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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, 2022

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, 2022 (the "**Reporting Period**"), together with the unaudited comparative figures for the six months ended June 30, 2021.

FINANCIAL HIGHLIGHTS			
	For the six	months	
	ended Ju	ne 30,	Period-to-period
	2022	2021	change
	(Unaudited)	(Unaudited)	-
	USD'000	USD'000	
Revenue	3,218	2,853	12.8%
Gross Profit	2,462	2,203	11.8%
Loss for the period	(16,060)	(43,118)	-62.8%
Add:			
Change in fair value of convertible			
redeemable preferred shares	_	22,040	-100.0%
Share awards	949	8,347	-88.6%
Listing expenses	_	2,464	-100.0%
Non-IFRS adjusted net loss for the period ⁽¹⁾	(15,111)	(10,267)	47.2%

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) With respect to our product pipeline and market share, InterVapor[®] was approved for marketing in China in March 2022. The Company has completed surgeries on the first group of patients using the InterVapor[®] in July 2022, after it was approved for marketing in China. During the first half year of 2022, our products were sold to 33 countries and regions all over the world, including the United States, the United Kingdom, Germany, France, Japan, etc.
- (ii) With respect to our research and development, we have completed the first in man clinical trial for Targeted Lung Denervation (TLD) Radiofrequency Ablation System in July 2022, whereby 9 patients were enrolled, and we expect to launch register clinical trial in the first quarter of 2023 and end the last subject follow-up in the third quarter of 2023. In July 2022, we have completed the product design and submit the type examination of InterVapor for Lung Cancer.
- (iii) With respect to our partnerships, we reached a strategic cooperation agreement with Healium Medical Ltd., an Israeli company and specializing in the R&D of ultrasound energy therapy and imaging monitoring, in February 2022. The cooperation integrates energy ablation and ultrasound technology, allowing the operator to monitor the status of the ablated tissues in real time, which enables the predictable outcomes of treatment, thus improving the safety of the operation, simplifying the operation procedures, and promoting the popularization of interventional technology in the treatment of pulmonological diseases. The cooperation has been approved by Israel IIA, and the R&D design input and output confirmation has started in May 2022.
- (iv) In July 2022, we successfully held the unveiling ceremony of "Multi-Disciplinary Diagnostics of Pulmonary Nodules" which was jointly established by Shanghai United Family Healthcare, a leading high-end private medical institution in China under New Frontier Health Corporation. We are going to jointly explore the new diagnosis and treatment service mode of respiratory intervention and other cutting-edge technologies targeting groups with high-end medical demands, which will promote the early diagnosis and treatment of lung cancer, and it will continue to provide patients with the global leading minimally invasive interventional diagnosis and treatment of lung diseases in the future.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS

For the six months ended 30 June

	Notes	2022 (Unaudited) <i>USD'000</i>	2021 (Unaudited) <i>USD'000</i>
REVENUE	5	3,218	2,853
Cost of sales		(756)	(650)
Gross profit		2,462	2,203
Other income and gains Selling and distribution expenses Administrative expenses Impairment losses on financial assets, net Research and development costs Other expenses Finance costs Changes in fair value of convertible redeemable preferred shares	5	543 (5,300) (4,261) (139) (9,138) (174) (52)	2,308 (5,638) (11,927) (35) (7,755) (123) (110) (22,040)
LOSS BEFORE TAX	6	(16,059)	(43,117)
Income tax expense	7	(1)	(1)
LOSS FOR THE PERIOD		(16,060)	(43,118)
Attributable to: Owners of the parent Non-controlling interests		(16,060)	(42,724) (394)
		(16,060)	(43,118)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (USD)	9	(0.03)	(0.19)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the six months ended 30 June

	2022 (Unaudited) <i>USD'000</i>	2021 (Unaudited) <i>USD'000</i>
LOSS FOR THE PERIOD	(16,060)	(43,118)
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that may be reclassified to profit or loss in subsequent periods: Exchange differences on translation of		
foreign operations	(1,377)	97
OTHER COMPREHENSIVE INCOME FOR THE PERIOD, NET OF TAX	(1,377)	97
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	(17,437)	(43,021)
Attributable to:		
Owners of the parent Non-controlling interests	(17,437)	(42,630) (391)
	(17,437)	(43,021)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	30 June 2022 (Unaudited) <i>USD'000</i>	31 December 2021 (Audited) USD'000
NON-CURRENT ASSETS			
Property, plant and equipment		2,501	2,729
Intangible assets		6,530	7,036
Equity investment designated at fair value through other comprehensive income		3,150	
Right-of-use assets		1,471	1,907
Finance lease receivables		70	72
Trade receivables	10	1,709	1,681
Prepayments, other receivables and other assets		296	451
Pledged deposits		213	213
Total non-current assets		15,940	14,089
CURRENT ASSETS Inventories		4 227	4 102
Finance lease receivables		4,327 20	4,192 44
Trade and bills receivables	10	4,220	5,663
Prepayments, other receivables and other assets	10	1,834	1,586
Pledged deposits		323	25
Cash and cash equivalents		205,105	227,207
Total current assets		215,829	238,717
CURRENT LIABILITIES			
Trade payables	11	87	400
Lease liabilities		628	739
Other payables and accruals		3,760	7,438
Bank overdrafts		31	13
Contract liabilities		183	374
Total current liabilities		4,689	8,964
NET CURRENT ASSETS		211,140	229,753
TOTAL ASSETS LESS CURRENT LIABILITIES		227,080	243,842

