Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2216)

(I) ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2023; 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, 2023 (the "Reporting Period"), together with the audited comparative figures for the year ended December 31, 2022.

	Year ended	Year ended	
	December 31,	December 31,	Year-to-year
	2023	2022	change
	USD'000	USD'000	
Revenue	10,255	9,413	8.9%
Gross Profit	7,227	7,315	-1.2%
Loss for the year	(28,092)	(28,036)	0.2%
Add:			
Share awards	556	1,123	-50.5%
Non-IFRS adjusted net loss for			
the year ⁽¹⁾	(27,536)	(26,913)	2.3%
Cash and specified financial			
assets	156,647	188,435	-16.9%

BUSINESS HIGHLIGHTS

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

(i) In terms of clinical and product R&D:

- (a) We have completed the follow-up visit to the pivotal clinical trial of Zhiheng RF-II in the first quarter of 2023. The product is the world's first transbronchial interventional treatment product for lung cancer, which has completed the ablation of peripheral lung cancer lesions through transbronchoscopic radiofrequency ablation. The clinical research data showed that the study has a technical success rate of 99.35% and a 6-month complete ablation rate of the main lesion being 93.8%. Meanwhile, there is a relatively low incidence of common complications such as pneumothorax and bleeding in thermal ablation for lung cancer in this study. The research results confirmed the safety and efficacy of RF-II in the treatment of lung cancer. The full results of this study were presented at academic conferences such as the 2023 Annual Scientific Meeting of the European Respiratory Society (ERS). The study data is used for the applications for NMPA.
- (b) For the Targeted Lung Denervation (TLD) Radiofrequency Ablation System, an innovative device for the treatment of acute exacerbation of COPD, we completed the first case of Registered Clinical Trials in July 2023. The clinical trial will evaluate the safety and efficacy of Broncus TLD Ablation System in the treatment of COPD, and is planned to enroll 189 patients at more than 20 trial sites in China. As of December 31, 2023, the enrollment of over 40 patients has been completed at more than 20 trial sites.

(ii) In terms of market access:

- (a) In July 2023, the domestic version of our InterVapor® disposable transbronchial endoscopic thermal vapor treatment catheter obtained the NMPA registration certificate;
- (b) In October 2023, the domestic version of our InterVapor® thermal vapor treatment equipment obtained the NMPA registration certificate;
- (c) In September 2023, the domestic version of <u>LungPoint</u>, our lung navigation product, obtained the NMPA registration certificate;
- (d) In September 2023, our BroncTru[™] disposable transbronchoscopic puncture dilatation catheter obtained the NMPA registration certificate;
- (e) In 2023, InterVapor® was successively approved in Thailand, Chinese Taiwan, Malaysia and Indonesia.

(iii) In terms of commercialization:

- (a) InterVapor® for COPD has been commercialized and applied in more than 20 hospitals in China. About 100 hospitals tried the technology, while the product prices of the disposable thermal vapor treatment catheter were collected by the open and fair procurement platform in over 20 provinces and cities, and the insurance coverage gradually being implemented.
- (b) According to public information statistics by the Company, the market share of our navigation products in China reached 40%.
- (c) After commercialization in China, the disposable transbronchoscopic puncture dilatation catheter for BroncTru[™] has been clinically applied in multi-scenarios in Chest Hospital of Shanghai Jiao Tong University and other hospitals.
- (d) In 2023 financial year, our products covered various countries and regions all over the world, including the United States, the United Kingdom, Germany, France, India, etc.

As at December 31, 2023, the Company has obtained, among others, the following qualifications and certifications at the national and provincial level: National Hightech Enterprise, Zhejiang Science and Technology SMEs, Broncus R&D Center of High-tech Enterprise for Minimally Invasive Interventional Diagnosis and Treatment Devices for Lung Diseases in Zhejiang province, etc. With the support of the government, the Company will continue to enhance its comprehensive strengths, and create a comprehensive solution for interventional pulmonology.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2023

	Notes	2023 USD'000	2022 USD'000
REVENUE	5	10,255	9,413
Cost of sales	_	(3,028)	(2,098)
Gross profit		7,227	7,315
Other income and gains Selling and distribution expenses Administrative expenses Impairment losses on financial assets, net Research and development costs Other expenses Finance costs	57	6,019 (11,486) (8,929) 121 (20,154) (804) (83)	4,785 (11,189) (9,229) (438) (19,167) (12) (98)
LOSS BEFORE TAX	6	(28,089)	(28,033)
Income tax expense	8 _	(3)	(3)
LOSS FOR THE YEAR	=	(28,092)	(28,036)
Attributable to: Owners of the parent Non-controlling interests	-	(28,091) (1) (28,092)	(28,036)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (USD)	10 =	(0.06)	(0.06)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2023

	2023 USD'000	2022 USD'000
LOSS FOR THE YEAR	(28,092)	(28,036)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	(603)	(2,160)
OTHER COMPREHENSIVE INCOME FOR THE		
YEAR, NET OF TAX	(603)	(2,160)
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	(28,695)	(30,196)
Attributable to:		
Owners of the parent Non-controlling interests	(28,694) (1)	(30,196)
	(28,695)	(30,196)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2023

