelines and business operations, with some milestones summarised below:

(i) With respect to the market access and market share of our product, "Mist Fountain", a disposable nebulizing micro-catheter for endoscope, was officially approved for marketing in China in October 2022. BioStarNeedle, a disposable endoscope suction biopsy needle, was approved in the European Union in September 2022. In March 2023, our six products, namely LungPoint, Archimedes, Lungpoint Plus, and Arhchimedes Access Kit (Flexneedle, Sheath and Balloon), were officially approved for marketing by MD-15 regulations of the India authorities.

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Our core product InterVapor® thermal vapor treatment system has been clinically applied in nearly 20 hospitals in more than 10 provinces/cities in China, after it was approved for marketing in China in March 2022, and the disposable thermal vapor treatment catheter has obtained the sunshine online procurement price in more than 14 provinces/cities.

According to the public information statistics by the Company, in 2022, our navigation products ranked first in China's installed market share.

(ii) With respect to our research and development, the registration clinical trial enrollment for RF-II was completed in December 2021. At present, the data collection of all the primary trial endpoints of the clinical study has been completed, and the clinical study results of the primary endpoints are under evaluation, the clinical trial report of which is expected to be completed in the second quarter of 2023.

For the Targeted Lung Denervation (TLD) Radiofrequency Ablation System, an innovative device for the treatment of acute exacerbation of COPD, the enrollment in the first-in-man (FIM) clinical trials was completed in July 2022, with 9 patients enrolled. The last subject follow-up visit is expected to be completed in the third quarter of 2023. In November 2022, the launch meeting of its multi-center pre-marketing clinical trial investigator program was successfully held, the program passed the review of the Ethics Committee of the leading researcher in February 2023, and the registration clinical trial will be launched in the first quarter of 2023.

In 2022, we participated in the 2022 "Leading Goose" (領雁) R&D project in Zhejiang Province to conduct research on new technologies for the diagnosis and treatment of respiratory diseases.

(iii) With regard to partnership, in May 2022, we officially launched the cooperation to introduce the ultrasound technology into the field of respiratory intervention treatment with Healium Medical Ltd., an Israeli company specializing in the R&D of ultrasound energy therapy and imaging monitoring;

In July 2022, we and Shanghai United Family Healthcare jointly established the "Multi-Disciplinary Diagnostics of Pulmonary Nodules", to jointly explore the new diagnosis and treatment service mode of respiratory intervention targeting groups with high-end medical demands;

In December 2022, we signed a strategic cooperation agreement on medical-engineering integration, with the Guangzhou Institute of Respiratory Health with regard to the lung radio frequency ablation system project & the adjustable and bendable bronchoscope sheath project;

Since December 2022, as the representative for cooperation in the respiratory intervention ecosystem, Broncus signed a partnership agreement for the digital medical innovation center with AstraZeneca.

Core products

InterVapor®

InterVapor® is the world's first and only Thermal Vapor Treatment System to treat lung diseases including COPD and lung cancer. It is a therapeutic device that delivers thermal vapor bronchoscopically to the lung to achieve targeted ablation.

We first initiated the pre-clinical R&D for InterVapor® in September 2010, and commenced our first trial in West China Hospital, the PRC in November 2017 and BTVA Registry study in April 2018. With our seamless effort in research and development, in 2018, InterVapor® was accredited with an EC certificate (CE 678945) from the BSI Group, the Netherlands B.V. and was classified as a Class II medical device in the European Economic Area. In March 2022, InterVapor® was approved by NMPA with registration certificate number (國械註進 20223090145 and 國械註進 20223090144). In July, the first clinical applications of InterVapor® were completed in Guangdong Province and Shaanxi Province after the approval for marketing in China, and the clinical applications were quickly carried out in Liaoning Province, Beijing City and other places, thus significantly benefiting the patients. Despite the impact of the pandemic, the progress in the procurement of the product and its entry into hospitals in China was promoted in an orderly manner. The product prices of the disposable thermal vapor treatment catheter were collected by the open and fair procurement platform in over 14 provinces and cities, which provides a price reference for medical institutions in bargaining and procurement.

Based on our InterVapor® system, we have developed InterVapor® for COPD and InterVapor Plus for lung cancer targeting COPD treatment and lung cancer treatment, respectively.

- InterVapor® for COPD is designed for COPD treatment through thermal vapor energy ablation. It delivers thermal vapor to the airway of the targeted location of the lung, which requires precise catheter placement and enhanced imaging. It is the world's first interventional pulmonology device using thermal vapor based energy.

- InterVapor plus 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 by the application of thermal vapor to the bronchus of the lung region targeted for treatment and can sufficiently cover the lesion area with appropriate dose of energy.

