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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 INTERIM RESULTS FOR THE SIX MONTHS ENDED JUNE 30, 2023

The board (the “**Board**”) of directors (the “**Directors**”) of Broncus Holding Corporation (the “**Company**”) is pleased to announce the unaudited consolidated interim results of the Company and its subsidiaries (collectively, the “**Group**”, “**we**” or “**us**”) for the six months ended June 30, 2023 (the “**Reporting Period**”), together with the unaudited comparative figures for the six months ended June 30, 2022.

#### FINANCIAL HIGHLIGHTS

	For the six months ended June 30,		Period-to- period change
	2023 (Unaudited) USD'000	2022 (Unaudited) USD'000	
<b>Revenue</b>	<b>5,234</b>	3,218	62.6%
<b>Gross Profit</b>	<b>4,026</b>	2,462	63.5%
<b>Loss for the period</b>	<b>(14,731)</b>	(16,060)	-8.3%
<b>Add:</b>			
Share awards	<b>440</b>	949	-53.6%
<b>Non-IFRS adjusted net loss for the period<sup>(1)</sup></b>	<b><u>(14,291)</u></b>	<u>(15,111)</u>	<u>-5.4%</u>

<sup>(1)</sup> Please refer to 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 significant progress with respect to our product pipelines and business operations, including:

- (i) In terms of marketing, the Group recorded a revenue of US\$5.234 million as at June 30, 2023, representing an increase of 62.6% as compared to that of the same period last year, among which, sales revenue from Mainland China amounted to US\$4.251 million, representing a period-to-period increase of 114.4%, which was mainly attributable to the following factors:
  - (a) the rising market penetration of our lung navigation products, including LungPro<sup>®</sup>, LungPoint Plus and LungPoint<sup>®</sup>, has further consolidated our competitive edges and maintained a sound growth momentum.
  - (b) InterVapor<sup>®</sup> has been pressing ahead in respect of online bidding and tendering for hospital application in all provinces, and the product's technological innovation in COPD treatment with thermal vapor has been recognized by the majority of Chinese clinical experts for its safety and efficacy.
  - (c) the accelerating market expansion of our other diagnostic and therapeutic consumables that resulted in increased revenue contribution.
  - (d) Progress in Asia-Pacific countries

In the first half of 2023, we continued to follow up on our targeted customers in the Asian market and launched a number of training programs for overseas doctors. As of July 25, 2023, we have completed three training sessions for doctors in the Asia-Pacific region, with the participation of 20 clinicians from Thailand, the Philippines, India, Taiwan and Hong Kong; we have also participated in the 2023 APCB conference in Malaysia and organized a special seminar, and held six promotional seminars in India, with the participation of a cumulative total of more than 4,000 professional audiences, which have helped to drive the sales of our navigation system and InterVapor<sup>®</sup> in the Asia-Pacific region.

- (e) In the first half of 2023, our products were available in 33 countries and regions worldwide, including, among others, the United States, the United Kingdom, Germany, France, Singapore, Thailand, India and Korea.

(ii) In terms of clinical development,

- (a) we completed the first investigational procedure in the pre-marketing clinical trials of our Targeted Lung Denervation (TLD) Ablation System in July 2023. The clinical trial will evaluate the safety and efficacy of Broncus TLD Ablation System in the treatment of COPD, and is planned to enroll 189 patients at more than twenty trial sites in China. The enrollment is expected to be completed in the fourth quarter of 2024.
- (b) we completed the follow-up visit to the pivotal clinical trial of our core product, RF-II, in the first quarter of 2023, and are now carrying out a statistical analysis on the 12-month follow-up visits to the 126 subjects enrolled in the trial. The product, which applies radiofrequency ablation technique via bronchoscopic pathway, is able to ablate peripheral lesions of lung cancer when combined with our puncture tunnel establisher for lung tissue. On August 5, 2023, Professor Li Shiyue from the First Affiliated Hospital of Guangzhou Medical University reported postoperative 6-month data of the study. The data shows that the study has a technical success rate of 99.35% and a 6-month complete ablation rate of the main lesion being 92.06%. Meanwhile, there is a relatively low incidence of common complications such as pneumothorax and bleeding in thermal ablation for lung cancer in this study. The full results of this study are expected to be presented at the 2023 Annual Scientific Meeting of the European Respiratory Society (ERS), and acceptance of the manuscript has been confirmed by the ERS Secretariat. The study data are intended to be used for the license applications for NMPA medical device.

(iii) In terms of product development, we finalized the design of and completed type testing submission for InterVapor<sup>®</sup>, our product for lung cancer treatment, in July 2023.

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

*For the six months ended 30 June 2023*

	<i>Notes</i>	<b>2023</b> <b>(Unaudited)</b> <b>USD'000</b>	2022 (Unaudited) USD'000
<b>REVENUE</b>	5	<b>5,234</b>	3,218
Cost of sales		<u>(1,208)</u>	<u>(756)</u>
Gross profit		<b>4,026</b>	2,462
Other income and gains	5	<b>2,512</b>	543
Selling and distribution expenses		<b>(6,365)</b>	(5,300)
Administrative expenses		<b>(4,609)</b>	(4,261)
Impairment of trade receivables, net	6	<b>201</b>	(139)
Research and development costs		<b>(10,232)</b>	(9,138)
Other expenses		<b>(219)</b>	(174)
Finance costs		<u>(43)</u>	<u>(52)</u>
<b>LOSS BEFORE TAX</b>	6	<b>(14,729)</b>	(16,059)
Income tax expense	7	<u>(2)</u>	<u>(1)</u>
<b>LOSS FOR THE PERIOD</b>		<u><b>(14,731)</b></u>	<u>(16,060)</u>
Attributable to:			
Owners of the parent		<u><b>(14,731)</b></u>	<u>(16,060)</u>
<b>LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
Basic and diluted (USD)	9	<u><b>(0.03)</b></u>	<u>(0.03)</u>

**INTERIM CONDENSED CONSOLIDATED STATEMENT OF  
COMPREHENSIVE INCOME**

*For the six months ended 30 June 2023*

	<b>2023</b> <b>(Unaudited)</b> <i>USD'000</i>	2022 (Unaudited) <i>USD'000</i>
<b>LOSS FOR THE PERIOD</b>	<u><b>(14,731)</b></u>	<u>(16,060)</u>
<b>OTHER COMPREHENSIVE INCOME</b>		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	<u>(1,871)</u>	<u>(1,377)</u>
<b>OTHER COMPREHENSIVE INCOME FOR THE PERIOD, NET OF TAX</b>	<u><b>(1,871)</b></u>	<u>(1,377)</u>
<b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>	<u><b>(16,602)</b></u>	<u>(17,437)</u>
Attributable to:		
Owners of the parent	<u><b>(16,602)</b></u>	<u>(17,437)</u>

**INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

		<b>30 June 2023 (Unaudited) USD'000</b>	31 December 2022 (Audited) USD'000
	<i>Notes</i>		
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		1,777	2,402
Intangible assets		5,308	5,910
Right-of-use assets		1,414	1,354
Financial assets at fair value through profit or loss		9,203	7,603
Finance lease receivables		54	67
Trade receivables	10	1,517	1,493
Prepayments, other receivables and other assets		268	247
		<u>19,541</u>	<u>19,076</u>
<b>CURRENT ASSETS</b>			
Inventories		4,913	4,298
Finance lease receivables		26	25
Trade and bills receivables	10	10,310	8,598
Prepayments, other receivables and other assets		1,099	1,510
Pledged deposits		238	526
Time deposits with original maturity over three months		71,234	81,153
Cash and cash equivalents		97,278	106,756
		<u>185,098</u>	<u>202,866</u>
<b>CURRENT LIABILITIES</b>			
Trade payables	11	370	321
Lease liabilities		763	652
Other payables and accruals		4,867	6,116
Bank overdrafts		19	29
Contract liabilities		239	299
		<u>6,258</u>	<u>7,417</u>
Total current liabilities		<u>6,258</u>	<u>7,417</u>
<b>NET CURRENT ASSETS</b>		<u>178,840</u>	<u>195,449</u>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<u>198,381</u>	<u>214,525</u>

	<b>30 June 2023 (Unaudited) USD'000</b>	31 December 2022 (Audited) USD'000
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>	<b>198,381</b>	214,525
<b>NON-CURRENT LIABILITIES</b>		
Lease liabilities	<b>786</b>	790
Other payables and accruals	<b>175</b>	175
Contract liabilities	<b>82</b>	102
Total non-current liabilities	<b>1,043</b>	1,067
Net assets	<b>197,338</b>	213,458
<b>EQUITY</b>		
<b>Equity attributable to owners of the parent</b>		
Share capital	<b>12</b>	12
Reserves	<b>197,326</b>	213,446
Total equity	<b>197,338</b>	213,458

# NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

30 June 2023

## 1. CORPORATE INFORMATION

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

The Company is an investment holding company. During the period, the Company's subsidiaries were principally engaged in research and development, and the manufacture and commercialisation of medical device and consumables.

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

## 2. BASIS OF PREPARATION

The unaudited interim condensed consolidated financial information for the six months ended 30 June 2023 has been prepared in accordance with International Accounting Standard ("IAS") 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual consolidated financial statements for the year ended 31 December 2022.

The unaudited interim condensed consolidated financial information has been prepared under the historical cost convention, except for financial assets at fair value through profit or loss, which has been measured at fair value. The interim condensed consolidated financial information is presented in United States dollar ("USD") and all values are rounded to the nearest thousand (USD'000) except when otherwise indicated.

## 3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2022, except for the adoption of the following new and revised International Financial Reporting Standards ("IFRSs") for the first time for the current period's financial information.

IFRS 17	<i>Insurance Contracts</i>
Amendments to IFRS 17	<i>Insurance Contracts</i>
Amendment to IFRS 17	<i>Initial Application of IFRS 17 and IFRS 9 — Comparative Information</i>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i>
Amendments to IAS 8	<i>Definition of Accounting Estimates</i>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i>
Amendments to IAS 12	<i>International Tax Reform — Pillar Two Model Rules</i>



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

- (a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has applied the amendments since 1 January 2023. The amendments did not have any impact on the Group's interim condensed consolidated financial information but are expected to affect the accounting policy disclosures in the Group's annual consolidated financial statements.
- (b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. The Group has applied the amendments to changes in accounting policies and changes in accounting estimates that occur on or after 1 January 2023. Since the Group's policy of determining accounting estimates aligns with the amendments, the amendments did not have any impact on the financial position or performance of the Group.
- (c) Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions.

Prior to the initial application of these amendments, the Group applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. Upon initial application of these amendments, the Group recognised (i) a deferred tax asset for all deductible temporary differences associated with lease liabilities (provided that sufficient taxable profit is available), and (ii) a deferred tax liability for all taxable temporary differences associated with right-of-use assets as at 1 January 2022. The deferred tax asset and the deferred tax liability arising from lease contracts of the same subsidiary have been offset in the condensed consolidated statement of financial position for presentation purposes.

The Group has applied the amendments on temporary differences related to leases as at 1 January 2022, there was no significant cumulative effect unrecognised as an adjustment to the balance of retained profits or other component of equity as appropriate at that date. The adoption of amendments to IAS 12 did not have significant impact on the consolidated statement of financial position as at 31 December 2022 and the consolidated statement of profit or loss for the year end 31 December 2022. Therefore, retained earnings as at 1 January 2022 and the comparative information was not restated and continues to be reported under unrevised IAS 12.

- (d) Amendments to IAS 12 International Tax Reform — Pillar Two Model Rules introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. Entities are required to disclose the information relating to their exposure to Pillar Two income taxes in annual periods beginning on or after 1 January 2023, but are not required to disclose such information for any interim periods ending on or before 31 December 2023. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Group.

#### 4. OPERATING SEGMENT INFORMATION

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

##### Geographical information

###### (a) Revenue from external customers

	For the six months ended 30 June	
	2023 (Unaudited) USD'000	2022 (Unaudited) USD'000
Mainland China	4,251	1,983
European Union	720	763
USA	127	51
Other countries/regions	136	421
	5,234	3,218

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

(b) *Non-current assets*

	<b>30 June 2023 (Unaudited) USD'000</b>	31 December 2022 (Audited) USD'000
USA	5,270	6,104
Mainland China	3,324	3,626
European Union	22	27
Other countries/regions	4	4
	<hr/>	<hr/>
Total	<b>8,620</b>	<b>9,761</b>

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:

	<b>For the six months ended 30 June</b>	
	<b>2023 (Unaudited) USD'000</b>	2022 (Unaudited) USD'000
Customer A	3,578	1,617

**5. REVENUE, OTHER INCOME AND GAINS**

An analysis of revenue is as follows:

	<b>For the six months ended 30 June</b>	
	<b>2023 (Unaudited) USD'000</b>	2022 (Unaudited) USD'000
<i>Revenue from contracts with customers</i>		
Sale of medical devices and consumables	5,012	2,972
Provision of services	222	246
	<hr/>	<hr/>
	<b>5,234</b>	<b>3,218</b>

## Disaggregated revenue information for revenue from contracts with customers

	For the six months ended 30 June	
	2023	2022
	(Unaudited)	(Unaudited)
	USD'000	USD'000
<b>Geographical markets</b>		
Mainland China	4,251	1,983
European Union	720	763
USA	127	51
Other countries/regions	136	421
	<u>5,234</u>	<u>3,218</u>
<b>Timing of revenue recognition</b>		
Goods transferred at a point in time	5,012	2,972
Services transferred over time	222	246
	<u>5,234</u>	<u>3,218</u>

