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Acotec Scientific Holdings Limited
先瑞達醫療科技控股有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 6669)

ANNUAL RESULTS ANNOUNCEMENT
FOR THE YEAR ENDED DECEMBER 31, 2021

ANNUAL RESULTS HIGHLIGHTS

FINANCIAL HIGHLIGHTS

	Year ended December 31, 2021 RMB'000	Year ended December 31, 2020 RMB'000	Year-to-year change
Revenue	303,813	193,975	56.6%
Gross profit	265,939	163,780	62.4%
Loss before tax	(67,243)	(31,447)	113.8%
Loss for the year	(79,077)	(44,292)	78.5%
add adjusted items*:			
Share-based payments	33,356	51,956	-35.8%
Net exchange loss on the translation of listing proceeds	9,350	-	N/A
Loss (gain) on fair value change of preferred shares	33,458	(447)	N/A
Listing expenses	41,129	10,317	298.7%
Deferred tax asset reversal	4,174	-	N/A
Adjusted Net Profit for the year	42,390	17,534	141.8%

* The detail of the adjusted items refers to Non-IFRS Measures of this annual results announcement

BUSINESS HIGHLIGHTS

In 2021, we made significant progress in research and development. During the year ended December 31, 2021, five products were sent for type testing, seven products were under clinical trial, two products completed clinical trial, two products applied for registration with NMPA and two products received approval (including one upgraded product of AcoArt Orchid® & Dhalia™). We also registered ten additional patents during the year ended December 31, 2021.

Besides our significant progress in research and development, our admission efforts to hospital are also advancing. As of December 31, 2021, our BTK DCB (Below-The-Knee Drug-Coated Balloons) had been admitted into 288 hospitals and listed as a candidate for online procurement in 27 provinces and autonomous regions. Our ATK DCB (Above-The-Knee Drug-Coated Balloons) had been admitted into 1,283 hospitals. Our Peripheral Aspiration Catheter which was launched in November 2021 had been listed as a candidate for online procurement on the national procurement platform.

The stable and positive direction of our production and research contributed to the rapid growth of our annual revenue directly. For the year ended December 31, 2021, our revenue reached approximately RMB303.8 million, representing a year-on-year increase of approximately 56.6%. Our Core Products, AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™, were the major contributors of our revenue.

The change in layout of our products represented our further expansion from the artery sector to the vein sector officially.

In August 2021, our peripheral vacuum aspiration pump was approved to launch. Our Peripheral Aspiration System (AcoStream™) was approved to launch three months later. As of December 31, 2021, all of our products under the Peripheral Thrombus Aspiration system had been launched, which made us become the first Chinese enterprise possessing originated technologies and ability to provide comprehensive solution in such sector.

We accelerated our globalization process and our products entered international markets in full speed.

For research and development, we established Acotec Technologies Limited (“**Acotec Technologies**”) in California, U.S. in 2021 with a primary focus on the research and development of forward-looking and innovative products (the “**U.S. R&D Center**”). Mr. Scott WILSON acts as the general manager of Acotec Technologies. Mr. Wilson has over 25 years of experience in medical product development. Before joining us, Mr. Wilson served as a vice president of R&D at Silk Road Medical, a vascular medical device company. Prior to these roles, Mr. Wilson had leadership roles at Concentric Medical, which was acquired by Stryker Neurovascular. Mr. Wilson was the lead director and engineer at Concentric Medical that developed multiple product lines, including Trevo Stentriever, Flow Gate and Distal Access Catheters (DAC).

In the same year, four global top medical experts joined the Scientific Advisory Board of Acotec and provided guidance to the clinical trials and launch of our Core Products in the U.S. and Europe, which assisted the global IDE study of AcoArt BTK. We believe the joining of Mr. Wilson and his team as well as four experts will serve as a booster of the global layout of our Group and further improved the chain of production and research.

With respect to our sales, three DCB products were approved to launch in Brazil. As of December 31, 2021, our products had completed commercialization across 12 countries accumulatively. We are of the view that the acceleration of our Group’s globalization process will diversify the revenue stream of our Company and facilitate us to respond to market changes more flexibly. In addition to diversifying our revenue, our globalization process has laid down a solid foundation of our production and research, which forms a benign closed loop of corporate operations.

We continued to strengthen our efforts in clinical promotions and promote the innovation of clinical therapies of vascular intervention.

Since the launch of AcoArt Orchid® & Dhalia™, our first and China's first peripheral DCB product, we have already initiated our efforts in clinical promotion and education. Since the commencement of research and development of our products, we have never relaxed our promotion efforts in clinical treatments. We have been promoting the innovation of clinical therapies of vascular intervention, so as to provide brand-new solutions for peripheral intravascular diseases to patients.

During the year ended December 31, 2021, our Peripheral Aspiration System (AcoStream™) was approved to launch, which enabled us to become the first Chinese enterprise possessing originated technologies and ability to provide comprehensive solution in such sector. We will continue to carry on the market cultivation of our new products, so as to provide new treatment methods to clinical patients.

We continued to reinforce our talent pool and improve our team building.

As of December 31, 2021, we had approximately 400 employees in total. The research and development team grew to 86 members. Our original technical team covers the aspects of material science, mechanical design manufacturing, chemistry and biomedical engineering. During the year ended December 31, 2021, we supplemented our research and development team with technicians in the field of electronic science and technology, automation and computer programming, which further improved our talent pool. We believe that the support of talents from different aspects will accelerate the implementation of our multi product pipeline projects.

Our new product pipelines were multi-pronged and advanced as scheduled.

In 2021, we carried out in-depth investigations and discussion in respect of artery calcification, vein market and vascular aneurysm and we started to prepare for our business presence in these sectors. As of December 31, 2021, we had developed 6 new products, including peripheral IVL system (vascular surgery), peripheral coil (vascular surgery), and coronary IVL system (cardiology). The progress of production development had been advancing in an extremely quick pace. We are of the view that these results are attributable to two reasons.

First of all, it is attributable to our insight into, judgment of and prediction of market potentials. Decades of experience in the industry enables to make better decisions and judgments to develop these potential markets.

Secondly, it is attributable to our first-class execution capabilities. We spent only seven months from kicking off the project to finalizing the design our IVL system. In addition, our remaining product lines advanced as scheduled according to the original plans.

