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

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2216)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2021

The board (the "**Board**") of directors (the "**Directors**") of Broncus Holding Corporation (the "**Company**") is pleased to announce the audited consolidated results of the Company and its subsidiaries (collectively, the "**Group**", "**we**" or "**us**") for the year ended December 31, 2021 (the "**Reporting Period**"), together with the audited comparative figures for the year ended December 31, 2020.

FINANCIAL HIGHLIGHTS

	Year ended December 31, 2021 *USD'000*	Year ended December 31, 2020 *USD'000*	Year-to-year change
Revenue	**10,891**	3,259	234.2%
Gross Profit	**8,742**	2,506	248.8%
Loss for the year	**(236,178)**	(48,786)	384.1%
Add:			
Change in fair value of convertible redeemable preferred shares	**198,874**	27,620	620.0%
Share awards	**9,011**	509	1,670.3%
Listing expenses	**4,639**	1,599	190.1%
Non-IFRS adjusted net loss for the year[(1)]	**(23,654)**	(19,058)	24.1%

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

BUSINESS HIGHLIGHTS

On September 24, 2021, the Company was successfully listed on The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**"). 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, H-Marker was approved in China in June 2021; LungPoint Plus was officially launched in US/EU in March 2021; InterVapor was approved in China in March 2022 and was approved in India in March 2021; LungPoint, LungPoint Plus, Archimedes and FleXNeedle Biopsy Needle, Archimedes Sheath and Archimedes Dilation Balloon were approved in India in August 2021.

Over the course of the financial year of 2021, 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, in June and December 2021, we established a "Broncus pulmonary disease interventional technology training base" respectively with Shandong Public Health Clinical Center and Xi'an International Medical Center Hospital; in November 2021, the team under Professor V. Nagarjuna Maturu from Yashoda Hospital successfully completed the first lung volume reduction surgery using InterVapor in India; and we successfully launched the real world study project "Evaluation of the Safety and Efficacy of Bronchoscopic Transparenchymal Nodule Access (BTPNA) in the Sampling Diagnosis of Peripheral Pulmonary Lesions"; and we completed enrollment for registered clinical trial for RF-II in China and released the phased data of the clinical study of the 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;

In September 2021, the company completed the first clinical application of its Targeted Lung Denervation (TLD) radiofrequency ablation system in West China Hospital of Sichuan University. Our TLD products have completed enrollment of six clinical cases as of the date of this announcement.

(iii) With respect to our partnerships, we reached a strategic cooperation agreement with United Family Healthcare Group, a leading high-end private medical institution in China under New Frontier Health Corporation, in December 2021; and we reached a strategic cooperation agreement with Healium Medical Ltd., an Israeli company specializing in the R&D of ultrasound energy therapy and imaging monitoring, in February 2022.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2021

	Notes	**2021** ***USD'000***	2020 *USD'000*
REVENUE	*5*	**10,891**	3,259
Cost of sales		**(2,149)**	(753)
Gross profit		**8,742**	2,506
Other income and gains	*5*	**3,129**	1,074
Selling and distribution expenses		**(12,706)**	(6,352)
Administrative expenses		**(18,546)**	(7,722)
Impairment losses on financial assets, net		**(584)**	(214)
Research and development costs		**(16,759)**	(9,353)
Other expenses		**(407)**	(456)
Finance costs	*7*	**(170)**	(647)
Changes in fair value of convertible redeemable preferred shares		**(198,874)**	(27,620)
LOSS BEFORE TAX	*6*	**(236,175)**	(48,784)
Income tax expense	*8*	**(3)**	(2)
LOSS FOR THE YEAR		**(236,178)**	(48,786)
Attributable to:			
Owners of the parent		**(235,784)**	(48,237)
Non-controlling interests		**(394)**	(549)
		(236,178)	(48,786)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted	*10*	**USD(0.79)**	USD(0.22)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2021

	2021	2020
	USD'000	*USD'000*
LOSS FOR THE YEAR	**(236,178)**	(48,786)
OTHER COMPREHENSIVE INCOME/(LOSS)		
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**162**	(295)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	**162**	(295)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(236,016)**	(49,081)
Attributable to:		
Owners of the parent	**(235,625)**	(48,510)
Non-controlling interests	**(391)**	(571)
	(236,016)	(49,081)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2021

	Notes	**2021**	2020
		USD'000	*USD'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**2,729**	2,473
Intangible assets		**7,036**	8,258
Right-of-use assets		**1,907**	1,984
Finance lease receivables		**72**	97
Trade receivables	*11*	**1,681**	–
Prepayments, other receivables and other assets		**451**	170
Pledged deposits		**213**	213
Total non-current assets		**14,089**	13,195
CURRENT ASSETS			
Inventories		**4,192**	3,051
Finance lease receivables		**44**	23
Trade and bills receivables	*11*	**5,663**	2,936
Prepayments, other receivables and other assets		**1,586**	1,852
Due from a related party		**–**	7
Pledged deposits		**25**	25
Cash and cash equivalents		**227,207**	18,788
Total current assets		**238,717**	26,682
CURRENT LIABILITIES			
Trade payables	*12*	**400**	357
Lease liabilities		**739**	512
Other payables and accruals		**7,438**	9,133
Interest-bearing bank and other borrowings	*13*	**13**	3,730
Contract liabilities		**374**	495
Total current liabilities		**8,964**	14,227
NET CURRENT ASSETS		**229,753**	12,455
TOTAL ASSETS LESS CURRENT LIABILITIES		**243,842**	25,650