An analysis of other income and gains is as follows:

	For the six months ended 30 June	
	2023	2022
	(Unaudited)	(Unaudited)
	USD'000	USD'000
<b>Other income</b>		
Bank interest income	2,312	245
Government grants	45	160
Interest income from non-current receivables	28	36
Others	2	8
	<u>2,387</u>	<u>449</u>
<b>Gains</b>		
Fair value gains net:		
Financial assets at fair value through profit or loss	92	–
Gain on disposal of items of property, plant and equipment	26	94
Gain on termination of leases	7	–
	<u>125</u>	<u>94</u>
	<u>2,512</u>	<u>543</u>

## 6. LOSS BEFORE TAX

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

	<b>For the six months ended 30 June</b>	
	<b>2023</b>	<b>2022</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
	<b>USD'000</b>	<b>USD'000</b>
Cost of inventories sold	<b>1,195</b>	756
Cost of services provided	<b>13</b>	–
Research and development costs	<b>10,232</b>	9,138
Impairment of trade receivables, net	<b>(201)</b>	139
Foreign exchange differences, net	<b>218</b>	160
Equity-settled share award expenses	<b>440</b>	949

## 7. 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.

The Group calculates the period income tax expense using the tax rate that would be applicable to the expected total annual earnings. The major components of income tax expense in the interim condensed consolidated statement of profit or loss are:

	<b>For the six months ended 30 June</b>	
	<b>2023</b>	<b>2022</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
	<b>USD'000</b>	<b>USD'000</b>
Current — USA		
Charge for the period	<b>2</b>	1

## 8. DIVIDEND

No interim dividend has been paid or declared by the Company for the six months ended 30 June 2023 (six months ended 30 June 2022: Nil).

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

The calculation of the basic loss per share amounts is based on the loss for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 488,474,965 in issue during the period (six months ended 30 June 2022: 487,555,811). As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the period (six months ended 30 June 2022: Nil) in respect of a dilution as the impact of equity-settled share award arrangements had an anti-dilutive effect on the basic loss per share amounts presented.

## 10. TRADE AND BILLS RECEIVABLES

	<b>30 June 2023 (Unaudited) USD'000</b>	31 December 2022 (Audited) USD'000
<b>Current:</b>		
Trade receivables	<b>9,629</b>	9,837
Bills receivable	<b>1,702</b>	–
	<u><b>11,331</b></u>	<u>9,837</u>
<b>Non-current:</b>		
Trade receivables	<b>1,518</b>	1,494
Impairment	<b>12,849</b> <b>(1,022)</b>	11,331 (1,240)
	<u><b>11,827</b></u>	<u>10,091</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.

Included in the Group's trade receivables was an amount of USD1,767,000 (31 December 2022: USD1,987,000) due from a Group's related party.

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

	<b>30 June 2023 (Unaudited) USD'000</b>	31 December 2022 (Audited) USD'000
Within 3 months	<b>4,401</b>	5,511
3 to 6 months	<b>16</b>	67
6 to 12 months	<b>3,791</b>	1,914
1 to 2 years	<b>1,917</b>	2,599
	<u><b>10,125</b></u>	<u>10,091</u>

## 11. 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:

	<b>30 June 2023 (Unaudited) USD'000</b>	31 December 2022 (Audited) USD'000
Within 3 months	<b>368</b>	308
3 to 6 months	<b>1</b>	11
6 to 12 months	<b>1</b>	1
Over 1 year	<b>–</b>	1
	<b>370</b>	321

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

## **MANAGEMENT DISCUSSION AND ANALYSIS**

### **MARKET REVIEW**

There has been an increasing trend in the global prevalence of chronic obstructive pulmonary disease (COPD) and lung cancer that has been propelled by aging population, air pollution and smoking habit in recent years. This has led to a heightened awareness of respiratory diseases among the public. Due to limited treatment approaches, we also see a huge market demand for minimally invasive solutions to treat lung diseases.

According to Frost & Sullivan, there was a COPD-affected population of 226.3 million globally and 106.2 million in China in 2021, respectively, and such population is expected to increase to 258.4 million globally and 109.6 million in China by 2025, respectively. According to Frost & Sullivan, among the COPD patients, 27.0% are at severe or extremely severe stages in China. If not being treated properly, the mortality rate of these patients will reach 54.0% within five years. Hence, the overall COPD-affected population is in active demand of effective COPD therapeutic solutions that can accurately target varying stages.

Global lung cancer incidence reached approximately 2.2 million population in 2020 and is expected to further increase to 2.5 million by 2025. China has the highest incidence of lung cancer in the world with a lung cancer population accounting for 41.9% of that of the globe, while the overall Chinese population accounts for 18.2% of the global population. In China, the number of new lung cancer patients reached approximately 0.9 million in 2020 and is expected to further increase to more than 1.0 million by 2025. Among these patients, over half of them are diagnosed with the cancer already at late stages at first diagnosis with a five-year survival rate as low as 12.6% for stage III lung cancer patients and even lower at 2.9% for stage IV patients, according to Frost & Sullivan. The overall lung cancer population is in active demand of treatment solutions that can effectively enable earlier diagnostics and hence higher survival rate.

### **BUSINESS REVIEW**

Founded in 2012, we are a pioneer medical device company in the field of interventional pulmonology, providing innovative precise interventional diagnosis and treatment solutions to lung diseases in China and globally. Based on our whole lung access navigation technology and encompassing navigation, diagnoses and treatment, our integrated interventional pulmonology platform addresses the pain points of the existing diagnosis and treatment paradigms and significant unmet medical needs for lung diseases by improving the diagnosis and treatment effects of lung cancer and COPD.

As at June 30, 2023, we had 13 products globally registered, 9 products in the process of registration application and other new products under various development stages. Our core products are InterVapor® and RF-II. InterVapor® is the world's first and only non-



implantable medical device to treat COPD, which has opened up a new path for treating lung cancer using thermal vapor based energy. RF-II is a radiofrequency ablation system used in conjunction with a disposable sterile radiofrequency ablation catheter and the only radiofrequency ablation system taking the transbronchial approach specifically for lung cancer.

Our vision is to be a global leader in the transformation of lung diseases treatments.

We completed the first pre-market clinical surgery for Targeted Lung Denervation (TLD) Ablation System on July 4, 2023. Such TLD product is expected to be important for COPD treatment by providing tissue ablation deep inside the main bronchi of the lungs for targeted reduction of vagus nerve fibers to reduce the tension and mucus production in the airway and relieve airway obstruction.