As of December 31, 2022, the clinical history of InterVapor® includes (1) step-up trial; (2) next-step trial; (3) Vaporize trial; (4) West China Hospital trial; and (5) BTVA Registry study. We completed the patient enrollment and follow-up visit in the next-step trial in June 2020, and the formal study report was completed before September 2021. We also completed the clinical study report on the Vaporize trial in July 2021 to explore the use of InterVapor® for a new indication (lung cancer). The results of the study suggest that bronchoscopic thermal vapor ablation of lung tumors is feasible and well tolerated without major surgery-related complications. With regard to the BTVA Registry Study in EU, as at February 9, 2023, a total of 354 therapeutic procedures were performed on 231 patients enrolled in 17 study centers, without reports on device-related serious adverse events. We plan to close the Registry study upon the commencement of the German government-sponsored BENTO study. In 2023, we will plan to launch various BTVA multicenter clinical studies in China to discuss product use scenarios in more dimensions and to further improve safety information collection.

We are also in the process of preparing the FDA 510k clearance of InterVapor® for COPD in the United States. The InterVapor® registration application was submitted to the Philippine competent authority in February 2022 and to the Malaysian competent authority in November 2022. It is currently under review and is expected to be approved in the second quarter of 2023.

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. RF-II is classified as a Class III medical device in China and Class II medical device in EU and the U.S.

The enrollment in the registered clinical trial of RF-II was completed in December 2021. Data collection for all major trial endpoints of the clinical study was completed, and trial data are being cleaned. The clinical trial report on the study is expected to be completed in the second quarter of 2023 and will be submitted to NMPA for completion of the medical device marketing review process. Clinical study results for its primary endpoint are being evaluated. In addition, we are preparing an application for the FDA 510k approval and CE registration submission for RF-II. We will also cooperate with key opinion leaders to hold regular training courses for doctors to explain relevant technologies in more detail. After we start the research and development process, RF-II is expected be commercialized within seven years.

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET INTERVAPOR® AND RF-II SUCCESSFULLY.

Our other products and product candidates

TLD

TLD, a Targeted Lung Denervation product developed jointly with West China Hospital of Sichuan University, is the first product independently developed by China for the treatment of COPD by transbronchial radiofrequency ablation, which is expected to be important for COPD treatment by providing deeper tissue ablation around the main bronchus in the lungs to reduce the tension and mucus production in the airway and relieve airway obstruction. TLD mainly destroys motor axons of the peripheral bronchial nerve, blocks parasympathetic transmission in the pulmonary and reduces acetylcholine release, resulting in effects similar to anticholinergics which include reducing airway smooth muscle tension and mucus production, thereby alleviating airway obstruction.

We completed the clinical trial of the first application of the Targeted Lung Denervation (TLD) radiofrequency ablation system in the human body in July 2022 and completed the enrollment of all subjects in July 2022. All subject follow-up visits will be completed in July 2023. The clinical trial report for the study will not be completed before the time point and is expected to be published by the end of 2023. The clinical trial investigator protocol discussion meeting for the key clinical study on TLD products was held in November 2022, the program passed the review of the Ethics Committee of the leading researcher in February 2023, and the study was scheduled to be officially launched in the first quarter of 2023. The study was a prospective, randomized, single-blind, sham-operated group-controlled multicenter clinical trial. A total of 189 patients with moderate to severe COPD were planned to be enrolled in 26 research centers in China to evaluate the safety and effectiveness of the product. The study is expected to have a 28-month enrollment period and a 12-month follow-up period, with LPOs expected in July 2026. Clinical trial reports and data publicity will not be completed before the time point.

"Mist Fountain", a disposable nebulizing micro-catheter for endoscope

The "Mist Fountain" nebulizing micro-catheter is used in conjunction with the endoscope. Under the guidance of the navigation system, it can accurately reach the lesion site, atomize and administer the drug, and directly deliver the drug to the lung lesion tissue. The product has strong compatibility and multiple indications. It is compatible with many kinds of drugs and is mainly used for accurate anti-inflammation, local hemostasis, phlegm reduction and elimination, staining location, local anesthesia, etc.

Through the microfluidic chip, the "Mist Fountain" nebulizing micro-catheter sprays out the drug with a particle size as small as about 20μm, which enables the direct delivery of the particles of the drug to local lesion tissues, the increased local drug concentration, the more uniform distribution, the long attachment duration, the long anti-inflammation and the stable drug effect. The catheter body is made of safe materials and features good drug compatibility with various drugs, as well as wide indications. The front end of the microfluidic chip is blunt, which enables the smooth entry of the catheter in the operation process and protects the bronchial tube wall, showing good safety, thus reducing the risk of tissue damage. It features compatibility with bronchoscopes of different brands, simple operation and high popularity.

The product was officially approved for marketing by Zhejiang Medical Products Administration in October 2022, thus becoming the only approved nebulizing micro-catheter in China. The product with multiple patented technologies helps explore a wide range of applications of drugs in conjunction with devices in the treatment of lung diseases.

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 the operation process of other existing positioning tools, H-Marker is simpler, more reliable and less likely to damage blood vessels with its self-expanding characteristics and spindle shape.