	Notes	2023 USD'000	2022 USD'000
NON-CURRENT ASSETS			
Property, plant and equipment		2,398	2,402
Right-of-use assets		2,157	1,354
Other intangible assets		8,970	5,910
Financial assets at fair value through profit or loss		8,878	7,603
Finance lease receivables		42	67
Trade receivables	11	-	1,493
Prepayments, other receivables and other assets	11	708	247
Total non-current assets		23,153	19,076
CURRENT ASSETS			
Inventories		4,709	4,298
Finance lease receivables		26	25
Trade receivables	11	9,959	8,598
Prepayments, other receivables and other assets		1,311	1,510
Pledged deposits		238	526
Time deposits with original maturity			
over three months		72,845	81,153
Cash and cash equivalents		83,564	106,756
Total current assets		172,652	202,866
CURRENT LIABILITIES			
Trade payables	12	399	321
Lease liabilities		1,115	652
Other payables and accruals		6,944	6,116
Bank overdrafts		16	29
Contract liabilities		684	299
Total current liabilities		9,158	7,417
NET CURRENT ASSETS		163,494	195,449
TOTAL ASSETS LESS			
CURRENT LIABILITIES		186,647	214,525

	2023 USD'000	2022 USD'000
TOTAL ASSETS LESS		
CURRENT LIABILITIES	186,647	214,525
NON-CURRENT LIABILITIES		
Lease liabilities	1,224	790
Other payables and accruals	_	175
Contract liabilities	53	102
Total non-current liabilities	1,277	1,067
Net assets	<u>185,370</u>	213,458
EQUITY		
Equity attributable to owners of the parent		
Share capital	12	12
Reserves	185,359	213,446
	185,371	213,458
Non-controlling interests	(1) _	
Total equity	185,370	213,458

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 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 and contingent consideration payable 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 new and revised IFRSs for the first time for the current year's consolidated financial statements.

IFRS 17 Insurance Contracts

Amendments to IAS 1 and Disclosure of Accounting Policies

IFRS Practice Statement 2

Amendments to IAS 8 Definition of Accounting Estimates

Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising

from a Single Transaction

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

- (a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has disclosed the material accounting policy information in note 2 to the consolidated financial statements. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Group's consolidated financial statements.
- (b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. Since the Group's approach and policy align with the amendments, the amendments had no impact on the Group's consolidated financial statements.
- (c) Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions. Since the Group's policy aligns with the amendments, the amendments did not have any impact on the financial position or performance of the Group.
- (d) Amendments to IAS 12 International Tax Reform Pillar Two Model Rules introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to 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

	2023 USD'000	2022 USD'000
Chinese Mainland	6,465	5,813
European Union	1,848	2,016
USA	264	172
Other countries/regions	1,678	1,412
Total Revenue	10,255	9,413

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

(b) Non-current assets

	2023	2022
	USD'000	USD'000
Chinese Mainland	6,461	3,626
USA	4,620	6,104
Israel	2,994	_
European Union	16	27
Other countries/regions	4	4
Total non-current assets	14,095	9,761

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:

	2023	2022
	USD'000	USD'000
Customer A	6 217	4 970
Customer A	6,317	4,870

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2023	2022
	USD'000	USD'000
Revenue from contracts with customers		
Sale of medical devices and consumables	11,984	8,929
Licensing of intellectual property rights*	(2,152)	_
Provision of services	423	436
Revenue from other sources		
Gross rental income	_	48
Total	10,255	9,413

^{*} In November 2023, the Group terminated the licence agreement with NoahTron Intelligence Medtech (Hangzhou) Co., Ltd. ("NoahTron Intelligence") and a total revenue of USD2,152,000 was reversed in 2023 based on the termination agreement.

Revenue from contracts with customers

(a) Disaggregated revenue information

	2023	2022
	USD'000	USD'000
Geographical markets		
Chinese Mainland	6,465	5,813
European Union	1,848	1,968
USA	264	172
Other countries/regions	1,678	1,412
	10,255	9,365
Timing of revenue recognition		
Goods transferred at a point in time	9,832	8,929
Services transferred over time	423	436
	10,255	9,365

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:

	2023 USD'000	2022 USD'000
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Sale of medical devices and consumables	26	45
Provision of services	269	328
	295	373

(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 straightline 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:

	2023	2022
	USD'000	USD'000
Amounts expected to be recognised as revenue:		
Within one year	749	471
After one year	53	102
	802	573

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:

	2023	2022
	USD'000	USD'000
Other income		
Government grants (note a)	21	497
Bank interest income	6,041	2,558
(Reversal of)/income on interest from non-current receivables	(80)	70
Others	23	106
Total other income	6,005	3,231
Gains		
Gain on disposal of items of property, plant and equipment	7	_
Gain on termination of leases	7	_
Foreign exchange gains, net	_	691
Fair value gains, net:		
Financial assets at fair value through profit or loss		863
Total gains	14	1,554
Total other income and gains	6,019	4,785

Note:

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

6. LOSS BEFORE TAX

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

	2023	2022
	USD'000	USD'000
Cost of inventories sold	3,086	2,098
Cost of services provided	111	_
Cost of licensing of intellectual property rights	(250)	_
Research and development costs	20,154	19,167
(Gain)/loss on disposal of items of property,		
plant and equipment	(7)	5

7. FINANCE COSTS

An analysis of finance costs is as follows:

	2023 USD'000	2022 USD'000
Interest on lease liabilities	83	98

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 Chinese Mainland were entitled to a preferential income tax rate of 5% (2022: 2.5%) for small and micro enterprises except that Hangzhou Broncus Medical Co., Ltd. was subject to CIT at a rate of 15% (2022: 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% (2022: 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 19% (2022: 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% (2022: 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% (2022: 16.5%) on the estimated assessable profits arising in Hong Kong during the year.