	Note	**2021**	2020
		USD'000	*USD'000*
TOTAL ASSETS LESS CURRENT LIABILITIES		**243,842**	25,650
NON-CURRENT LIABILITIES			
Lease liabilities		**1,196**	1,419
Other payables and accruals		**200**	–
Contract liabilities		**28**	77
Interest-bearing bank and other borrowings	*13*	**–**	458
Convertible redeemable preferred shares		**–**	146,137
Total non-current liabilities		**1,424**	148,091
Net assets/(liabilities)		**242,418**	(122,441)
EQUITY			
Equity attributable to owners of the parent			
Share capital		**12**	6
Reserves		**242,406**	(120,519)
		242,418	(120,513)
Non-controlling interests		**–**	(1,928)
Total equity		**242,418**	(122,441)

1. CORPORATE AND GROUP INFORMATION

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

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

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

2. BASIS OF PREPARATION

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

3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

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

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	*Interest Rate Benchmark Reform – Phase 2*
Amendment to IFRS 16	*Covid-19-Related Rent Concessions beyond 30 June 2021* (early adopted)

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

(a) Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 address issues not dealt with in the previous amendments which affect financial reporting when an existing interest rate benchmark is replaced with an alternative risk-free rate ("RFR"). The amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount of financial assets and liabilities when accounting for changes in the basis for determining the contractual cash flows of financial assets and liabilities, if the change is a direct consequence of the interest rate benchmark reform and the new basis for determining the contractual cash flows is economically equivalent to the previous basis immediately preceding the change. In addition, the amendments permit changes required by the interest rate benchmark reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued. Any gains or losses that could arise on transition are dealt with through the normal requirements of IFRS 9 to measure and recognise hedge ineffectiveness. The amendments also provide a temporary relief to entities from having to meet the separately identifiable requirement when an RFR is designated as a risk component. The relief allows an entity, upon designation of the hedge, to assume that the separately identifiable requirement is met, provided the entity reasonably expects the RFR risk component to become separately identifiable within the next 24 months. Furthermore, the amendments require an entity to disclose additional information to enable users of financial statements to understand the effect of interest rate benchmark reform on an entity's financial instruments and risk management strategy.

Since the Group had no interest-bearing bank and other borrowings denominated in USD and foreign currencies based on any interbank offered rates as at 31 December 2021, the amendment did not have any impact on the financial position and performance of the Group.

(b) Amendment to IFRS 16 issued in March 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the COVID-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods beginning on or after 1 April 2021 with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

The Group has early adopted the amendment on 1 January 2021. However, the Group has not received COVID-19-related rent concessions and plans to apply the practical expedient when it becomes applicable within the allowed period of application.

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

	2021	2020
	USD'000	*USD'000*
Mainland China	**6,022**	1,267
European Union	**2,087**	749
USA	**718**	382
Other countries/regions	**2,064**	861
	10,891	3,259

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

(b) Non-current assets

	2021	2020
	USD'000	*USD'000*
USA	**7,098**	8,415
Mainland China	**4,819**	4,340
European Union	**43**	31
Other countries/regions	**3**	9
Total	**11,963**	12,795

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:

	2021	2020
	USD'000	*USD'000*
Customer A	**2,250**	N/A*
Customer B	**2,152**	N/A*
Customer C	**N/A***	565
Customer D	**N/A***	449

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

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2021	2020
	USD'000	*USD'000*
Revenue from contracts with customers		
Sale of medical devices and consumables	**8,241**	2,788
Licensing of intellectual property rights	**2,152**	–
Provision of services	**488**	428
Revenue from other sources		
Gross rental income	**10**	43
	10,891	3,259

Revenue from contracts with customers

(a) Disaggregated revenue information

	2021	2020
	USD'000	*USD'000*
Geographical markets		
Mainland China	**6,022**	1,267
European Union	**2,087**	749
USA	**708**	339
Other countries/regions	**2,064**	861
	10,881	3,216
Timing of revenue recognition		
Goods transferred at a point in time	**10,393**	2,788
Services transferred over time	**488**	428
	10,881	3,216

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

	2021	2020
	USD'000	*USD'000*
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Sale of medical devices and consumables	**260**	27
Provision of services	**231**	266
	491	293

(b) Performance obligations

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

Sale of medical devices and consumables

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

Provision of services

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

Licensing of intellectual property rights

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

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

	2021	2020
	USD'000	*USD'000*
Amounts expected to be recognised as revenue:		
Within one year	**381**	675
After one year	**28**	77
	409	752

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

An analysis of other income and gains is as follows:

	2021	2020
	USD'000	*USD'000*
Other income		
Government grants *(note a)*	**1,840**	352
Compensation from a licence agreement	**1,000**	–
Compensation from termination of a distribution agreement	**–**	632
Bank interest income	**117**	11
Interest income from non-current receivables	**44**	65
Others	**14**	–
	3,015	1,060
Gains		
Gain on disposal of items of property, plant and equipment	**96**	–
Gain on termination of leases	**18**	14
	114	14
	3,129	1,074

Note:

(a) In April 2020, the Group's two subsidiaries in the United States received loans totalling USD1,098,000 under the Paycheck Protection Program ("PPP") administered by the Small Business Administration ("SBA"). The PPP is a part of the Coronavirus Aid, Relief, and Economic Security Act enacted by the United States Congress on 27 March 2020 in response to the covid-19 pandemic. The repayment of these loans, including interest, will be forgiven if the above-mentioned received loans comply with the forgiveness requirement of the PPP loan program, which should be approved by SBA. The Group submitted applications for the forgiveness of the PPP loans in December 2020 and they were pending for approvals as of 31 December 2020. As such, the amount totalling USD1,098,000 was recognised as debt and included in "Interest-bearing bank and other borrowings" as of 31 December 2020. Further details are disclosed in note 13 to the consolidated financial statements. 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 interests in March and May 2021, respectively, which were recognised as government grants with a total amount of USD1,108,000.

