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Broncus Holding Corporation

堃博医疗控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2216)

**ANNOUNCEMENT OF ANNUAL RESULTS
FOR THE YEAR ENDED DECEMBER 31, 2024
AND
CHANGE IN USE OF NET PROCEEDS**

The Board is pleased to announce the audited consolidated results of the Company and its subsidiaries for the Reporting Period, together with the audited comparative figures for the year ended December 31, 2023.

FINANCIAL HIGHLIGHTS

	Year ended December 31, 2024 USD'000	Year ended December 31, 2023 USD'000	Year-to-year change
Revenue	8,131	10,255	-21%
Gross Profit	6,139	7,227	-15%
Loss for the year	(15,303)	(28,092)	-46%
Add:			
Share awards	236	556	-58%
Non-IFRS adjusted net loss for the year⁽¹⁾	(15,067)	(27,536)	-45%
Cash and bank balances and deposits	139,346	156,647	-11%

⁽¹⁾ Please refer to the section headed “Non-IFRS Measures” in this 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 progress with respect to our product pipelines and business operations, with some milestones summarised below:

➤ ***Clinical Progress and Standard Development***

Over the past year, our flagship products have demonstrated promising clinical results across a range of therapeutic areas. We also remain to prioritize advancement of post-marketing clinical trials and the facilitating expert consensus building.

- In April, the expert consensus on diagnosis, localization, and treatment of peripheral lung nodules under augmented reality optical whole lung diagnostic and therapeutic navigation guidance were officially released.
- In July, the thematic Seminar on Standardized Clinical Application of Bronchoscopic Thermal Vapor Lung Volume Reduction for COPD was held, with the aim of establishing an expert consensus on the Standardized Clinical Application of BTVA.
- In August, the clinical trial results of BRONC-RF II were published in the authoritative academic journal *Respirology*, validating the advantages of our proprietary Transbronchial Radiofrequency Ablation System (BroncAblate®) in lung tumor treatment in terms of safety and efficacy, providing strong clinical evidence supporting the development and application of the transbronchial ablation system as a treatment method for lung tumors.
- In September, the kick-off meeting for the post-marketing clinical study of InterVapor®, titled “A prospective, single-arm, multicenter clinical study evaluating the efficacy and safety of BTVA in treating Heterogeneous Emphysema distribution” was successfully held.
- Patients have been successfully enrolled in our pre-marketing clinical trial for the interventional treatment product of acute exacerbation of COPD, the targeted lung denervation. As of December 31, 2024, more than 50% of the patients have been enrolled.

➤ ***Commercialization and Promotion of Innovative Techniques***

We have developed a multitude of innovative products in the field of interventional pulmonology and pioneered related clinical techniques. We fully acknowledge that promoting innovative techniques entails a challenging endeavor requiring extensive and rigorous preparatory efforts. Despite various obstacles, our management and marketing teams have worked closely together to advance the clinical application of BTVA, EBUS-TTCB and other techniques in hospitals across provinces and cities, including Beijing, Shanghai, Shandong, Jiangsu, Hunan, Jiangxi, Henan, Yunnan, Tibet, Xinjiang and others, providing safe and effective solutions for patients and physicians.

- In July, Professor Hou Gang (侯剛)'s team innovatively utilized the BroncTru® disposable transbronchoscopic dilatation catheter to develop a procedure named Endobronchial Ultrasound-Guided Tunnel Cryobiopsy which is expected to become a new, safe, and feasible method for mediastinal lymph node cryobiopsy.
- In September, our BroncAblate® was successfully combined use with surgical robots at Shanghai Chest Hospital, where Professor Sun Jiayuan (孫加源)'s team performed the world's first robot-assisted bronchoscopic radiofrequency ablation surgery for lung cancer. This breakthrough has expanded the possibilities for interventional diagnosis and treatment of lung diseases, offering new perspectives and paving the way for advancing the treatment threshold of lung diseases, in particular lung cancer.
- Since the launch of InterVapor® Thermal Vapor Treatment System in China, nearly 200 hospitals have conducted pilot use/trials for the system, and its efficacy in treating severe COPD has been widely recognized by patients and healthcare providers.
- In March 2025, our lung imaging processing software, BroncQCT® (the “**Software**”), has officially received approval from the Zhejiang Medical Products Administration for marketing in China. The Software is expected to enhance physicians' efficiency in examining lung computed tomography (CT) images, providing support for clinical auxiliary diagnosis and treatment, and promoting more efficient and precise diagnostic processes.

➤ ***Expanding our business globally***

We are a pioneering company in the field of Interventional Pulmonology, with a clear strategic focus on expanding our global business operations. By the end of 2024, our global footprints have expanded to 37 countries/regions worldwide, including the U.S., the United Kingdom, Italy, Germany, Singapore, India, Australia and others. Regarding market access, to date, we have obtained 66 registration certificates overseas, including the two new FDA approvals for Biostar® and BroncTru® during the year and the certifications for LungPro® in Singapore and Malaysia. During 2024, our product applications were successfully progressed in several countries, including Poland, Saudi Arabia, with a year-on-year increase of 29% in revenue from overseas sales.

Our Company has grown with recognition in various fields, as we were successively awarded a number of honours, including the first prize of 2023 Science and Technology Progress Award of Sichuan Province (四川省科學技術進步一等獎), the second prize of the 13th Innovation and Entrepreneurship Competition in China – Medical materials and high-end consumables (Growth Division) (第十三屆中國創新創業大賽醫用材料和高端耗材專業賽(成長組)二等獎), Award of Excellence in ESG communications and investors relationship (ESG溝通與投資者關係卓越獎) and Outstanding IR Team of the Year.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2024

	Notes	2024 USD'000	2023 USD'000
REVENUE	5	8,131	10,255
Cost of sales		<u>(1,992)</u>	<u>(3,028)</u>
Gross profit		6,139	7,227
Other income and gains	5	9,345	6,019
Selling and distribution expenses		(8,490)	(11,486)
Administrative expenses		(7,265)	(8,929)
Impairment losses on financial assets, net		(1,401)	121
Research and development costs		(11,471)	(20,154)
Other expenses		(2,073)	(804)
Finance costs	7	<u>(84)</u>	<u>(83)</u>
LOSS BEFORE TAX	6	(15,300)	(28,089)
Income tax expense	8	<u>(3)</u>	<u>(3)</u>
LOSS FOR THE YEAR		<u>(15,303)</u>	<u>(28,092)</u>
Attributable to:			
Owners of the parent		(15,303)	(28,091)
Non-controlling interests		<u>-</u>	<u>(1)</u>
		<u>(15,303)</u>	<u>(28,092)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (USD)	10	<u>(0.03)</u>	<u>(0.06)</u>

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2024

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
LOSS FOR THE YEAR	<u>(15,303)</u>	<u>(28,092)</u>
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(826)</u>	<u>(603)</u>
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	<u>(826)</u>	<u>(603)</u>
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	<u>(16,129)</u>	<u>(28,695)</u>
Attributable to:		
Owners of the parent	<u>(16,129)</u>	<u>(28,694)</u>
Non-controlling interests	<u>-</u>	<u>(1)</u>
	<u>(16,129)</u>	<u>(28,695)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION*31 December 2024*

	<i>Notes</i>	31 December 2024 USD'000	31 December 2023 USD'000
NON-CURRENT ASSETS			
Property, plant and equipment		1,279	2,398
Right-of-use assets		310	2,157
Other intangible assets		7,706	8,970
Financial assets at fair value through profit or loss		14,670	8,878
Finance lease receivables		19	42
Prepayments, other receivables and other assets		121	708
		<hr/>	<hr/>
Total non-current assets		24,105	23,153
CURRENT ASSETS			
Inventories		3,599	4,709
Finance lease receivables		26	26
Trade receivables	<i>11</i>	7,863	9,959
Prepayments, other receivables and other assets		956	1,311
Pledged deposits		238	238
Structured deposits		40,291	–
Time deposits with original maturity over three months		52,344	72,845
Cash and cash equivalents		46,473	83,564
		<hr/>	<hr/>
Total current assets		151,790	172,652
CURRENT LIABILITIES			
Trade payables	<i>12</i>	255	399
Lease liabilities		296	1,115
Other payables and accruals		5,089	6,944
Bank overdrafts		22	16
Derivative financial instruments		170	–
Contract liabilities		586	684
		<hr/>	<hr/>
Total current liabilities		6,418	9,158
NET CURRENT ASSETS		<hr/> 145,372	<hr/> 163,494
TOTAL ASSETS LESS CURRENT LIABILITIES		<hr/> 169,477	<hr/> 186,647

	31 December 2024 USD'000	31 December 2023 USD'000
TOTAL ASSETS LESS CURRENT LIABILITIES	<u>169,477</u>	<u>186,647</u>
NON-CURRENT LIABILITIES		
Lease liabilities	–	1,224
Contract liabilities	–	53
Total non-current liabilities	<u>–</u>	<u>1,277</u>
Net assets	<u>169,477</u>	<u>185,370</u>
EQUITY		
Equity attributable to owners of the parent		
Share capital	12	12
Reserves	<u>169,466</u>	<u>185,359</u>
	169,478	185,371
Non-controlling interests	<u>(1)</u>	<u>(1)</u>
Total equity	<u>169,477</u>	<u>185,370</u>

NOTES TO CONSOLIDATED FINANCIAL INFORMATION

31 December 2024

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 are located at Room 801, 8/F, Building 8, No. 88 Jiangling Road, Xixing Street, Binjiang District, Hangzhou, Zhejiang Province, People's Republic of China (the "PRC") and Room 1101-4, Building 1, No. 502 Linping Avenue, Linping District Economic and Technological Development Zone, Hangzhou, Zhejiang Province, 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 IFRS Accounting Standards as 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, derivative financial instruments 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 revised IFRS Accounting Standards for the first time for the current year's consolidated financial statements.

Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> (the "2020 Amendments")
Amendments to IAS 1	<i>Non-current Liabilities with Covenants</i> (the "2022 Amendments")
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i>

The nature and the impact of the revised IFRS Accounting Standards are described below:

- (a) Amendments to IFRS 16 specify the requirements that a seller-lessee uses in measuring the lease liability arising in a sale and leaseback transaction to ensure the seller-lessee does not recognise any amount of the gain or loss that relates to the right of use it retains. Since the Group has no sale and leaseback transactions with variable lease payments that do not depend on an index or a rate occurring from the date of initial application of IFRS 16, the amendments did not have any impact on the financial position or performance of the Group.
- (b) The 2020 Amendments clarify the requirements for classifying liabilities as current or non-current, including what is meant by a right to defer settlement and that a right to defer must exist at the end of the reporting period. Classification of a liability is unaffected by the likelihood that the entity will exercise its right to defer settlement. The amendments also clarify that a liability can be settled in its own equity instruments, and that only if a conversion option in a convertible liability is itself accounted for as an equity instrument would the terms of a liability not impact its classification. The 2022 Amendments further clarify that, among covenants of a liability arising from a loan arrangement, only those with which an entity must comply on or before the reporting date affect the classification of that liability as current or non-current. Additional disclosures are required for non-current liabilities that are subject to the entity complying with future covenants within 12 months after the reporting period.

The Group has reassessed the terms and conditions of its liabilities as at 1 January 2023 and 2024 and concluded that the classification of its liabilities as current or non-current remained unchanged upon initial application of the amendments. Accordingly, the amendments did not have any impact on the financial position or performance of the Group.

- (c) Amendments to IAS 7 and IFRS 7 clarify the characteristics of supplier finance arrangements and require additional disclosure of such arrangements. The disclosure requirements in the amendments are intended to assist users of financial statements in understanding the effects of supplier finance arrangements on an entity's liabilities, cash flows and exposure to liquidity risk. As the Group does not have supplier finance arrangements, the amendments did not have any impact on the Group's consolidated financial statements.

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

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Mainland China	3,214	6,465
European Union	2,628	1,848
Other countries/regions	2,289	1,942
Total revenue	<u>8,131</u>	<u>10,255</u>

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

(b) Non-current assets

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Mainland China	3,471	6,461
USA	3,329	4,620
Israel	2,500	2,994
European Union	9	16
Other countries/regions	13	4
Total non-current assets	<u>9,322</u>	<u>14,095</u>

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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Customer A	–	6,317
Customer B	1,547	–
Customer C	1,432	522

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
<i>Revenue from contracts with customers</i>		
Sale of medical devices and consumables	7,571	11,984
Licensing of intellectual property rights*	–	(2,152)
Provision of services	560	423
	<u>8,131</u>	<u>10,255</u>
Total	<u><u>8,131</u></u>	<u><u>10,255</u></u>

* In November 2023, the Group terminated the licence agreement with NoahTron Intelligence Medtech (Hangzhou) Co., Ltd. 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*

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Geographical markets		
Mainland China	3,214	6,465
European Union	2,628	1,848
Other countries/regions	2,289	1,942
	<u>8,131</u>	<u>10,255</u>
Total	<u><u>8,131</u></u>	<u><u>10,255</u></u>
Timing of revenue recognition		
Goods transferred at a point in time	7,571	9,832
Services transferred over time	560	423
	<u>8,131</u>	<u>10,255</u>
Total	<u><u>8,131</u></u>	<u><u>10,255</u></u>

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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Sale of medical devices and consumables	281	26
Provision of services	269	269
	<u>550</u>	<u>295</u>
Total	<u><u>550</u></u>	<u><u>295</u></u>

(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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Amounts expected to be recognised as revenue:		
Within one year	452	749
After one year	134	53
Total	586	802

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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Other income		
Government grants (<i>note a</i>)	1,296	21
Bank interest income	6,534	6,041
Reversal of interest from non-current receivables	–	(80)
Others	5	23
	<u>7,835</u>	<u>6,005</u>
Gains		
Gain on disposal of non-current assets	–	14
Foreign exchange gains, net	610	–
Fair value adjustments of contingent consideration	900	–
	<u>1,510</u>	<u>14</u>
Total other income and gains	<u><u>9,345</u></u>	<u><u>6,019</u></u>

Note:

- (a) The government grants mainly represent incentives received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new product development and compensation for expenditure incurred on certain projects. There were no unfulfilled conditions or contingencies attached to these grants.

6. LOSS BEFORE TAX

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

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Cost of inventories sold	1,921	3,086
Cost of services provided	22	111
Cost of licensing of intellectual property rights	–	(250)
Research and development costs	11,471	20,154
Loss/(gain) on disposal of items of property, plant and equipment	780	(7)
	<u><u>780</u></u>	<u><u>(7)</u></u>

7. FINANCE COSTS

An analysis of finance costs is as follows:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Interest on lease liabilities	<u><u>84</u></u>	<u><u>83</u></u>

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 5% (2023: 5%) for small and micro enterprises except that Hangzhou Broncus was subject to CIT at a rate of 25% (2023: 15%) 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% (2023: 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% (2023: 19%) on the estimated assessable profits arising in Netherlands 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% (2023: 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% (2023: 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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Current – USA		
Charge for the year	<u>3</u>	<u>3</u>

9. DIVIDEND

No dividend has been paid or declared by the Company during the year (2023: nil).

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

The calculation of the basic loss per share amount 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 488,860,643 (2023: 488,570,732) outstanding 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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
<u>Loss</u>		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	<u>(15,303)</u>	<u>(28,091)</u>
	Number of shares	
	2024	2023
<u>Shares</u>		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	<u>488,860,643</u>	<u>488,570,732</u>

As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2024 and 2023 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

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Current		
Trade receivables	<u>10,344</u>	<u>11,065</u>
Impairment	<u>(2,481)</u>	<u>(1,106)</u>
Total	<u>7,863</u>	<u>9,959</u>

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.

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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Within 3 months	1,630	5,889
3 to 6 months	64	45
6 to 12 months	1,785	3,862
1 to 2 years	4,384	163
	<hr/>	<hr/>
Total	7,863	9,959
	<hr/> <hr/>	<hr/> <hr/>

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:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Within 3 months	253	232
3 to 6 months	–	166
6 to 12 months	–	1
Over 1 year	2	–
	<hr/>	<hr/>
Total	255	399
	<hr/> <hr/>	<hr/> <hr/>

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

13. RELATED PARTY TRANSACTIONS

Name	Relationship
Hangzhou Dinova Medical Technology Co., Ltd. (“ Hangzhou Dinova ”)**	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 (“ Hangzhou Jingliang ”)**	An entity controlled by Mr. Michael Yi Wei Zhao and Mr. Zhenjun Zi before acquisition

* In September 2023, the Company acquired 100% of shares of FHC.

** In December 2023, Hangzhou Broncus acquired 100% of shares of Hangzhou Jingliang.

*** Mr. Michael Yi Wei Zhao resigned as a non-executive director and the chairman of the board of directors on 19 April 2024, Hangzhou Dinova and Dinova Healthcare have ceased to be related parties of the Group since then.

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

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Management service from:		
Hangzhou Dinova (<i>note (i)</i>)	—	157
	<u> </u>	<u> </u>
Purchase of research service from:		
Fibernova (<i>note (ii)</i>)	N/A	350
	<u> </u>	<u> </u>

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.

(b) Outstanding balances with related parties:

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Other payables and accruals: *		
Hangzhou Dinova	<u>N/A</u>	<u>104</u>
Contingent consideration payables:		
Dinova Healthcare	<u>N/A</u>	<u>831</u>

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 in September 2023.

* The balances are trade in nature.

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

	2024 <i>USD'000</i>	2023 <i>USD'000</i>
Salaries, allowances and benefit in kind	291	706
Pension scheme contributions	6	19
Equity-settled share award expenses	<u>57</u>	<u>1</u>
Total compensation paid to key management personnel	<u>354</u>	<u>726</u>

MANAGEMENT DISCUSSION AND ANALYSIS

BUSINESS OVERVIEW

OUR PROFILE

Focus on the interventional treatment of Chronic Obstructive Pulmonary Disease (referred to as “**COPD**”) and lung cancer, we are pioneers in the field of Interventional Pulmonology, providing innovative solutions for lung diseases in China and globally. In the large-scale, underdeveloped and rapidly growing interventional respiratory medicine market, leveraging China’s first and only real-time imaging-based full-lung navigation technology, we have established a comprehensive “navigation-diagnosis-treatment” platform for interventional respiratory disease treatment platform. This platform addresses the pain points of existing treatment models and the unmet clinical needs of lung diseases, leading the transformation of diagnosis and treatment paradigms and advancing the field of lung diseases into the era of precision medicine.

OUR VISION

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

OUR MISSION

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

In 2024, we observed increased volatility in biopharmaceutical sector compared to previous years, influenced by macroeconomic factors, structural elements, and cyclical reasons. Nevertheless, the public’s growing awareness of healthy living continues to drive demand in biopharmaceutical industry, the advancement of life sciences and the launch of new products have not slowed down. Against this backdrop, as a pioneer in the field of interventional pulmonology, we remain dedicated to the research, development, and enhancement of interventional treatment product pipelines for lung diseases, particularly lung cancer and COPD. Our goal is to advance interventional pulmonology therapies, effectively alleviate patients’ symptoms, improve their quality of life, and potentially extend their survival. We also acknowledge that the development of the biopharmaceutical industry is propelled by addressing unmet clinical needs, refining existing treatment methods, and achieving technological breakthroughs. In the field of interventional pulmonology, interventional therapeutic solutions of lung cancer and COPD are currently integrating these critical factors. We are indeed making sustained efforts to align with and amplify the development trend of the industry.