We completed the follow-up visit to the pivotal clinical trial of our core product, RF-II, in the first quarter of 2023, and are now carrying out a statistical analysis on the 12-month follow-up visits to the 126 subjects enrolled in the trial. The product, which applies radiofrequency ablation technique via bronchoscopic pathway, is able to ablate peripheral lesions of lung cancer when combined with our puncture tunnel establisher for lung tissue. During the Chinese Medical Association 11th National Academic Conference on Respiratory Endoscopy and Interventional Pulmonology on August 5, 2023, Professor Li Shiyue from the First Affiliated Hospital of Guangzhou Medical University, the coordinating principal investigator (PI) of the study, reported postoperative 6-month data of the study. The data shows that the study has a technical success rate of 99.35% and a 6-month complete ablation rate of the main lesion being 92.06%. Meanwhile, there is a relatively low incidence of common complications such as pneumothorax and bleeding in thermal ablation for lung cancer in this study. The full results of this study are expected to be presented at the 2023 Annual Scientific Meeting of the European Respiratory Society (ERS), and acceptance of the manuscript has been confirmed by the ERS Secretariat. The study data are intended to be used for the license applications for NMPA medical device.

As at June 30, 2023, the Company has obtained, among others, the following qualifications and certifications at the national and provincial level: National High-tech Enterprise, Zhejiang Science and Technology SMEs, Broncus R&D Center of High-tech Enterprise for Minimally Invasive Interventional Diagnosis and Treatment Devices for Lung Diseases in Zhejiang province, Hangzhou Technology Start-ups Cultivating Project Enterprise , and Hangzhou Enterprise High-tech R&D Center. With the support of the government, the Company will continue to enhance its comprehensive strengths, and create a comprehensive solutions of interventional pulmonology.

## Our products and product pipeline

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

	Indication	Portfolio	Region	Preclinical	Clinical Trial	Registration
Treatment	COPD	InterVapor® for COPD <sup>(2)(8)(9)</sup>	China	Launch for sale, China (March 2022)		
			EU	Launch for sale, EU (January 2018)		
			Others	Launch for sale, UK, Switzerland, Taiwan, Hong Kong, India, Thailand, Singapore, Malaysia, Australia		
		TLD Ablation System <sup>(8)</sup>	China	Registration for clinical trial launched starting from January 2023	2025.9	2026.12
	Lung Cancer/ Lung Nodules	InterVapor® for Lung Cancer <sup>(3)(8)(9)</sup>	China	In design stage	2025.12	2027.3
			EU	In design stage		2027.Q4
		RF-SEG Generator + RF-iCon Ablation Catheter (RF-II) <sup>(8)</sup>	China <sup>(4)</sup>	Clinical trial in process	2023.3	2024.6
			EU <sup>(5)</sup>	CE registration in process		2025.Q3
		H-Marker <sup>(6)(8)</sup>	China			Launch for sale (June 2021)
	Percutaneous RFA probe <sup>(8)</sup>	China	In design stage	2022.12	2025.6	2026.12
Other Pulmonary Diseases	Disposable Nebulizing Micro-Catheter for Endoscope	China			Launch for sale, China (October 2022)	
Navigation	Navigation Platform <sup>(1)</sup>	LungPoint <sup>(8)</sup>	China	Launch for sale, China (December 2014)		
			US	Launch for sale, US (March 2009)		
			EU	Launch for sale, EU (June 2010)		
		LungPoint Plus/ Archimedes Lite <sup>(8)</sup>	China	Launch for sale, China (December 2020)		
			US/EU	Launch for sale, US/EU (March 2021)		
		LungPro/Archimedes System <sup>(2)</sup>	China	Launch for sale, China (October 2017)		
			US	Launch for sale, US (February 2014)		
New-Generation Navigation Platform <sup>(8)</sup>	China	In design stage	2024.6	2025.12	2027.3	
Diagnosis	Lung Cancer/ Lung Nalules	FlexNeedle <sup>(8)</sup>	China	Launch for sale, China (December 2014)		
			US	Launch for sale, US (April 2009)		
			EU	Launch for sale, EU (July 2013)		
		ATV FlexNeedle CN <sup>(7)(8)</sup>	China	Launch for sale, China (November 2019)		
		BioStarNeedle <sup>(8)</sup>	China	Launch for sale, China (June 2020)		
			EU	Launch for sale, EU (September 2022)		
		ATV Sheath <sup>(8)</sup>	China	Launch for sale, China (June 2018)		
			US	Launch for sale, US (October 2013)		
		ATV Balloon <sup>(8)</sup>	EU	Launch for sale, EU (July 2014)		
			China	Launch for sale, China (June 2018)		
		Steerable Sheath <sup>(8)</sup>	US	Launch for sale, US (October 2013)		
			EU	Launch for sale, EU (July 2014)		
		Disposable Transbronchial Puncture Dilation Catheter	China	Launch for sale, China (July 2020)		
EU			2023.8	2025.Q1		

### Notes:

- Our navigation systems have been approved for marketing in the U.S., the EU and the PRC. Post-market study (EAST 2 Trial) for the Archimedes System has been completed.
- In March 2022, InterVapor® has been granted approval for marketing by the NMPA.
- The clinical study report of R&D clinical trial (VAPORIZE trial) was completed in July 2021.
- The Company has completed the enrollment of all subjects for the RF II clinical trial.
- Expect to apply for registrations in the EU mainly based on the clinical data collected in China.
- The clinical trial has been completed and the registration in the PRC was approved in June 2021.
- The version of FlexNeedle manufactured in China.
- Our in-house developed products refer to products that we have developed as the sponsor of their clinical trials.

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

## **Business highlights**

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

- (i) In terms of marketing, the Group recorded a revenue of US\$5.234 million as at June 30, 2023, representing an increase of 62.6% as compared to that of the same period last year, among which, sales revenue from Mainland China amounted to US\$4.251 million, representing a period-to-period increase of 114.4%, which was mainly attributable to the following factors:
  - (a) the rising market penetration of our lung navigation products, including LungPro®, LungPoint Plus and LungPoint®, has further consolidated our competitive edges and maintained a sound growth momentum.
  - (b) InterVapor® has been pressing ahead in respect of online bidding and tendering for hospital application in all provinces, and the product's technological innovation in COPD treatment with thermal vapor has been recognized by the majority of Chinese clinical experts for its safety and efficacy.
  - (c) the accelerating market expansion of our other diagnostic and therapeutic consumables that resulted in increased revenue contribution.
  - (d) Progress in Asia-Pacific countries

In the first half of 2023, we continued to follow up on our targeted customers in the Asian market and launched a number of training programs for overseas doctors. As of July 25, 2023, we have completed three training sessions for doctors in the Asia-Pacific region, with the participation of 20 clinicians from Thailand, the Philippines, India, Taiwan and Hong Kong; we have also participated in the 2023 APCB conference in Malaysia and organized a special seminar, and held six promotional seminars in India, with the participation of a cumulative total of more than 4,000 professional audiences, which have helped to drive the sales of our navigation system and InterVapor® in the Asia-Pacific region.