The Board is pleased to announce the audited consolidated results of the Group for the Reporting Period. The content of this annual results announcement has been prepared in accordance with applicable disclosure requirements under the Listing Rules in relation to preliminary announcements of annual results which is prepared in accordance with the IFRS issued by the IASB. Such annual results have also been reviewed and confirmed by the Board and the Audit Committee. Unless otherwise stated, the financial data of the Company are presented in RMB.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2021

	<i>NOTES</i>	Year ended December 31,	
		2021	2020
		RMB'000	RMB'000
Revenue	5	303,813	193,975
Cost of sales		(37,874)	(30,195)
Gross profits		265,939	163,780
Other income	6	11,433	4,645
Other gains and losses, net	7	(8,837)	730
(Loss) gain on fair value change of preferred shares		(33,458)	447
Impairment losses under expected credit loss model, net of reversal		813	(1,130)
Selling and distribution expenses		(58,801)	(32,581)
Research and development expenses		(141,288)	(83,487)
Administrative expenses		(58,091)	(72,112)
Listing expenses		(41,129)	(10,317)
Finance costs	8	(3,824)	(1,422)
Loss before tax		(67,243)	(31,447)
Income tax expense	9	(11,834)	(12,845)
Loss and total comprehensive expense for the year	10	(79,077)	(44,292)
Loss and total comprehensive expense attributable to:			
Owners of the Company		(79,077)	(43,842)
Non-controlling interest		–	(450)
		(79,077)	(44,292)
Loss per share			
– Basic (<i>RMB Yuan</i>)	12	(0.32)	(0.24)
– Diluted (<i>RMB Yuan</i>)		(0.32)	(0.24)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT DECEMBER 31, 2021

	<i>NOTES</i>	As at December 31,	
		2021	2020
		RMB'000	RMB'000
Non-current assets			
Property, plant and equipment		33,398	22,655
Right-of-use assets		16,836	19,947
Intangible assets		2,995	2,000
Rental deposits		2,503	1,834
Deposits paid for acquisition of property, plant and equipment		6,688	2,188
Deferred tax assets		271	4,926
Goodwill		1,150	1,150
		63,841	54,700
Current assets			
Inventories		41,553	28,538
Trade and bill receivables	<i>13</i>	44,214	29,518
Prepayments, deposits and other receivables		18,824	9,599
Amount due from a shareholder		–	227
Amount due from a preferred shareholder		–	3,262
Bank balances and cash		1,137,184	147,097
Pledged bank deposits		1,750	–
		1,243,525	218,241
Current liabilities			
Trade and other payables	<i>14</i>	62,159	35,746
Dividend payable		–	326,245
Contract liabilities		8,016	8,432
Tax payable		5,131	6,511
Provisions		–	1,511
Lease liabilities		6,806	5,679
Bank borrowings		6,000	20,000
		88,112	404,124
Net current assets (liabilities)		1,155,413	(185,883)
Total assets less current liabilities		1,219,254	(131,183)

		As at December 31,	
	<i>NOTES</i>	2021	2020
		RMB'000	RMB'000
Capital and reserves (deficits)			
Share capital	15	20	14
Reserves (deficits)		1,207,174	(281,023)
		<hr/>	<hr/>
Total equity (net deficits)		1,207,194	(281,009)
		<hr/>	<hr/>
Non-current liabilities			
Lease liabilities		11,765	15,736
Preferred shares		–	133,760
Deferred tax liabilities		295	330
		<hr/>	<hr/>
		12,060	149,826
		<hr/>	<hr/>
		1,219,254	(131,183)
		<hr/>	<hr/>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2021

1. CORPORATE INFORMATION

Acotec Scientific Holdings Limited (the “**Company**”) was incorporated in the Cayman Islands on December 3, 2020 as an exempted company with limited liability under the Companies Act, Cap 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands. The Company is an investment holding company and the Company became the holding company of the entities now comprising the Company and its subsidiaries (collectively referred as the “**Group**”) upon completion of the group reorganisation. The Group is principally engaged in research and development of Percutaneous Transluminal Angioplasty (“**PTA**”) balloons and drug-coated balloons (“**DCB**”) products. The Group also launched the Peripheral Aspiration System (AcoStream™) in 2021.

The address of the Company’s registered office is PO Box 309, Uglund House, Grand Cayman, KY1-1104, Cayman Islands. The principal place of business of the Company is 4-5/F., Building No. 1, No.16 Hongda Road North, Beijing Economic-Technological Development Area, Beijing, the PRC.

The shares of the Company have been listed on The Stock Exchange of Hong Kong Limited (“**Stock Exchange**”) with effect from August 24, 2021.

The consolidated financial statements are presented in Renminbi (“**RMB**”) which is also the functional currency of the Company and the subsidiaries located in Mainland China and Hong Kong.

2. BASIS OF PREPARATION AND PRESENTATION OF CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements have been prepared based on the accounting policies which conform with International Financial Reporting Standards (“**IFRSs**”) issued by International Accounting Standards Board (“**IASB**”) and conventions applicable for group reorganisation.

The consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statements of cash flows of the Group which include the results have been prepared as if the Company had always been the holding company of the companies then comprising the Group and the current group structure had been in existence during the year ended December 31, 2020, or since their respective dates of incorporation/establishment or acquisition, where it is a shorter period.

3. APPLICATION OF AMENDMENTS TO INTERNATIONAL FINANCIAL REPORTING STANDARDS (“IFRSs”)

The Group has applied all International Accounting Standards, IFRSs and amendments that are effective for the annual periods beginning on or after January 1, 2021 for the preparation of the consolidated financial statements.

In addition, the Group applied the agenda decision of the IFRS Interpretations Committee (the “Committee”) of the International Accounting Standards Board (the “IASB”) issued in June 2021 which clarified the costs an entity should include as “estimated costs necessary to make the sale” when determining the net realisable value of inventories.

New and Amendments to IFRSs in issue but not yet effective

The Group has not early applied the following new and amendments to IFRSs that have been issued but are not yet effective:

IFRS 17	Insurance Contracts and the related Amendments ³
Amendments to IFRS 3	Reference to the Conceptual Framework ²
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture ⁴
Amendment to IFRS 16	Covid-19 Related Concession Rent beyond 30 June 2021 ¹
Amendments to IAS 1	Classification of Liabilities as Current or Non-current ³
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies ³
Amendments to IAS 8	Definition of Accounting Estimates ³
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction ³
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended Use ²
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract ²
Amendments to IFRS Standards	Annual Improvements to IFRS Standards 2018–2020 ²

¹ Effective for annual periods beginning on or after April 1, 2021

² Effective for annual periods beginning on or after January 1, 2022

³ Effective for annual periods beginning on or after January 1, 2023

⁴ Effective for annual periods beginning on or after a date to be determined

Except for the amendments to IAS 12 *Income Taxes*, the directors of the Group anticipate that the application of other new and amendments to IFRSs will have no material impact on the Group’s financial position and performance and/or the disclosures to the financial statements when they become effective.