During the Reporting Period, we overcame multiple headwinds, focus on our core business and enhance internal operational efficiency and quality, and concentrated the resources on the clinical trials, registration and commercialization process of our core interventional pulmonology treatment products. Our overall business remained stable, with a significant decrease in losses compared to the corresponding period of last year and continuous optimization of cash flow. Our innovative products have entered more hospitals both domestically and internationally, providing safe and effective clinical solutions for patients and healthcare providers. Meanwhile, we have kept up the pace in clinical and research efforts, further creating momentum for our products.

- ***Clinical Progress and Standard Development***

Over the past year, our flagship products have demonstrated promising clinical results across a range of therapeutic areas. We also continue to prioritize advancement of post-marketing clinical trials and the facilitating expert consensus building.

- In April, the expert consensus on diagnosis, localization, and treatment of peripheral lung nodules under augmented reality optical whole lung diagnostic and therapeutic navigation guidance were officially released. The Interventional Study Group of the Respiratory Disease Branch of the Chinese Medical Association drafted the “Expert Consensus on Diagnosis, Localization, and Treatment of Peripheral Lung Nodules under Augmented Reality Optical Whole Lung Diagnostic and Therapeutic Navigation Guidance” with the collaboration of experts from various disciplines, which provides recommendations and clinical guidance on the indications and contraindications, equipment and instruments, handling of perioperative period, operational process, and complication management for the diagnosis, localization, and treatment of peripheral lung nodules under augmented reality optical whole lung diagnostic and therapeutic navigation technology.
- In July, the thematic Seminar on Standardized Clinical Application of Bronchoscopic Thermal Vapor Lung Volume Reduction for COPD was held during the 12th Chinese Medical Association Respiratory Endoscopy and Interventional Pulmonology Academic Conference in 2024. Experts exchanged their views and shared experiences on the Standardized Procedure of Bronchoscopic Thermal Vapor Ablation (referred to as (“**BTVA**”), with the aim of “establishing an expert consensus on the Standardized Clinical Application of Bronchoscopic Thermal Vapor Lung Volume Reduction for COPD”.
- In August, the clinical trial results of BRONC-RF II were published in the authoritative academic journal *Respirology*, validating the advantages of our proprietary Transbronchial Radiofrequency Ablation System (BroncAblate®) in lung tumor treatment in terms of safety and efficacy, providing strong clinical evidence supporting the development and application of the transbronchial ablation system as a treatment method for lung tumors, marking a new era in minimally invasive interventional therapy for lung cancer.
- In September, the kick-off meeting for the “prospective, single-arm, multicenter clinical study evaluating the efficacy and safety of BTVA in treating Heterogeneous Emphysema distribution” was duly held. Investigators from multiple centers jointly discussed the clinical study protocol and reached a preliminary consensus. This post-marketing clinical study of InterVapor® Thermal Vapor Treatment System is expected to generate high-quality clinical evidence, offering a safe and effective therapeutic option for patients.
- Patients have been successfully enrolled for our pre-marketing clinical trial for the interventional treatment product of acute exacerbation of COPD, the targeted lung denervation. As of December 31, 2024, more than half of the patients have been enrolled.

- ***Commercialization and Promotion of Innovative Techniques***

We have self-developed numerous innovative products in the interventional pulmonology diagnostic and therapeutic field and pioneered various clinical techniques based on these products. We fully recognize that promoting innovative techniques is a battle that requires extensive and arduous preliminary efforts. Despite various challenges, our management and marketing teams have worked closely together to advance the clinical application of BTVA, EBUS-TTCB and other techniques in hospitals across Beijing, Shanghai, Shandong, Jiangsu, Hunan, Jiangxi, Henan, Yunnan, Tibet, Xinjiang and other provinces and cities, providing safe and effective solutions for patients and physicians.

- In July, Professor Hou Gang (侯剛)’s team from the National Center for Respiratory Medicine (China-Japan Friendship Hospital) published their latest case study in Endoscopic Ultrasound (EUS), a first-tier journal of the Chinese Academy of Sciences, titled “Endobronchial ultrasound-guided transbronchial tunnel cryobiopsy for mediastinal lymphadenopathy (with video).” The team innovatively utilized the BroncTru® disposable transbronchoscopic dilatation catheter to perform transbronchial mediastinal cryobiopsy (EBUS-TTCB) under endobronchial ultrasound (EBUS) guidance. Professor Hou Gang’s team named this procedure Endobronchial Ultrasound-Guided Tunnel Cryobiopsy (referred to as “**EBUS-TTCB**”) and expressed his view that EBUS-TTCB is expected to become a new, safe, and feasible method for mediastinal lymph node cryobiopsy.
- In September, our BroncAblate® was successfully combined with surgical robots at Shanghai Chest Hospital, where Professor Sun Jiayuan (孫加源)’s team performed the world’s first robot-assisted bronchoscopic radiofrequency ablation surgery for lung cancer. This breakthrough has expanded the possibilities for interventional diagnosis and treatment of lung diseases, offering new perspectives and paving the way for advancing the treatment threshold of lung diseases, in particular lung cancer.
- Since the launch of InterVapor® Thermal Vapor Treatment System in China, nearly 200 hospitals have conducted pilot use/trials for the system, and its efficacy in treating severe COPD has been widely recognized by patients and healthcare providers.
- In March 2025, our lung imaging processing software, BroncQCT®, has officially received approval from the Zhejiang Medical Products Administration for marketing in China. The Software is expected to enhance physicians’ efficiency in examining lung computed tomography (CT) images, providing support for clinical auxiliary diagnosis and treatment, and promoting more efficient and precise diagnostic processes.

- ***Expanding our business globally***

We are a pioneering company in the field of Interventional Pulmonology, with a clear strategic focus on expanding our global business operations. By the end of 2024, our global footprints have expanded to 37 countries/regions worldwide, including the U.S., the United Kingdom, Italy, Germany, Singapore, India, Australia and others. Regarding market access, to date, we have obtained 66 registration certificates overseas, including the two new FDA approvals for Biostar® and BroncTru® during the year and the certifications for LungPro® in Singapore and Malaysia. During 2024, Our product applications were successfully progressed in several countries, including Poland and Saudi Arabia, with a year-on-year increase of 29% in revenue from overseas sales.

- ***Financial performance***

The Company's total revenue for the Reporting Period amounted to US\$8.1 million; losses for the year narrowed to US\$15.3 million from US\$28.1 million for FY2023, representing a year-on-year decrease of 46% in losses. As of 31 December 2024, we have sufficient cash reserves of US\$139.3 million, including cash and cash equivalents, time deposits, structured deposits and pledged deposits.

Our Company has grown with recognition in various fields, as we were successively awarded a number of honours, including the first prize of 2023 Science and Technology Progress Award of Sichuan Province (四川省科學技術進步一等獎), the second prize of the 13th Innovation and Entrepreneurship Competition in China – Medical materials and high-end consumables (Growth Division) (第十三屆中國創新創業大賽醫用材料和高端耗材專業賽(成長組)二等獎), Award of Excellence in ESG communications and investors relationship (ESG 溝通與投資者關係卓越獎) and Outstanding IR Team of the Year.

Products and product lines

To the date of this announcement, our main products 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® Thermal 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. BroncAblate® Radiofrequency Ablation System is the world's first transbronchial interventional treatment product for lung cancer. Our Targeted Lung Denervation (referred to as "TLD") Radiofrequency Ablation System is the first self-developed targeted radiofrequency ablation system in China to reduce the risk of acute exacerbation of COPD.

Lung Cancer Treatment Pipeline

On April 4, 2024, the International Agency for Research on Cancer (IARC) released the cancer statistics for various regions worldwide in 2022: Lung cancer was the most prevalent form of cancer in 2022, with nearly 2.5 million new cases globally (accounting for 12.4% of all cancers worldwide), and it had the highest mortality rate, with an estimated 1.8 million deaths due to lung cancer (18.7%). China has the highest incidence of lung cancer in the world. In 2022, China had 1.06 million new lung cancer cases (accounting for approximately 22%), ranking first among cancers. At the same time, the number of lung cancer deaths also far exceeds other types of cancer, reaching 733,300, accounting for 28.4% of the total cancer deaths. It is expected that this number will further increase to more than 1.0 million by 2025.

With the advancements in lung cancer diagnostic technology, particularly the widespread adoption of genetic testing, the number of lung cancer patients requiring respiratory endoscopy and interventional treatment has increased significantly. Physicians can help patients achieve early diagnosis effectively through our bronchoscopic biopsy surgery guided by our lung navigation system and adopt safe and effective treatment solutions, including using our BroncAblate® for radiofrequency ablation of lung tumors, to achieve higher survival rates.

Currently, the treatment of lung cancer is mainly based on chemotherapy, radiotherapy and surgery with greater side effects and trauma. 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.

BroncAblate® Radiofrequency Ablation System

BroncAblate® Radiofrequency Ablation System (referred to as “**BroncAblate®**”) is the world’s first transbronchial interventional treatment product for lung cancer. It is an interventional treatment of lung cancer developed by the medical-industrial joint effort of us in co-operation with the First Hospital of Guangzhou Medical University. It is a radiofrequency ablation system used in conjunction with the disposable lung radiofrequency ablation catheter and the radio frequency energy generator. Guided by navigation platform (LungPro®), it acts on lung tumors via a bronchoscope to perform ablation to the lung tumors.

The follow-up visit to the registered clinical trial of BroncAblate®, namely BRONC-RF II, was completed in March 2023. In August 2024, the clinical trial results of BRONC-RF II were published in the authoritative academic journal *Respirology*, validating its advantages in lung tumor treatment in terms of safety and efficacy, providing robust clinical evidence supporting the development and application of the transbronchial ablation system as a treatment method for lung tumors, marking a new era in minimally invasive interventional therapy for lung cancer. At the end of 2023, the product approval has been submitted to the NMPA, which is progressing smoothly.