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

6. LOSS BEFORE TAX

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

	2021	2020
	USD'000	*USD'000*
Cost of inventories sold	**1,825**	647
Cost of services provided	**64**	95
Cost of licensing of intellectual property rights	**250**	–
Research and development costs*	**16,759**	9,353
Depreciation of property, plant and equipment	**773**	287
Depreciation of right-of-use assets	**670**	658
Amortisation of intangible assets**	**1,248**	1,247
Impairment of trade receivables, net	**584**	214
Write-down of inventories to net realisable value***	**10**	11
Government grants	**(1,840)**	(352)
Interest income from non-current receivables	**(44)**	(65)
Bank interest income	**(117)**	(11)
Compensation from termination of a distribution agreement	**–**	(632)
Compensation from a licence agreement	**(1,000)**	–
(Gain)/loss on disposal of items of property, plant and equipment	**(96)**	31
Changes in fair value of convertible redeemable preferred shares	**198,874**	27,620
Lease payments not included in the measurement of lease liabilities	**331**	158
Auditor's remuneration	**279**	22
Listing expenses	**4,639**	1,599
Foreign exchange differences, net	**322**	252
Employee benefit expense (excluding directors' and chief executive's remuneration):		
Wages and salaries	**13,174**	9,109
Pension scheme contributions****	**1,057**	339
Staff welfare expenses	**2,499**	1,577
Equity-settled share award expenses	**3,096**	509
	19,826	11,534

* The research and development costs include USD8,556,000 (2020: USD4,270,000) relating to employee benefit expense.

** The amortisation of intangible assets for the year is included in "Research and development costs" in the consolidated statement of profit or loss.

*** The write-down of inventories to net realisable value for the year is included in "Cost of sales" in the consolidated statement of profit or loss.

**** There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

7. FINANCE COSTS

An analysis of finance costs is as follows:

	2021	2020
	USD'000	*USD'000*
Interest on bank and other borrowings	**51**	465
Interest on lease liabilities	**119**	82
Interest on other loans from related parties	**–**	100
	170	647

8. INCOME TAX

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

PRC

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), the subsidiaries which operate in Mainland China were entitled to a preferential income tax rate of 2.5% (2020: 5%) for small and micro enterprises except that Hangzhou Broncus Medical Co., Ltd. was subject to CIT at a rate of 15% (2020: 25%) for a High and New Technology Enterprise on the taxable income effective on 1 January 2021.

USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of up to 21% (2020: 21%) on the taxable income arising in the USA during the year.

Netherlands

The subsidiary incorporated in Netherlands was subject to income tax at the rate of 15% (2020: 16.5%) on the estimated assessable profits arising in Netherlands during the year.

Australia

The subsidiary incorporated in Australia was subject to income tax at the rate of 27.5% (2020: 27.5%) on the estimated assessable profits arising in Australia during the year.

Cayman Islands

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

Hong Kong

The subsidiary incorporated in Hong Kong was subject to income tax at the rate of 16.5% (2020: 16.5%) on the estimated assessable profits arising in Hong Kong during the year.

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

	2021	2020
	USD'000	*USD'000*
Current – USA		
Charge for the year	**3**	2

9. DIVIDEND

No dividend has been paid or declared by the Company during the year (2020: Nil).

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

The calculation of the basic loss per share amounts is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 298,960,470 (2020: 223,778,680) in issue during the year, as adjusted to reflect the share subdivision, which were deemed to have been issued by way of subdivision throughout the years ended 31 December 2021 and 2020. The number of shares for the current period has been arrived at after eliminating the shares of the Company held under the restricted stock unit scheme.

The calculation of basic loss per share is based on:

	2021	2020
	USD'000	*USD'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation	**(235,784)**	(48,237)

	Number of shares	
	2021	2020
Shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation	**298,960,470**	223,778,680

As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2021 and 2020 in respect of a dilution as the impact of the convertible redeemable preferred shares and equity-settled share award arrangements had an anti-dilutive effect on the basic loss per share amounts presented.

11. TRADE AND BILLS RECEIVABLES

	2021	2020
	USD'000	*USD'000*
Current		
Trade receivables	**5,996**	3,193
Bills receivable	**514**	–
	6,510	3,193
Non-current		
Trade receivables	**1,682**	–
	8,192	3,193
Impairment	**(848)**	(257)
	7,344	2,936

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

Included in the Group's trade receivables were an amount of USD1,924,000 (2020: USD988,000) 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:

	2021	2020
	USD'000	*USD'000*
Within 3 months	**4,194**	1,360
3 to 6 months	**1,951**	58
6 to 12 months	**667**	14
1 to 2 years	**18**	516
2 to 3 years	**–**	–
Over 3 years	**–**	988
	6,830	2,936

12. TRADE PAYABLES

	2021	2020
	USD'000	*USD'000*
Trade payables	**400**	357

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

	2021	2020
	USD'000	*USD'000*
Within 3 months	**397**	346
3 to 6 months	**1**	3
6 to 12 months	**2**	2
Over 1 year	**–**	6
	400	357