4. BASIS OF PREPARATION OF CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements have been prepared in accordance with the accounting policies which conform with IFRSs issued by IASB. For the purpose of preparation of the consolidated financial statements, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the consolidated financial statements included applicable disclosures required by the Rules Governing the Listing of Securities on HKEX (“Listing Rules”) and by the Hong Kong Companies Ordinance.

The consolidated financial statements have been prepared on the historical cost basis except for certain financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies.

5. REVENUE AND SEGMENT INFORMATION

Disaggregation of revenue from contracts with customers:

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Type of goods		
PTA balloons	4,581	3,696
DCB	299,165	190,279
Others	67	–
Total	303,813	193,975
Type of customer		
Distributors	291,582	182,179
Hospitals	5,578	5,922
Oversea customers	6,653	5,874
Total	303,813	193,975

The Group mainly sells PTA balloons and DCB to its distributors. During the year ended December 31, 2021 and 2020, based on the sales contract terms, the Group normally request 50%-100% advances from distributors upon signing sales agreements or placing orders.

Segment information

For the purpose of resource allocation and assessment of segment performance, the management of the Group, being the chief operating decision maker, focuses and reviews on the overall results and financial position of the Group as a whole which are prepared based on the same accounting policies. Accordingly, the Group has only one single operating segment and no further analysis of the single segment is presented.

Geographical information

All of the Group's non-current assets are located in the PRC.

Information about the Group's revenue from external customers is presented based on the location of the customers.

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Mainland China	297,160	188,101
Europe	4,315	4,149
Others	2,338	1,725
	<u>303,813</u>	<u>193,975</u>

6. OTHER INCOME

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Government grants	6,708	4,604
Interest income from bank deposits	4,725	41
	<u>11,433</u>	<u>4,645</u>

7. OTHER GAINS AND LOSSES, NET

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Gain on fair value change of financial assets measured at fair value through profit or loss	57	588
Net exchange (loss) gain	(8,785)	133
(Loss) gain on disposal of property, plant and equipment	(95)	3
Others	(14)	6
	<u>(8,837)</u>	<u>730</u>

8. FINANCE COSTS

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Interest expenses on lease liabilities	1,022	1,022
Interest expenses on bank borrowings	2,802	400
	<u>3,824</u>	<u>1,422</u>

9. INCOME TAX EXPENSE

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Current enterprise income tax	7,214	8,930
Deferred tax	4,620	3,915
	<u>11,834</u>	<u>12,845</u>

No Hong Kong profits tax was provided for as there was no estimated assessable profits of the company that was subject to Hong Kong profits tax for both years

Under the Law of the PRC on Enterprise Income Tax (the “**EIT Law**”) and Implementation Regulation of the EIT Law, the tax rate of the PRC subsidiaries is 25% for both years.

Taxation arising in other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions. The subsidiary in the United States of America are subject to Federal Income tax at a tax rate of 21% and the State Income tax of 7.25%.

Acotec Scientific Co., Ltd. has been accredited as a “New and High Technical Enterprise” by the Science and Technology Bureau of Beijing and relevant authorities in December 2020 for a term of three years from 2020 to 2022. In accordance with the “Notice of the State Tax Bureau of the Ministry of Finance Regarding Certain Preferential Treatment Policies on Enterprise Income Tax”, New and High Technical Enterprise is subject to income tax at a tax rate of 15%.

Pursuant to Caishui [2016] No. 52 issued by the State Council of PRC, with effect from May 1, 2016, Acotec Scientific Co., Ltd is accredited as a “Social Welfare Entity”, an amount equivalent to the total salaries paid to staff with physical disability is further deducted from the taxable income.

The tax charge for the year can be reconciled to the loss before tax per the consolidated statements of profit or loss and other comprehensive income as follows:

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Loss before tax	(67,243)	(31,447)
Tax at the applicable tax rate of 25%	(16,811)	(7,862)
Tax effect of expenses not deductible for tax purpose	33,241	16,328
Tax effect of income not taxable for tax purpose	–	(253)
Effect of additional tax deduction for research and development expenses	(26,948)	(11,194)
Additional tax benefits to a Social Welfare Entity	(17)	(16)
Tax effect of deductible temporary differences not recognised	532	1,110
Tax effect on tax losses not recognised	25,421	14,834
Utilisation of tax losses previously not recognised	(630)	–
Effect on different tax rate of subsidiaries	(2,954)	(102)
	11,834	12,845

10. LOSS FOR THE YEAR

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Loss for the year has been arrived at after charging (crediting):		
Directors' remuneration	6,577	56,094
Other staff costs		
– Salaries, bonus and other benefits	85,733	49,785
– Retirement benefits scheme contributions	5,996	228
– Share-based payments	33,356	2,121
Total staff costs	131,662	108,228
Auditors' remuneration	2,000	176
Cost of inventories recognised as an expense	20,569	16,329
Royalty fees (included in cost of sales)	15,289	10,021
Write-down of inventories	2,016	3,845
Loss (gain) on disposal of property, plant and equipment	95	(3)
Depreciation of property, plant and equipment	5,497	2,180
Depreciation of right-of-use assets	6,412	5,416
Amortisation of intangible assets	494	254
Total depreciation and amortisation	12,403	7,850
Capitalised in inventories	(2,694)	(2,489)
	9,709	5,361

11. DIVIDEND

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Dividend to the immediate holding company of the Company recognised as distribution during the year:		
2020 interim – USD0.30375 per share, in aggregate		
USD50,000,000 (equivalent to RMB327,255,000)	–	327,255

The dividend payable as at December 31, 2020 which represented the 2020 interim dividend amounted to USD50,000,000 (equivalent to RMB326,245,000), has been settled during the year ended December 31, 2021.

No dividend was proposed for ordinary shareholders of the Company during 2021, nor has any final dividend been proposed since the end of the reporting period (2020: nil).

12. LOSS PER SHARE

The calculation of the basic and diluted loss per share attributable to the owners of the Company is based on the following data:

	Year ended December 31,	
	2021	2020
Loss for the year attributable to the owners of the Company for the purpose of calculating basic and diluted per share (RMB'000)	<u>(79,077)</u>	<u>(43,842)</u>
Weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share	<u>248,065,296</u>	<u>186,295,821</u>

The weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share has been determined on the assumption that the group reorganisation as disclosed in the prospectus of the global offering of the Company had been effected since January 1, 2020.