At the end of September, BroncAblate® was successfully combined with surgical robots at Shanghai Chest Hospital, where Professor Sun Jiayuan (孫加源)’s team performed the world’s first robot-assisted bronchoscopic radiofrequency ablation surgery for lung cancer. This breakthrough has expanded the possibilities for interventional diagnosis and treatment of lung diseases, offering new perspectives and paving the way for advancing the treatment threshold of lung diseases, in particular lung cancer.

BroncAblate® is well ahead in the field of radiofrequency ablation for the treatment of lung cancer. After the product is launched, we will also collaborate with key opinion leaders to introduce our unique technology by holding training sessions.

COPD Treatment Pipeline

In the 2024 issue of the *Chinese Journal of Tuberculosis and Respiratory Diseases*, a research team led by Professor Luo Fengming (羅鳳鳴) from West China Hospital, Sichuan University, stated that Chronic Obstructive Pulmonary Disease (COPD) is a common chronic respiratory disease. Currently, there are nearly 100 million COPD patients in China, making COPD the third leading cause of death in China. Meanwhile, China facing the world’s highest economic losses related to COPD. As a result, COPD has become a major public health concern, significantly impacting the health of the Chinese population.

In 2024, the National Health Commission of the PRC included COPD management in the National Basic Public Health Service Program. Local governments are required to provide services in accordance with the Guidelines for Health Services for Patients with Chronic Obstructive Pulmonary Disease (Trial)(《慢性阻塞性肺疾病患者健康服務規範(試行)》), which specify the service recipients, content, procedures, performance targets, and quality control requirements. The National Health Commission the PRC has also implemented several initiatives, such as the “Healthy Breathing (幸福呼吸)” program for standardized and tiered COPD diagnosis and treatment in China. The inclusion of COPD health services in the basic public health service program will further transform COPD prevention and control, marking a historic and groundbreaking advancement.

The current standard treatment for COPD remains predominantly the use of inhaled medications, complemented by non-pharmacological interventions. However, despite receiving standard treatment, some patients remain unable to effectively control their symptoms or experience frequent acute exacerbations, leading to a continued decline in lung function and a significant impact on their quality of life, highlighting the urgent need for new treatment options. As the development of inhaled medications is slowing, the field of COPD interventional therapy is expected to experience skyrocketing growth, with thermal vapor lung volume reduction being the center of attention.

Our COPD treatment pipeline includes the InterVapor[®] Thermal Vapor Treatment System and the TLD Radiofrequency Ablation System, which are used respectively for the treatment of severe and very severe COPD as well as acute exacerbations of COPD. Among them, InterVapor[®] has obtained the registration certificates including CE and NMPA, and has been commercialized in some countries/regions worldwide, while the TLD Radiofrequency Ablation System is currently in the clinical research stage.

InterVapor[®] Thermal Vapor Treatment System

InterVapor[®] Thermal Vapor Treatment System (referred to as “**InterVapor[®]**”) is the world’s only non-implantable medical device for interventional treatment of COPD and is used for the treatment of severe and very severe COPD and lung diseases such as lung cancer. It has a strong intellectual property portfolio and is the world’s first and only interventional pulmonology device utilizing thermal vapor energy. InterVapor[®] delivers thermal vapor to the lungs via bronchoscopy to achieve targeted ablation of lung lesions. The innovative technique of Bronchoscopic Thermal Vapor Ablation (BTVA) treats patients with chronic obstructive pulmonary disease.

As an innovative technique for treating COPD, BTVA has demonstrated significant improvements in lung function and quality of life for COPD patients and is expected to become an important treatment method for COPD. Given that BVTA is a safe, effective and minimally invasive treatment technique, InterVapor[®] was granted the “Breakthrough Device” status by FDA in 2019. In the same year, BTVA was officially included in the recommended treatment methods by internationally recognized COPD guidelines, GOLD, marking the sixth consecutive year that it has been included in the recommendation.

Currently, InterVapor® has received CE, NMPA, and other registration certifications, and the product has been approved for commercialization in Europe, China, Hong Kong, Australia, Singapore, India, Thailand, and other countries/regions. As the world's first and only non-implantable interventional treatment device for COPD, InterVapor® stands at the forefront of innovation, demonstrating our position as a pioneering product. Unlike the well-established “import substitution” market, we have been making steady progress, overcoming a series of hurdles along the commercialization procedure step by step, from product registration, pricing approval, open procurement, clinical adoption, hospital inclusion, and reimbursement, and have achieved significant milestones. As of December 31, 2024, approximately 200 hospitals in China have tried the technology. The treatment results have been widely recognized by physicians and patients. At the same time, in line with the national policy encouraging domestic production and considering cost optimization, we have achieved domestic production, and have now achieved localization of the products. In addition, the procurement and hospital admission process of the product in the PRC is progressing in an orderly manner. Currently, its disposable thermal vapor treatment catheter has been listed on the Sunshine Procurement Platform in 30 provinces/cities nationwide, and it has been included in the National Reimbursement Drug List in two provinces in China, providing access assurance for hospital price negotiations and procurement.

Meanwhile, the Company is actively promoting post-marketing clinical research and the development of expert consensus for InterVapor®, aiming to accumulate more clinical evidence-based medical data for the product and its procedure. This effort is intended to facilitate the clinical application and commercialization of the product.

In June 2024, the Bronchoscopic Thermal Vapor Ablation technology made its appearance at the national health technology promotion project selection and exhibition. Professor Ouyang Haifeng of the Chest Hospital, Xi'an International Medical Center Hospital, introduced and promoted the technology.

In July 2024, the “Symposium on the Standardized Clinical Application of Thermal Vapor Lung Volume Reduction for COPD” was held during the 12th Academic Conference on Respiratory Endoscopy and Interventional Pulmonology of the Chinese Medical Association. During the symposium, experts shared their perspectives and experiences on the Standardized Procedure for Thermal Vapor Lung Volume Reduction, aiming to facilitate the development of the “Expert Consensus on Standardized Clinical Application of Thermal Vapor Lung Volume Reduction for COPD”.

We are actively conducting a series of post-marketing clinical studies for the InterVapor® in China. Led by Shanghai Chest Hospital, “the Multicenter, Randomized Controlled Study Titled Evaluation of the Efficacy and Safety of Precise Subsegmental Targeted Bronchoscopic Thermal Vapor Ablation (BTVA) for the Treatment of Severe Emphysema” held its project kick-off meeting in November 2023. Currently, the study is in the process of patient enrollment.

In September 2024, the launch meeting for the “Prospective, Single-Arm, Multicenter Clinical Study to Evaluate the Efficacy and Safety of Bronchoscopic Thermal Vapor Ablation (BTVA) in the Treatment of Heterogeneous Emphysema distribution” was grandly held. Researchers from multiple centers thoroughly discussed various details of the trial and reached a consensus. These post-market clinical studies of the InterVapor® Thermal Vapor Ablation System are expected to collect more comprehensive and high-quality evidence-based medical data, providing safer and more effective treatment options for COPD patients.

In November 2024, to raise public awareness of COPD, we collaborated with medical institutions across ten provinces and cities to successfully organize more than ten “2024 World COPD Day Free Clinic Events”. These events attracted active participation from numerous patients and their families. We partnered with local professional hospital teams to provide free medical consultations, health check-ups, and disease management guidance, receiving widespread praise and recognition. Through these activities, we aim not only to offer immediate assistance to patients but also to enhance public understanding of COPD, promoting early diagnosis and treatment. We believe that through continuous efforts and the support of all sectors of society, we can create a healthier and more vibrant future for COPD patients.

Targeted Lung Denervation (TLD) Radiofrequency Ablation System

TLD Radiofrequency Ablation System developed by us in collaboration with West China Hospital of Sichuan University, is the first self-developed product in China for the treatment of acute exacerbations of COPD (referred to as “AE COPD”) by transbronchial radiofrequency ablation. The product provides deeper tissue ablation around the main bronchus in the lungs to reduce the tension and mucus production in the airway and relieve airway obstruction.

The register clinical trial of TLD was launched in 2023. The study was a prospective, randomized, single-blinded, sham-operated 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 for assessing the safety and efficacy of the product. As of December 31, 2024, nearly 100 patients have been enrolled in over 20 research centers. The interim investigator meeting for this clinical trial has been held, and the phase data showed a general improvement in the clinical performance of patients. The study is expected to complete all subject follow-up visits in 2026. Clinical trial reports and data publicity will be completed no earlier than the time point.

This product focuses on the interventional treatment of COPD, integrating medical and engineering expertise to innovate the development system for AE COPD interventional treatment equipment. It has conducted the world’s first targeted lung denervation ablation using domestically developed equipment. Leveraging the professional strengths of respiratory medicine, it has filled the gap in interventional AE COPD treatment in China, offering the “Broncus Solution” for COPD treatment. Due to the product’s leading-edge nature, Broncus Medical, as one of the main contributing entities, was honored with the “First Prize of Sichuan Provincial Science and Technology Progress Award” (四川省科學技術進步一等獎). At the same time, at the finals of the 13th China Innovation and Entrepreneurship Competition in the Medical Materials and High-End Consumables Professional Category, the Company was awarded the “Second Prize in the Medical Materials and High-End Consumables Professional Category (Growth Group) (醫用材料和高端耗材專業賽(成長組)二等獎)”.

Main Products for Other Lung Disease Diagnostic Pipeline

***Mist Fountain®*, a disposable nebulizing micro-catheter for endoscope**

The Mist Fountain®, a disposable nebulizing micro-catheter for endoscope (referred to as “**Mist Fountain®**”) 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 airway anaesthesia, precise antibacterial and anti-inflammatory, tuberculosis drug delivery, phlegm reduction and elimination, thoracic surgery staining location, etc.