	30 June 2022 (Unaudited) <i>USD'000</i>	31 December 2021 (Audited) <i>USD'000</i>
TOTAL ASSETS LESS CURRENT LIABILITIES	227,080	243,842
NON-CURRENT LIABILITIES		
Lease liabilities	876	1,196
Other payables and accruals	200	200
Contract liabilities	4	28
Total non-current liabilities	1,080	1,424
Net assets	226,000	242,418
EQUITY Equity attributable to owners of the parent Share capital Reserves	12 225,988	12 242,406
		242,400
Total equity	226,000	242,418

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION 30 June 2022

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, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. The head office and principal place of business in China is located at No. 88 Jiangling Road, Xixing Street, Binjiang District, Hangzhou, Zhejiang Province, People's Republic of China (the "**PRC**").

The Company is an investment holding company. During the 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 2022 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 2021.

The unaudited interim condensed consolidated financial information has been prepared under the historical cost convention, except for equity investment designated at fair value through other comprehensive income, 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 2021, except for the adoption of the following revised International Financial Reporting Standards ("IFRSs") for the first time for the current period's financial information.

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

The nature and impact of the revised IFRSs are described below:

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

- (b) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced while making property, plant and equipment available for use on or after 1 January 2021. the amendments did not have any impact on the financial position or performance of the Group.
- (c) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.
- (d) Annual Improvements to IFRS Standards 2018-2020 sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:
 - IFRS 9 *Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively to financial liabilities that are modified or exchanged on or after 1 January 2022. As there was no modification of the Group's financial liabilities during the period, the amendment did not have any impact on the financial position or performance of the Group.
 - IFRS 16 *Leases*: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying IFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying IFRS 16.

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	
	2022	2021
	(Unaudited)	(Unaudited)
	USD'000	USD'000
Mainland China	1,983	662
European Union	763	1,032
USA	51	379
Other countries/regions	421	780
	3,218	2,853

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

(b) Non-current assets

	30 June 2022	31 December 2021
	(Unaudited) USD'000	(Audited) <i>USD'000</i>
USA Mainland China European Union Other countries/regions	6,497 4,163 31	7,098 4,819 43 3
Total	10,691	11,963

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

Information about major customers

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

	For the six months ended 30 June	
	2022	2021
	(Unaudited)	(Unaudited)
	USD'000	USD'000
Customer A	1,617	N/A*
Customer B	N/A*	531

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

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	For the six months ended 30 June	
	2022	
	(Unaudited)	(Unaudited)
	USD'000	USD'000
Revenue from contracts with customers		
Sale of medical devices and consumables	2,972	2,627
Provision of services	246	216
Revenue from other sources		
Gross rental income		10
	3,218	2,853

Disaggregated revenue information for revenue from contracts with customers

	For the six months ended 30 June	
	2022	2021
	(Unaudited)	(Unaudited)
	USD'000	USD'000
Geographical markets		
Mainland China	1,983	662
European Union	763	1,032
USA	51	369
Other countries/regions	421	780
	3,218	2,843
Timing of revenue recognition		
Goods transferred at a point in time	2,972	2,627
Services transferred over time	246	216
	3,218	2,843

An analysis of other income and gains is as follows:

	For the six months ended 30 June	
	2022 (Unaudited) <i>USD'000</i>	2021 (Unaudited) <i>USD'000</i>
Other income		
Government grants	160	1,236
Compensation from a licence agreement	-	1,000
Bank interest income	245	24
Interest income from non-current receivables	36	14
Others	8	
	449	2,274
Gains		
Gain on disposal of items of property, plant and equipment	94	16
Gain on termination of leases		18
	94	34
	543	2,308

6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging:

	For the six months ended 30 June 2022 2021	
	(Unaudited)	(Unaudited)
	USD'000	USD'000
Cost of inventories sold	756	608
Cost of services provided	-	42
Research and development costs	9,138	7,755
Impairment of trade receivables, net	139	35
Depreciation of property, plant and equipment	459	352
Depreciation of right-of-use assets	353	325
Amortisation of intangible assets	626	625
Changes in fair value of convertible redeemable preferred shares	-	22,040
Foreign exchange differences, net	160	38
Auditor's remuneration	80	2
Equity-settled share award expenses	949	8,347
Listing expenses		2,464

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:

	For the six month	For the six months ended 30 June		
	2022	2021		
	(Unaudited)	(Unaudited)		
	USD'000	USD'000		
Current – USA				
Charge for the period	1	1		

8. DIVIDEND

No interim dividend has been paid or declared by the Company for the six months ended 30 June 2022 (six months ended 30 June 2021: 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 487,555,811 in issue during the period (six months ended 30 June 2021: 228,049,860, as adjusted to reflect the share subdivision which was deemed to have been issued by way of subdivision throughout the six months ended 30 June 2021). 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 2021: 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

	30 June 2022 (Unaudited) <i>USD'000</i>	31 December 2021 (Audited) <i>USD'000</i>
Current : Trade receivables Bills receivable	5,185	5,996 514
	5,185	6,510
Non-current : Trade receivables	1,710	1,682
Impairment	6,895 (966)	8,192 (848)
	5,929	7,344

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 USD1,956,000 (31 December 2021: USD1,924,000) 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:

	30 June 2022 (Unaudited) <i>USD'000</i>	31 December 2021 (Audited) USD'000
Within 3 months	2,341	4,194
3 to 6 months	107	1,951
6 to 12 months	3,151	667
1 to 2 years	330	18
	5,929	6,830

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:

	30 June 2022 (Unaudited) <i>USD'000</i>	31 December 2021 (Audited) <i>USD'000</i>
Within 3 months 3 to 6 months 6 to 12 months Over 1 year	86 1	397 1
	87	400

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

MANAGEMENT DISCUSSION AND ANALYSIS

MARKET REVIEW

Facing the global prevalence of COPD and lung cancer that has been propelled by aging population, air pollution and smoking habit, we see a huge market need for minimally invasive solutions to treat lung diseases. According to Frost & Sullivan, 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 extreme severe stages in China, who would face a mortality rate of 54.0% within five years without proper treatment and hence, the overall COPD-affected population is in active demand of effective COPD therapeutic solutions that can accurately target varying stages. 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 global, while the overall Chinese population accounts for 18.2% of the global population. In China, the number of new lung cancer patients reached approximately 0.9 million in 2020 and is expected to further increase to more than 1.0 million by 2025. Among these patients, over half of them are diagnosed with the cancer already at late stages at first diagnosis with a five-year survival rate as low as 12.6% for stage III patients and 2.9% for stage IV patients, according to Frost & Sullivan. The overall lung cancer population is in active demand of diagnostic solutions that can effectively enable earlier diagnostics and hence higher survival rate as well as alternative to existing treatment options of lung cancer.

BUSINESS REVIEW

Founded in 2012, we are a pioneer medical device company in the field of interventional pulmonology, providing innovative lung solutions in China and globally. Leveraging 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, 2022, we had 17 products and major product candidates under various development stages. Our core products are the InterVapor system and RF Generator + RF Ablation Catheter. InterVapor[®] is the world's first and only Thermal Vapor Treatment System to treat lung diseases including COPD and lung cancer. RF-II is a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer.

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

We have completed the first in man clinical trial for Targeted Lung Denervation (TLD) Radiofrequency Ablation System in the second quarter of 2022. 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.

In March 2022, the results of the clinical study (referred to as the EASTII study) of realizing the biopsy of peripheral lung lesions via the unique fusion fluoroscopy and vessel localization technology of LungPro augmented reality optical whole lung diagnosis and treatment navigation system of Broncus conducted at 10 top hospitals and research centers in China, Germany and the United States, were published in the journal Respirology. This study confirms the safety and efficacy of this technology for biopsy and diagnosis of peripheral lung lesions, especially adjacent and non-bronchial lesions.

On March 16, 2022, Broncus's core product InterVapor[®], the Company's thermal vapor treatment system, has been granted approval for marketing by the NMPA, denoting the official commercialization of the world's only such product in China. This is the first NMPA-approved thermal vapor energy ablation systems in China and in the world for the treatment of COPD, and it is the only minimally invasive interventional lung volume reduction product that can achieve sequential staged treatment targeting the lung segment level, thereby leading to a new era of interventional pulmonary in China. We have completed surgeries on the first group of patients using InterVapor[®] in July 2022, after it was approved for marketing in China. The surgeries were completed by teams of professionals led by Professor Long Fa of the Department of Respiratory, Shenzhen Hospital, University of Chinese Academy of Science; and Professor Ouyang Haifeng of the Department of Respiratory and Critical Care Medicine, Chest Hospital, Xi'an International Medical Center Hospital, respectively.

Broncus has obtained the certification of "High tech enterprise research and development center in Zhejiang province" and "Phoenix enterprise" in Binjiang District, Hangzhou in 2022. This is the government's recognition and affirmation of Broncus in innovative R&D strength. With the support of the government, Broncus will continue to enhance its comprehensive strengths, and create a comprehensive solutions of interventional pulmonology.

Pursuant to the MSCI Global Micro Cap Indexes released by MSCI on May 12, 2022, the Company is in MSCI HONG KONG INDEX Additions list, with effect from May 31, 2022.