Diluted loss per share for the year ended December 31, 2021 did not assume conversion of preferred shares and exercise of over-allotment option (2020: did not assume conversion of preferred shares), as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended December 31, 2021 and 2020 are the same as basic loss per share.

13. TRADE AND BILL RECEIVABLES

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
Trade receivables from contracts with customers	44,540	14,849
Less: Impairment losses under expected credit loss model	(326)	(1,139)
	<u>44,214</u>	<u>13,710</u>
Bill receivables	–	15,808
	<u>44,214</u>	<u>29,518</u>

As at January 1, 2020, trade receivables from contracts with customers amounted to RMB4,437,000.

The following is an aged analysis of trade receivables, and net of impairment losses under expected credit loss model, presented based on revenue recognition date at the end of the reporting period.

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
0–90 days	39,400	9,026
91–180 days	1,109	2,343
181–365 days	3,705	2,341
	<u>44,214</u>	<u>13,710</u>

As at December 31, 2020, total bills received amounting to RMB15,808,000 are held by the Group for settlement of trade receivables during the year ended December 31, 2021.

As at December 31, 2021, included in the Group's trade receivables balance before impairment losses under expected credit loss model are debtors with aggregate carrying amount of RMB294,000 (2020: RMB1,831,000) which are past due. Out of the past due balances RMB224,000 (2020: RMB326,000) has been past due 90 days or more and are considered as default.

14. TRADE AND OTHER PAYABLES

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
Trade payables	7,139	3,194
Accrued expenses		
– research and development expenses	13,276	2,681
– selling and distribution expenses	1,314	568
– salaries and bonus	23,994	12,029
– legal and professional fees	2,826	2,101
Other tax payable	8,961	4,415
Other payable		
– legal case settlement	1,521	–
– listing expenses	–	6,793
– issue costs	–	2,136
– other payable of purchase of property, plant and equipment	475	–
– other payable of purchase of intangible assets	611	–
– others	2,042	1,829
	<u>62,159</u>	<u>35,746</u>

The average credit period on purchases of goods and services of the Group is 90 days.

The following is an aged analysis on trade payables of the Group presented based on the invoices dates.

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
0 to 90 days	6,970	3,151
91–180 days	169	43
	<u>7,139</u>	<u>3,194</u>

15. SHARE CAPITAL

	Numbers of shares	Amount USD	Amount RMB'000
Authorized ordinary shares of USD0.00001 each At December 3, 2020, December 31, 2020 and December 31, 2021	<u>10,000,000,000</u>		
Issued and fully paid			
At December 3, 2020 (date of incorporation)	1	_*	_*
Add: Issuance of shares upon group reorganisation	<u>213,603,233</u>	<u>2,136</u>	<u>14</u>
At December 31, 2020	213,603,234	2,136	14
Add: Issuance of shares for restricted share unit scheme	12,228,440	122	1
Issuance of shares under employee incentive platform	11,242,275	112	1
Conversion of preferred shares upon global offering	13,678,102	137	1
Issuance of shares upon global offering	68,633,000	686	4
Less: Re-designate of ordinary shares as preferred shares	<u>(5,995,880)</u>	<u>(59)</u>	<u>(1)</u>
At December 31, 2021	<u>313,389,171</u>	<u>3,134</u>	<u>20</u>

* Less than USD1/RMB1,000

MANAGEMENT DISCUSSION AND ANALYSIS

BUSINESS REVIEW

We are a global leading medical device technology platform company in China. Leveraging on our four unique technology platforms (including drug-coating technology, radiofrequency ablation technology, polymer material technology and aspiration platform technology), we are focusing on the provision of solutions of cutting-edge intravascular interventional treatments. We have already built over 30 product pipelines so far, which are capable of providing endovascular minimally-invasive interventional solutions for five areas consisting of vascular surgery, cardiology, nephrology, neurology and andrology. Based on the extendability and efficiency of our four technology platforms, we wish to leverage on our advantages in production and research through continuous innovation and continue to meet the clinical needs of vascular interventional treatments, so as to provide solutions of full-body vascular interventional treatments to the patients worldwide and safeguard their health and wellness.

We successfully listed our Shares on the main board of the Stock Exchange on August 24, 2021. The Prospectus in relation to the Global Offering was published on the website of the Stock Exchange on August 12, 2021.

BUSINESS HIGHLIGHTS

In 2021, we made significant progress in research and development. During the year ended December 31, 2021, five products were sent for type testing, seven products were under clinical trial, two products completed clinical trial, two products applied for registration with NMPA and two products received approval (including one upgraded product of AcoArt Orchid® & Dhalia™). We also registered ten additional patents during the year ended December 31, 2021.

Besides our significant progress in research and development, our admission efforts to hospital are also advancing. As of December 31, 2021, our BTK DCB (Below-The-Knee Drug-Coated Balloons) had been admitted into 288 hospitals and listed as a candidate for online procurement in 27 provinces and autonomous regions. Our ATK DCB (Above-The-Knee Drug-Coated Balloons) had been admitted into 1,283 hospitals. Our Peripheral Aspiration Catheter which was launched in November 2021 had been listed as a candidate for online procurement on the national procurement platform.

The stable and positive direction of our production and research contributed to the rapid growth of our annual revenue directly. For the year ended December 31, 2021, our revenue reached approximately RMB303.8 million, representing a year-on-year increase of approximately 56.6%. Our Core Products, AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™, were the major contributors of our revenue.

The change in layout of our products represented our further expansion from the artery sector to the vein sector officially.

In August 2021, our peripheral vacuum aspiration pump was approved to launch. Our Peripheral Aspiration System (AcoStream™) was approved to launch three months later. As of December 31, 2021, all of our products under the Peripheral Thrombus Aspiration system had been launched, which made us become the first Chinese enterprise possessing originated technologies and ability to provide comprehensive solution in such sector.

We accelerated our globalization process and our products entered international markets in full speed.

For research and development, we established Acotec Technologies Limited (“**Acotec Technologies**”) in California, U.S. in 2021 with a primary focus on the research and development of forward-looking and innovative products (the “**U.S. R&D Center**”). Mr. Scott WILSON acts as the general manager of Acotec Technologies. Mr. Wilson has over 25 years of experience in medical product development. Before joining us, Mr. Wilson served as a vice president of R&D at Silk Road Medical, a vascular medical device company. Prior to these roles, Mr. Wilson had leadership roles at Concentric Medical, which was acquired by Stryker Neurovascular. Mr. Wilson was the lead director and engineer at Concentric Medical that developed multiple product lines, including Trevo Stentriever, Flow Gate and Distal Access Catheters (DAC).