Mist Fountain® is 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. As of December 31, 2024, the product was used in nearly 7,200 operations, including bronchoscopic surgeries and RICU clinical scenarios. Its applications encompass airway anesthesia, atomized drug delivery (e.g., tuberculosis medications, anti-inflammatory drugs), and the treatment of conditions such as bronchitis, tuberculosis, and bronchiectasis.

Currently, the product has been listed on the Sunshine Procurement Platform in 30 provinces/cities nationwide, providing access assurance for hospital price negotiations and procurement.

BroncTru®, a disposable transbronchoscopic dilatation catheter

BroncTru® is a disposable transbronchoscopic dilatation catheter (referred to as “**BroncTru®**”). Under the guidance of the navigation system, BroncTru® can create an 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, the new generation of BTPNA by BroncTru® can rapidly create access to the lesion outside the airway through streamlined one-step “puncture-expansion” procedure. It simplifies the procedure, greatly reduces the time of traditional operation and the difficulty, 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. It can also realize follow-up treatment with therapeutic devices.

The product was officially approved for marketing by Zhejiang Medical Products Administration (浙江省藥品監督管理局) in September 2023. Having certain patent technologies, the product has been applied in multi-scenarios in the field of diagnosis and treatment of lung diseases. Since its launch in China, it has been clinically applied in a number of top clinical centers across the country. Its application scenarios include, but are not limited to lung biopsy and laser ablation, bronchoscopic lung cavity puncture biopsy and lavage, as well as transbronchial needle aspiration biopsy (TBNA). These procedures have garnered widespread recognition from physicians.

In November 2024, Professor Sun Jiayuan from Shanghai Chest Hospital, in collaboration with the Respiratory and Critical Care Medicine team at the First Affiliated Hospital of Xinjiang Medical University, successfully performed the nation’s first navigation-guided cryoablation of a patient with lung adenocarcinoma via a transeptal puncture tunnel, using the LungPro® and BroncTru®. The successful implementation of this procedure represents another advancement in application of LungPro® and BroncTru® for complementary therapeutic surgeries. The integration of navigation and tunneling techniques enables allows physicians to quickly establish a pathway, significantly reducing operation time and enhancing subsequent treatment options.

Professor Hou Gang (侯剛)’s team from the National Center for Respiratory Medicine (China Japan Friendship Hospital) published the latest case sharing in the Endoscopic Ultrasound (EUS) journal, a first-tier journal of the Chinese Academy of Sciences, innovatively using BroncTru® for transbronchial mediastinal cryobiopsy (EBUS-TTCB) under endobronchial ultrasound guidance. In comparison to traditional high-frequency needle knife airway incision, this method simplifies the tunneling process, completing the transbronchial mediastinal cryobiopsy under endobronchial ultrasound guidance more quickly and safely.

Currently, the product has been listed on the Sunshine Procurement Platform in over 30 provinces/cities nationwide.

Navigation Platform, Flexible Surgical Robots and Lung Imaging Processing Software

LungPoint, LungPoint Plus/Archimedes Lite and LungPro/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 System**” outside China), to serve the different needs of hospitals at all levels for the functionality of lung navigation products. These products will be updated and iterated based on the feedback from clinical use.

- LungPoint, or LungPoint Virtual Bronchoscopic Navigation (VBN) System, is a computer-assisted image-based navigation software system which, along with a set of biopsy tools, provides physicians 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 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 in the PRC since late 2020 and was launched for sale in EU and the United States in March 2021.
- LungPro System, known as the Archimedes System outside of China (the “**LungPro/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 EU by the BSI in 2014, and the PRC by the NMPA in 2017.

Augmented Reality Optical Whole Lung Diagnostic and Therapeutic Navigation (LungPro) is a new technology that integrates augmented reality and optical navigation technology based on virtual bronchoscopic navigation to assist bronchoscopy. This technology expands the operable range of peripheral pulmonary lesions, derives new diagnosis and treatment method, and has become one of the important methods in the diagnosis and treatment of pulmonary nodules.

In order to standardize the clinical operation of Augmented Reality Optical Whole Lung Diagnostic and Therapeutic Navigation technology and guide its application in clinical practice, the Interventional Study Group of the Respiratory Disease Branch of the Chinese Medical Association organized multidisciplinary experts to conduct multiple rounds of discussions and took the lead in formulating the “Expert Consensus on Diagnosis, Localization, and Treatment of Peripheral Lung Nodules under Augmented Reality Optical Whole Lung Diagnostic and Therapeutic Navigation Guidance” (《增強現實光學全肺診療導航引導下肺外周結節診斷、定位及治療專家共識》), which provides recommendations and clinical guidance on the indications and contraindications, equipment and instruments, perioperative management, operating procedures and complication management of the diagnosis, localization and treatment of peripheral pulmonary nodules applicable to Augmented Reality Optical Whole Lung Diagnostic and Therapeutic Navigation technology. During the period of rapid development of bronchoscopy navigation technology, this expert consensus is of great significance for improving the success rate of diagnosis and treatment and reducing the incidence of navigation-related adverse events.

Flexible Natural Orifice Transluminal Surgical Robot

In view of the high demand and high growth rate of interventional pulmonary therapy, we further expanded the field of flexible surgical robot based on the advanced and patented navigation technology of pulmonary interventional diagnosis and treatment and key transbronchial radiofrequency ablation technology breakthroughs in lung cancer interventional treatment.

Surgical robots are innovative intelligent medical devices that need to perform delicate surgical operations in the narrow space of human body. As the world’s leader in the research and development of augmented reality optical navigation system, we are the only one company in the world to have the whole-lung-reach augmented reality real-time image navigation system. Mastering the core algorithms and software technologies and gaining the world’s leading fiber grating shape sensing technology through the acquisition of Israel’s Fibernova, the Company would develop advanced automatic multi-modal image registration and fusion technology to meet the needs of more accurate and safe surgical navigation, which constitute “eyes” and “brain” of the pulmonary surgical robots. Upon the acquisition of Hangzhou Jingliang Science and Technology Co., Ltd., the Company supplemented relevant technologies such as robot control and driving force for system platform development, and accelerated the project progress of flexible natural orifice transluminal surgical robot. Coupled with the strength of the research and development of robotic arms, the Company managed to fully cover the functions of “eyes”, “brain”, “hands”, “body” and “therapy” of robots.

At present, our flexible natural orifice transluminal surgical robot is in the early stage of research.

BRONCQCT® LUNG IMAGING PROCESSING SOFTWARE

Lung imaging processing software, BroncQCT®, has officially received approval from the Zhejiang Medical Products Administration for marketing in China. The approval of the Software for marketing reflects the Group’s ongoing commitment to developing solutions that improve clinical benefits, and further consolidates the Company’s position in the field of precision interventional diagnostics and treatment for pulmonary diseases. The Software is expected to enhance physicians’ efficiency in examining lung computed tomography (CT) images, providing support for clinical auxiliary diagnosis and treatment, and promoting more efficient and precise diagnostic processes.

The Software utilizes algorithms to process CT images, performing pulmonary segmentation and analysis that enables the visualization of quantitative data and three-dimensional reconstruction of lung structures, generating CT reading reports for specialist physicians, offering significant clinical value across multiple applications. The Software can be deployed to facilitate efficient large-scale screening within patient populations, identifying individuals with specific pulmonary characteristics. Furthermore, the Software supports analysis of imaging of different periods from the same individual patient, allowing for objective comparison and monitoring of pulmonary parameter evolution over time, thereby optimizing clinical workflow efficiency. When integrating the Software with the Company’s interventional therapeutic portfolio, including the InterVapor® Thermal Vapor Treatment System and BroncAblate® Radiofrequency Ablation System, we can provide a comprehensive solution for pulmonary diseases from screening to diagnosis and further to treatment, thus providing an integrated approach to pulmonary health preservation.

THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET TLD, RF-II AND ENDOLUMINAL ROBOT SYSTEM OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

Research and Development

We focus on developing innovative technologies and products for navigation, diagnosis and treatment of pulmonary diseases. We have a well-established track record in the development and commercialization of interventional pulmonology medical devices. To strengthen our R&D capabilities, we implement an efficient R&D model that combines international technologies with local R&D cost advantage to support our intellectual property portfolio and product iterations.

Leveraging our strong R&D capabilities and integrated technology platform, we continue to make steady advancements in product development, upgrade our existing products to address the varying needs of physicians and, where appropriate, expand the range of applications of our products to provide physicians and patients with more comprehensive treatment options.

Manufacturing

During the Reporting Period, our manufacturing activities were conducted at two production centers located in Hangzhou, China and San Jose, the United States, we manufacture navigation products and InterVapor® (import version), FlexNeedle and ATV Kits in our San Jose, California facility in the United States, meanwhile, our Hangzhou facility is responsible for producing navigation products, InterVapor® (domestic version) and various therapeutic products. 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., both facilities comply with ISO13485 standards.

In order to leverage the labor and material cost advantages in China compared to the U.S., we are progressively relocating our product manufacturing processes to China. Currently, the Hangzhou factory has the capacity to manufacture navigation products, InterVapor® (including the disposable catheters and devices) and various consumable products for lung diseases treatment. The LungPoint domestic version and the LungPro System domestic version were registered and approved by the NMPA in September 2023 and in the third quarter of 2024 respectively. To date, we have localized our imported products and new therapeutic products will be manufactured in-house in China.

We can rapidly expand our production capacity in response to market needs to satisfy the ever-increasing market demand.

Quality System

In accordance with regulations and standards such as ISO13485, China's NMPA GMP, the OSR by the FDA of the United States and the EU's MDR, we have established an international quality management system.