- (e) In the first half of 2023, our products were available in 33 countries and regions worldwide, including, among others, the United States, the United Kingdom, Germany, France, Singapore, Thailand, India and Korea.

- (ii) In terms of clinical development,
- (a) we completed the first investigational procedure in the pre-marketing clinical trials of our Targeted Lung Denervation (TLD) Ablation System in July 2023. The clinical trial will evaluate the safety and efficacy of Broncus TLD Ablation System in the treatment of COPD, and is planned to enroll 189 patients at more than twenty trial sites in China. The enrollment is expected to be completed in the fourth quarter of 2024.
  - (b) we completed the follow-up visit to the pivotal clinical trial of our core product, RF-II, in the first quarter of 2023, and are now carrying out a statistical analysis on the 12-month follow-up visits to the 126 subjects enrolled in the trial. The product, which applies radiofrequency ablation technique via bronchoscopic pathway, is able to ablate peripheral lesions of lung cancer when combined with our puncture tunnel establisher for lung tissue. On August 5, 2023, Professor Li Shiyue from the First Affiliated Hospital of Guangzhou Medical University reported postoperative 6-month data of the study. The data shows that the study has a technical success rate of 99.35% and a 6-month complete ablation rate of the main lesion being 92.06%. Meanwhile, there is a relatively low incidence of common complications such as pneumothorax and bleeding in thermal ablation for lung cancer in this study. The full results of this study are expected to be presented at the 2023 Annual Scientific Meeting of the European Respiratory Society (ERS), and acceptance of the manuscript has been confirmed by the ERS Secretariat. The study data are intended to be used for the license applications for NMPA medical device.
- (iii) In terms of product development, we finalized the design of and completed type testing submission for InterVapor<sup>®</sup>, our product for lung cancer treatment, in July 2023.

## **Core products**

### ***InterVapor<sup>®</sup>***

InterVapor<sup>®</sup> is the world's first and only Thermal Vapor Treatment System to treat lung diseases including COPD and lung cancer. InterVapor<sup>®</sup> consists of therapeutic devices and a disposable sterile therapeutic catheter that delivers thermal vapor through the bronchoscopic working passageway to the lung to achieve targeted thermal vapor ablation.

We initiated the pre-clinical R&D for InterVapor<sup>®</sup> in September 2010, and commenced our first trial in West China Hospital, the PRC in November 2017 and BTVA Registry study in April 2018. The product was approved for sale in the EU in 2018. In March 2022, InterVapor<sup>®</sup> was approved for marketing by the China National Medical Products Administration (NMPA) with registration certificate number (國械註進20223090144 and 國械註進20223090145).

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

- InterVapor® for COPD is designed for COPD treatment through thermal vapor energy ablation. It delivers thermal vapor to the targeted location of the lung, which requires precise catheter placement and enhanced imaging. It is the world's first interventional pulmonology device using thermal vapor based energy.
- InterVapor® for Lung Cancer is designed for lung cancer treatment through continuous release of thermal vapor energy into the lung. It is designed to ablate lung lesions by the application of thermal vapor to the bronchus targeted for treatment and can sufficiently cover the lesion area to achieve full ablation with appropriate dose of energy.

The clinical history of InterVapor® up to June 30, 2023 includes (1) the STEP-UP trial, one of the core clinical trials related to InterVapor for COPD, the results of this trial were published in the world's renowned medical journal The Lancet , (2) the NEXT-STEP trial, (3) the VAPORIZE trial, (4) the West China Hospital trial, a trial to evaluate the therapeutic effect and safety of thermal vapor ablation for lung volume reduction in patients with heterogeneous emphysema among Asian populations, and (5) the BTVA Registry study. We have completed the patient enrollment and follow-up visits for the NEXT-STEP trial by June 2020, and its formal study report has been completed by September 2021. We have also completed the clinical study report for the VAPORIZE trial in July 2021 to explore the use of InterVapor® to a new indication (lung cancer). The result shows that no major procedure-related complications occurred under such surgical method and bronchoscopic thermal vapor ablation of lung tumors is feasible and well tolerated. A retrospective/prospective, observational, multi-center, post-market registration clinical study entitled “Registry of Patients with Emphysema Treated with BTVA” (BTVA Registry) is currently underway in Europe, and as of July 2023, 236 subjects have been enrolled in the study. The study is currently recruiting subjects.

We are also in the process of preparing the application for registration of InterVapor® for COPD in Korea.

Since InterVapor® was approved for sale in Mainland China, it has been successfully put to clinical use in more than 40 hospitals in 21 provinces and cities.

## ***RF-II***

RF-II is a radiofrequency ablation system used in conjunction with a disposable sterile radiofrequency ablation catheter, which acts on lung tumors via a bronchoscope to perform ablation to the lung tumors. It is currently the only radiofrequency ablation system taking the transbronchial approach specifically for lung cancer globally. RF-II is classified as a Class III medical device in China and Class II medical device in the EU and the U.S..

The follow-up visit to the pivotal clinical trial of RF-II was completed in the first quarter of 2023. A statistical analysis of the 12-month follow-up visits to the 126 subjects enrolled in the trial is being conducted. The product, which applies radiofrequency ablation technique via bronchoscopic pathway, is able to ablate peripheral lesions of lung cancer when combined with our puncture tunnel establisher for lung tissue. On August 5, 2023, Professor Li Shiyue from the First Affiliated Hospital of Guangzhou Medical University reported postoperative 6-month data of the study. The data shows that the study has a technical success rate of 99.35% and a 6-month complete ablation rate of the main lesion being 92.06%. Meanwhile, there is a relatively low incidence of common complications such as pneumothorax and bleeding in thermal ablation for lung cancer in this study. The full results of this study are expected to be presented at the 2023 Annual Scientific Meeting of the European Respiratory Society (ERS), and acceptance of the manuscript has been confirmed by the ERS Secretariat. The study data are intended to be used for the license applications for NMPA medical device. In addition, we are preparing the application for the EU CE marking certification of RF-II. We will also collaborate with key opinions leaders to host regular training sessions with doctors to further explain the underlying technology. RF-II is expected to kick off commercialization within seven years since we initiated the R&D process.

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

### **Our other products and product candidates**

#### ***TLD***

The Targeted Lung Denervation product (TLD) is expected to be important for COPD treatment by providing tissue ablation deep inside the main bronchi of the lungs for targeted reduction of vagus nerve fibers to reduce the tension and mucus production in the airway and relieve airway obstruction.