Israel

The subsidiary incorporated in Israel was subject to income tax at the rate of 23% on the estimated assessable profits arising in Israel during the year.

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

	2023	2022
	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 (2022: 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 488,570,732 (2022: 487,749,376) 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:

	2023 USD'000	2022 USD'000
Loss Loss attributable to ordinary equity holders of the parent,		
used in the basic loss per share calculation	(28,091)	(28,036)
	Nun	nber of shares
	2023	2022
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	488,570,732	487,749,376

As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2023 and 2022 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 RECEIVABLES

	2023 USD'000	2022 USD'000
Current		
Trade receivables	11,065	9,837
	11,065	9,837
Non-current		
Trade receivables		1,494
	11,065	11,331
Impairment	(1,106)	(1,240)
Total	9,959	10,091

Certain of the Group's trading terms with its customers are on credit. The credit period is generally three to six months. Each customer has a maximum credit limit. The Group seeks to maintain strict control over its outstanding receivables. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

Included in the Group's trade receivables were an amount of nil (2022: USD1,987,000) due from a Group's related party.

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:

	2023 USD'000	2022 USD'000
Within 3 months	5,889	5,511
3 to 6 months	45	67
6 to 12 months	3,862	1,914
1 to 2 years	163	2,599
Total	9,959	10,091

12. TRADE PAYABLES

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

	2023 USD'000	2022 USD'000
Within 3 months	232	308
3 to 6 months	166	11
6 to 12 months	1	1
Over 1 year		1
	399	321

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

13. RELATED PARTY TRANSACTIONS

("Hangzhou Jingliang")

Name	Relationship
Hangzhou Dinova Medical Technology Co., Ltd. ("Hangzhou Dinova")	An entity controlled by Mr. Michael Yi Wei Zhao
NoahTron Intelligence	An entity controlled by Mr. Michael Yi Wei Zhao
Dinova Healthcare Holding Corporation ("Dinova Healthcare")	An entity controlled by Mr. Michael Yi Wei Zhao
Fibernova Ltd ("Fibernova")	An entity controlled by Mr. Michael-Yi Wei Zhao before acquisition
Fibernova Holding Corporation ("FHC")	An entity controlled by Mr. Michael-Yi Wei Zhao before acquisition
Hangzhou Jingliang Science and Technology Co., Ltd	An entity controlled by

Mr. Michael-Yi Wei Zhao and

Mr. Zhenjun Zi before acquisition

(a) The Group had the following transactions with related parties during the year:

	2023 USD'000	2022 USD'000
Management service from: Hangzhou Dinova (note (i))	157	172
Purchase of research service from: Fibernova (note (ii))	350	

Notes:

- (i) The fees paid for management service were charged based on the actual costs.
- (ii) The fees paid for research service were charged based on the actual costs.

Other transactions with related parties:

- (i) In September 2023, the Company acquired 100% of shares of FHC and its subsidiaries, which is a related party transaction since FHC is controlled by Mr. Michael Yi Wei Zhao before the acquisition. As at 31 December 2023, the cash consideration of USD1,700,000 has been paid and the rest amount is outstanding and assessed to be contingent.
 - In December 2023, Hangzhou Broncus Medical Co., Ltd. acquired 100% of shares of Hangzhou Jingliang, which is a related party transaction since Hangzhou Jingliang is controlled by Mr. Michael Yi Wei Zhao and Mr. Zhenjun Zi before the acquisition. As at 31 December 2023, the cash consideration of RMB5,400,000 has been paid.
- (ii) On 7 September 2021, a subsidiary of the Group entered into a licence agreement with NoahTron Intelligence and a non-exclusive licence was granted to NoahTron Intelligence by payment at USD250,000 per year for a period of ten years. In November 2023, the Group terminated the licence agreement with NoahTron Intelligence, and paid NoahTron Intelligence US\$500,000 as consideration of the termination agreement.

(b) Outstanding balances with related parties:

	2023 USD'000	2022 USD'000
Other payables and accruals: Hangzhou Dinova*	104	116
Trade receivables: NoahTron Intelligence*		1,987
Contingent consideration payables: Dinova Healthcare	831	

The other payables and accruals to Hangzhou Dinova were unsecured, interest-free and repayable on demand.

The contingent consideration payable to Dinova Healthcare was the contingent payment for the acquisition of FHC by the Group.

(c) Compensation of key management personnel of the Group:

	2023	2022
	USD'000	USD'000
Salaries, allowances and benefit in kind	661	1,033
Pension scheme contributions	19	25
Equity-settled share award expenses	1	96
Total compensation paid to key management personnel	681	1,154

The related party transactions in respect of licensing of intellectual property rights to NoahTron Intelligence above also constitute connected transactions or continuing connected transactions as defined in Chapter 14A of the Listing Rules.

^{*} The balances are trade in nature.

MANAGEMENT DISCUSSION AND ANALYSIS

Business Overview

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 world's exclusive whole lung access navigation technology, we have developed an integrated interventional pulmonology platform including navigation, diagnosis and treatment. We provide safe and effective interventional treatments for lung cancer and COPD through a series of lung disease diagnosis and treatment products, thus addressing the pain points of the existing diagnosis and treatment paradigms and meeting the significant clinical medical needs for lung diseases.

As at December 31, 2023, we had 19 products and major products under various development stages, including a number of innovative pulmonary interventional products that are the only ones of their kind in the world or in China. Among which, the InterVapor® Therapy Vapor Treatment System is the world's first and only implantable medical device to treat COPD, and its feasibility for the treatment of lung cancer has been proven by clinical trials. RF-II Radiofrequency Ablation System is the world's first transbronchial interventional treatment product for lung cancer. TLD is the first self-developed targeted radiofrequency ablation system in China to reduce the risk of acute exacerbation of COPD.