In the same year, four global top medical experts joined the Scientific Advisory Board of Acotec and provided guidance to the clinical trials and launch of our Core Products in the U.S. and Europe, which assisted the global IDE study of AcoArt BTK. We believe the joining of Mr. Wilson and his team as well as four experts will serve as a booster of the global layout of our Group and further improved the chain of production and research.

With respect to our sales, three DCB products were approved to launch in Brazil. As of December 31, 2021, our products had completed commercialization across 12 countries accumulatively. We are of the view that the acceleration of our Group’s globalization process will diversify the revenue stream of our Company and facilitate us to respond to market changes more flexibly. In addition to diversifying our revenue, our globalization process has laid down a solid foundation of our production and research, which forms a benign closed loop of corporate operations.

We continued to strengthen our efforts in clinical promotions and promote the innovation of clinical therapies of vascular intervention.

Since the launch of AcoArt Orchid® & Dhalia™, our first and China’s first peripheral DCB product, we have already initiated our efforts in clinical promotion and education. Since the commencement of research and development of our products, we have never relaxed our promotion efforts in clinical treatments. We have been promoting the innovation of clinical therapies of vascular intervention, so as to provide brand-new solutions for peripheral intravascular diseases to patients.

During the year ended December 31, 2021, our Peripheral Aspiration System (AcoStream™) was approved to launch, which enabled us to become the first Chinese enterprise possessing originated technologies and ability to provide comprehensive solution in such sector. We will continue to carry on the market cultivation of our new products, so as to provide new treatment methods to clinical patients.

We continued to reinforce our talent pool and improve our team building.

As of December 31, 2021, we had approximately 400 employees in total. The research and development team grew to 86 members. Our original technical team covers the aspects of material science, mechanical design manufacturing, chemistry and biomedical engineering. During the year ended December 31, 2021, we supplemented our research and development team with technicians in the field of electronic science and technology, automation and computer programming, which further improved our talent pool. We believe that the support of talents from different aspects will accelerate the implementation of our multi product pipeline projects.

Our new product pipelines were multi-pronged and advanced as scheduled.

In 2021, we carried out in-depth investigations and discussion in respect of artery calcification, vein market and vascular aneurysm and we started to prepare for our business presence in these sectors. As of December 31, 2021, we had developed 6 new products, including peripheral IVL system (vascular surgery), peripheral coil (vascular surgery), and coronary IVL system (cardiology). The progress of production development had been advancing in an extremely quick pace. We are of the view that these results are attributable to two reasons.

First of all, it is attributable to our insight into, judgment of and prediction of market potentials. Decades of experience in the industry enables to make better decisions and judgments to develop these potential markets.

Secondly, it is attributable to our first-class execution capabilities. We spent only seven months from kicking off the project to finalizing the design our IVL system. In addition, our remaining product lines advanced as scheduled according to the original plans.

BUSINESS OVERVIEW

In 2021, we carried out in-depth investigations and discussion in respect of artery calcification, vein market and vascular aneurysm and we started to prepare for our business presence in these sectors. For peripheral aspiration system, our products under the peripheral thrombus aspiration system have all been launched, which made us become the first Chinese enterprise possessing originated technologies and ability to provide comprehensive solution in such sector. As of December 31, 2021, we have developed six new products, including peripheral IVL system (vascular surgery), peripheral coil (vascular surgery) and coronary IVL system (cardiology). The progress of production development has been advancing in an extremely quick pace. With a view to enhance our capacity of manufacture, our facility in Shenzhen, with approximately 2,400 sq.m., successfully obtained the ISO 13485 certificate qualification and ability to supply the tubes for manufacturing balloon catheters in 2021.

Products and Pipeline

Our products and product candidates are Class I, Class II and Class III medical devices under the classification criteria of the NMPA. The following chart summarizes the key information of our full product portfolio as of December 31, 2021, including five commercialized products, the indication expansion for our Core Products in three therapeutic areas, and 28 additional product candidates:

	Products and Product Candidates	Indications / Applications	Key Technologies	Phase		Estimated approval
				Pre-clinical Studies	Clinical Studies	
Vascular Surgery	AcoArt Orchid® & Dhalia™/Orchid Plus★	Superficial femoral artery (SFA) and popliteal artery (PPA) disease	Drug coating technology	China	NMPA	N/A
	AcoArt Tulip™ & Litos™★	Below-the-knee (BTK) artery disease	Drug coating technology	China	CE	N/A
	AcoArt Iris™ & Jaemip™	PTA Balloon applied in PTA procedure	Polymer materials	USA	NMPA	N/A
	AcoArt Lily™ & Rosmarin™	PTA Balloon applied in PTA procedure	Polymer materials	China	NMPA	N/A
	Peripheral Aspiration System▲ AcoStream™	DVT, ALL and PE	Aspiration platform	China	NMPA	N/A
	Radiofrequency Ablation System	Saphenous varicose veins	RF platform			2022
	Lower Limb Stentimus DCB	SFA and PPA disease	Drug coating technology			2025
	Peripheral Spot Stent	SFA and PPA disease	Polymer materials			2024
	Peripheral Triple-Guidewire Balloon	SFA and PPA disease	Polymer materials			2023
	Peripheral Scoring Balloon	SFA and PPA disease	Polymer materials			2023
	Peripheral Rotational Atherectomy Device	Intravascular calcium	Polymer materials			2025
	Peripheral IVL System	Intravascular calcium	Polymer materials			2026
	Peripheral Coil	Embolization	Polymer materials			2024
	Carotid Stent	Carotid artery stenosis	Polymer materials			2025
Peripheral Thrombectomy Device	DVT, ALL and PE	Polymer materials			2022	
Peripheral Support Catheter▲	Peripheral CTO lesion	Polymer materials			2022	
Above-The-Knee PTA Balloon▲	PTA	Polymer materials			2022	
Below-The-Knee PTA Balloon▲	PTA	Polymer materials			2022	
2nd Gen Peripheral Aspiration System▲	DVT, ALL and PE	Polymer materials			2023	
AcoArt Camella™ (DCB)	Coronary small vessel diseases	Drug coating technology	China		2024	
Coronary Sirolimus (DCB)	Bifurcation lesions	Drug coating technology	China		2024	
Coronary Scoring Balloon	PTCA	Polymer materials			2023	
Coronary IVL System	Coronary lesion calcium	Polymer materials			2026	
Coronary Rotational Atherectomy Device	Intravascular calcium	Polymer materials			2025	
Coronary CTO Recanalization Balloon▲	Coronary CTO	Polymer materials			2023	
Guiding Extension Catheter▲	Coronary CTO	Polymer materials			2023	
Coronary CTO Anegrade Micro-Catheter▲	Coronary CTO	Polymer materials			2023	
Coronary Double-Lumen Selecting Catheter▲	Bifurcation lesions	Polymer materials			2023	
Coronary Retrograde Micro-Catheter▲	Coronary CTO	Polymer materials			2023	
AcoArt Orchid® & Dhalia™/Orchid Plus★ (DCB)	Arteriovenous fistula stenosis	Drug coating technology	China		2022	
AV Scoring Balloon	AVF PTA procedure	Polymer materials	China		2023	
High-Pressure Balloon▲	AVF PTA procedure	Polymer materials	China		2023	
AcoArt Orchid® & Dhalia™/Orchid Plus★ (DCB)	Vertebral atherosclerotic stenosis	Drug coating technology	China		2024	
AcoArt Daisy™ (DCB)	Intracranial atherosclerotic stenosis	Drug coating technology	China		2024	
Intracranial PTA Balloon▲	Intracranial PTA procedure	Polymer materials			2022	
AcoArt Orchid® & Dhalia™/Orchid Plus★	Vasculogenic erectile dysfunction	Drug coating technology			2025	
AcoArt Tulip™ & Litos™ (DCB)★	Vasculogenic erectile dysfunction	Drug coating technology			2025	