The Company establishes and maintains a high-standard and stringent quality management system, implementing strict quality control procedures in every aspect, including R&D, clinical trials, registration, procurement, production, sales, and after-sales service. At the same time, a large amount of resources is invested in quality control to manage and improve product quality. Multiple procedures are conducted to inspect raw materials, manufacturing processes, semi-finished products, and finished products, in order to ensure the effectiveness and consistency of product quality and that the products are in stable and reliable quality.

Intellectual Property

Based on the patent-first product development strategy, the Company has secured several domestic and international patents in the field of interventional pulmonary treatment, consolidating its strong moat in the field.

As of December 31, 2024, Broncus held the following IPs:

Type of IPs	Quantity
Patent for invention	214
Patent for utility model	308
Design patent	63
Trademark	120
Total	705

Commercialization

In 2024, the Company's product commercialization advanced steadily, demonstrating our capabilities in established commercialization and globalization. We always adhere to market demand orientation. Our professional marketing team, consisting of professionals with academic, marketing education, clinical support, and sales and promotion skills, is gradually developing both domestic and global markets around three key participants of hospitals, physicians, and patients through a proactive commercialization strategy. To this end, our strategies include:

- Establishing benchmark hospitals to serve as the model, influence other hospitals within the region

During the market promotion of our innovative medical devices such as InterVapor®, in order to enhance product awareness and recognition, we adopt a promotion model of establishing benchmark hospitals and then reduplicating to regional hospitals. We steadily implement the early-stage product application in benchmark hospitals with strong academic status and clinical strength, accumulating clinical evidence and experience. Thereafter, we provide experience exchange activities between benchmark hospitals and reduplicated hospitals, sharing best practices in patient screening, surgical experience, and post-operative care, promoting the operating procedures of innovative at other hospitals.

In Europe, we have a stable local sales team and have adopted a strategy of establishing benchmark country influence to promote product marketing. For example, we have successfully applied BTPNA and BTVA procedures in top centers such as the Chest Hospital of Heidelberg in Germany. The academic influence of these procedures has facilitated their implementation and product adoption in countries like Eastern Europe, such as Poland and Estonia, and initial results have been seen.

In 2024, our sales in South Asia remained stable and continued to grow steadily; in Southeast Asia, we completed the first sales in the top hospital of Thailand; we successfully performed the first overseas RFA surgery at the King Chulalongkorn Memorial Hospital in Thailand, and completed the first tender in Saudi Arabia and other countries in the Middle East.

Meanwhile, the registration and market access of our products were being actively and steadily advanced overseas. During the year, Our Biostar® and BroncTru® have obtained registration certificates from FDA successively, and our LungPro® has obtained registration certificates in Singapore and Malaysia successively. As of December 31, 2024, we have a total of 83 registration certificates at home and abroad, and a number of products are in the process of global registration.

- Actively expanded industry influence

We participate in domestic and international academic conferences in the field of respiratory intervention and brand academic promotion activities organized by relevant associations to continuously deepen our academic influence in the industry. We have participated in/organized a total of nearly 200 conferences worldwide, including many industry-leading events, such as the China Medical Equipment Conference and 2024 Medical Equipment Exhibition, the 2024 Annual Meeting of the Chinese Medical Association for Respiratory Diseases, the 12th Chinese Medical Association Respiratory Endoscopy and Interventional Pulmonology Academic Conference, Annual Meeting of the European Respiratory Society (ERS 2024), the 28th Congress of the Asian Pacific Society of Respirology (APSR 2024), the 23rd World Congress of Bronchology and Interventional Pulmonology/World Congress of Bronchoesophagology (WCBIP/WCBE 2024) Etc., to promote the clinical popularization of technologies such as navigation, BTVA, and radiofrequency ablation, and drive the growth of regional surgical volume.

Meanwhile, we met the clinical training needs for advanced procedures such as BTPNA, RFA (radiofrequency ablation) and BTVA through professional education platforms such as the “Animal Experiment and Surgery Observation Project of Broncus” and “Diagnosis and Treatment Workshop”. We also deepen the knowledge and understanding of the respiratory interventional diagnosis “Broncus Solutions” among experts at home and abroad through continuous practical exchange activities, and popularize innovative cutting-edge technologies and high-quality professional technical support in clinical surgery as soon as possible, increase the application rate of products in potential hospitals and new hospitals, and also provide a communication platform for Chinese and foreign lung disease experts to learn from each other and have in-depth discussions on pulmonary disease solutions.

- Continuous professional development for physicians and dissemination of expert consensus statements physicians

To promote the adoption of our interventional pulmonology products and related innovative techniques, we continuously update physicians’ understanding of our innovative techniques through clinical case sharing and product demonstrations at international and domestic academic conferences.

To improve the standardization of interventional diagnosis and treatment services for COPD and lung cancer in China, we are committed to promoting the implementation of various expert consensus on treatments. In April 2024, the expert consensus on navigation titled “Expert Consensus on Diagnosis, Localization, and Treatment of Peripheral Lung Nodules under Augmented Reality Optical Whole Lung Diagnostic and Therapeutic Navigation Guidance” was jointly drafted and released by the Interventional Study Group of the Respiratory Disease Branch of the Chinese Medical Association and the Interventional Study Group of the Respiratory Disease Branch of the Zhejiang Medical Association.

Under the leadership of Professor Li Shiyue (李時悦), Deputy Director of the Respiratory Disease Branch of the Chinese Medical Association, Head of the Interventional Pulmonology Group, Deputy Director of the Guangzhou Institute of Respiratory Health, and Director of the Department of Respiratory Medicine at the First Affiliated Hospital of Guangzhou Medical University, several centers across the PRC initiated a thematic seminar, establishing an expert consensus on the “Standardized Clinical Application of Bronchoscopic Thermal Vapor Lung Volume Reduction for COPD”. During the seminar, experts exchanged views and shared experiences on the “Standardized Procedure for Bronchoscopic Thermal Vapor Lung Volume Reduction”, aiming to establish the an expert consensus on the “Standardized Clinical Application of Bronchoscopic Thermal Vapor Lung Volume Reduction for COPD”.

We also actively conduct a series of post-market clinical studies on InterVapor® in China. The kick-off meeting of the project “Multi-center, Randomized Controlled Study to Evaluate the Effectiveness and Safety of Precision Subsegmental Targeted Bronchoscopic Thermal Vapor Ablation (BTVA) for the Treatment of Severe Emphysema” led by Shanghai Chest Hospital was held in November 2023, and the study is currently in the process of patient enrollment. The kick-off meeting of the “Prospective, Single-arm, Multi-center Clinical Study to Evaluate the Effectiveness and Safety of Bronchial Endoscopic Thermal Vapour Ablation Therapy (BTVA) for the Treatment of Heterogeneous Emphysema distribution” was grandly held in September. Researchers from multiple centers fully discussed many details of the trial and reached an agreement. These post-market clinical studies of the InterVapor® Thermal Vapour Treatment System are expected to collect abundant high-quality evidence-based medical data and bring safe and effective COPD treatment options to more patients.

- Promote awareness of pulmonary disease knowledge through diverse offline channels

To enhance the willingness of lung disease patients, particularly those COPD patients, to seek treatment, we have disseminated knowledge about lung disease treatment through expert interviews, online live forums, physicians-patient interactive Q&A sessions, patient exchange meetings, and new media communication channels. By leveraging real clinical cases and surgical outcomes, we aim to strengthen patients’ motivation to pursue treatment. In November 2024, in collaboration with healthcare institutions across ten provinces and cities, we successfully organized over than ten “2024 World COPD Day Charity Clinics”, which garnered active participation from numerous patients and their families. Through these initiatives, we not only provide immediate support to patients but also strive to increase public awareness of COPD, promoting early diagnosis and timely treatment. We believe that through sustained efforts and support from all sectors of society, we can create a healthier and more vibrant future for COPD patients. In addition, for patients who have already undergone treatment, we offer comprehensive disease management services, encompassing consultation, surgery, and postoperative follow-up, thereby enhancing patients’ satisfaction.

- Actively facilitate market access in a systematic orderly manner

The Company actively facilitated the advancements in the procurement of its products and their entry into hospitals across China. Our consumable products, such as InterVapor[®] disposable thermal vapor therapy catheter, BroncTru[®] disposable transbronchoscopic puncture dilatation catheter and Mist Fountain[®] disposable nebulizing micro-catheter for endoscope, have been successfully listed on the Sunshine Procurement Platform in many provinces and cities nationwide, such as Jiangsu, Zhejiang, Shanghai, Shandong, Guangzhou, and Shenzhen, This ensures accessibility hospital price negotiations and procurement processes, thereby enabling our products quickly penetrate into more hospitals, so as to rapidly increase our sales volume and market share.to rapidly penetrate a broader range of hospitals and effectively boosting both sales volume and market share.

We have also proactively worked to facilitate within medical insurance coverage. To date, the BTVA procedure utilizing InterVapor[®] has been incorporated into medical insurance coverage in two provinces.

Meanwhile, the National Healthcare Security Administration (NHSA) has progressively advanced reforms in medical service pricing and officially released the Guidelines for the Establishment of Respiratory System Medical Service Price Projects (Trial) 《呼吸系統醫療服務價格項目立項指南(試行)》 in early March 2025. The BTVA procedure involving InterVapor[®] and the RF procedure involving BroncAblate[®] were both incorporated into these guidelines with clearly defined corresponding medical service items. Moving forward, NHSA will guide provincial healthcare security bureaus to establish price benchmarks based on these guidelines. We anticipate that the commercialization process of our products will be accelerated following the implementation of national policy initiatives.

Major government R&D grants, funding, subsidies and tax preference

During the Reporting Period, the Company received government grants totaling US\$1.3 million (as of December 31, 2023: US\$0.02 million).