We have received the designation of H-Marker as a Class II "innovative medical device", which is eligible for expedited approval, by Zhejiang MPA (浙江省藥品監督管理局) in October 2020 and obtained the Zhejiang MPA approval in June 2021.

LungPoint, LungPoint Plus/Archimedes Lite and Archimedes systems

As the world's only provider of transbronchial whole lung augmented reality navigation technology, we currently have three marketed navigation products, including LungPoint, LungPoint Plus (known as "Archimedes Lite" outside Asia) and LungPro (known as "Archimedes" outside China).

- LungPoint, or LungPoint Virtual Bronchoscopic Navigation, is a computer-assisted image-based navigation software system which, along with a set of biopsy tools, provides doctors with real-time path navigation within the airways and further localization guidance to a targeted area of interest in the lung for lung biopsy and other procedures. LungPoint was approved for marketing and commercial use in the U.S. by the FDA in 2009, the EU by the BSI in 2011, and the PRC by the NMPA in 2014. LungPoint is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

- LungPoint Plus/Archimedes Lite, which was launched in 2020, 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 and was launched for sale in EU and the U.S. in March 2021. LungPoint Plus is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

- The LungPoint ATV System, also known as LungPro in China or the Archimedes System outside China (the "**Archimedes System**"), is an upgraded product based on the LungPoint VBN system. The Archimedes System takes the application of the VBN technology to the next level by adopting a novel approach to enable precise navigation and localize peripheral lesions away from or adjacent to the airway. The Archimedes System was approved for marketing and commercial use in the U.S. by the FDA in 2014, the EU by the BSI in 2014, and the PRC by the NMPA in 2017. The Archimedes System is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET H-MARKER, LUNGPOINT, LUNGPOINT PLUS/ARCHIMEDES LITE, THE ARCHIMEDES SYSTEM, OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

Manufacturing

During the Reporting Period, we carried out our manufacturing activities at our production centers based in Hangzhou, China and San Jose, the U.S. where we manufacture navigation products and InterVapor® in the U.S. and certain consumables in China. The production center in Hangzhou, China occupies an aggregate of gross floor area of approximately 3,122 sq.m. and the production center in San Jose, the U.S., occupies an aggregate area of approximately 863 sq.m.

Manufacturing of our therapeutic products and product candidates

Historically, early navigation products were developed by our U.S. team and we have mainly manufactured our navigation products in the U.S. In order to leverage the labor and material cost advantages in China over the U.S., we are in the process of moving the manufacturing process of our products gradually to China. Starting from June 2021, we have begun to manufacture our H-Marker in our Hangzhou facility. We started to produce our other therapeutic products (including InterVapor® products) in Hangzhou factory in 2021. It is expected that NMPA registration approval will be obtained for domestic InterVapor® in May 2023, and the subsequent production process will completely move to China.

Manufacturing of our navigation systems

Our navigation systems, including our LungPoint, LungPoint Plus and Archimedes System, are manufactured in our San Jose, California facility in the U.S. This facility is ISO13485 compliant and Broncus Medical is the manufacturer of record in US 510(k) clearance and European CE Marked LungPoint products. NMPA correction notice was received on October 27, 2022 for domestic LungPoint, which is expected to be approved in May 2023. A registration application for the domestic Archimedes system (whole lung navigation system, known as LungPro in China) is expected to be submitted in the first quarter of 2023 and approved in September 2023.

Manufacturing of our diagnosis medical consumables and product candidates

Our main production facility for diagnosis medical consumables and product candidates is our Hangzhou facility. We can expand our production capacity quickly in response to market demand.

Research and development

We focus on developing innovative technologies and products for navigation, diagnosis and treatment of pulmonary diseases. We have a proven track record of developing and commercializing interventional pulmonology medical devices. To strengthen our R&D capabilities, we adopt an efficient R&D model that combines international technologies with local R&D cost advantage, and participate in government scientific research projects, such as the 2022 "Leading Goose" (領雁) R&D project in Zhejiang Province, to support our intellectual property portfolio and product iterations.

We are engaged in ongoing R&D activities to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, reliability, and to expand the applications of our products as appropriate. As of the date of this announcement, we had 18 product candidates in various stages.

The expenditure on the R&D activities of InterVapor® and RF-II primarily consisted of:

- clinical trials of InterVapor® on lung cancer in China and U.S. or the EU;
- clinical trials of RF-II and its research and development in China;
- construction of InterVapor® R&D laboratory and investment in the R&D equipment used for InterVapor®;
- post-marketing studies in China, U.S., EU and other countries; and
- registration in China, U.S and other countries

Sales and marketing

Currently, we primarily sell and market our interventional pulmonary products in the U.S., Europe and Asia. As our current products and product candidates receive more marketing approval or CE Marking certification, we expect to generate more sales globally.

We adopt both direct sales and sales through distributors arrangement. During the Reporting Period, we sell products both directly to hospitals and through distributors, including our navigation systems such as the Archimedes System and LungPoint, InterVapor® catheter and certain medical consumables. In line with market practice, we sell a significant portion of our navigation systems to distributors who resell our products to hospitals. The following table sets forth the number of hospitals to which we sold products directly for the year indicated.