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	ClinicalTrial	Registration	
			China		Laun	hch for sale, China (March, 2022)	
			US	FDA 510 (K) registration application in	preparation	2023.3	
	COPD	InterVapor for COPD ⁽²⁾⁽⁸⁾⁽⁹⁾	EU		Lau	inch for sale, EU (January, 2018)	
			Others	Launch	n for sale, UK, Switzerland, Taiw	an, Hong Kong, India, Australia	
		TLD Ablation System ⁽⁸⁾	China	Clinical trial starting from August 2021	2025.9	2026.12	
ent			China	In design stage	2025.12 >	2027.3	
atm.		InterVapor for Lung Cancer ⁽³⁾⁽⁸⁾⁽⁹⁾	US/EU	In design stage		2023.6 for soft tissue	
Treatment		RF-SEG Generator + RF-iCon	China ⁽⁴⁾	Clinical trial in process	2023.3	2024.3	
	Lung Cancer/	Ablation Catheter (RF-II) ⁽⁸⁾	US/EU ⁽⁵⁾	FDA 510 (K)/CE; registration in process	s	2023.6 for soft tissue	
	Lung Nodules	EMPOWER RF Ablation	US		Lau	nch for sale, US (February, 2019)	
		Catheter (RF-I) ⁽⁸⁾	EU		La	aunch for sale, EU (March, 2019)	
		H-Marker ⁽⁶⁾⁽⁸⁾	China			Launch for sale (June, 2021)	
		Percutaneous RFA probe ⁽⁸⁾	China	In design stage	2025.6	2026.12	
			China		Launch	for sale, China (December, 2014)	
		Lung Point ⁽⁸⁾	US		La	aunch for sale, US (March, 2009)	
			EU		l	Launch for sale, EU (June, 2010)	
_		Lung Point Plus/Archimedes Lite ⁽⁸⁾	China		Launch	for sale, China (December, 2020)	
Navigation	Navigation Platform ⁽¹⁾		US/EU		Launc	ch for sale, US/EU (March, 2021)	
viga		LungPro/Archimedes System ⁽³⁾	China		Laund	ch for sale, China (October, 2017)	
Nav			US		Lau	nch for sale, US (February, 2014)	
			EU			Launch for sale, EU (July, 2014)	
		New-Generation Navigation Platform ⁽⁸⁾	China	In design stage 2023.6	>>		
			China		Launch	for sale, China (December, 2014)	
		FlexNeedle ⁽⁸⁾	US			Launch for sale, US (April, 2009)	
			EU			Launch for sale, EU (July, 2013)	
		ATV FleXNeedle CN ⁽⁷⁾⁽⁸⁾	China			for sale, China (November, 2019)	
10		BioStarNeedle ⁽⁸⁾	China			unch for sale, China (June, 2020)	
Diagnosis	Lung Cancer/		China		Lau	unch for sale, China (June, 2018)	
agn	Lung Nalules	ATV Sheath ⁽⁸⁾	US	Launch for sale, US (October, 201			
ā			EU			Launch for sale, EU (July, 2014)	
			China		Laı	unch for sale, China (June, 2018)	
	ATV Balloon ⁽⁸⁾	US			unch for sale, US (October, 2013)		
			EU	CU Launch for sale, EU (July, 2014			
		Steerable Sheath ⁽⁸⁾	China				

Notes:

- 1. Our navigation systems have been approved for marketing in the U.S., EU and PRC. Post-market study (EAST 2 Trial) for the Archimedes System has been completed.
- 2. In March 2022, the Company's InterVapor has been granted approval for marketing by the NMPA.
- 3. The clinical study report of R&D clinical trial (VAPORIZE trial) was completed in July 2021.
- 4. The Company has completed the enrollment of all subjects for the clinical trial.
- 5. Expect to leverage clinical data collected in China to apply for registrations in the U.S. and EU.
- 6. The clinical trial has been completed and the registration in the PRC was approved in June 2021.
- 7. The version of FleXNeedle manufactured in China.
- 8. Our in-house developed products refer to products that we have developed as the sponsor of their clinical trials.
- 9. Subsequent to the acquisition of InterVapor[®] from Uptake Medical Corp, we continue to improve InterVapor[®] by sponsoring clinical trials in China and overseas to obtain approvals from local authorities.

Business highlights

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

(i) With respect to our product pipeline and market share, InterVapor was approved for marketing in China in March 2022. The Company has completed surgeries on the first group of patients using the InterVapor[®] in July 2022, after it was approved for marketing in China.

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

- (ii) With respect to our research and development, we have completed the first in man clinical trial for Targeted Lung Denervation (TLD) Radiofrequency Ablation System in July 2022, whereby 9 patients were enrolled, and we expect to launch register clinical trial in the first quarter of 2023 and end the last subject follow-up in the third quarter of 2023. In July 2022, we have completed the product design and submit the type examination of InterVapor for Lung Cancer.
- (iii) With respect to our partnerships, we reached a strategic cooperation agreement with Healium Medical Ltd., an Israeli company and specializing in the R&D of ultrasound energy therapy and imaging monitoring, in February 2022. The cooperation integrates energy ablation and ultrasound technology, allowing the operator to monitor the status of the ablated tissues in real time, which enables the predictable outcomes of treatment, thus improving the safety of the operation, simplifying the operation procedures, and promoting the popularization of interventional technology in the treatment of pulmonological diseases. The cooperation has been approved by Israel IIA, and the R&D design input and output confirmation has been started in May 2022.
- (iv) In July 2022, we successfully held the unveiling ceremony of "Multi-Disciplinary Diagnostics of Pulmonary Nodules" which was jointly established by Shanghai United Family Healthcare, a leading high-end private medical institution in China under New Frontier Health Corporation. We are going to jointly explore the new diagnosis and treatment service mode of respiratory intervention and other cutting-edge technologies targeting groups with high-end medical demands, which will promote the early diagnosis and treatment of lung cancer, and it will continue to provide patients with the global leading minimally invasive interventional diagnosis and treatment of lung diseases in the future.

Core products

InterVapor

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

We first initiated the pre-clinical R&D for InterVapor in September 2010, and commenced our first trial in West China Hospital, the PRC in November 2017 and BTVA Registry study in April 2018. With our seamless effort in R&D, in 2018, InterVapor[®] was accredited with an EC certificate (CE 678945) from the BSI Group, the Netherlands B.V. ("**BSI**") and was classified as a Class II medical device in the European Economic Area. In March 2022, InterVapor[®] was approved for marketing by NMPA with registration certificate number (國械註進 20223090145 and 國械註進 20223090144).