We completed the first pre-market clinical surgery for Targeted Lung Denervation (TLD) Ablation System in July 2023. In this clinical trial, the safety and efficacy of Broncus TLD Ablation System by the treatment of COPD will be investigated at more than twenty sites across China where 189 patients will be enrolled, and we expect to end the last subject follow-up visit by the end of 2025. Such TLD product is expected to be important for COPD treatment by providing deeper tissue ablation around the main bronchus in the lungs to reduce the tension and mucus production in the airway and relieve airway obstruction. TLD mainly destroys motor axons of peripheral bronchial nerve, blocks parasympathetic transmission in pulmonary and reduces acetylcholine release, resulting in effects similar to anticholinergics which includes reducing airway smooth muscle tension and mucus production, thereby improving airway obstruction.

**THERE IS NO ASSURANCE THAT WE WILL BE ABLE TO ULTIMATELY DEVELOP AND MARKET TLD OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.**

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

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

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

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

***LungPoint, LungPoint Plus/Archimedes Lite and the Archimedes System***

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

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

- LungPoint Plus, which was launched in 2020, provides real-time navigation within the airways for lung biopsy and other procedures through reconstruction of CT-based images and simultaneous display of actual and simulated images for more accurate and effective pathway planning to the target. LungPoint Plus has been commercialized internationally since late 2020 and was launched for sale in the EU and the U.S. in March 2021. LungPoint Plus is classified as a Class II medical device by the FDA, as a Class IIa medical device in the EU, and as a Class III medical device by the NMPA.
- The LungPoint ATV System, also known as LungPro in China or the Archimedes System outside China (the “**Archimedes System**”), is an upgraded product based on the LungPoint VBN system. The Archimedes System takes the application of the VBN technology to the next level by adopting a novel approach to enable precise navigation and localize peripheral lesions away from or adjacent to the airway. The Archimedes System was approved for marketing and commercial use in the U.S. by the FDA in 2014, the EU by the BSI in 2014, and the PRC by the NMPA in 2017. The Archimedes System is classified as a Class II medical device by the FDA, as a Class IIa medical device in the EU, and as a Class III medical device by the NMPA.

## **Manufacturing**

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

### ***Manufacturing of our therapeutic products and product candidates***

Historically, early navigation products were developed by our U.S. team and we have mainly manufactured our navigation products in the U.S.. In order to leverage the labor and material cost advantages in China over the U.S., we are in the process of moving the manufacturing process of our products gradually to China. Starting from June 2021, we have begun to manufacture our H-Marker in our Hangzhou facility. We have commenced the manufacturing of our other therapeutic products in our Hangzhou facility in 2021, including the InterVapor, and the entire manufacturing process of InterVapor, which is domestically produced in Hangzhou, is expected to move to China after obtaining the regulatory approval in the third quarter of 2023.

### ***Manufacturing of our navigation systems***

Our navigation systems, including our LungPoint, LungPoint Plus and Archimedes System, are manufactured in our San Jose, California facility in the U.S.. This facility is ISO13485 compliant and Broncus Medical is the manufacturer of record in FDA 510(k)



clearance and European CE Marked LungPoint products. We have completed localization R&D verification and product trial installation of LungPoint in China and have submitted the registration application with NMPA to further complete the localization of the manufacturing process. We expect the registration to be completed in the third quarter of 2023. The localization of the Archimedes System manufacturing started in April 2022, and the application for NMPA registration has been completed. It is expected to be approved for commercial sale by the first quarter of 2024.

### ***Manufacturing of our diagnosis medical consumables and product candidates***

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

### **Research and development**

We focus on developing innovative technologies and products for navigation, diagnosis and treatment of pulmonary diseases. We have a proven track record of developing and commercializing interventional pulmonology medical device products. To strengthen our R&D capabilities, we adopt an efficient R&D model that combines international technologies with local R&D cost advantage to support our intellectual property portfolio and product iterations.

We are engaged in ongoing R&D activities to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, reliability, and to expand the applications of our products as appropriate. As at June 30, 2023, we had 13 products globally registered, 9 products in the process of registration application and other new products under various development stages.

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

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

## Sales and marketing

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

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

	<b>For the six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Direct sales to hospitals	<b>60</b>	48
• Europe	<b>26</b>	26
• USA	<b>30</b>	14
• PRC (Mainland)	<b>0</b>	3
• Others	<b>4</b>	5

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

	<b>For the six months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Distributors	<b>37</b>	36
• PRC (Mainland)	<b>27</b>	20
• Europe	<b>6</b>	7
• Asia (excluding PRC (Mainland)) and other regions	<b>4</b>	9

For the six months ended June 30, 2023, our revenue generated from distributors and direct sales amounted to approximately US\$4.4 million and US\$0.8 million, respectively, compared to US\$2.5 million and US\$0.7 million in the corresponding period last year.

## **Intellectual property**

As at June 30, 2023, we had a total of 796 issued patents and patent applications which consisted of 387 issued patents (including pending announcements) and 187 patent applications in China and 109 issued patents and 113 patent applications overseas including key markets such as the U.S. and the EU. Among the patents obtained, 150 and 117 of them are related to InterVapor® and RF-II, respectively.

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

During the Reporting Period, the Company received government grants totaling US\$0.05 million (six months ended June 30, 2022: US\$0.2 million).

## **FUTURE AND PROSPECTS**

Facing the global prevalence of COPD and lung cancer that has been propelled by aging population, air pollution and smoking habit, we see a huge market demand for minimally invasive solutions to treat lung diseases. There was a COPD-affected population of 226.3 million globally and 106.2 million in China in 2020, respectively, and such population is expected to increase to 258.4 million globally and 109.6 million in China by 2025, respectively. We plan to expand our sales network by providing more doctor training and patient education, promoting equipment installations and deepening our penetration in hospitals. With our proprietary Bronchoscopic Trans-Parenchymal Nodule Access technology, we plan to promote the awareness of our navigation platform as an indispensable tool for interventional pulmonology diagnosis and treatment among hospitals, doctors and patients.

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

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

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

Looking into the second half of 2023 and the year of 2024, we plan to sponsor an investigator-initiated, single arm, and prospective trial under the title of BLAST in 2023 and aim for conclusion in 2024. The trial aims to treat patients with severe COPD and lower lobe predominant emphysema with vapor ablation and is expected to enroll 25 subjects. We also plan to conduct two separate clinical trials under the title of BENTO and TARGET. In particular, the randomised controlled clinical trial in BENTO investigates the patient benefit (primary endpoint: patient-reported disease-specific quality-of-life scores at 9 months) of using bronchoscopic thermal ablation to both upper lobes for lung volume reduction in the German healthcare system and is intended to enroll 224 subjects. The program is scheduled to commence in the third quarter of 2023 and is expected to conclude by the end of 2024. TARGET is a multi-center clinical trial in France enrolling 150 subjects at 20 research sites to assess changes in FEV1 and health-related quality of life in patients with upper lobe-dominated heterogeneous emphysema after 12 months of continuous fractionated treatment with InterVapor®. The trial is scheduled to commence in July 2023 and is expected to conclude by the end of the third quarter of 2024. In addition, we plan to carry out a series of clinical studies for InterVapor and certain post-market clinical studies in a few other regions. Clinical trials are expected to be conducted in China and Europe between 2023 and 2025 for lung cancer indications. Our planned post-market clinical studies include studies to be conducted in China between 2022 and 2024 and in India between 2021 and 2028.