	For the year ended December 31,	
	2022	2021
Direct sales to hospitals	**66**	68
• Europe	**39**	33
• USA	**20**	22
• PRC (Mainland)	**3**	7
• Others	**4**	6

The following table set forth the number of distributors to whom we directly sold products for the year indicated.

	For the year ended December 31,	
	2022	2021
Distributors	**55**	43
• PRC (Mainland)	**36**	22
• Europe	**8**	10
• Asia (excluding China) and other regions	**11**	11

For the year ended December 31, 2022, our revenue generated from distributors and direct sales accounted for approximately US$7.1 million and US$2.3 million, respectively, compared to US$6.0 million and US$4.9 million in the corresponding period last year.

Intellectual Property

As of December 31, 2022, we obtained 748 patents and patent applications which consisted of 359 issued patents (including pending announcements) and 198 patent applications in China and 105 issued patents and 86 patent applications overseas including key markets such as the U.S. and the EU. Among the patents obtained, 117 and 50 of them are related to InterVapor® and RF-II, respectively.

Strategic Cooperation

In February 2022, we entered into a strategic cooperation agreement with Healium Medical Ltd. ("**Healium**"), an Israeli company specializing in the development of ultrasound energy therapy and imaging monitoring. The cooperation aims to integrate energy ablation and ultrasound technology, so that the operator can realize real-time monitoring of the state of ablated tissues without frequently changing devices, thus effectively avoiding insufficiency or excess of energy in the treatment process, promoting the predictability of treatment results, simplifying the operation, improving the safety and effectiveness of the operation, and the popularization of interventional surgery in the treatment of lung diseases. The cooperation was approved by Israel IIA and the input and output confirmation of R&D design was officially initiated in May 2022.

In July 2022, we and Shanghai United Family Healthcare jointly established the "Multi-Disciplinary Diagnostics of Pulmonary Nodules", to cover the population with high-end commercial insurance. This is the first step in the strategic cooperation between the parties. In the future, the parties will continue to jointly explore new models of respiratory intervention diagnosis and treatment services as well as other cutting-edge technologies for groups with high-end medical needs.

In November 2022, we entered into a strategic partnership with Eternal Asia, a leading enterprise in supply chain services in China, so as to give full play to the core advantages of the parties, integrate resources through a cooperation platform, complement each other's advantages, and enhance competitiveness. Eternal Asia will use its professional supply chain services to facilitate the coverage of Broncus pulmonary intervention diagnosis and treatment products over a wider market.

In December 2022, we signed a strategic cooperation agreement on medical-engineering integration, with Guangzhou Institute of Respiratory Health with regard to the lung radio frequency ablation system project & the adjustable and bendable bronchoscope sheath project. Based on their respective advantages in medical resources and technology platforms, the parties will establish a comprehensive, wide-coverage and diversified cooperation system, to actively promote the deep integration and technological innovation of medicine and engineering, and usher in a new era of interventional therapy for lung cancer.

Since December 2022, as the representative for cooperation in the respiratory intervention ecosystem, Broncus signed a partnership agreement for the digital medical innovation center with AstraZeneca. During the cooperation, the integrated diagnosis and treatment products can be displayed in the digital medical innovation center of AstraZeneca in Hangzhou. The parties will also jointly participate in a series of training activities of the Respiratory Intervention Training College.

FUTURE AND PROSPECTS

People deeply understand and pay attention to lung health, in the face of the global spread of COPD and lung cancer as a result of the aging population, air pollution and smoking habits, and the pandemic. We see a huge market demand for solutions for minimally invasive treatment of lung diseases. The global and Chinese populations with COPD in 2021 were 233.6 million and 107 million, respectively. The number of patients with COPD in the world and China is expected to increase to 258.4 million and 109.6 million respectively by 2025. We plan to expand our sales network by providing more doctor training and patient education, facilitating equipment installation and deepening our penetration in hospitals. Through our proprietary BTPNA technology, we plan to raise the awareness of hospitals, doctors and patients about the navigation platform as an indispensable tool for interventional pulmonology diagnosis and treatment, and promote the penetration of navigation equipment in hospitals through the development and commercialization of a series of therapeutic products.

With respect to InterVapor® being granted marketing approval by the NMPA, we anticipate our key future marketing strategies to include, firstly, to promote as leader in differentiating treatment areas and further grow utilization through professional education and market promotion after our treatments are approved by the NMPA; secondly, to take advantage of opportunities to initiate controller installation and accelerate equipment hospital listing; thirdly, to focus on mobilizing our internal sales team via targeted coaching and progress tracking to drive consumable utilization.

By leveraging our more established experience in sales and marketing of LungPoint and the Archimedes System, we plan to expand our sales of LungPoint Plus and other medical consumables in China.