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

The clinical history of InterVapor up to June 30, 2022 includes (1) the STEP-UP trial, one of the core clinical trials related to InterVapor for COPD, the results of this trials was 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). There result shows that no major procedure-related complications occurred and the findings demonstrate bronchoscopic thermal vapor ablation of lung tumors is feasible and well tolerated. For the BTVA Registry Study in EU, as of March 11, 2022, a total of 313 treatment procedures were completed for 205 patients enrolled across 17 open sites. We expect patient enrollment for the BTVA Registry Study to be completed by the end of 2022. Preliminary results supported favorable risk profile for patients with severe heterogeneous emphysema, and the study is planned to carry out five-year follow-up visits to the enrolled patients and expected to be completed by 2027.

We are also in the process of preparing the FDA 510(k) clearance of InterVapor[®] for COPD in the United States and registration of the product in South Korea.

We have completed surgeries on the first group of patients using InterVapor[®] in July 2022, after it was approved for marketing in China.

In addition, we have completed the first in man clinical trial for Targeted Lung Denervation (TLD) Radiofrequency Ablation System in July 2022, whereby 9 patients were enrolled, and we expect to launch register clinical trial in the first quarter of 2023 and end the last subject follow-up in the third quarter of 2023. 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.

RF-II

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

Registration clinical trial enrollment for RF-II was completed in December 2021. In addition, we are preparing the application for the FDA 510(k) clearance of RF-II. In November 2021, we released the phased data of the clinical study of its RF-II radiofrequency ablation system for the treatment of lung cancer through the bronchus at the 25th Annual Congress of the Asian Pacific Society of Respirology (APSR 2021), which initially demonstrated its clinical efficacy. We will also collaborate with key opinions leaders to host regular training sessions with doctors to further explain the underlying technology. The primary efficacy endpoint assessment is expected to be completed in the first quarter of 2023. 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 INTERVAPOR[®] AND RF-II SUCCESSFULLY.

Our other products and product candidates

H-Marker

H-Marker is a self-developed pulmonary surgery marker that is used to mark the location of the lung nodule to achieve precise positioning during surgical pneumonectomy. When used, it is temporarily implanted into the lung through the airway and removed afterwards by surgery. Compared with the operation process of other existing positioning tools, H-Marker is simpler, more reliable and less likely to damage blood vessels with its self-expanding characteristics and spindle shape.

During the year of 2021, we have completed the patient enrollment and all follow-up visits for a prospective, multi-center, single group clinical study of our H-Marker to evaluate the safety and effectiveness of H-Marker in the localization of pulmonary nodules. A total of 76 eligible subjects enrolled in the trial. We have received the designation of H-Marker as a Class II "innovative medical device", which is eligible for expedited approval, by Zhejiang MPA in October 2020 and obtained the approval from Zhejiang MPA in June 2021.

LungPoint, LungPoint Plus/Archimedes Lite and the Archimedes System

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

- LungPoint, or LungPoint[®] Virtual Bronchoscopic Navigation, is a computer-assisted image-based navigation software system which, along with a set of biopsy tools, provides doctors with real-time path navigation within the airways and further localization guidance to a targeted area of interest in the lung for lung biopsy and other procedures. LungPoint was approved for marketing and commercial use in the U.S. by the FDA in 2009, the EU by the BSI in 2011, and the PRC by the NMPA in 2014. LungPoint is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.
- LungPoint Plus, which was launched in 2020, provides real-time navigation within the airways for lung biopsy and other procedures through reconstruction of CT-based images and simultaneous display of actual and simulated images for more accurate and effective pathway planning to the target. LungPoint Plus has been commercialized internationally since late 2020 and was launched for sale in EU and the U.S. in March 2021. LungPoint Plus is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.
 - The LungPoint ATV System, also known as LungPro in China or the Archimedes System outside China (the "Archimedes System"), is an upgraded product based on the LungPoint VBN system. The Archimedes System takes the application of the VBN technology to the next level by adopting a novel approach to enable precise navigation and localize peripheral lesions away from or adjacent to the airway. The Archimedes System was approved for marketing and commercial use in the U.S. by the FDA in 2014, the EU by the BSI in 2014, and the PRC by the NMPA in 2017. The Archimedes System is classified as Class II medical device by the FDA, as Class IIa medical device in the EU, and as Class III medical device by the NMPA.

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

Manufacturing

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

Manufacturing of our therapeutic products and product candidates

Historically, early navigation products were developed by our U.S. team and we have mainly manufactured our navigation products in the U.S.. In order to leverage the labor and material cost advantages in China over the U.S., we are in the process of moving the manufacturing process of our products gradually to China. Starting from June 2021, we have begun to manufacture our H-Marker in our Hangzhou facility. We have commenced the manufacturing of our other therapeutic products in our Hangzhou facility in 2021, including the InterVapor products, and expect to completely move the manufacturing process to China after obtaining the regulatory approval in the end of 2022.

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 first quarter of 2023. The localization of the Archimedes System manufacturing started in April 2022 with design verification in progress. The type testing report has been submitted in June 2022.

Manufacturing of our diagnosis medical consumables and product candidates

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

Research and development

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

We are engaged in ongoing R&D activities to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, reliability, and to expand the applications of our products as appropriate. As of the date of this announcement, we had 12 product candidates in various stages of development.

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

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

Sales and marketing

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

We adopt both direct sales and sales through distributors arrangement. During the Reporting Period, we sold products both directly to hospitals and through distributors, including our navigation systems such as the the Archimedes System and LungPoint, InterVapor cathether 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.