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

13. INTEREST-BEARING BANK AND OTHER BORROWINGS

	Effective interest rate (%)	Maturity	*Notes*	**As at 31 December 2021** ***USD'000***	As at 31 December 2020 *USD'000*
Current					
Bank loan – secured					
– RMB20,000,000	5.87	2021	*(a)*	**–**	3,065
Bank overdraft					
– secured	–	On demand	*(b)*	**13**	25
Bank loans – unsecured					
– current portion of long term loans of USD1,098,000	1.00	2021		**–**	640
				13	3,730
Non-current					
Bank loans – unsecured					
– non-current portion of long term loans of USD1,098,000	1.00	2022		**–**	458
				13	4,188
Analysed into:					
Within one year or on demand				**13**	3,730
In the second year				**–**	458
				13	4,188

Notes:

(a) The subsidiary of the Group and a director of the Group, namely Hangzhou Broncus Medical Co., Ltd. and Mr. Michael Yi Wei Zhao, have guaranteed certain of the Group's bank loans amounting to RMB20,000,000 as at 31 December 2020. The guarantee was released in full in April 2021.

(b) The Group's overdraft facilities amounting to USD80,000 (2020: USD80,000), of which USD13,000 (2020: USD25,000) had been utilised, were secured by the pledge of certain of the Group's time deposits amounting to USD25,000 (2020: USD25,000).

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

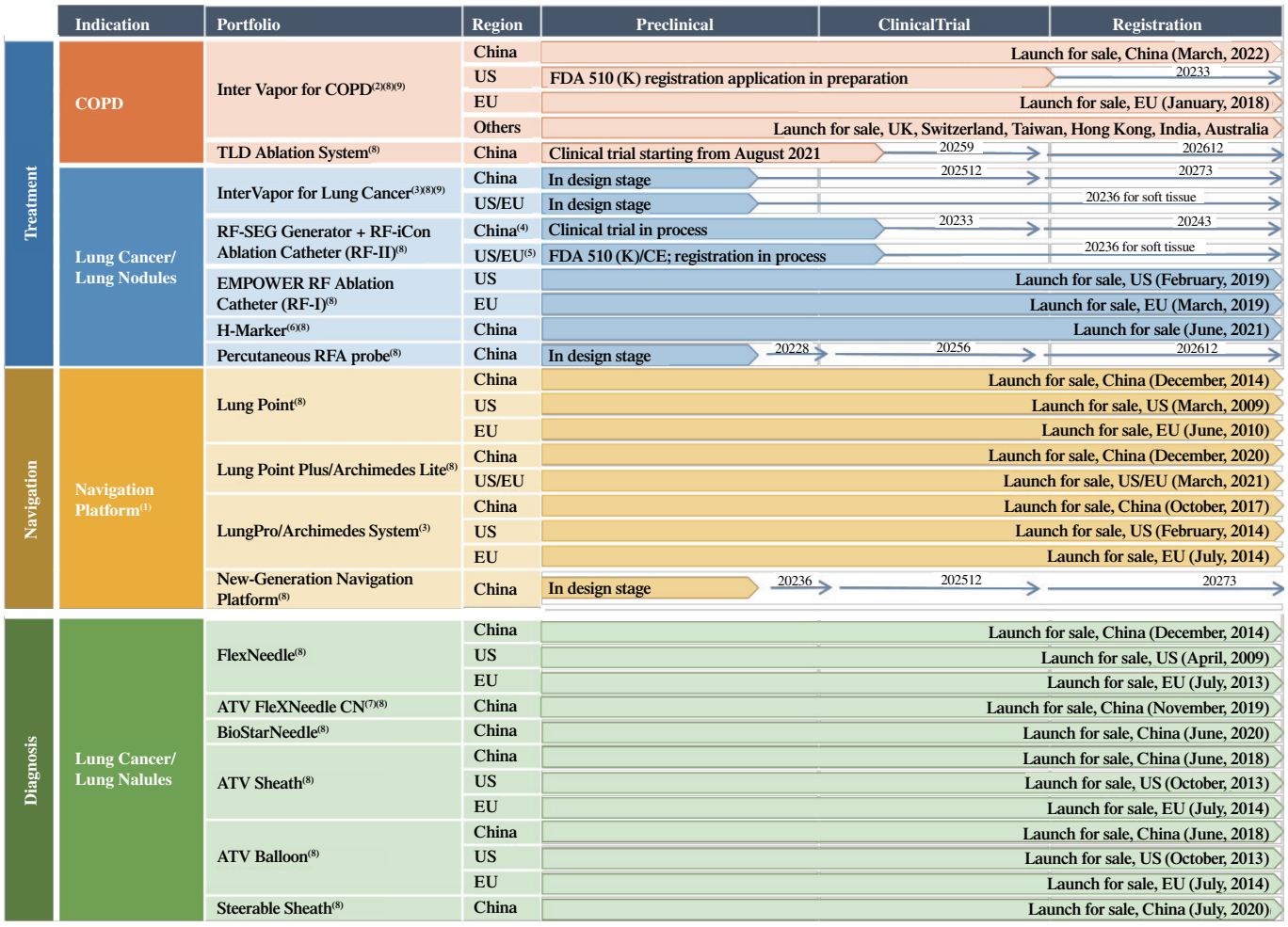
BUSINESS REVIEW

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 of December 31, 2021, we had 17 products and major product candidates under various development stages. Our core products are the InterVapor and RF-II. InterVapor is the world's first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer. RF-II is a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer.