Our Products and Product Pipeline

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

	Indication	Portfolio	Region	Preclinical	Clinical Trial	Registration			
	COPD		China	Launch for sale, China (March 2022)					
		InterVapor® for COPD(2)(8)(9)	EU	Launch for sale, EU (January 2018)					
Treatment			Others	Launch for sale, UK, Switzerland, Chines	se Taiwan, Hong Kong, India, Thai	land, Singapore, Malaysia, Australia etc.			
		InterVapor® for COPD (domestic version) ⁽⁸⁾	China			Launch for sale, China (October 2023)			
		TLD Ablation System ⁽⁸⁾	China	Clinical trial for NMPA registration from Januar	y 2023 2026.7	→ end of 2027			
	Lung Cancer/ Lung Nodules	InterVapor® for Lung Cancer ⁽³⁾⁽⁸⁾⁽⁹⁾	China	Preclinical study					
			EU	Preclinical study		0005			
		RF-SEG Generator + RF-iCon Ablation Catheter (RF-II) ⁽⁸⁾	China ⁽⁴⁾	NMPA registration in process		2025			
			EU ⁽⁵⁾	CE registration in process		2027			
		H-Marker ⁽⁶⁾⁽⁸⁾	China			Launch for sale (June 2021)			
		Disposable Nebulizing Micro-Catheter for Endoscope ⁽⁶⁾	China			Launch for sale, China (October 2022)			
	Pulmonary Diseases	Disposable Transbronchial Puncture	China		Li	aunch for sale, China (September 2023)			
		Dilation Catheter ⁽⁸⁾	EU			2027			
		LungPoint [®]	China		L	aunch for sale, China (December 2014)			
			US	Launch for sale, US (March 2009)					
			EU			Launch for sale, EU (June 2010)			
=		LungPoint (domestic version)(8)	China		La	aunch for sale, China (September 2023)			
Navigation	Navigation	M Archimedes Lite ⁽⁸⁾	China		L	aunch for sale, China (December 2020)			
vig v	Platform and Robots		US/EU			Launch for sale, US/EU (March 2021)			
물		LungPro/Archimedes System ⁽³⁾	China			Launch for sale, China (October 2017)			
			US			Launch for sale, US (February 2014)			
			EU			Launch for sale, EU (July 2014)			
		Endoluminal Robotic System	China	In design stage 2026	> 2027	\rightarrow \longrightarrow			
	Lung Cancer/ Lung Nalules		China		L	Launch for sale, China (December 2014)			
		FlexNeedle ⁽⁸⁾		Launch for sale, US (Apr					
			EU			Launch for sale, EU (July 2013)			
		ATV FleXNeedle CN ⁽⁷⁾⁽⁸⁾	China	Launch for sale, China (No					
		D:- C+A (0)	China	China		Launch for sale, China (June 2020)			
sis		BioStarNeedle ⁽⁸⁾	EU			Launch for sale, EU (September 2022)			
Diagnosis		ATV Sheath ⁽⁸⁾	China			Launch for sale, China (June 2018)			
) ja			US			Launch for sale, US (October 2013)			
			EU			Launch for sale, EU (July 2014)			
			China			Launch for sale, China (June 2018)			
		ATV Balloon ⁽⁸⁾ EU				Launch for sale, US (October 2013)			
						Launch for sale, EU (July 2014)			
		Steerable Sheath ⁽⁸⁾	China			Launch for sale, China (July 2020)			

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 trial was completed in March 2023.
- 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 of clinical trials.
- 9. Subsequent to the acquisition of InterVapor® from Uptake Medical Corp, we continued to improve InterVapor® by sponsoring clinical trials in China and overseas to obtain approvals from local authorities.

Major Product Pipeline

InterVapor®

InterVapor® is the world's first and only Thermal Vapor Treatment System to treat lung diseases including COPD and lung cancer, and it is also the world's only interventional non-implantable medical device to treat COPD. It is a therapeutic device that delivers thermal vapor bronchoscopically to the lung to achieve targeted ablation. Based on our thermal vapor targeted ablation technology, 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 at 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 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.

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 efforts in R&D, in 2018, InterVapor® was accredited with an EC Certificate (CE678945) 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 the NMPA with the registration certificate number (國械註進20223090145 and 國械註進 20223090144). In July and October 2023, the disposable transbronchial endoscopic thermal vapor treatment catheter and thermal vapor treatment devise for domestic InterVapor® was approved by the NMPA, with registration certificate numbers (國械註准20233091032 and 國械註准20233091468) respectively.

Since its launch in China, InterVapor® has been clinically applied in over 20 provinces across the country, with obvious clinical benefits for patients. Meanwhile, 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 20 provinces and cities across the country, providing access guarantee for medical institutions in bargaining and procurement.

As of December 31, 2023, 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 patient enrollment and follow-up visits for the NEXT-STEP trial in June 2020, and the formal study report was completed by September 2021. We have 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 study results showed that the bronchoscopic thermal vapor ablation of lung tumors is feasible and well tolerated without major surgical-related complications. With regard to the BTVA Registry study in the EU, as at the end of 2023, a total of 239 patients were enrolled in 17 study centers, without reports on device-related serious adverse events.

InterVapor® has been granted approval in Thailand, Chinese Taiwan, Malaysia and Indonesia in 2023, and the registration application has been submitted to the competent authority in the Philippines in June 2023 and is under review currently.