We plan to expand our R&D team globally to ensure continuous technology and product innovation and enrich our intellectual property portfolio mapping across existing and future technologies with precise market positioning. We plan to increase spending on artificial intelligence and machine learning to accumulate large sets of clinical data and cases in the application of diagnosis and treatment procedures guided by our navigation systems.

Looking forward to 2023, we will continuously promote pre-marketing clinical trials of products under development and improve the EBM evidence for marketed products through post-marketing clinical studies that meet regulatory requirements. A key clinical study of the TLD product is planned to be initiated in the first quarter of 2023. It is a prospective, randomized, single-blind, sham-operated group-controlled multicenter clinical trial. A total of 189 patients with moderate to severe COPD were planned to be enrolled in 26 research centers in China to evaluate the safety and effectiveness of the product. The study is expected to have a 28-month enrollment period and a 12-month follow-up period. All subject follow-up visits are expected to be completed in July 2026. Clinical trial reports and data publicity will not be completed before the time point. We plan to conduct an investigator-initiated, multicenter, randomized controlled clinical study in the UK to evaluate the use of BTVA in the treatment of middle and/or lower lobe emphysema for which no data are currently available, which is expected to be completed by 2024. We also plan to conduct a prospective, multicenter, single-blind, randomized controlled study entitled Targeted Segmental Vapor Ablation Treatment of Emphysema with Upper LobePredominance: A Randomized Controlled Trial of InterVapor® in France and Germany, which is scheduled to start in the second quarter of 2023 and be completed by 2025. We plan to support a government-sponsored, prospective, multicenter, single-blind, randomized controlled trial in Germany, entitled Targeted Segmental Vapor Ablation Treatment of Emphysema with Upper LobePredominance: A randomized Controlled Trial of InterVapor®, which is expected to start in the fourth quarter of 2023 and be completed by 2025. In addition, we plan to conduct a series of clinical studies focusing on lung cancer indications and some post-marketing clinical studies for InterVapor® in several other regions. Clinical trials of lung cancer indications are expected to be conducted in China and Europe from 2023 to 2025. Our planned post-marketing clinical studies include the post-marketing clinical studies to be conducted in China from 2022 to 2024 and the post-marketing clinical studies to be conducted in India from 2021 to 2028.

The impact of COVID-19

During the COVID-19 outbreak, there were delays in the patient enrollment process and data entry for some of our clinical trials, mainly due to government policies and preventive measures taken by hospitals. Because of our business, preclinical studies and clinical trials in China, we made more progress in clinical trials in the first quarter of 2022 as compared with the same period of the previous year. Although the COVID-19 outbreak, which began at the end of October 2022 and spread across various provinces of China, affected normal medical services in some hospitals, all other operations of the Company were normal as at the date of the announcement.

Nevertheless, our revenue for the year ended December 31, 2022 was US$9.4 million, representing an increase of 8%, excluding revenue from licensing fees, as compared with the year ended December 31, 2021. As the precedent of the COVID-19 outbreak is limited, we cannot predict its ultimate impact on our business. There is no assurance that the COVID-19 outbreak will not further escalate or materially and adversely affect our results of operations.

FINANCIAL REVIEW

Overview

The following discussion is based on, and should be read in conjunction with, the financial information and notes included elsewhere in this announcement.

Revenue

For the Reporting Period, the revenue of the Group was US$9.4 million, representing an increase of 8%, excluding revenue from licensing fees, compared with US$8.7 million in the corresponding period last year.

Other income and gains

For the Reporting Period, our other income and gains consist primarily of government grants, bank interest income, foreign exchange gains and fair value gains from financial assets at fair value through profit or loss. Total other income and gains were approximately US$4.8 million for the year ended December 31, 2022, representing an increase of approximately US$1.7 million from the year ended December 31, 2021, mainly due to an increase in interest income from US$0.1 million to US$2.6 million.

R&D expenses

Our R&D costs mainly consist of staff costs for our research and development employees, depreciation and amortization, raw material costs, technical service fees, clinical trial expenses, travel and business related expenses and share awards.

Our technical service fees refer to the service fees we paid to our third-party service providers for complementary services needed for product development, including development of low-value consumables, product testing and other services. Clinical trial expenses include expenses incurred for conducting clinical trials, including payment to CROs and hospitals in relation to our clinical trials.

For the year ended December 31, 2022 and 2021, we incurred R&D costs of approximately US$19.2 million and US$16.8 million, respectively, representing an increase of 14.4%. The increase in our R&D costs was mainly due to (i) increased staff cost from US$7.0 million in 2021 to US$10.4 million in 2022 due to the expansion of our R&D team arising from the expansion of R&D projects and the acceleration of the process; and (ii) increased technical service fees in relation to the strategic cooperation with Healium Medical Ltd., an Israeli company specializing in the imaging monitoring.