Our products and product pipeline

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



Notes:

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

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

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

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

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

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

7. The version of FleXNeedle manufactured in China.

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

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

Business highlights

On September 24, 2021, the Company was successfully listed on The Stock Exchange of Hong Kong Limited (the "Stock Exchange"). 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, H-Marker was approved in China in June 2021; LungPoint Plus was officially launched in US/EU in March 2021; InterVapor was approved in China in March 2022 and was approved in India in March 2021; LungPoint, LungPoint Plus, Archimedes and FleXNeedle Biopsy Needle, Archimedes Sheath and Archimedes Dilation Balloon were approved in India in August 2021.

Over the course of the financial year of 2021, 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, in June and December 2021, we established a "Broncus pulmonary disease interventional technology training base" respectively with Shandong Public Health Clinical Center and Xi'an International Medical Center Hospital; in November 2021, the team under Professor V. Nagarjuna Maturu from Yashoda Hospital successfully completed the first lung volume reduction surgery using InterVapor in India; and we successfully launched the real world study project "Evaluation of the Safety and Efficacy of Bronchoscopic Transparenchymal Nodule Access (BTPNA) in the Sampling Diagnosis of Peripheral Pulmonary Lesions"; and we completed enrollment for registered clinical trial for RF-II in China and released the phased data of the clinical study of the 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;

In September 2021, the company completed the first clinical application of its Targeted Lung Denervation (TLD) radiofrequency ablation system in West China Hospital of Sichuan University. Our TLD products have completed enrollment of six clinical cases as of the date of this announcement.

(iii) With respect to our partnerships, we reached a strategic cooperation agreement with United Family Healthcare Group, a leading high-end private medical institution in China under New Frontier Health Corporation, in December 2021; and we reached a strategic cooperation agreement with Healium Medical Ltd., an Israeli company specializing in the R&D of ultrasound energy therapy and imaging monitoring, in February 2022.

Core products

InterVapor

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

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

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 December 31, 2021 (1) the STEP-UP trial, (2) the NEXT-STEP trial, (3) the VAPORIZE trial, (4) the West China Hospital trial 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 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 510k clearance of InterVapor for COPD in the United States and registration of the product in South Korea.

In addition, we expect the clinical trial for Targeted Lung Denervation (TLD) Radiofrequency Ablation System to be finished in the second quarter of 2022. Such expect such TLD product 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. Targeted lung denervation (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 510k 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. 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 Reporting Period, 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 (浙江省藥品監督管理局) in October 2020 and obtained the Zhejiang MPA approval in June 2021.

LungPoint, LungPoint Plus/Archimedes Lite and 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 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 US 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 expect to submit the registration application with NMPA after we obtain the model inspection report by the end of 2021 to further complete the localization of the manufacturing process. We expect the registration to be completed in the second quarter of 2023. The localization of the Archimedes System manufacturing started in April 2022 with design verification in progress. The model inspection is expected to be initiated in April 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 sell 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 year indicated.

	For the year ended December 31,	
	2021	2020
Direct sales to hospitals	**68**	38
• Europe	**33**	18
• USA	**22**	13
• PRC (Mainland)	**7**	3
• Others	**6**	4

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

	For the year ended December 31,	
	2021	2020
Distributors	**43**	21
• PRC (Mainland)	**22**	9
• Europe	**10**	4
• Asia (excluding China) and other regions	**11**	8

For the year ended December 31, 2021, our revenue generated from distributors and direct sales accounted for approximately US$6.0 million and US$4.9 million, respectively, compared to US$1.0 million and US$2.2 million in the corresponding period last year.

Intellectual Property

As of December 31, 2021, we obtained 658 patents and patent applications which consisted of 186 issued patents (including pending announcements) and 322 patent applications in China and 99 issued patents and 51 patent applications overseas including key markets such as the U.S. and the EU. Among the patents obtained, 71 and 23 of them are related to InterVapor and RF-II, respectively.

Strategic Cooperation

We reached a strategic cooperation agreement with United Family Healthcare Group, a leading high-end private medical institution in China under New Frontier Health Corporation, in December 2021. This cooperation aims in exploring a new diagnosis and treatment service model with interventional pulmonology and penetrating into the middle-to-high end private healthcare markets. In the future, we will jointly establish a lung specialist medical center to promote our core products and medical devices and expertise in the treatment of lung diseases.

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.

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

During the Reporting Period, the Company received government grants totaling US$1.8 million. In April 2020, the Group's two subsidiaries in the U.S. received loans in the amount of approximately US$1.1 million under the Paycheck Protection Program ("**PPP**") administered by the Small Business Administration. The program is part of the *Coronavirus Aid, Relief, and Economic Security Act* enacted by the United States Congress on March 27, 2020 in response to the COVID-19 pandemic. The Group received the notices of PPP forgiveness payment from the Small Business Administration regarding the approval of its application for forgiveness of US$311,000 and US$787,000 in principal and associated interest in March and May 2021, respectively, which were recognised as government grants. The remaining government grants mainly represent incentives received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new product development and compensation for expenditure incurred on certain projects.

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 as leader in differentiating treatment areas and further grow utilization through professional education and market promotion after our treatments are approved by the NMPA; second, to take advantage of opportunities to initiate controller installation and accelerate equipment hospital listing; thirdly, to focus on mobilizing our internal sales team via targeted coaching and progress tracking to drive consumable utilization.

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

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

Looking into 2022, we plan to evaluate the use of BTVA for the treatment of emphysema with middle and/or lower lobe predominance, for which no existing data are available. We plan to conduct a 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 March 2022, and aim to complete the trial in 2023. We also plan to conduct a prospective, multi-center, single blind, randomized controlled study under the title of Targeted Segmental Vapor Ablation Treatment of Emphysema with Upper Lobe Predominance: A randomized controlled trial of InterVapor® in France and Germany, which is planned to commence by the third quarter of 2022 and is expected to be completed in 2023. 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 include 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 quarter of 2021 has exceeded that of the corresponding period last year. Despite the recurred delta variant of COVID-19 in several provinces across China in late July 2021, 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 year ended December 31, 2021, being US$10.9 million, increased by over 230% as compared to US$3.3 million for the year ended December 31, 2020. 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 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.