★ Core Product ☆ Indication expansion of Core Product ▲ Exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials (《免于进行临床试验医疗器械目录》) promulgated by the NMPA, as amended.  Commercialization

Note:

We have been continuously improving the performance of AcoArt Orchid® & Dhalia™. As advised by NMPA and as part of our business strategy, we decided not to register Orchid Plus as a separate product. Alternatively, we applied to register Orchid Plus as an upgrade version of AcoArt Orchid® & Dhalia™ with improved delivery balloon catheter system, and received the revised NMPA approval for AcoArt Orchid® & Dhalia™ in November 2021.

Our Core Products

1. AcoArt Orchid® & Dhalia™

AcoArt Orchid® & Dhalia™ is a paclitaxel DCB used to prevent stenosis or occlusion in superficial femoral artery (SFA) and popliteal artery (PPA) for the treatment of lower extremity artery disease (LEAD) with a vascular interventional approach. It is compatible with the guidewire of 0.035” (Orchid®) and 0.018” (Dhalia™).

We received the CE Marking for AcoArt Orchid® in 2014 and the NMPA approval for AcoArt Orchid® & Dhalia™ in 2016. AcoArt Orchid® & Dhalia™ was the first peripheral DCB product launched in China. As of December 31, 2021, we had also launched AcoArt Orchid® in twelve other countries including Germany, Italy, Switzerland, Czech Republic, Ecuador, Estonia, Hungary, India, South Africa, Spain, Turkey and Brazil. As of December 31, 2021, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals or registrations.

We are expanding the indications of AcoArt Orchid® & Dhalia™ to address the underserved medical needs of hemodialysis patients with Arteriovenous Fistula (AVF) stenosis. In May 2018, we initiated an RCT for our AcoArt Orchid® & Dhalia™ indicated for treating AVF stenosis in China to evaluate its safety and efficacy. The RCT enrolled a total of 244 trial subjects in 11 hospitals in China, with the General Hospital of People’s Liberation Army as the principal investigator institution. The 244 subjects were randomized in a 1:1 ratio to a study group, where the subjects receive the treatment using AcoArt Orchid® & Dhalia™, and a control group, where the subjects receive the treatment using PTA balloons. We have completed the six-month followups and the twelve-month follow-ups for all the trial subjects. According to the six-month follow-ups statistics, patency rate of DCB group is 91.4%, as comparing to the 66.9% patency rate for PTA group. According to the twelve-month follow-ups statistics, patency rate of DCB group is 66.1%. In nephrology, our AcoArt Orchid® & Dhalia™ has finished the enrollment, and we expect to receive the NMPA approval in 2022. In neurology, our AcoArt Orchid® & Dhalia™ is currently enrolling, and we expect to receive the NMPA approval in 2024.

We have been continuously improving the performance of AcoArt Orchid® & Dhalia™. As advised by NMPA and as part of our business strategy, we decided not to register Orchid Plus as a separate product. Alternatively, we applied to register Orchid Plus as an upgrade version of AcoArt Orchid® & Dhalia™ with improved delivery balloon catheter system, and received the revised NMPA approval for AcoArt Orchid® & Dhalia™ in November 2021.

For the year ended December 31, 2021, our revenue generated from the sales of AcoArt Orchid® & Dhalia™ in China and overseas amounted to approximately RMB275.07 million.

2. *AcoArt Tulip™ & Litos™*

AcoArt Tulip™ & Litos™ is a paclitaxel DCB used to prevent stenosis or occlusion in below-the-knee (BTK) arteries for the treatment of chronic limb-threatening ischemia with a vascular interventional approach. It is compatible with the guidewire of 0.018” (Tulip™) and 0.014” (Litos™). We received the CE Marking for AcoArt Tulip™ & Litos™ in 2014, the FDA “breakthrough device” designation for AcoArt Litos™ in 2019 and the NMPA approval for market for AcoArt Tulip™ & Litos™ in December 2020, and successfully launched it in China in January 2021. As of December 31, 2021, we had also launched AcoArt Tulip™ & Litos™ in twelve other countries including Germany, Italy, Switzerland, Czech Republic, Ecuador, Estonia, Hungary, India, South Africa, Spain, Turkey and Brazil. As of December 31, 2021, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals or registrations.

In January 2022, we submitted an IDE application for AcoArt Litos™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter to the Center for Devices and Radiological Health of the FDA. We are also selecting business partners for conducting clinical trials for AcoArt Litos™ in the U.S..

For the year ended December 31, 2021, our revenue generated from the sales of AcoArt Tulip™ & Litos™ in China and overseas amounted to approximately RMB24.09 million.

Other Key Product Candidates

In vascular surgery, other than our Core Products, we have three other commercialized products and 14 product candidates in pipeline. In cardiology, we have ten product candidates in pipeline. In nephrology, we have two product candidates in pipeline. In neurology, we have two product candidates in pipeline. We are also expanding the indications of our AcoArt Orchid® & Dhalia™ for the treatment of vasculogenic ED.