	For the six months ended June 30,	
	2022	2021
Direct sales to hospitals	48	50
• Europe	26	25
• USA	14	16
• PRC (Mainland)	3	4
• Others	5	5

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

	For the six months ended June 30,	
	2022	2021
Distributors	36	34
• PRC (Mainland)	20	16
• Europe	7	5
• Asia (excluding PRC (Mainland)) and other regions	9	13

For the six months ended June 30, 2022, our revenue generated from distributors and direct sales amounted to approximately US\$2.5 million (*unaudited*) and US\$0.7 million (*unaudited*), respectively, compared to US\$1.7 million (*unaudited*) and US\$1.2 million (*unaudited*) in the corresponding period last year.

Intellectual property

As at June 30, 2022, we had a total of 676 issued patents and patent applications which consisted of 254 issued patents (including pending announcements) and 266 patent applications in China and 102 issued patents and 54 patent applications overseas including key markets such as the U.S. and the EU. Among the patents obtained, 96 and 30 of them are related to InterVapor and RF-II, respectively.

Strategic cooperation

We entered into a strategic cooperation agreement with Healium Medical Ltd. ("**Healium**"), an Israeli company focusing on the R&D of ultrasound energy therapy and image monitoring, in February 2022. The cooperation integrates energy ablation and ultrasound technology, allowing the operator to monitor the status of the ablated tissues in real time without switching between instruments frequently, which effectively avoids the situation of insufficient or excess energy during the treatment process, enables the predictable outcomes of treatment and simplifies the operation procedures, thus improving the safety and efficacy of the operation and promoting the popularization of interventional technology in the treatment of pulmonological diseases. The cooperation has been approved by Israel IIA, and the R&D design input and output confirmation has been started in May 2022.

In July 2022, we successfully held the unveiling ceremony of "Multi-Disciplinary Diagnostics of Pulmonary Nodules" which was jointly established by Shanghai United Family Healthcare, a leading high-end private medical institution in China under New Frontier Health Corporation. We are going to jointly explore the new diagnosis and treatment service mode of respiratory intervention and other cutting-edge technologies targeting groups with high-end medical demands, which will promote the early diagnosis and treatment of lung cancer, and it will continue to provide patients with the global leading minimally invasive interventional diagnosis and treatment of lung diseases in the future.

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

During the Reporting Period, the Company received government grants totaling US\$0.2 million (six months ended June 30, 2021: US\$1.2 million). The Group received the notices of PPP forgiveness payment from the SBA regarding the approval of its application for forgiveness of USD311,000 and USD787,000 in principal and associated interest in March and May 2021, respectively, which were recognised as government grants for the six months ended June 30, 2021. And no such income for the six months ended June 30, 2022.

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 need 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.

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

We plan to expand our R&D team globally to ensure continuous technology and product innovation and enrich our intellectual property portfolio mapping across existing and future technologies with precise market positioning. We plan to increase spending on artificial intelligence and machine learning to accumulate large sets of clinical data and cases in the application of diagnosis and treatment procedures guided by our navigation systems. Looking into the second half of 2022 and the year of 2023, we plan to sponsor an Investigator-Initiated prospective, multi-center, randomized controlled study under the title of Bronchoscopic Lung Volume Reduction using the InterVapor System for the Treatment of Emphysema with Middle and/or Lower Lobe Predominance – Expanding InterVapor Trial in early 2023, and aim to complete the trial in 2024. We also plan to conduct two separate prospective, multi-center, single blind, randomized controlled study under the title of Targeted Segmental Vapor Ablation Treatment of Emphysema with Upper LobePredominance: A randomized controlled trial of InterVapor[®] in France and Germany, which are planned to commence by the third quarter of 2022 and first quarter of 2023 and are expected to be completed in 2023 and 2024 respectively. In addition, we plan to carry out a series of clinical studies for InterVapor with a focus on lung cancer indication 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 to be conducted in China between 2022 and 2024 and in India between 2021 and 2028.

THE IMPACT OF COVID-19

During the COVID-19 outbreak, we experienced some delays in the patient enrollment process and data entry for certain of our clinical trials, particularly at the beginning of the COVID-19 pandemic mainly due to the government policy and precautionary measures taken by the hospitals. Since we conduct business and engage in preclinical studies and clinical trials in China, our clinical trial progress in the first half of 2022 has exceeded that of the corresponding period last year. Despite the recurred delta variant of COVID-19 in several provinces across China in late February 2022, as at the date of this announcement, all other operations of the Company have been conducted as normal so far.

Despite of the foregoing, our revenue for the first half of 2022, being US\$3.2 million, increased by 12.8% as compared to US\$2.9 million in the corresponding period last year. However, the COVID-19 pandemic is with limited precedent, and it is therefore not possible to predict the impact that it will ultimately have on our business operation or our industry. There is also no assurance that the COVID-19 outbreak will not further escalate or have a material adverse effect on our results of operations.