RF-II

RF-II is the world's first transbronchial interventional treatment product for lung cancer. It is a radiofrequency ablation system used in conjunction with the disposable lung radiofrequency ablation catheter and the radio frequency energy generator, which acts on lung tumors via a bronchoscope to perform ablation to the lung tumors and effectively promote the advanced treatment of lung cancer. RF-II is classified as a Class III medical device in China and a Class II medical device in the EU and the United States.

Currently, the treatment of lung cancer is mainly based on chemotherapy, radiotherapy and surgical operations with greater side effects and trauma, 80% of lung cancer patients are not suitable for surgical operations according to expert consensus. Radiofrequency ablation is a minimally-invasive, repeatable targeted therapy for lung tumors, providing a new treatment for patients. With the development and widespread of radiofrequency ablation technology, this new solution of precise minimally invasive intervention is expected to become the mainstream trend in the future, which can be used alone or combined treatment with drugs and surgery.

RF-II is well ahead in the field of radiofrequency ablation for the treatment of lung cancer. The follow-up visit to the registered clinical trial of RF-II, namely BRONC-RF-II, was completed in March 2023 and has been submitted to the NMPA for completion of the medical device marketing review process in December 2023. A total of 126 patients with lung cancer were included in the trial for the treatment of radiofrequency ablation system. The study has a technical success rate of 99.35% and a 6-month complete ablation rate being 93.8%. Meanwhile, there is a lower incidence of common complications such as pneumothorax and bleeding in thermal ablation for lung cancer in this study as compare to similar treatments. The results of the study confirmed the safety and efficacy of RF-II in the clinical treatment of lung cancer. In addition, we are preparing the application for the CE registration submission for RF-II. The trial was conducted at renowned hospitals in China, including Guangzhou Institute of Respiratory Health, Shanghai Chest Hospital, West China Hospital of Sichuan University, Beijing Chaoyang Hospital affiliated with Capital Medical University, and Sir Run Run Shaw Hospital affiliated with the Zhejiang University School of Medicine etc. After the product launch its commercialization, we will also collaborate with key opinion leaders to introduce our unique technology by holding training sessions.

RF-II is expected to kick off commercialization within seven years since we initiated the R&D process.

TLD

TLD, a Targeted Lung Denervation product jointly developed with West China Hospital of Sichuan University, is the first self-developed product in China for the treatment of COPD by transbronchial radiofrequency ablation, which is expected to be crucial to 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.

The First-In-Man clinical trial of the TLD Radiofrequency Ablation System was completed in July 2023, and register clinical trial of TLD products was launched in the first quarter of 2023. The study was a prospective, randomized, single-blinded, shamoperated group-controlled multicenter clinical trial. A total of 189 patients with moderate to severe COPD were planned to be enrolled in over 20 research centers in China will cover the safety and efficacy of the product. The first case was completed in July 2023. By the end of 2023, more than 40 patients have been enrolled in over 20 research centers. The study is expected to complete all subject follow-up visits in July 2026, Clinical trial reports and data publicity will be completed no earlier than the time point.

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

The "Mist Fountain" nebulizing micro-catheter is used in conjunction with the endoscopy. 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 the Zhejiang Medical Products Administration in October 2022, thus becoming the only approved nebulizing microcatheter 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.

 $BroncTru^{TM}$, a disposable transbronchoscopic puncture dilatation catheter

Bronc $Tru^{^{\text{TM}}}$, a disposable transbronchoscopic puncture dilatation catheter is used in conjunction with the endoscopy, which can be applied to the Bronchoscopic Transparenchymal Nodule Access (BTPNA) and biopsy of peripheral bronchial inaccessible lesion. Under the guidance of the navigation system, Bronc $Tru^{^{\text{TM}}}$ can create a accurate access to lesions outside the airway, especially the peripheral isolated pulmonary nodules that are not visible under X-ray, and create a direct access to the lesion site to realize the diagnosis and follow-up treatment in whole lung.

Compared with the traditional BTPNA, using the new generation of BTPNA by BroncTru™, can rapidly create access to the lesion outside the airway through "puncture-expansion" procedure. It simplifies the procedure, greatly reduces the time of traditional operation, improves the efficiency and facilitates, the popularization of operation. The product is compatible with the existing biopsy tools and future radiofrequency ablation treatment devices, and its multi-safety design can minimize the risk of inadvertent operation and improve intraoperative safety, which enables quicker and accurate diagnosis and treatment.

The product was officially approved for marketing by the Zhejiang Medical Products Administration in September 2023. The product with multiple patents has been applied in multi-scenarios in the field of diagnosis and treatment of lung diseases.

Navigation platforms: LungPoint, LungPoint Plus/Archimedes Lite and Archimedes System

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 airway 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 United States 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 United States 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.
- LungPoint ATV System, also known as LungPro in China or the Archimedes System outside of China (the "Archimedes System"), is an upgraded product based on 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 airways. The Archimedes System was approved for marketing and commercial use in the United States by the FDA in 2014, the UN 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, a Class IIa medical device by the NMPA.

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET TLD AND RF-II 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 United States, where we manufacture navigation products and InterVapor® in the United States, and LungPoint, LungPoint Plus and various therapeutic products in China. The production center in Hangzhou, China occupies an aggregate gross floor area of approximately 3,122 sq.m. and the production center in San Jose, the United States occupies an aggregate gross floor area of approximately 863 sq.m.