Devices Targeting Vascular Surgery

Other than our Core Products, we have three commercialized products, namely AcoArt Iris™ & Jasmin™, AcoArt Lily™ & Rosmarin™ and Peripheral Aspiration System (AcoStream™), and 14 product candidates in pipeline.

Commercialized Products

1. **AcoArt Iris™ & Jasmin™** is a PTA balloon used to open up narrowing or occlusive vessels for the treatment of SFA/PPA lesions with a vascular interventional approach. We received the NMPA approval for AcoArt Iris™ & Jasmin™ in 2014 and successfully renewed its registration certificate for another five years in June 2019. We also obtained CE Marking for AcoArt Iris™ in 2017. As of December 31, 2021, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals or registrations.

2. **AcoArt Lily™ & Rosmarin™** is a PTA balloon used to open up narrowing or occlusive vessels for the treatment of BTK lesions with a vascular interventional approach. We received the NMPA approval for AcoArt Lily™ & Rosmarin™ in 2015 and successfully renewed its registration certificate for another five years in May 2020. We also obtained CE Marking for AcoArt Lily™ & Rosmarin™ in 2017. As of December 31, 2021, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals or registrations.

For the year ended December 31, 2021, our revenue from the sales of AcoArt Iris™ & Jasmin™ and AcoArt Lily™ & Rosmarin™ was approximately RMB4.58 million.

3. **Peripheral Aspiration System (AcoStream™)** consists of a single-use suction connection tube, a suction pump and a thrombus aspiration catheter designed for use in the percutaneous aspiration thrombectomy for treatment of pulmonary thrombosis and lower extremity deep vein thrombosis (DVT). We received the NMPA approval for the product in November 2021. Besides, the suction pump of Peripheral Aspiration System (AcoStream™) was approved by NMPA on August 5, 2021.

For the year ended December 31, 2021, our revenue from the sales of Peripheral Aspiration System (AcoStream™) was approximately RMB35.40 thousand.

Product Candidates in Pipeline

4. **Peripheral Support Catheter** is designed to enhance access to small peripheral vessels. Our peripheral support catheters are used together with guidewires to recanalize complex total occlusion lesions and BTK lesions and to reduce the difficulty of performing surgeries on complex lesions and BTK lesions. Our peripheral support catheter has been sent for type testing. We expect to receive the NMPA approval in 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL SUPPORT CATHETER SUCCESSFULLY.

5. **Above-The-Knee PTA Balloon** is a second-generation high-pressure tapered PTA balloon designed for dilation of the femoropopliteal artery in the lower extremity. Our above-the-knee PTA balloon is currently under development. We expect to make the product registration submission for the product with the NMPA in 2022 and to receive the NMPA approval in 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR ABOVE-THE-KNEE PTA BALLOON SUCCESSFULLY.

6. **Below-The-Knee PTA Balloon** is a second-generation high-pressure tapered PTA balloon designed for dilation of the infrapopliteal artery in the lower extremity. Our below-the-knee PTA balloon is currently under development. Our below-the-knee PTA balloon has been sent for type testing. We expect to receive the NMPA approval in 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR BELOW-THE-KNEE PTA BALLOON SUCCESSFULLY.

7. **Peripheral Triple-Guidewire Balloon** incorporates three guidewires around the balloon to achieve focused vasodilatation. We expect to make the product registration submission for the product with the NMPA in 2022 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL TRIPLE-GUIDEWIRE BALLOON SUCCESSFULLY.

8. **Radiofrequency Ablation System** consists of a radiofrequency generator and an endovenous radiofrequency catheter (AcoArt Cedar™). Our radiofrequency ablation system has finished the enrollment. We expect to receive the NMPA approval in 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR RADIOFREQUENCY ABLATION SYSTEM SUCCESSFULLY.

9. **Peripheral Rotational Atherectomy Device** has an exclusively designed drill with high-speed rotary grinding heads used in chronic total occlusion (CTO) treatment. Our peripheral rotational atherectomy device is currently in the stage of pre-clinical study. We expect to make the product registration submission for the product with the NMPA in 2023 and to receive the NMPA approval in 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL ROTATIONAL ATHERECTOMY DEVICE SUCCESSFULLY.

10. **Peripheral Spot Stent** is designed for treatment of atherosclerotic lesions in femoropopliteal arteries and post-PTA vascular dissections. Our peripheral spot stent has been sent for type testing and is currently under clinical trial. We expect to receive the NMPA approval in 2024.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL SPOT STENT SUCCESSFULLY.

11. **Lower Limb Sirolimus DCB** is a sirolimus coated balloon product indicated for PAD. Our lower limb sirolimus DCB's therapeutic effect has been preliminary validated by the pig coronary model. Our lower limb sirolimus DCB is currently enrolling. We expect to receive the NMPA approval in 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR LOWER LIMB SIROLIMUS DCB SUCCESSFULLY.

12. **Peripheral Scoring Balloon** has a scoring element embedded on the balloon. Our peripheral scoring balloon is currently in the stage of pre-clinical study. We expect to make the product registration submission for the product with the NMPA in 2022 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL SCORING BALLOON SUCCESSFULLY.

13. **2nd Gen Peripheral Aspiration System** is the upgraded product of our current peripheral aspiration system product. Our 2nd gen peripheral aspiration system is currently under development. We expect to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR 2ND GEN PERIPHERAL ASPIRATION SYSTEM SUCCESSFULLY.

14. **Peripheral IVL System** is a intravascular lithotripsy device mounted on a conventional balloon angioplasty. Energizing the lithotripsy device will generate pulsatile energy to disrupt hard calcium among the lesion, to allow subsequent dilation of stenotic lesion with lower balloon pressure and ultimately to reduce the rate of stent implantation. Our peripheral IVL system is currently under development. We expect to receive the NMPA approval in 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL IVL SYSTEM SUCCESSFULLY.

15. **Peripheral Thrombectomy Device** features a nitinol retrievable stent and is designed to capture the clot in peripheral veins. Our peripheral thrombectomy device is currently under development. We expect to receive the NMPA approval in 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL THROMBECTOMY DEVICE SUCCESSFULLY.

16. **Peripheral Coil** is designed to embolize peripheral vessel or aneurysm. Our peripheral coil is currently under development. We expect to receive the NMPA approval in 2024.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PERIPHERAL COIL SUCCESSFULLY.