Year ended December 31, 2021 compared to year ended December 31, 2020

	For the year ended December 31,	
	2021	2020
	US$'000	*US$'000*
Revenue	**10,891**	3,259
Cost of sales	**(2,149)**	(753)
Other income and gains	**3,129**	1,074
Selling and distribution expenses	**(12,706)**	(6,352)
Administrative expenses	**(18,546)**	(7,722)
Impairment losses on financial assets, net	**(584)**	(214)
Research and development costs	**(16,759)**	(9,353)
Other expenses	**(407)**	(456)
Finance costs	**(170)**	(647)
Changes in fair value of convertible redeemable preferred shares	**(198,874)**	(27,620)
Income tax expense	**(3)**	(2)
Loss for the year	**(236,178)**	(48,786)
Other comprehensive income/(loss) for the year, net of tax	**162**	(295)
Total comprehensive loss for the year	**(236,016)**	(49,081)

Revenue

For the Reporting Period, the revenue of the Group was US$10.9 million, representing an increase of over 230% compared with US$3.3 million in the corresponding period last year, mainly due to significant 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$3.1 million, representing an increase of 181.8% compared with approximately US$1.1 million in the corresponding period last year.

Our other income consist primarily of government grants, compensation from a license agreement, compensation from termination of a distribution agreement, bank interest income and interest income from non-current receivables. Total other income was approximately US$3.0 million for the year ended December 31, 2021, representing an increase of approximately US$1.9 million from the year ended December 31, 2020, mainly due to (i) an increase of government grants as two subsidiaries of the Group in the United States received loans of a total US$1.1 million under the PPP administered by the Small Business Administration in April 2020. In March and May 2021, the Group received the notices of PPP forgiveness payment from the Small Business Administration regarding the approval of its application for forgiveness of USD311,000 and USD787,000 in principal and associated interests, respectively, which were recognised as government grants with a total amount of USD1,108,000; and (ii) compensation from a license agreement amounting to US$1.0 million.

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$114,000 for the year ended December 31, 2021, representing an increase of approximately US$100,000 from the year ended December 31, 2020.

R&D expenses

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

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

For the year ended December 31, 2021 and 2020, we incurred R&D costs of approximately US$16.8 million and US$9.4 million, respectively, representing an increase of 78.7%. The increase in our R&D costs was mainly due to (i) increased staff cost from US$4.1 million for the year ended December 31, 2020 to US$7.0 million for the year ended December 31, 2021 due to the expansion of our R&D team; (ii) increased cost of share award expenses from US$0.2 million for the year ended December 31, 2020 to US$1.6 million for the year ended December 31, 2021; (iii) increased clinical trial fees from US$0.5 million for the year ended December 31, 2020 to US$1.5 million for the year ended December 31, 2021.

	Year ended 31 December 2021		Year ended 31 December 2020	
	USD'000	***Proportion***	*USD'000*	*Proportion*
Raw material costs	**1,342**	**8.0%**	854	9.1%
Staff cost	**7,000**	**41.8%**	4,074	43.6%
Travel and business related expenses	**345**	**2.1%**	154	1.6%
Office expenses	**330**	**2.0%**	193	2.1%
Technical service fees	**1,577**	**9.4%**	1,153	12.3%
Clinical trial expenses	**1,504**	**9.0%**	514	5.5%
Depreciation and amortization	**2,346**	**14.0%**	1,764	18.9%
Others	**764**	**4.4%**	451	4.8%
Share awards	**1,551**	**9.3%**	196	2.1%
Total	**16,759**	**100.0%**	9,353	100.0%

Selling and distribution expenses

For the year ended December 31, 2021 and 2020, our selling and distribution expenses were US$12.7 million and US$6.4 million, respectively, representing an increase of 98.4%. The increase in our selling and distribution expenses was mainly due to (i) our increased marketing and advertising expenses from US$0.8 million for the year ended December 31, 2020 to US$2.8 million for the year ended December 31, 2021, as a result of the increase in marketing activities in China in 2021 as the impacts of COVID-19 have eased in China since 2021, (ii) our increased staff costs from US$4.1 million for the year ended December 31, 2020 to US$6.2 million for the year ended December 31, 2021 due to the expansion of our sales team, and (iii) our increased share award expenses from US$0.1 million for the year ended December 31, 2020 to US$1.2 million for the year ended December 31, 2021.

Administrative expenses

For the year ended December 31, 2021 and 2020, our total administrative expenses were approximately US$18.5 million and US$7.7 million, respectively. The increase was mainly due to (i) our increased Global Offering related professional service fees from US$1.6 million for the year ended December 31, 2020 to US$4.6 million for the year ended December 31, 2021 as a result of the costs incurred for the Global Offering, and (ii) our increased share award expenses from US$0.2 million for the year ended December 31, 2020 to US$6.3 million for the year ended December 31, 2021.

Liquidity and capital resources

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

As at December 31, 2021, our cash and bank balances totalled US$227.2 million, as compared to US$18.8 million as at December 31, 2020. The increase was mainly due to the completion of the Series D financing and proceeds received from the Global Offering. For further details of the Series D financing, please refer to "History, Reorganization and Corporate Structure" section of the Company's prospectus dated September 13, 2021 (the "**Prospectus**").