Manufacturing of our therapeutic products

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. We have commenced the manufacturing of our other therapeutic products (including InterVapor® products) in our Hangzhou facility in 2021, and the domestic InterVapor® (including disposable catheters and device) has been granted registration approval by the NMPA in July and October 2023, thus fully realized in-house manufacturing.

Manufacturing of our navigation systems

Our navigation systems, including LungPoint, LungPoint Plus and Archimedes System, are manufactured in our San Jose, California facility in the United States. The facility is ISO13485 compliant and Broncus Medical is the manufacturer of record in the U.S. 510(k) clearance and European CE Marked LungPoint products. Domestic LungPoint (bronchoscopic placement navigation system) has obtained the NMPA registration approval in September 2023. Domestic Archimedes System (whole lung navigation system, known as LungPro in China) is expected to be approved in the third quarter of 2024.

Manufacturing of our diagnosis medical consumables and product candidates

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

Innovation and 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 products. To strengthen our R&D capabilities, we adopt an efficient R&D model that combines international technologies with local R&D cost advantage to support our intellectual property portfolio and product iterations.

We are engaged in ongoing R&D activities to deliver clinical 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 19 product candidates in various stages.

Intellectual Property

As of December 31, 2023, we obtained 844 patents and patent applications, including 400 issued patents and 194 patent applications in China, and 117 issued patents and 136 patent applications overseas, including major markets such as the United States and the EU. Among the patents obtained, 127 and 53 of them were related to InterVapor® and RF-II, respectively.

COMMERCIALIZATION

Market Review

Facing the global prevalence of COPD and lung cancer that has been propelled by aging population, air pollution and smoking habits, we see a huge market demand for minimally invasive solutions to treat lung diseases. According to Frost & Sullivan, in 2022, there were 233.6 million cases of COPD in the world and 107 million cases in China, which are expected to increase to 258.4 million and 109.6 million by 2025, respectively. On November 16, 2022, the 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. In addition, the median number of acute exacerbation of COPD patients in China was 3 in the past year, and patients under acute exacerbation condition accounted for approximately 51.6% of COPD patients. Patients with onset of COPD require emergency admission to the ICU wards. Therefore, the entire population of COPD patients, especially patients in the severe and extremely severe conditions, is in great need of effective COPD therapeutic solutions.

Global lung cancer incidence reached approximately 2.26 million 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 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.

Marketing

In 2023, we comprehensively launched the respiratory interventional diagnosis "Broncus Scheme", forming a closed loop of respiratory interventional diagnosis and treatment logic of "positioning-arrival-diagnosis-treatment". With navigation as the basic diagnosis platform, we take the interventional treatment of COPD and lung cancer as the core starting point, progressively advancing respiratory intervention into the treatment era.

Currently, we primarily sell and market our interventional pulmonary products in the U.S., Europe and Asia. In 2023 financial year, our products were sold to various countries and regions, including the United States, the United Kingdom, Germany, France, etc. As our current products and product candidates receive more marketing approvals or CE Marking certification, we expect to generate more sales globally.

InterVapor® Thermal Vapor Treatment System is the first innovative non-implantable medical device in the world to treat COPD with bronchial intervention, creating a precedent for thermal vapour in the field of respiratory intervention and a transbronchial thermal vapour lung ablation (BTVA), which has been included in the Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline consecutively for years 2019-2023 and recommended for patients with severe and very severe emphysema. The treatment technology based on InterVapor® is highly innovative and groundbreaking, which has been clinically proven to be effective and safe, making up for the current effective treatment of patients with severe emphysema. In 2019, InterVapor® was awarded "Breakthrough Device" by the U.S. FDA. Although innovative medical devices have addressed clinical pain points, there are still difficulties such as clinical surgical promotion, science popularization among patients, complicated hospital admission and bidding process in the pre-marketing stage. After the launch of InterVapor® in China, we have achieved certain results through our efforts. As at the date of this announcement, InterVapor® has been commercialized and applied in more than 20 hospitals. About 100 hospitals have tried the technology. Meanwhile, 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 20 provinces and cities across the country.

According to public information statistics by the Company, the market share of our lung navigation products in China reached 40%.

BroncTru[™], the disposable transbronchoscopic puncture dilatation catheter, has been applied in multi-scenarios in the field of diagnosis and treatment of lung diseases. After commercialization, it has been clinically applied in multi-scenarios in Chest Hospital of Shanghai Jiao Tong University and other hospitals.

MARKET OUTLOOK AND FUTURE PLANS

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 minimally invasive solutions to treat lung diseases. According to Frost & Sullivan, in 2022, there were 233.6 million cases of COPD in the world and 107 million cases in China, which are expected to increase to 258.4 million and 109.6 million by 2025, respectively. As a global leader in interventional diagnosis and treatment products for lung diseases, we offer a full range of solutions from navigation platforms to diagnosis and treatment, and expand into the field of minimally invasive interventional surgery with surgical robots in the future through the R&D of our own flexible surgical robots.

We plan to expand our sales network by providing systematic doctor training and patient education, raising the awareness of hospitals, doctors and patients about the navigation platform as an indispensable tool for interventional pulmonology diagnosis and treatment, and raising the awareness of interventional treatment for lung diseases to promote the launch of our products and deepen the penetration of treatment products in hospitals. Meanwhile, through the penetration of our proprietary BTPNA technology and the development and commercialization of a series of therapeutic products such as RF-II and TLD, the penetration of navigation devices in hospitals is further promoted.