	Year ended December 31, 2022		Year ended December 31, 2021	
	US$'000	***Proportion***	*US$'000*	*Proportion*
Staff cost	**10,446**	**54.5%**	7,000	41.8%
Technical service fees	**2,537**	**13.2%**	1,577	9.4%
Depreciation and amortization	**2,426**	**12.7%**	2,346	14.0%
Raw material costs	**909**	**4.7%**	1,342	8.0%
Share awards	**859**	**4.5%**	1,551	9.3%
Others	**668**	**3.5%**	764	4.4%
Clinical trial expenses	**623**	**3.3%**	1,504	9.0%
Travel and business related expenses	**346**	**1.8%**	345	2.1%
Office expenses	**353**	**1.8%**	330	2.0%
Total	**19,167**	**100.0%**	16,759	100.0%

Selling and distribution expenses

For the year ended December 31, 2022 and 2021, our selling and distribution expenses were US$11.2 million and US$12.7 million, respectively, representing a decrease of 11.9%. The decrease in our selling and distribution expenses was mainly due to our decreased share award expenses.

Administrative expenses

For the year ended December 31, 2022 and 2021, our total administrative expenses were approximately US$9.2 million and US$18.5 million, respectively. The decrease was mainly due to (i) our professional service fees incurred for the Global Offering in 2021 and (ii) our decreased share award expenses.

Liquidity and capital resources

The Group has always adopted a prudent treasury management policy. The Group places strong emphasis on having funds readily available and accessible and is in a stable liquidity position with sufficient funds in standby banking facilities to cope with daily operations and meet its future development demands for capital.

As at December 31, 2022, our cash and bank balances and deposits totalled US$188.4 million, as compared to our cash and bank balances and deposits of US$227.2 million as at December 31, 2021. The decrease was mainly due to the R&D investment, sales promotion, daily operation and other expenses incurred by the Company as well as the external investment.

The following table sets forth a condensed summary of the Group's annual consolidated statement of cash flows for the years indicated and analysis of balances of cash and cash equivalents for the years indicated:

	Year ended December 31,	
	2022	2021
	US$'000	*US$'000*
Net cash flows used in operating activities	**(30,954)**	(31,494)
Net cash flows used in investing activities	**(87,569)**	(1,753)
Net cash flows (used in)/from financing activities	**(572)**	241,822
Net (decrease)/increase in cash and cash equivalents	**(119,095)**	208,575
Cash and cash equivalents at the beginning of the year	**227,207**	18,788
Effect of foreign exchange rate changes, net	**(1,356)**	(156)
Cash and cash equivalents at the end of the year	**106,756**	227,207
Analysis of balances of cash and cash equivalents	**106,756**	227,207
Cash and cash equivalents as stated in the consolidated statement of financial position	**106,756**	227,207

As at December 31, 2022, cash and cash equivalents were mainly denominated in Hong Kong dollars, United States dollars and Renminbi.

Bank Borrowings and Gearing

The Group's overdraft facilities amounting to US$80,000 (2021: US$80,000), of which US$29,000 (2021: US$13,000) had been utilised were secured by the pledge of certain of the Group's time deposits amounting to US$25,000 (2021: US$25,000).

The Group monitored capital using gearing ratio. As at December 31, 2022 and December 31, 2021, the Group's gearing ratio (total debt less cash and cash equivalent as a percentage of total equity as of the end of the year) were negative values.

Foreign Exchange Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between US$ and other currencies in which the Group conducts business may affect the Group's financial condition and results of operations.

In response to the foreign exchange risk, the Company seeks to limit its exposure to foreign currency risk by minimizing its net foreign currency position to reduce the impact of the foreign exchange risk on the Company. During the Reporting Period, the Group had not engaged in any foreign exchange hedging related activity.

Contingent Liabilities

As at December 31, 2022, the Group did not have any significant contingent liabilities.

Charge or Restrictions on Assets

As of December 31, 2022, the Group had pledged deposits of US$526,000 (December 31, 2021: US$238,000). The pledged deposits were placed to secure the Group's bank overdraft facilities, the Group's service and rent deposits. Save as disclosed in this announcement, the Group did not pledge any group assets.

NON-IFRS MEASURES

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

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

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

	Year ended December 31,	
	2022	2021
	US$'000	*US$'000*
Loss for the year	**(28,036)**	(236,178)
Add:		
Changes in fair value of convertible redeemable preferred shares	**–**	198,874
Share awards[(1)]	**1,123**	9,011
Listing expenses	**–**	4,639
Non-IFRS adjusted net loss for the year[(2)]	**(26,913)**	(23,654)

Notes:

(1) Represent the total expenses associated with the shares we granted to our sales and marketing employees, administrative employees and research and development employees.

(2) We consider changes in fair value of convertible redeemable preferred shares, share awards and listing expenses as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the changes in fair value of convertible redeemable preferred shares, share awards and listing expenses provides useful information to investors in facilitating a comparison of our operating performance from year to year.