FUTURE AND PROSPECTS

Looking ahead, we will maintain our corporate vision and continue to strive for the further consolidation of our position as a global leader in minimally invasive interventional diagnosis and treatment of lung diseases. Leveraging our navigation platform and two energy control technologies – radiofrequency and thermal vapor – we will focus on the development and commercialization of Broncus solutions for respiratory interventional diagnosis and treatment both in China and globally. Additionally, we will continue to advance various foundational and supporting technologies, ultimately bringing benefits to patients and healthcare providers worldwide.

We will continue to enhance the market penetration and influence of the Company’s therapeutic products for COPD and other diseases in the PRC market. Simultaneously, we will prioritize advancing the pre-market clinical trials for our pipeline product TLD and the registration process for the BroncAblate[®] Radiofrequency Ablation System, with the aim of achieving commercialization at the earliest possible time to address significant unmet clinical needs.

As a Chinese medical device company with global technological advantages and demonstrated expertise, we will continue to strategically expand our global business, introduce products with globally competitive such as InterVapor®, BroncAblate® to the global market, and providing high-quality medical services to a broader patients population worldwide.

Meanwhile, we remain committed to implementing cost control measures to enhance profitability while proactively capitalizing on policy support and industry development opportunities. By leveraging our superior product performance, outstanding sales and marketing capabilities, as well as our extensive distribution network, we aim to further expand our market share and solidify our position as leader in the field of Interventional Pulmonology.

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

During the Reporting Period, the revenue of the Group was mainly derived from sale of medical devices and consumables. For the year ended December 31, 2024, the revenue of the Group was US\$8.1 million, representing a decrease of 20.7% when compared with US\$10.3 million in the corresponding period of last year. This is mainly due to the decline in revenue in mainland China. On the one hand, the Company has lowered the price of InterVapor catheters in 2024 to improve the affordability of patients, which directly led to a decline in revenue. On the other hand, the revenue of navigation equipment decreased due to market influence. With successive launches of the Group's therapeutic consumable products, continuous deepening in market education on respiratory interventional therapy and improving patient recognition, revenue from the Group's products has sustainable growth potential.

Cost of sales

Cost of sales mainly consisted of staff costs, raw material costs, depreciation and amortization, utility costs and others. For the year ended December 31, 2024, the Group's cost of sales was US\$2.0 million, representing a decrease of 34.2% from US\$3.0 million in the corresponding period of last year.

Gross profit and gross profit margin

Gross profit for the year ended December 31, 2024 was US\$6.1 million, representing a decrease of 15.1% when compared with US\$7.2 million for the corresponding period of last year. Gross profit margin was calculated by dividing gross profit with revenue. The Group's gross profit margin for the year ended December 31, 2024 was 75.5%, compared with 70.5% recorded for the year ended December 31, 2023. The vapor products sold during the year were mainly produced in China. After localization, the cost of production dropped significantly, and the gross profit margin of Vapor products increased by 5.7% when compared with the previous year.

Other income and gains

During the Reporting Period, our other income and gains mainly consisted of bank interest income and government grants. For the year ended December 31, 2024, the total amount of other income and gains was approximately US\$9.3 million, representing an increase of approximately US\$3.3 million when compared with the year ended December 31, 2023, this was mainly due to an increase of US\$1.3 million in government grants, as well as an increase in interest income and foreign exchange gains.

Selling and distribution expenses

For the year ended December 31, 2024, our selling and distribution expenses were US\$8.5 million, representing a year-on-year decrease of approximately US\$3.0 million, or 26.1%, when compared with the year ended December 31, 2023. This was primarily due to the effective optimization of our selling expenses through various initiatives.

R&D expenses

Our R&D costs mainly consisted 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. R&D trial expenses consisted of expenses incurred on clinical trials, including payment to CROs and hospitals in relation to our clinical trials.

Our R&D costs for the years ended December 31, 2024 and 2023 were approximately US\$11.5 million and US\$20.2 million, respectively, representing a decrease of 43.1%. The decrease in our R&D costs was mainly due to our focus on the research and development of core products, and at the same time due to the Chinese R&D team completed localization of production for the full range of navigation products and InterVapor products in 2024 and in the second half of 2023, respectively, and the Company further adopted cost optimization, control of expenses and other measures to reduce R&D expenses.

	For the year ended December 31, 2024		For the year ended December 31, 2023	
	US\$'000	Proportion	US\$'000	Proportion
Staff cost	5,681	49.5%	10,851	53.9%
Depreciation and amortization	2,558	22.3%	2,386	11.8%
Technical service fees	704	6.1%	2,364	11.7%
Clinical trial expenses	672	5.9%	1,496	7.4%
Raw material costs	284	2.5%	760	3.8%
Share awards	92	0.8%	318	1.6%
Others	1,480	12.9%	1,979	9.8%
Total	11,471	100.0%	20,154	100.0%

Administrative Expenses

For the years ended December 31, 2024 and 2023, our total administrative expenses were approximately US\$7.3 million and US\$8.9 million, respectively, representing a year-on-year decrease of 18.6%. This was mainly attributable to the improvement of operating efficiency through various measures adopted by us to control 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 to cope with daily operations and meet its capital needs for future development.

As of December 31, 2024, our total amount of cash and bank balances and deposits was US\$139.3 million, while our amount of cash and bank balances and deposits was US\$156.6 million as of December 31, 2023. The decrease was mainly due to the Company's daily operating expenses. For the year ended December 31, 2024, the Company's cash and bank balances decreased by US\$17.3 million, representing a decrease of US\$14.5 million or 46% from the previous year, which was mainly due to the Company's focus on core product research and development, and control of expenses through various measures to improve operating efficiency.

As at December 31, 2024, the Group's cash and bank balances were mainly denominated in US dollars, Hong Kong dollars and Renminbi.

Bank Borrowings and Gearing

The Group's overdraft facilities amounting to USD30,000 (December 31, 2023: USD84,000), which were denominated in US\$, of which USD22,000 (December 31, 2023: USD16,000) had been utilised, were secured by the pledge of certain of the Group's time deposits amounting to USD25,000 (December 31, 2023: USD25,000).

The Group monitored capital using gearing ratio. The Group's gearing ratio (calculated as the sum of borrowings and lease liabilities divided by total equity) as at 31 December 2024 was 0.2% (December 31, 2023: 1.3%)

Foreign Exchange Risk

The functional currency of the Group is US\$. The functional currency of its overseas subsidiaries is primarily US\$, while the functional currency of subsidiaries based in the PRC is RMB. 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 continuously monitors foreign exchange exposure and will consider implementing appropriate hedging strategies if necessary.

Contingent Liabilities

As at December 31, 2024, the Group did not have any contingent liabilities.

Charge or Restrictions on Assets

As of December 31, 2024, the Group had pledged deposits of US\$238,000 (December 31, 2023: US\$238,000). The pledged deposits were placed to secure the Group's bank overdraft facilities and as security provided to the Group's lessor. Save as disclosed in this announcement, the Group did not pledge any other group assets. The Group's structured deposits, amounting to US\$40,291,037.04, were held to support foreign exchange trading contracts between the Group and banks.

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,	
	2024	2023
	US\$'000	US\$'000
Loss for the year	(15,303)	(28,092)
Add:		
Share-based expenses ⁽¹⁾	236	556
Non-IFRS adjusted net loss for the year ⁽²⁾	<u>(15,067)</u>	<u>(27,536)</u>

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

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2024 (2023: Nil).

CAPITAL COMMITMENT

The capital commitment as at December 31, 2024 was approximately US\$5.2 million (as at December 31, 2023: US\$12.6 million), which was related to the capital contribution payable to purchase limited partnership interests.

Save as disclosed, we did not have any other material capital commitments as of December 31, 2024.

SIGNIFICANT INVESTMENTS HELD AND MATERIAL ACQUISITION AND DISPOSAL OF SUBSIDIARIES, ASSOCIATES AND JOINT VENTURES

As of December 31, 2024, the Group did not have any significant investments. During the Reporting Period, the Group did not have any material 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 part 2 of the CG Code as contained in Appendix C1 to the Listing Rules as its own code of corporate governance practices. During the Reporting Period, the Company has complied with all the applicable code provisions as set out in part 2 of the CG Code, except for the following deviation:

Pursuant to the code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Mr. Hong Xu (“**Mr. Xu**”) is currently the chairman of the Board and the chief executive officer of the Company (the “**CEO**”). The Board believes that, in view of Mr. Xu’s experience, personal profile and his roles within the Group, Mr. Xu is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of the business of the Group as the CEO. The Board also believes that the combined role of the chairman of the Board and the CEO can promote an effective execution of strategic initiatives and facilitate the flow of information between management and the Board. The Board will continue to review and consider the splitting of the roles of the chairman of the Board and the CEO of the Company from time to time, and by taking into account the circumstances of the Group as a whole.

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.

NON-COMPLIANCE WITH RULES 3.10(1), 3.10A, 3.21 AND 3.27A OF THE LISTING RULES

Professor Joseph Wan Yee Lau (“**Professor Lau**”), an independent non-executive Director since September 13, 2021, and a member of each of the Audit committee and the Nomination Committee, passed away on February 7, 2024.

Following the passing away of Professor Lau, the Company did not meet (i) the minimum number of independent non-executive directors in the Board required under Rule 3.10(1) of the Listing Rules; (ii) the requirement under Rule 3.10A of the Listing Rules which stipulates that independent non-executive directors must represent at least one-third of the Board; (iii) the minimum number of members in the audit committee required under Rule 3.21 of the Listing Rules; and (iv) the requirement under Rule 3.27A of the Listing Rules which stipulates that the nomination committee must comprise a majority of independent non-executive directors.