With respect to InterVapor®, our key marketing strategies will include, firstly, enhancing our position as a leader in differentiated therapeutic areas and further improving utilization through professional education and marketing; secondly, accelerating the process of product procurement, introduction into hospitals and medical insurance; thirdly, focusing on mobilizing our internal sales team via targeted coaching and progress tracking to drive consumable utilization.

By leveraging our extensive experience in promoting LungPoint and Archimedes System, we plan to expand the sales of other diagnostic consumables. Our R&D team will continue to deepen our efforts in the field of pulmonary intervention, mainly focusing on the R&D of products for the treatment of lung diseases, continuously improving the alignment of our major products with clinical needs, and sustaining technological and product innovation. Meanwhile, we will consolidate and enrich our intellectual property portfolio of existing and future technologies through precise market positioning, forming strong defensibility for our patents. We also plan to increase spending on artificial intelligence and machine learning to accumulate large sets of clinical data and cases to further improve the performance of our navigation systems and diagnosis and treatment procedures.

In 2024, with the launch of the Company's domestic series of navigation system, the navigation system in China will gradually shift to the lower-tier market, which also paves the way for the subsequent increase in treatment and diagnostic consumables. Since most of the Company's product offerings are innovative technologies and product solutions, this year we will also made market access in various regions as a key task, laying a solid foundation for subsequent product launches and volume growth.

Looking forward to 2024, we will continue to promote the pre-marketing clinical trials of our product candidates, and improve the evidence-based medical evidence of our marketed products through post-marketing clinical studies that meet regulatory requirements.

- a. The pivotal clinical study of the TLD product was 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 efficacy 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.
- b. We plan to support a government-sponsored prospective, multi-center, single-blind, randomized controlled trial in Germany, titled Targeted Segmental Vapor Ablation Treatment of Emphysema with Upper LobePredominance: A randomized Controlled Trial of InterVapor®, which is expected to initiate in the fourth quarter of 2023 and be completed by 2025.
- c. We plan to conduct a series of clinical studies focusing on lung cancer indications and certain post-marketing clinical studies for InterVapor® in several other regions. Clinical trials for lung cancer indications are expected to be conducted in China and Europe from 2023 to 2025. Our planned post-marketing clinical studies include post-marketing clinical studies to be conducted in China from 2023 to 2025 and post-marketing clinical studies to be conducted in India from 2021 to 2028.

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 mainly derived from sale of medical devices and consumables. For the year ended December 31, 2023, the revenue of the Group was US\$10.3 million, representing an increase of 8.9%, compared with US\$9.4 million in the corresponding period last year. Of which, the revenue generated from sale of medical devices and consumables was US\$12.4 million, representing an increase of 31.8% as compared to last year.

The following table sets out a breakdown of revenue by product:

Revenue	For the ye December US'000		For the ye December US'000	
Revenue from product sales and after-sales services Navigation products Vapor products Other consumables and after-sales services	5,987 5,152 1,268	48.3 % 41.5 % 10.2 %	5,874 2,485 1,054	62.4% 26.4% 11.2%
Sub-total	12,407	100.0%	9,413	100.0%
Licensing fees	(2,152)			
Total	10,255		9,413	

Note:

(1) Vapor products include Vaopr devices and consumables.

Costs of Sales

Costs of sales mainly consist of staff cost, raw material costs, depreciation and amortization, utility costs and others. For the year ended December 31, 2023, the Group's costs of sales was US\$3.0 million, representing an increase of 44.3% from US\$2.1 million in the corresponding period last year, mainly due to an increase in revenue from product sales.

Gross Profit and Gross Profit Margin

For the year ended December 31, 2023, gross profit was US\$7.2 million, representing a decrease of 1.2% from US\$7.3 million in the corresponding period last year. Gross profit margin is calculated based on gross profit divided by revenue. Excluding the effect of income from licensing fees, the Group's gross profit margin on products sold decreased from 78% for the year ended December 31, 2022 to 74% for the year ended December 31, 2023, which was due to the fact that, on the one hand, the products currently sold were mainly navigation and vapor products manufactured in the US with a slight increase in production costs as compared with last year, and on the other hand, sales revenue in China was affected by the exchange rate, and the gross profit margin also declined.

Other Income and Gains

For the Reporting Period, our other income and gains consist primarily government grants and bank interest income. For the year ended December 31, 2023, total other income and gains were approximately US\$6.0 million, representing an increase of US\$1.2 million from the year ended December 31, 2022, mainly due to an increase in interest income from US\$2.6 million to US\$ 6.0 million.

Selling and Distribution Expenses

For the years ended December 31, 2023 and 2022, our selling and distribution expenses were US\$11.5 million and US\$11.2 million, respectively, representing an increase of 2.7%. Our sales revenue increased, but selling and distribution expenses remained substantially stable.

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, 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 years ended December 31, 2023 and 2022, we incurred R&D costs of approximately US\$20.2 million and US\$19.2 million, respectively, representing an increase of 5.1%. The increase in our R&D costs was mainly due to an increase in clinical trial fees from US\$0.6 million to US\$1.5 million as a result of an increase in the number of clinical trials.

	For the year ended December 31, 2023		For the year ended December 31, 2022	
	US\$'000	Proportion	US\$'000	Proportion
Staff cost	10,851	53.9%	10,446	54.5%
Technical service fees	2,364	11.7%	2,537	13.2%
Depreciation and amortization	2,386	11.8%	2,426	12.7%
Clinical trial expenses	1,496	7.4%	623	3.3%
Raw material costs	760	3.8%	909	4.7%
Share awards	318	1.6%	859	4.5%
Others	1,979	9.8%	1,367	7.1%
Total	20,154	100.0%	19,167	100.0%

Administrative Expenses

For the years ended December 31, 2023 and 2022, our total administrative expenses were approximately US\$8.9 million and US\$9.2 million, respectively.