CORPORATE GOVERNANCE RELATED INFORMATION

Compliance with the Corporate Governance Code

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in the CG Code as contained in Appendix 14 to the Listing Rules as its own code of corporate governance practices. The Board is of the view that during the Reporting Period, the Company has complied with all the applicable code provisions as set out in the CG Code. The Board will continue to review and monitor the code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

Compliance with the Model Code

The Company has adopted the Model Code set out in Appendix 10 to the Listing Rules as its code of conduct regarding dealings in the securities of the Company by the Directors, and the Group's employees who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company's securities. Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Model Code during the Reporting Period.

No incident of non-compliance of the Model Code by the employees was noted by the Company during the Reporting Period.

Purchase, Sale or Redemption of the Company's Securities

During the Reporting Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed the Company's listed securities.

Significant Investment Held and Material Acquisition and Disposal of Subsidiaries, Associates and Joint Ventures

During the Reporting Period, the Group did not have any significant investments, acquisitions or disposals of subsidiaries, associates and joint ventures. In addition, except for the expansion strategies disclosed in sections "Business" and "Future Plans and Use of Proceeds" in the Prospectus, the Group does not have any specific plans for significant investments or acquisition of material capital assets or other businesses. The Group, however, will continue to identify product line expansion opportunities.

Material Litigation

The Company was not involved in any material litigation or arbitration during the Reporting Period. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the Reporting Period.

Employee and Remuneration Policy

As at December 31, 2022, the Group had 376 employees. The Group's employees' remuneration consists of salaries, bonuses, share-based incentive plans, pension scheme contributions and other welfare payments. In accordance with applicable laws in China and other relevant jurisdictions, we have made contributions to social security insurance funds and housing funds for the employees of the Group.

We conduct new staff training regularly to guide new employees and help them adapt to the new working environment. In addition, we provide on-line and in-person formal and comprehensive company-level and department-level training to our employees in addition to on-the-job training. We also encourage our employees to attend external seminars and workshops to enrich their technical knowledge and develop competencies and skills.

During the Reporting Period, the total staff costs (including Director's emoluments and excluding share award expenses) were approximately US$22.4 million (for the same period in 2021: US$17.3 million).

Use of Net Proceeds from the Global Offering

The total net proceeds from the issue of Shares by the Company in its listing on the Stock Exchange amounted to approximately HK$1,620.0 million, after deducting the underwriting commission and other expenses payable by the Company in connection with the Global Offering.

As at December 31, 2022, the Company has utilized approximately HK$302 million of the proceeds from the Global Offering. There was no change in the intended use of net proceeds and the expected timeline as disclosed in the Prospectus. The balance of the unutilized net proceeds amount to approximately HK$1,318 million as at the end of the Reporting Period and the Company intends to apply such net proceeds in accordance with the purposes as set out in the table below:

	Approximate % of total net proceeds *(%)*	**Planned use of actual net proceeds** *HKD'million*	**Amount of unutilized net proceeds as at 1 January 2022** *HKD'million*	**Amount of utilized net proceeds for the Reporting Period** *HKD'million*	**Utilized net proceeds as at the end of the Reporting Period** *HKD'million*	**Net proceeds unutilized as at the end of the Reporting Period** *HKD'million*	**Expected timeframe for utilizing the remaining net proceeds**
Development and commercialisation of InterVapor®	29.0%	469.2	460.4	90.9	99.7	369.5	Expected to be fully utilized by 2030
Development and commercialisation of RF-II	21.0%	339.4	331.0	31.2	39.6	299.8	Expected to be fully utilized by 2030
R&D of other product candidates	18.5%	299.9	280.9	62.8	81.8	218.1	Expected to be fully utilized by 2030
Production line expansion of our manufacturing facility	9.2%	149.2	149.2	0	0	149.2	Expected to be fully utilized by 2026
M&A, investing in or acquiring new pipelines	13.2%	213.2	213.2	0	0	213.2	Expected to be fully utilized by 2026
Working capital and other general corporate purposes	9.2%	149.2	136.4	68.1	80.9	68.3	Expected to be fully utilized by 2026
Total	100.0%	1,620.0	1,570.9	253.0	302.0	1,318.0	

Audit Committee

During the Reporting Period, the Audit Committee of our Company (the "**Audit Committee**") comprises three independent non-executive Directors, namely Dr. Pok Man Kam, Professor Joseph Wan Yee Lau and Dr. Jian Ji. Following Dr. Jian Ji's resignation taking effect on August 30, 2022, Ms. Yee Sin Wong has been appointed as a member of the Audit Committee with effect from August 30, 2022. Dr. Pok Man Kam, being the chairman of the Audit Committee, holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The Audit Committee has reviewed the annual consolidated financial statements for the year ended December 31, 2022 with the management of the Company. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

Auditor

The financial information contained in this announcement does not constitute the Group's audited accounts for the year ended December 31, 2022, but represents an extract from the consolidated financial statements for the year ended December 31, 2022 which have been audited by the auditor of the Company, Ernst & Young, in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants.