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

	Year ended December 31,	
	2021	2020
	US$'000	*US$'000*
Net cash flows used in operating activities	**(31,494)**	(15,588)
Net cash flows used in investing activities	**(1,753)**	(1,089)
Net cash flows from financing activities	**241,822**	32,225
Net increase in cash and cash equivalents	**208,575**	15,548
Cash and cash equivalents at the beginning of the year	**18,788**	3,085
Effect of foreign exchange rate changes, net	**(156)**	155
Cash and cash equivalents at the end of the year	**227,207**	18,788
Analysis of balances of cash and cash equivalents	**227,207**	18,788
Cash and cash equivalents as stated in the statement of financial position	**227,207**	18,788

As at December 31, 2021, cash and cash equivalents were mainly denominated in Hong Kong dollars, United States dollars and Renminbi.

Bank Borrowings and Gearing

As at December 31, 2021, the Group's outstanding borrowings of US$13,000 (December 31, 2020: US$4.2 million) were denominated in USD. The Group's overdraft facilities amounting to US$80,000 and US$80,000, of which US$13,000 and US$25,000 had been utilized as at December 31, 2021 and December 31, 2020, 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 December 31, 2021 and December 31, 2020, the Group's gearing ratio (total debt less cash and cash equivalent as a percentage of total equity as of the end of the year) were negative values.

Foreign Exchange Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between USD 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 of December 31, 2021, the Group did not have any significant contingent liabilities.

Charge or Restrictions on Assets

As of December 31, 2021, the Group had pledged deposits of US$238,000 (December 31, 2020: US$238,000). The pledged deposits were placed to secure the Group's bank overdraft facilities and the Group's rent deposits. Save as disclosed in this announcement, the Group did not pledge any group assets.

NON-IFRS MEASURES

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

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

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

	Year ended December 31,	
	2021	2020
	US$'000	*US$'000*
Loss for the year	**(236,178)**	(48,786)
Add:		
Change in fair value of convertible redeemable preferred shares	**198,874**	27,620
Share awards[(1)]	**9,011**	509
Listing expenses	**4,639**	1,599
Non-IFRS adjusted net loss for the year[(2)]	**(23,654)**	(19,058)

Notes:

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

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

CORPORATE GOVERNANCE RELATED INFORMATION

Compliance with the Corporate Governance Code

As the Company's Shares were not listed on the Stock Exchange before the Listing, the CG Code set out in Appendix 14 to the Listing Rules is only applicable to the Company since the Listing Date. The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in the CG Code as contained in Appendix 14 to the Listing Rules as its own code of corporate governance practices. The Board is of the view that since the Listing Date and up to December 31, 2021, the Company has complied with all the applicable code provisions as set out in the CG Code. The Board will continue to review and monitor the code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

Compliance with the Model Code

As the Company's Shares were not listed on the Stock Exchange before the Listing, the provisions regarding compliance with the Model Code is only applicable to the Company since the Listing Date. 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 since the Listing Date and up to December 31, 2021.

No incident of non-compliance of the Model Code by the employees was noted by the Company since the Listing Date and up to December 31, 2021.

Purchase, Sale or Redemption of the Company's Securities

During the period from the Listing Date to December 31, 2021, neither the Company nor any of its subsidiaries had purchased, sold or redeemed the Company's listed securities.

Significant Investment Held

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 year ended December 31, 2021. The Directors are also not aware of any material litigation or claims that were pending or threatened against the Group during the year ended December 31, 2021.

Employee and Remuneration Policy

As at December 31, 2021, the Group had 300 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 17.3 million (for the same period in 2020: 11.4 million).

Use of Net Proceeds from the Global Offering

The total net proceeds from the issue of Shares by the Company in its listing on the Stock Exchange amounted to approximately HK$1,620.0 million, after deducting the underwriting commission and other expenses payable by the Company in connection with the Global Offering. The balance of unutilized net proceeds amounted to approximately HK$1,570.9 million as at the end of the Reporting Period and the Company intends to use them in the same manner and proportions as described in the Prospectus and proposes to use the unutilized net proceeds in accordance with the expected timetable disclosed in the table below.

	Use of proceeds in the same manner and proportion as stated in the Prospectus *HK$ in million*	**Actual use of proceeds as at the end of the Reporting Period** *HK$ in million*	**Net proceeds unutilized as at the end of the Reporting Period** *HK$ in million*	**Expected timeframe for utilizing the remaining unutilized net proceeds**
approximately 29.0% to fund going and planned R&D and commercial launches of InterVapor	469.2	8.8	460.4	Expected to be fully utilized by 2030
approximately 21.0% to fund ongoing and planned R&D and commercial launches of RF-II	339.4	8.4	331.0	Expected to be fully utilized by 2030
approximately 18.5% for our other products and product candidates	299.9	19.0	280.9	Expected to be fully utilized by 2030
approximately 9.2% for our continued product line expansion of our manufacturing facilities, mainly including the construction of assembly workshops, weaving workshops, purification workshops and other production workshops, investment in production equipment	149.2	–	149.2	Expected to be fully utilized by 2026
approximately 13.2% for our continued expansion of product portfolio through potential acquisition	213.2	–	213.2	Expected to be fully utilized by 2026
approximately 9.2% for our working capital and other general corporate purposes	149.2	12.8	136.4	Expected to be fully utilized by 2026
Total	1,620.0	49.1	1,570.9	–

Audit Committee

The Audit Committee comprises three independent non-executive Directors, namely Dr. Pok Man Kam, Professor Joseph Wan Yee Lau and Dr. Jian Ji. The chairman of the Audit Committee is Dr. Pok Man Kam who holds the appropriate qualification as required under Rules 3.10(2) and 3.21 of the Listing Rules. The Audit Committee has reviewed the audited consolidated financial statements for the year ended December 31, 2021 with the management of the Company. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

Auditor

The financial information contained in this announcement does not constitute the Group's audited accounts for the year ended December 31, 2021, but represents an extract from the consolidated financial statements for the year ended December 31, 2021 which have been audited by the auditor of the Company, Ernst & Young, in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants.