## FINANCIAL REVIEW

### Overview

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

### Six months ended June 30, 2023 compared to six months ended June 30, 2022

	For the six months ended June 30,	
	2023	2022
	(Unaudited)	(Unaudited)
	US\$'000	US\$'000
<b>Revenue</b>	<b>5,234</b>	3,218
Cost of sales	(1,208)	(756)
Other income and gains	2,512	543
Selling and distribution expenses	(6,365)	(5,300)
Administrative expenses	(4,609)	(4,261)
Impairment of trade receivables, net	201	(139)
Research and development costs	(10,232)	(9,138)
Other expenses	(219)	(174)
Finance costs	(43)	(52)
Income tax expense	(2)	(1)
<b>Loss for the period</b>	<b>(14,731)</b>	(16,060)
<b>Other comprehensive income for the period, net of tax</b>	<b>(1,871)</b>	(1,377)
<b>Total comprehensive income for the period</b>	<b>(16,602)</b>	<b>(17,437)</b>

### Revenue

For the Reporting Period, the revenue of the Group was approximately US\$5.2 million, representing an increase of 62.6% compared with approximately US\$3.2 million in the corresponding period last year, which was mainly attributable to the new source of revenue growth brought by the launch of the Company's new therapeutic product, namely InterVapor<sup>®</sup>, whilst sales of our navigation products also registered an increase as the COVID-19 pandemic in China was receding.

### Other income and gains

For the Reporting Period, the total other income and gains were approximately US\$2.5 million, representing an increase of 362.6% compared with approximately US\$0.5 million in the corresponding period last year.

Our other income consists primarily of bank interest income, interest income from non-current receivables and government grants. Total other income was approximately US\$2.5 million for the six months ended June 30, 2023, representing an increase of approximately US\$2.0 million from the six months ended June 30, 2022, mainly due to increase in bank interest income from US\$0.2 million for the six months ended June 30, 2022 to US\$2.3 million for the six months ended June 30, 2023.

## **R&D costs**

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

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

For the six months ended June 30, 2023 and 2022, we incurred R&D costs of approximately US\$10.2 million and US\$9.1 million, respectively, representing an increase of 12.0%. The increase in our R&D costs was mainly due to the increase of staff costs from US\$4.5 million for the six months ended June 30, 2022 to US\$5.8 million for the six months ended June 30, 2023 as a result of the expansion of our R&D team.

	<b>For the six months ended June 30, 2023</b>		<b>For the six months ended June 30, 2022</b>	
	<b>(Unaudited)</b>		<b>(Unaudited)</b>	
	<i>US\$'000</i>	<i>Proportion</i>	<i>US\$'000</i>	<i>Proportion</i>
Staff costs	<b>5,814</b>	<b>56.8%</b>	4,452	48.7%
Depreciation and amortization	<b>1,224</b>	<b>12.0%</b>	1,221	13.4%
Technical service fees	<b>923</b>	<b>9.0%</b>	1,619	17.7%
Clinical trial expenses	<b>885</b>	<b>8.6%</b>	191	2.1%
Raw material costs	<b>337</b>	<b>3.3%</b>	426	4.7%
Share awards	<b>306</b>	<b>3.0%</b>	799	8.7%
Office expenses	<b>232</b>	<b>2.3%</b>	141	1.5%
Travel and business related expenses	<b>185</b>	<b>1.8%</b>	75	0.8%
Others	<b>326</b>	<b>3.2%</b>	214	2.4%
<b>Total</b>	<b>10,232</b>	<b>100.0%</b>	<b>9,138</b>	<b>100.0%</b>

### **Selling and distribution expenses**

For the six months ended June 30, 2023 and 2022, our selling and distribution expenses were US\$6.4 million and US\$5.3 million, respectively, representing an increase of 20.1%. As sales promotion activities were affected by the COVID-19 pandemic in China during the first half of 2022, whilst in the current period marketing and sales operation were able to commence properly as the pandemic had receded in 2023, our marketing expenses and travel expenses reported an increase, among which, (i) the marketing and advertising expenses increased from US\$0.7 million for the six months ended June 30, 2022 to US\$1.2 million for the six months ended June 30, 2023; (ii) travel expenses were US\$0.5 million for the six months ended June 30, 2022 and US\$0.8 million for the six months ended June 30, 2023 respectively.

### **Administrative expenses**

For the six months ended June 30, 2023 and 2022, our total administrative expenses were approximately US\$4.6 million and US\$4.3 million, respectively.

### **Liquidity and capital resources**

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

As at June 30, 2023, our cash and bank balances and time deposits over three months totalled US\$168.5 million, as compared to US\$188.0 million as at December 31, 2022. The decrease was mainly due to operational expenses incurred by the Company during the Reporting Period.

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

	<b>For the six months ended June 30,</b>	
	<b>2023 (Unaudited) USD'000</b>	2022 (Unaudited) USD'000
Net cash flows used in operating activities	<b>(15,916)</b>	(16,855)
Net cash flows from/(used in) investing activities	<b>8,794</b>	(151,900)
Net cash flows used in financing activities	<b>(278)</b>	(328)
Net decrease in cash and cash equivalents	<b>(7,400)</b>	(169,083)
Cash and cash equivalents at the beginning of the period	<b>106,756</b>	227,207
Effect of foreign exchange rate changes, net	<b>(2,078)</b>	(1,473)
Cash and cash equivalents at the end of the period	<b>97,278</b>	56,651
Analysis of balances of cash and cash equivalents	<b>97,278</b>	205,105
Cash and cash equivalents as stated in the interim condensed consolidated statement of financial position	<b><u>97,278</u></b>	<u>205,105</u>

As at June 30, 2023, cash and cash equivalents were mainly denominated in HK\$, US\$ and Renminbi.

### **Bank borrowings and gearing**

As at June 30, 2023, the Group's outstanding borrowings of US\$19,000 (December 31, 2022: US\$31,000) were denominated in US\$. The Group's overdraft facilities amounting to US\$80,000 and US\$80,000, of which US\$19,000 and US\$31,000 had been utilized as at June 30, 2023 and December 31, 2022, respectively, were secured by the pledge of certain of the Group's time deposits amounting to US\$25,000 and US\$25,000, respectively.

The Group monitored capital using gearing ratio. As at June 30, 2023 and December 31, 2022, the Group's gearing ratio (total debt less cash and cash equivalent as a percentage of total equity as of the end of the period/year) were negative values.