EVENTS AFTER THE REPORTING PERIOD

An indirect wholly-owned subsidiary of the Company has entered into a partnership agreement on March 28, 2023, pursuant to which, it has agreed to subscribe for a capital contribution in the amount of RMB125 million as a limited partner. The partnership fund focuses at investments in the digital medical devices and projects of related industries space, accordingly, it is considered that the aforesaid investment into the fund will be in the interests of the Company and its shareholders as a whole. For further details, please refer to the announcement of the Company dated March 29, 2023.

Save as aforesaid, the Company is not aware of any material subsequent events from December 31, 2022 to the date of this announcement.

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2022 (2021: Nil).

CLOSURE OF REGISTER OF MEMBERS AND RECORD DATE

The register of members of the Company will be closed from Wednesday, May 10, 2023 to Monday, May 15, 2023, both days inclusive, in order to determine the identity of Shareholders who are entitled to attend and vote at the AGM. Shareholders whose name appear on the register of member of the Company on Monday, May 15, 2023 will be entitled to attend and vote at the AGM. In order to be eligible to attend and vote at the AGM, all transfer documents accompanied by relevant share certificates must be lodged with the Company's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, Shops 1712-1716, 17th Floor Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong before 4:30 p.m. on Tuesday, May 9, 2023.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.broncus.com).

The annual report of the Company for the year ended December 31, 2022 containing all the information required by the Listing Rules will be despatched to the Company's Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

PROPOSED AMENDMENTS TO THE EXISTING MEMORANDUM AND ARTICLES OF ASSOCIATION AND ADOPTION OF THE NEW MEMORANDUM AND ARTICLES OF ASSOCIATION

The Board announces that it proposed to amend the Memorandum and Articles of Association and to adopt the amended and restated Memorandum and Articles of Association incorporating the amendments (the "**Proposed Amendments**") for the purpose of, among others, (i) bringing the Memorandum and Articles of Association in line with the Core Shareholders Protection Standards as set out in Appendix 3 to the Listing Rules; and (ii) allowing all general meetings to be held in the format of physical, electronic or hybrid meetings. Other minor amendments to the Memorandum and Articles of Association relate to corresponding and house-keeping changes.

The Proposed Amendments and the adoption of the amended and restated Memorandum and Articles of Association are subject to Shareholders's approval by way of a special resolution at the AGM. A circular containing, among other things, particulars relating to the Proposed Amendments and the adoption of the amended and restated Memorandum and Articles of Association together with a notice convening the AGM will be despatched to the Shareholders and published on the websites of the Stock Exchange and the Company in due course.

DEFINITIONS

"AGM"	the annual general meeting of the Company to be held on Monday, May 15, 2023
"associate(s)"	has the meaning ascribed to it under the Listing Rules
"Board" or "Board of Directors"	the board of Directors
"CG Code"	Corporate Governance Code as set out in Appendix 14 to the Listing Rules
"Company"	Broncus Holding Corporation (堃博医疗控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on April 30, 2012, whose Shares were listed and traded on the Stock Exchange
"COPD"	chronic obstructive pulmonary disease
"Director(s)"	member(s) of our board of directors, including all executive, non-executive and independent non-executive directors
"EU"	the European Union
"Global Offering"	the global offering of the Shares, comprising the Hong Kong public offering of 8,935,500 Shares and the international offering of 80,419,500 Shares
"Group," "our Group," "we" or "us"	the Company and our subsidiaries (or the Company and any one or more of our subsidiaries, as the context may require)
"HK$" or "HK dollars" or "Hong Kong dollars"	Hong Kong dollars, the lawful currency of Hong Kong
"Hong Kong" or "HK"	the Hong Kong Special Administrative Region of the PRC
"InterVapor®"	InterVapor® System, the world's first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time

"Memorandum and Articles of Association"	the existing memorandum of association and articles of association of the Company
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
"NMPA"	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
"PRC" or "China" or the "People's Republic of China"	the People's Republic of China, which for the purpose of this announcement and for geographical reference only, excludes Hong Kong, the Macau Special Administrative Region of the People's Republic of China and Taiwan
"R&D"	Research and development
"Reporting Period"	12 months ended December 31, 2022
"RF-II"	RF Generator + RF Ablation Catheter, a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer
"Shares"	ordinary share(s) in the share capital of the Company
"Shareholders"	holders of the Shares
"sq.m."	square meters
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"U.S." or "United States"	the United States of America
"US$" or "U.S. dollars"	United States dollars, the lawful currency for the time being of the United States
"%"	per cent

By order of the Board
Broncus Holding Corporation
ZHAO Michael Yi Wei
Chairman

Hong Kong, March 29, 2023

As at the date of this announcement, the Board comprises Mr. ZHAN Guowei and Mr. XU Hong as executive Directors, Mr. ZHAO Michael Yi Wei as Chairman and non-executive Director, Mr. ZI Zhenjun and Mr. ZHANG Ao as non-executive Directors, and Dr. KAM Pok Man, Professor LAU Joseph Wan Yee and Ms. WONG Yee Sin as independent non-executive Directors.