Subsequently, Mr. Zhenjun Zi (“**Mr. Zi**”), a non-executive Director, resigned with effect from March 1, 2024. Upon the resignation of Mr. Zi, the Company has complied with the requirement of Rule 3.10A of the Listing Rules.

On April 19, 2024, among other changes to the composition of the Board, Dr. David Scott Lim (“**Dr. Lim**”) was appointed as an independent non-executive Director and a member of each of the Audit Committee and Nomination Committee, upon which the Company has duly complied with the requirements under Rules 3.10(1), 3.21 and 3.27A of the Listing Rules.

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 (including sale of treasury shares). As at the end of the Reporting Period, no treasury shares were held by the Company.

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.

EMPLOYEES AND REMUNERATION POLICY

As at December 31, 2024, the Group had 200 employees, of which 178 were based in China and 22 were based overseas (primarily in the U.S., Europe and India).

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\$14.6 million (for the same period in 2023: US\$22.6 million).

Use of Net Proceeds from the Global Offering

The total net proceeds (the “**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, 2024, the Company has utilized approximately HK\$714.0 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\$906.1 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	285.4	52.1	233.3	Expected to be fully utilized by 2030
Development and commercialisation of RF-II	20.9%	339.4	286.8	21.3	265.5	Expected to be fully utilized by 2030
R&D of other product candidates	18.5%	299.9	114.3	50.3	64.0	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	194.0	–	194.0	Expected to be fully utilized by 2026
Working capital and other general corporate purposes	9.2%	149.2	41.5	41.4	0.1	Expected to be fully utilized by 2026
Total	100.0%	1,620.1	1,071.2	165.1	906.1	

Audit Committee

The Audit Committee of our Company (the “**Audit Committee**”) has reviewed the annual consolidated financial statements for the year ended December 31, 2024 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, 2024, but represents an extract from the consolidated financial statements for the year ended December 31, 2024 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, 2024 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, 2024 (2023: Nil).

CLOSURE OF REGISTER OF MEMBERS AND RECORD DATE

The register of members of the Company will be closed from Tuesday, May 13, 2025 to Friday, May 16, 2025, 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 Friday, May 16, 2025 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, at Shops 1712-1716, 17th Floor Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong before 4:30 p.m. on Monday, May 12, 2025.

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, 2024 containing all the information required by the Listing Rules will be provided to the Company's Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

CHANGE IN USE OF NET PROCEEDS

References are made to (i) the section headed “Future Plans and Use of Proceeds” in the prospectus of the Company dated September 13, 2021 (the “**Prospectus**”) in relation to the listing (the “**Listing**”) of the shares of the Company on the Main Board of the Stock Exchange by way of global offering, and (ii) the section headed “Corporate Governance Related Information – Use of Net Proceeds from the Global Offering” in this announcement, in which the utilization status of the Net Proceeds as at December 31, 2024 was disclosed.

For the reasons and benefits set out in the paragraphs headed “Reasons for and Benefits of the Change in Use of Net Proceeds” below, after careful consideration and detailed evaluation of the Group’s operations and business strategies, on March 31, 2025, the Board has resolved to change the intended use of the unutilised Net Proceeds with an updated expected timeline of full utilisation as follows:

Intended use of Net Proceeds	Amount of Net Proceeds allocated upon the Listing (<i>HK\$ million</i>)	Utilised amount as at December 31, 2024 (<i>HK\$ million</i>)	Unutilised amount as at December 31, 2024 (<i>HK\$ million</i>)	Revised allocation of unutilised amount of Net Proceeds (<i>HK\$ million</i>)	Updated expected timeline for use of the unutilised Net Proceeds
Development and commercialisation of InterVapor®	469.2	235.9	233.3	157.9	Expected to be fully utilized by 2030
Development and commercialisation of RF-II	339.4	73.9	265.5	168.8	Expected to be fully utilized by 2030
R&D of other product candidates	299.9	235.9	64.0	235.9	Expected to be fully utilized by 2030
Production line expansion of our manufacturing facility	149.2	–	149.2	48.8	Expected to be fully utilized by 2030
M&A, investing in or acquiring new pipelines	213.2	19.2	194.0	194.0	Expected to be fully utilized by 2030
Working capital and other general corporate purposes	149.2	149.1	0.1	100.7	Expected to be fully utilized by 2026
Total	<u>1,620.1</u>	<u>714.0</u>	<u>906.1</u>	<u>906.1</u>	

Save as disclosed in this announcement, there are no other changes to the use of the proceeds.

REASONS FOR AND BENEFITS OF THE CHANGE IN USE OF NET PROCEEDS

The Group has adopted a prudent and compliant approach to its operations. In its past business and production activities, the Group ensured that the Net Proceeds have been used in accordance with the purposes as disclosed in the section headed “Future Plans and Use of Proceeds” in the Prospectus.

However, in light of the evolving business needs of the Group and changes in the market environment, the Board, after carefully evaluating the Group's current operational conditions, future development strategies, and the global competitive landscape, proposes to revise the intended use of the proceeds from the Global Offering. This is to ensure optimal resource allocation within the Group and to enhance operational efficiency. The reasons and benefits for changing the use of proceeds are as follows:

Reallocation of Funds among Core Products

The Net Proceeds originally allocated to core products (including InterVapor®, RF-II and other product candidates) will be reallocated for the reasons set out below:

- (a) the registration, post-market clinical studies, and commercialization of core products InterVapor® and RF-II have been refocused from multiple countries and regions globally to China and parts of Asia. Additionally, follow-up R&D efforts for both products have mainly shifted to product iteration and functional improvements;
- (b) among other product candidates, the TLD Radiofrequency Ablation System is the first domestically developed TLD product in China, with significant industry-leading advantages. In 2023, it entered pivotal clinical trials. Additional funding is therefore needed to ensure the smooth progress of pre-market clinical trials and NMPA registration. Furthermore, iterative product development and intellectual property coverage will strengthen core technical barriers, thereby solidifying the Group's leadership position in interventional respiratory disease diagnosis and treatment; and
- (c) in response to the increasing prevalence of artificial intelligence ("AI") and machine learning in the market, the Group is aligning with industry trends by increasing AI-related expenditures for the research and development effort on the algorithm. This will allow the Group to accumulate a large amount of clinical data and cases to provide continuous algorithmic update and optimization for its proprietary full-lung reach technology. Additionally, the Group will accelerate the R&D of non-invasive bronchoscopic robotic products, aiming to realize the application of a navigation-diagnosis-treatment closed-loop system in surgical robotics for pulmonary diseases. These efforts will maintain the competitiveness of the Group's product portfolio and reinforce its industry-leading position.

Considering the above reasons, the Board believes that reallocating the allocation for the above products will enable the Group to seize new business opportunities in the current market environment, promote business growth, and achieve sustainable development.

Reduction in the Allocation of Funds for Production Line Expansion

To ensure production capacity, the Group initially planned to allocate funds for the continued expansion of production lines in its manufacturing facilities. However, under the multiple disruptions caused by the global biopharmaceutical industry cycle, macroeconomic conditions, and industrial changes, the commercialization of the Group's independently developed innovative interventional respiratory diagnosis and treatment products requires a longer investment period to achieve the expected market outcomes.

From the perspectives of operation, the Group has proactively reviewed and timely adjusted its production and business strategies, focusing on the R&D, market launch, and production of key products while simultaneously adjusting expenditures on expansion.

Following continuous assessments by the Board, the Group's current production capacity is sufficient to meet foreseeable demand under the existing market conditions. After consideration, the Board is of the view that large-scale capacity expansion is not necessary at this stage. Accordingly, the portion of Net Proceeds originally allocated for production line expansion can be reallocated for other uses, achieving the dual benefits of maintaining operational efficiency and improving the utilization of the Group's financial resources.

Going forward, the Group will continue to monitor market conditions and production demands, keeping the Group's development as the top priority, and will regularly review its capacity expansion plans to align with future needs.

Increase in the Allocation of Funds for Working Capital and Other General Corporate Purposes

The portion of Net Proceeds originally allocated for operations and other general corporate purposes have been nearly fully utilized. With the commercialization of core products and the launch of other pipeline products, the Group has begun to achieve self-sustainability and has gained a certain level of commercialization capability. However, at this stage, additional general working capital is still required to support the Group through a critical transition period.

The Board believes that increasing the allocation of the Net Proceeds for operations and other corporate purposes will enhance the Group's financial flexibility in terms of working capital and ensure sufficient resources to drive effective business development.

The Board confirms that there are no material changes in the nature of the business of the Group as set out in the Prospectus.

To the extent that the Net Proceeds are not immediately used for the purposes described above, the Company may hold such proceeds in short-term deposits or purchase short-term principal-protected wealth management products from qualified financial institutions in the PRC and Hong Kong so long as it is deemed to be in the best interests of the Company.

The Board considers that the re-allocation of the unutilised Net Proceeds will not have any material adverse impact on the existing business and operations of the Group and is in the best interest of the Company and its shareholders as a whole. The Board will continuously assess the plans for the use of the unutilised Net Proceeds and may revise or amend such plans where necessary to cope with the changing market conditions in order to strive for a better performance of the Group.

DEFINITIONS

“AGM”	the annual general meeting of the Company to be held on Friday, May 16, 2025
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Board”	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,” “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 “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

“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”	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
“R&D”	Research and development
“Reporting Period”	the year ended December 31, 2024
“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
“treasury share(s)”	has the meaning ascribed to it under the Listing Rules
“U.S.” or “United States”	the United States of America
“US\$”	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 31, 2025

As at the date of this announcement, the Board comprises Mr. Hong Xu as executive Director, Mr. Ao Zhang and Ms. Yanhong Kuang as non-executive Directors, and Dr. Pok Man Kam, Ms. Yee Sin Wong and Dr. David Scott Lim as independent non-executive Directors.