### **Foreign exchange risk**

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



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

### **Contingent liabilities**

As at June 30, 2023, the Group did not have any significant contingent liabilities.

### **Charge or restrictions on assets**

As of June 30, 2023, the Group had pledged deposits of US\$238,000 (December 31, 2022: US\$526,000). The pledged deposits were placed to secure the Group's bank overdraft facilities and as guarantees to the Group's lessor. Save as disclosed in this announcement, the Group did not pledge any group assets during the Reporting Period.

### **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 share awards expenses. Such non-IFRS measures allow investors to consider metrics used by our management in evaluating our performance. 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. Therefore, we do not consider share awards 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 period to our adjusted net loss for the period indicated:

	<b>For the six months ended June 30,</b>	
	<b>2023</b>	2022
	<b>(Unaudited)</b>	(Unaudited)
	<b>USD'000</b>	USD'000
Loss for the period	<b>(14,731)</b>	(16,060)
Add:		
Share awards <sup>(1)</sup>	<b>440</b>	949
Non-IFRS adjusted net loss for the period <sup>(2)</sup>	<b>(14,291)</b>	(15,111)

*Notes:*

- (1) Represent the total expenses associated with the shares we granted to our sales and marketing employees, administrative employees, R&D employees and external experts.
- (2) We consider 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 awards expenses provides useful information to investors in facilitating a comparison of our operating performance from year to year.

## **CORPORATE GOVERNANCE RELATED INFORMATION**

### **Compliance with the Corporate Governance Code**

The Company has adopted corporate governance practices based on the principles and code provisions as set out in the CG Code as its own code of corporate governance practices. During the six months ended June 30, 2023 and up to the date of this announcement, the Company has complied with all the applicable code provisions as set out in the CG Code.

### **Compliance with the Model Code**

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

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

## **Purchase, Sale or Redemption of the Company's Securities**

Neither the Company nor any of its subsidiaries has purchased, sold or redeemed any listed securities of the Company during the Reporting Period.

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

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

## **Material Litigation**

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

## **Employee and Remuneration Policy**

As at June 30, 2023, the Group had 314 employees. The Group's employees' remuneration consists of salaries, bonuses, share-based incentive plans, pension scheme contributions and other welfare payments. In accordance with applicable laws in China and other relevant jurisdictions, we have made contributions to social security insurance funds and housing funds for the employees of the Group.

We conduct new staff training regularly to guide new employees and help them adapt to the new working environment. In addition, we provide on-line and in-person formal and comprehensive company-level and department-level training to our employees in addition to on-the-job training. We also encourage our employees to attend external seminars and workshops to enrich their technical knowledge and develop competencies and skills. During the Reporting Period, the total staff costs (including Director's emoluments and excluding share award expenses) were approximately US\$12.2 million (six months ended 30 June 2022: US\$11.3 million).

## **Use of Net Proceeds from the Global Offering**

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

As at June 30, 2023, the Company has utilized approximately HK\$432.3 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 amounted to approximately HK\$1,187.7 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 January 1, 2023 HKD' million	Amount of utilized net proceeds as at the end of the Reporting Period HKD' million	Amount of net proceeds utilized for the Reporting Period HKD' million	Net proceeds unutilized as at the end of the Reporting Period HKD' million	Expected timeframe for utilizing the remaining net proceeds
Development and commercialisation of InterVapor®	29.0%	469.2	369.4	156.7	57.0	312.4	Expected to be fully utilized by 2030
Development and commercialisation of RF-II	21.0%	339.4	299.7	46.5	6.9	292.8	Expected to be fully utilized by 2030
R&D of other product candidates	18.5%	299.9	218.2	134.7	53.0	165.2	Expected to be fully utilized by 2030
Production line expansion of our manufacturing facility	9.2%	149.2	149.2	-	-	149.2	Expected to be fully utilized by 2026
M&A, investing in or acquiring new pipelines	13.2%	213.2	213.2	-	-	213.2	Expected to be fully utilized by 2026
Working capital and other general corporate purposes	9.2%	149.2	68.2	94.3	13.4	54.8	Expected to be fully utilized by 2026
<b>Total</b>	<b>100.0%</b>	<b>1,620.0</b>	<b>1,318.0</b>	<b>432.3</b>	<b>130.3</b>	<b>1,187.7</b>	

## Audit Committee

During the Reporting Period, the Audit Committee of our Company (the “**Audit Committee**”) consisted of three independent non-executive directors, namely, Dr. Pok Man Kam, Professor Joseph Wan Yee Lau and Ms. Yee Sin Wong. Dr. Pok Man Kam, being the chairman of the Audit Committee, holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The accounting information given in this announcement has not been audited or reviewed by the Company’s external auditor. The Group’s interim results for the six months ended June 30, 2023 have been reviewed by all members of the Audit Committee. Based on such a review, the Audit Committee was of the opinion that the Group’s unaudited interim results were prepared in accordance with applicable accounting standards.

## **EVENTS AFTER THE REPORTING PERIOD**

The Company is not aware of any material subsequent events from June 30, 2023 to the date of this announcement.

## **INTERIM DIVIDEND**

The Board has resolved not to declare the payment of an interim dividend for the six months ended June 30, 2023 (six months ended 30 June 2022: nil).

## **PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT**

This announcement is published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.broncus.com](http://www.broncus.com)). The interim report of the Company for the six months ended June 30, 2023 containing all the information required by the Listing Rules will be despatched to the Company's Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

## **DEFINITIONS**

“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Board” or “Board of Directors”	the board of Directors
“CG Code”	Corporate Governance Code as set out in Appendix 14 to the Listing Rules
“Company”	Broncus Holding Corporation (肇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
“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\$”, “HKD”, “HK dollars” or “Hong Kong dollars”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“InterVapor®”	InterVapor System, the world’s first and only Thermal Vapor Treatment System to treat lung diseases including COPD and lung cancer, including InterVapor Generator and InterVapor Catheter
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange, 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 10 to the Listing Rules
“NMPA”	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“PRC” or “China” or the “People’s Republic of China”	the People’s Republic of China, which for the purpose of this announcement and for geographical reference only, excludes Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“R&D”	Research and development
“Reporting Period”	six months ended June 30, 2023

“RF-II”	RF Generator + RF Ablation Catheter, a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer
“Shares”	ordinary share(s) in the share capital of the Company
“Shareholders”	holders of the Shares
“sq.m.”	square meters
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“U.S.”, “US”, “USA” or “United States”	the United States of America
“US\$”, “USD” or “U.S. dollars”	United States dollars, the lawful currency for the time being of the United States
“Zhejiang MPA”	Zhejiang Medical Products Administration (浙江省藥品監督管理局)
“%”	per cent

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

Hong Kong, August 29, 2023

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