FINANCIAL REVIEW

Overview

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

Six months ended June 30, 2022 compared to six months ended June 30, 2021

	For the six months ended June 30,	
	2022	2021
	(Unaudited)	(Unaudited)
	US\$'000	US\$'000
Revenue	3,218	2,853
Cost of sales	(756)	(650)
Other income and gains	543	2,308
Selling and distribution expenses	(5,300)	(5,638)
Administrative expenses	(4,261)	(11,927)
Impairment losses on financial assets, net	(139)	(35)
Research and development costs	(9,138)	(7,755)
Other expenses	(174)	(123)
Finance costs	(52)	(110)
Changes in fair value of convertible redeemable preferred shares	-	(22,040)
Income tax expense	(1)	(1)
Loss for the period	(16,060)	(43,118)
Other comprehensive income for the period, net of tax	(1,377) 97	
Total comprehensive income for the period	(17,437) (43,021)	

Revenue

For the Reporting Period, the revenue of the Group was approximately US\$3.2 million, representing an increase of 12.8% compared with approximately US\$2.9 million in the corresponding period last year, mainly due to the increase in the sale of medical devices and consumables during the Reporting Period.

Other income and gains

For the Reporting Period, the total other income and gains were approximately US\$0.5 million, representing an decrease of 76.5% compared with approximately US\$2.3 million in the corresponding period last year.

Our other income consist primarily of government grants, compensation from a license agreement, bank interest income and interest income from non-current receivables. Total other income was approximately US\$0.5 million for the six months ended June 30, 2022, representing a decrease of approximately US\$1.8 million from the six months ended June 30, 2021, mainly due to (i) the decrease of government grants from US\$1.2 million for the six months ended June 30, 2021 to US\$0.2 million for the six months ended June 30, 2022; and (ii) the compensation from a licence agreement of US\$1.0 million for the six months ended June 30, 2021, and no such income generated for the six months ended June 30, 2022.

Our total gains consist primarily of gain on disposal of items of property, plant and equipment and gain on termination of leases. Total gains was approximately US\$94,000 for the six months ended June 30, 2022, representing an increase of approximately US\$60,000 from the six months ended June 30, 2021.

R&D costs

Our R&D costs mainly consists 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, 2022 and 2021, we incurred R&D costs of approximately US\$9.1 million and US\$7.8 million, respectively, representing an increase of 17.8%. The increase in our R&D costs was mainly due to (i) the increase of staff costs from US\$3.0 million for the six months ended June 30, 2021 to US\$4.5 million for the six months ended June 30, 2022 as a result of the expansion of our R&D team; and (ii) the increase of technical service fee from US\$0.7 million for the six months ended June 30, 2021 to US\$1.6 million for the six months ended June 30, 2022.

	For the six months ended June 30, 2022 (Unaudited)				
	US\$'000	Proportion	US\$'000	Proportion	
Raw material costs	426	4.7%	552	7.1%	
Staff cost	4,452	48.7%	2,950	38.0%	
Travel and business related expenses	75	0.8%	109	1.4%	
Office expenses	141	1.5%	223	2.9%	
Technical service fees	1,619	17.7%	692	8.9%	
Clinical trial expenses	191	2.1%	536	6.9%	
Depreciation and amortization	1,221	13.4%	1,133	14.6%	
Others	214	2.4%	365	4.8%	
Share awards	799	8.7%	1,195	15.4%	
Total	9,138	100.0%	7,755	100.0%	

Selling and distribution expenses

For the six months ended June 30, 2022 and 2021, our selling and distribution expenses were US\$5.3 million and US\$5.6 million, respectively, representing a decrease of 6.0%. The decrease in our selling and distribution expenses was mainly due to the decrease of share awards from US\$0.9 million for the six months ended June 30, 2021 to US\$0.1 million for six months ended June 30, 2022.

Administrative expenses

For the six months ended June 30, 2022 and 2021, our total administrative expenses were approximately US\$4.3 million and US\$11.9 million, respectively. The decrease was mainly due to (i) the decrease of share awards from US\$6.2 million for the six months ended June 30, 2021 to US\$0.1 million for the six months ended June 30, 2022; and (ii) the listing expenses of US\$2.5 million for the six months ended June 30, 2021, and no such expenses recognized for the six months ended June 30, 2022.

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, 2022, our cash and bank balances and time deposits over three months totalled US\$205.1 million, as compared to US\$227.2 million as at December 31, 2021. The decrease was mainly due to operational expenses incurred by the Company.

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:

	For the six months ended June 30,	
	2022	2021
	(Unaudited)	(Unaudited)
	US\$'000	US\$'000
Net cash flows used in operating activities	(16,855)	(14,348)
Net cash flows used in investing activities	(151,900)	(1,372)
Net cash flows (used in)/from financing activities	(328)	34,484
Net (decrease)/increase in cash and cash equivalents	(169,083)	18,764
Cash and cash equivalents at the beginning of the period	227,207	18,788
Effect of foreign exchange rate changes, net	(1,473)	65
Cash and cash equivalents at the end of the period	56,651	37,617
Analysis of balances of cash and cash equivalents	205,105	37,617
Cash and cash equivalents as stated in the interim condensed		
consolidated statement of financial position	205,105	37,617

As at June 30, 2022, cash and cash equivalents were mainly denominated in HK\$, US\$ and Renminbi.

Bank borrowings and gearing

As at June 30, 2022, the Group's outstanding borrowings of US\$31,000 (December 31, 2021: US\$13,000) were denominated in US\$. The Group's overdraft facilities amounting to US\$80,000 and US\$80,000, of which US\$31,000 and US\$13,000 had been utilized as at June 30, 2022 and December 31, 2021, 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, 2022 and December 31, 2021, the Group's gearing ratio (total debt less cash and cash equivalent as a percentage of total equity as of the end of the 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, 2022, the Group did not have any significant contingent liabilities.