EVENTS AFTER THE REPORTING PERIOD

Indirect investment in New Frontier Health Corporation

On December 6, 2021, the Company entered into a subscription agreement (the "**Subscription Agreement**") to purchase limited partnership interests in Unicorn Holding Partners LP ("**Unicorn Holding**") with a capital commitment of US$3,000,000 (the "**Subscription**"), representing approximately 1.11% of the equity interest in Unicorn Holding immediately after the completion of such subscription. On January 13, 2022, the Subscription was accepted in whole and the payment was made in cash.

Unicorn Holding is a Cayman Islands exempted limited partnership which, directly and/or indirectly, acquired approximately 16.07% of the equity interest in New Frontier Health Corporation, which owns and operates United Family Healthcare (和睦家), a leading private provider offering comprehensive premium healthcare services in China consisting of a network of private hospitals and affiliated ambulatory clinics. Following completion of the Subscription, the Company indirectly owns approximately 0.18% equity interest in New Frontier Health Corporation through its interest in Unicorn Holding as a limited partner.

For details, please see the announcement "Discloseable Transaction – Acquisition of 0.18% Equity Interest in the Target Company" of the Company dated December 6, 2021.

Marketing approval for InterVapor®

In March 2022, the Company was granted marketing approval by the NMPA for InterVapor, denoting the official commercialization of the world's only such product in China. InterVapor is the first thermal vapor energy ablation system in China approved for "Priority Approval" for the treatment of COPD. It is a medical device that is needed imminently in clinics and no similar product has been approved in China. InterVapor is also safe and effective for patients with complete or incomplete fissure, and offers a solution with minimal invasion and disruption for patients with advanced COPD. The Company has obtained an exclusive patent for the use of thermal vapor for pulmonary treatments with a state-of-the-art technology. For details, please see the announcement "Inside Information Announcement – InterVapor®, The Thermal Vapor Treatment System, Approval for Marketing in China" of the Company dated March 21, 2022.

Save as disclosed above, the Company is not aware of any material subsequent events from December 31, 2021 to the date of this announcement.

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2021 (2020: Nil).

CLOSURE OF REGISTER OF MEMBERS AND RECORD DATE

The register of members of the Company will be closed from Tuesday, May 10, 2022 to Friday, May 13, 2022, both days inclusive, in order to determine the identity of Shareholders who are entitled to attend and vote at the annual general meeting to be held on Friday, May 13, 2022. Shareholders whose name appear on the register of member of the Company on Friday, May 13, 2022 will be entitled to attend and vote at the annual general meeting. In order to be eligible to attend and vote at the the annual general meeting, all transfer accompanied by relevant share certificates and transfer forms must be lodged with the Company's share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, Shops 1712-1716, 17th Floor Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong before 4:30 p.m. on Friday, May 6, 2022.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

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

The annual report of the Company for the year ended December 31, 2021 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.

"associate(s)"	has the meaning ascribed to it under the Listing Rules
"Board" or "Board of Directors"	the board of Directors
"Company"	Broncus Holding Corporation (堃博醫療控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability on April 30, 2012, whose Shares were listed and traded on the Stock Exchange
"COPD"	chronic obstructive pulmonary disease
"Director(s)"	member(s) of our board of directors, including all executive, non-executive and independent non-executive directors
"EU"	the European Union
"Global Offering"	the global offering of the Shares, comprising the Hong Kong public offering of 8,935,500 Shares and the international offering of 80,419,500 Shares
"Group," "our Group," "we" or "us"	the Company and our subsidiaries (or the Company and any one or more of our subsidiaries, as the context may require)
"HK$" or "HK dollars" or "Hong Kong dollars"	Hong Kong dollars, the lawful currency of Hong Kong
"Hong Kong" or "HK"	the Hong Kong Special Administrative Region of the PRC
"InterVapor"	InterVapor System, the world's first and only thermal vapor energy ablation system to treat lung diseases including COPD and lung cancer
"Listing Date"	September 24, 2021, being the date on which the Shares were listed on the Main Board of the Stock Exchange
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
"Model Code"	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
"NMPA"	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)

"PRC" or "China" or the "People's Republic of China"	the People's Republic of China, which for the purpose of this announcement and for geographical reference only, excludes Hong Kong, the Macau Special Administrative Region of the People's Republic of China and Taiwan
"R&D"	Research and development
"Reporting Period"	12 months ended December 31, 2021
"RF-II"	RF Generator + RF Ablation Catheter, a radiofrequency ablation system used in conjunction with a disposable lung radiofrequency ablation catheter and the only radiofrequency ablation system that specifically targets lung cancer
"Shares"	ordinary share(s) in the share capital of the Company
"Shareholders"	holders of the Shares
"sq.m."	square meters
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"U.S." or "United States"	the United States of America
"US$" or "U.S. dollars"	United States dollars, the lawful currency for the time being of the United States
"%"	per cent

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

Hong Kong, March 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 Dr. JI Jian as independent non-executive Directors.