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, 2023, our cash and bank balances and deposits totaled US\$156.6 million, as compared to our cash and bank balances and deposits of US\$188.4 million as at December 31, 2022. 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.

As at December 31, 2023, cash and cash equivalents were mainly denominated in United States dollars, Hong Kong dollars and Renminbi.

Bank Borrowings and Gearing

As at December 31, 2023, the Group's outstanding borrowings of US\$16,000 (December 31, 2022: US\$29,000) were denominated in US\$ and Shekel.

The Group's overseas credit card overdraft facilities amounting to US\$84,000 (2022: US\$80,000), of which US\$16,000 (2022: US\$29,000) had been utilized, were secured by certain of the Group's time deposits totaling US\$25,000 (2022: US\$25,000).

The Group monitored capital using gearing ratio. As at December 31, 2023, the Group's gearing ratio (calculated as total borrowings and lease liabilities divided by total equity) was 1.3% (December 31, 2022: 0.7%).

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. Our management monitors foreign exchange risk and considers appropriate hedging measures if necessary in the future.

Contingent Liabilities

As at December 31, 2023, the Group did not have any significant contingent liabilities.

Charge or Restrictions on Assets

As at December 31, 2023, the Group had pledged deposits of US\$238,000 (December 31, 2022: US\$526,000). The pledged deposits were placed to secure the Group's bank overdraft facilities and as guarantees to the Group's lessor. 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 nonrecurring 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:

	For the year ended December 31,	
	2023 20	
	US\$'000	US\$'000
Loss for the year	(28,092)	(28,036)
Add:		
Share awards ⁽¹⁾	556	1,123
Non-IFRS adjusted net loss for the year ⁽²⁾	(27,536)	(26,913)

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 the share awards 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 share awards expenses provides useful information to investors in facilitating a comparison of our operating performance from year to year.

SIGNIFICANT INVESTMENTS 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.

FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

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.

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 C1 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 C3 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.

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, 2023, the Group had 308 employees of which 266 were based in China while 42 were based overseas (mainly in the U.S., Europe, Israel and India). 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 22.6 million (for the same period in 2022: US\$22.4 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\$1,620.1 million, after deducting the underwriting commission and other expenses payable by the Company in connection with the Global Offering.

As at December 31, 2023, the Company has utilized approximately HK\$548.9 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\$1,071.2 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 the beginning of the Reporting Period HKD' million	Actual usage during the Reporting Period HKD' million	Amount of unutilized net proceeds 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	369.5	84.1	285.4	Expected to be fully utilized by 2030
Development and commercialisation of RF-II	21.0%	339.4	299.8	13.0	286.8	Expected to be fully utilized by 2030
R&D of other product candidates	18.5%	299.9	218.1	103.8	114.3	Expected to be fully utilized by 2030
Production line expansion of our manufacturing facility	9.2%	149.2	149.2	-	149.2	Expected to be fully utilized by 2026
M&A, investing in or acquiring new pipelines	13.2%	213.2	213.2	19.2	194.0	Expected to be fully utilized by 2026
Working capital and other general corporate purposes	9.2%	149.2	68.3	26.8	41.5	Expected to be fully utilized by 2026
Total	100.0%	1,620.1	1,318.1	246.9	1,071.2	

Audit Committee

The Audit Committee of our Company (the "Audit Committee") has reviewed the annual consolidated financial statements for the year ended December 31, 2023 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, 2023, but represents an extract from the consolidated financial statements for the year ended December 31, 2023 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

The Company is not aware of any material subsequent events from December 31, 2023 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, 2023 (2022: Nil).

CLOSURE OF REGISTER OF MEMBERS AND RECORD DATE

The register of members of the Company will be closed from Tuesday, May 14, 2024 to Monday, May 20, 2024, 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 20, 2024 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 Monday, May 13, 2024.

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, 2023 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 NINTH AMENDED AND RESTATED MEMORANDUM AND ARTICLES OF ASSOCIATION

This section of the announcement is made pursuant to Rule 13.51(1) of the Listing Rules.

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 relevant amendments made to the Listing Rules in respect of the electronic dissemination of corporate communications by listed issuers (effective from December 31, 2023); and (ii) make other consequential and housekeeping amendments.

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 (if necessary) 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 20, 2024
"associate(s)"	has the meaning ascribed to it under the Listing Rules
"Board" or "Board of Directors"	the board of Directors
"BSI"	the BSI Group, The Netherlands B.V., a notified body designated by the competent authorities to conduct conformity assessment of medical devices under the EU regulations
"CG Code"	Corporate Governance Code as set out in Appendix C1 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 "FDA" The United States Food and Drug Administration, a federal agency of the Department of Health and Human Services "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," the Company and our subsidiaries (or the Company and any "we" or "us" one or more of our subsidiaries, as the context may require) "HK\$" or "HK dollars" or Hong Kong dollars, the lawful currency of Hong Kong "Hong Kong dollars" "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 the ninth amended and restated memorandum and articles of Articles of association of the Company adopted by a special resolution Association" passed on May 15, 2023, as may be amended and/or restated from time to time "Model Code" the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 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 Chinese Taiwan

"Proposed Amendments"

has the meaning ascribed to it in this announcement

"R&D"

Research and development

"Reporting Period"

12 months ended December 31, 2023

"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

XU Hong

Executive Director

Hong Kong, March 28, 2024

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