Charge or restrictions on assets

As of June 30, 2022, the Group had pledged deposits of US\$536,000 (December 31, 2021: US\$238,000). The pledged deposits were placed to secure the Group's bank overdraft facilities and as guarantees to the Group's service provider and lessor. Save as disclosed in this announcement, the Group did not pledge any group assets.

NON-IFRS measures

To supplement our consolidated statements of profit or loss which are presented in accordance with IFRS, we also use adjusted net loss as non-IFRS measures, which are not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measures when shown in conjunction with the corresponding IFRS measures provides useful information to investors and management in facilitating a comparison of our operating performance from year to year by eliminating potential impacts of certain non-operational or one-off expenses that do not affect our ongoing operating performance, including changes in fair value of convertible redeemable preferred shares, share awards and listing expenses. Such non-IFRS measures allow investors to consider metrics used by our management in evaluating our performance. Changes in fair value of convertible redeemable preferred shares represent the changes in fair value of various rights associated with the preferred shares, which is 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 period to our adjusted net loss for the period indicated:

	For the six months ended June 30,	
	2022 20	
	(Unaudited)	(Unaudited)
	US\$'000	US\$'000
Loss for the period Add:	(16,060)	(43,118)
Change in fair value of convertible redeemable preferred shares	_	22,040
Share awards ⁽¹⁾	949	8,347
Listing expenses	_	2,464
Non-IFRS adjusted net loss for the period ⁽²⁾	(15,111)	(10,267)

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

CORPORATE GOVERNANCE RELATED INFORMATION

Compliance with the Corporate Governance Code

The Company has adopted corporate governance practices based on the principles and code provisions as set out in the the CG Code as its own code of corporate governance practices. During the six months ended June 30, 2022 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 set out in Appendix 10 to the Listing Rules as its code of conduct regarding dealings in the securities of the Company by the Directors, and the Group's employees who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company's securities. Specific enquiries have been made to all Directors and the Directors have confirmed that they have complied with the Model Code during the six months ended June 30, 2022 and up to the date of this announcement. No incident of non-compliance of the Model Code by the employees was noted by the Company during the six months ended June 30, 2022 and up to the date of this announcement.

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 six months ended June 30, 2022. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the six months ended June 30, 2022.

Employee and Remuneration Policy

As at June 30, 2022, the Group had 320 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\$11.3 million (six months ended 30 June 2021: US\$15.8 million).

Use of Net Proceeds from the Global Offering

The Company's Shares were listed on the Stock Exchange on September 24, 2021. The net proceeds from the Global Offering amounted to 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, 2022, the Company has utilized approximately HK\$184.0 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\$1,436.0 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 (%)	Amount of unutilized net proceeds as at 1 January 2022 <i>HKD million</i>	Planned use of actual net proceeds HKD'million	Utilized net proceeds as at the end of the Reporting Period HKD'million	Amount of utilized net proceeds for the Reporting Period HKD'million	Net proceeds unutilized as at the end of the Reporting Period <i>HKD</i> 'million	Expected timeframe for utilizing the remaining net proceeds
Development and commercialisation of InterVapor	29.0%	460.4	469.2	52.0	43.2	417.2	Expected to be fully utilized by 2030
Development and commercialisation of RF-II	21.0%	331.0	339.4	25.9	17.5	313.5	Expected to be fully utilized by 2030
R&D of other product candidates	18.5%	280.9	299.9	44.1	25.1	255.8	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	24.7	24.7	188.5	Expected to be fully utilized by 2026
Working capital and other general corporate purposes	9.2%	136.4	149.2	37.3	24.5	111.8	Expected to be fully utilized by 2026
Total	100.0%	1570.9	1620.0	184.0	135	1,436.0	

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 Dr. Jian Ji. 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, 2022 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

In July 2022, the Company has completed surgeries on the first group of patients using its InterVapor[®], after it was approved for marketing in China. During the course of the surgeries, InterVapor[®] delivered thermal vapor bronchoscopically to the targeted lung segment and transmitted energy through air convection, which overcomes the traditional obstacles of energy transmission due to the high air content in the lungs, and hence treating severely diseased lung segments. This method of treatment significantly improves the quality of life and lung function of patients and their exercise tolerance while preserving more healthy lung tissues.

This marked the official entry of InterVapor[®] into the clinical commercialization phase in China and is expected to benefit patients with COPD. The surgeries were completed by teams of professionals led by Professor Long Fa of the Department of Respiratory, Shenzhen Hospital, University of Chinese Academy of Science; and Professor Ouyang Haifeng of the Department of Respiratory and Critical Care Medicine, Chest Hospital, Xi'an International Medical Center Hospital, respectively.

For details, please see the announcement "Voluntary Announcement – Broncus Completed Surgeries on the First Group of Patients Using Its Intervapor[®], the Thermal Vapor Treatment System, after Approved for Marketing in China" of the Company dated July 18, 2022.

Save as disclosed above, the Company is not aware of any material subsequent events from June 30, 2022 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, 2022 (six months ended 30 June 2021: nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.broncus.com). The interim report of the Company for the six months ended June 30, 2022 containing all the information required by the Listing Rules will be despatched to the Company's Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

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 (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
"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, 2022
"RF-II"	RF Generator + RF Ablation Catheter, a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer
"Shares"	ordinary share(s) in the share capital of the Company
"Shareholders"	holders of the Shares
"sq.m."	square meters
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"U.S.", "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

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

Hong Kong, August 30, 2022

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.