17. **Carotid Stent** is indicated to provide physical support for narrowed carotid artery, which will cause ischemia of the brain. Our carotid stent is currently under development. We expect to receive the NMPA approval in 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CAROTID STENT SUCCESSFULLY.

Devices Targeting Cardiology

1. **Coronary CTO Antegrade Micro-Catheter** is designed for treating coronary artery CTO with an antegrade passing technique. Our coronary CTO antegrade micro-catheter is currently under development. We expect to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY CTO ANTEGRADE MICRO-CATHETER SUCCESSFULLY.

2. **Coronary CTO Recanalization Balloon** has a diameter of 0.8 mm, to be the smallest on the market once it is launched. It helps to address the problem of poor passage through small vessels that balloons existing on the market have. Our coronary CTO recanalization balloon is currently under development. We expect to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY CTO RECANALIZATION BALLOON SUCCESSFULLY.

3. **Coronary Double-Lumen Selecting Catheter** is designed for treating complex bifurcation lesions. Our coronary double-lumen selecting catheter is currently under development. We expect to make the product registration submission for the product with the NMPA in 2022 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY DOUBLE-LUMEN SELECTING CATHETER SUCCESSFULLY.

4. **Coronary Retrograde Micro-Catheter** is designed for treating coronary artery CTO with a retrograde passing technique. Our coronary retrograde micro-catheter is currently under development. We expect to make the product registration submission for the product with the NMPA in 2023 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY RETROGRADE MICRO-CATHETER SUCCESSFULLY.

5. **Guiding Extension Catheter** helps deliver stents and balloons through its guiding catheter in complicated lesions. Our guiding extension catheter is currently under development. We expect to make the product registration submission for the product with the NMPA in 2023 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR GUIDING EXTENSION CATHETER SUCCESSFULLY.

6. **Coronary Rotational Atherectomy Device** refers to our rotational atherectomy technology used in eliminating intracardiac intravascular hard plaque. Our coronary rotational atherectomy device is currently in the stage of pre-clinical study. We expect to make the product registration submission for the product with the NMPA in 2023 and to receive the NMPA approval in 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY ROTATIONAL ATHERECTOMY DEVICE SUCCESSFULLY.

7. **AcoArt Camellia™** is a paclitaxel DCB indicated for the treatment of coronary small-vessel diseases (SVD). We expect to complete the RCT in 2023. Our AcoArt Camellia™ is currently enrolling. We expect to receive the NMPA approval in 2024.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR ACOART CAMELLIA™ SUCCESSFULLY.

8. **Coronary Sirolimus DCB** is a sirolimus DCB indicated for the treatment of bifurcation lesions in coronary arteries. We have initiated an RCT for our coronary sirolimus DCB in January 2021 to evaluate the safety and efficacy of sirolimus DCB in treating bifurcation lesions in coronary arteries. We have initiated the subject enrollment of the RCT for our coronary sirolimus DCB in 2021, and expect to complete the enrollment in 2022. Our coronary sirolimus DCB is currently enrolling. We expect to receive the NMPA approval in 2024.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY SIROLIMUS DCB SUCCESSFULLY.

9. **Coronary Scoring Balloon** has a scoring element embedded on the balloon. Our coronary scoring balloon has been sent for type testing. We expect to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY SCORING BALLOON SUCCESSFULLY.

10. **Coronary IVL System** is a intravascular lithotripsy device mounted on a conventional balloon angioplasty. Energizing the lithotripsy device will generate pulsatile energy to disrupt hard calcium among the coronary lesion, to allow subsequent dilation of stenotic lesion with lower balloon pressure and ultimately to reduce the rate of stent implantation. Our coronary IVL system is currently under development. We expect to receive the NMPA approval in 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORONARY IVL SYSTEM SUCCESSFULLY.

Devices Targeting Nephrology

1. **High-Pressure Balloon** dilates arterial and venous access with a blasting pressure as high as 30 atm, higher than the blasting pressure of 25 atm of most existing balloons on the market. Our high-pressure balloon is currently under development. We expect to make the product registration submission for the product with the NMPA in 2022 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR HIGH-PRESSURE BALLOON SUCCESSFULLY.

2. **AV Scoring Balloon** has a scoring element embedded on the balloon. Our AV scoring balloon is currently in the stage of pre-clinical study. We expect to make the product registration submission for the product with the NMPA in 2022 and to receive the NMPA approval in 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR AV SCORING BALLOON SUCCESSFULLY.

Devices Targeting Neurology

1. **AcoArt Daisy™** is a rapid exchange system DCB indicated for the treatment of intracranial atherosclerotic stenosis (ICAS). As of December 31, 2021, we had enrolled ten patients in the RCT for AcoArt Daisy™, and expect to complete the RCT in 2022. Our AcoArt Daisy™ is currently enrolling. We expect to receive the NMPA approval in 2024.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR ACOART DAISY™ SUCCESSFULLY.

2. **Intracranial PTA Balloon** optimizes catheter platform and lubricant coating of the balloon to ensure the passage in a tortuous and narrow vascular environment and make the best vessel preparation for DCB. Our intracranial PTA balloon has been sent for type testing. We expect to receive the NMPA approval in 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR INTRACRANIAL PTA BALLOON SUCCESSFULLY.

Devices Targeting Andrology

In andrology, we are expanding the indications of our two Core Products, namely AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™, for the treatment of vasculogenic ED. We expect to initiate the clinical trial required by the NMPA in order for us to expand the indication of AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™ to treating vasculogenic ED. Our AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™ are currently enrolling. We expect to receive the NMPA approval in 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR ACOART ORCHID® & DHALIA™ AND ACOART TULIP™ & LITOS™ INDICATED FOR TREATING VASCULOGENIC ED.

Research and Development

We have a strong in-house research and development team of 86 members. The team is led by Ms. Weijia LI, Ms. Yaze LI, Mr. Ruijie ZHANG, Mr. Lizhong LU and Mr. Scott WILSON.

We primarily adopted a self-development business model. Our research and development team self-developed most of the key technologies used in our products and product candidates, and we own substantially all the rights pertaining to all our products and product candidates, except that the formula of the excipient used in our DCB products (which we believe is a key differentiating aspect of our products) was licensed from InnoRa GmbH, our business partner. Furthermore, as of December 31, 2021, we had a robust intellectual property portfolio, consisting of 27 registered patents and 13 pending patent applications. During the year ended December 31, 2021, we enhanced our research and development team with technicians in the field of electronic science and technology, automation and computer programming, which further improved our talent pool.

We also assembled a new team dedicating in the research and development of power-sourced devices located in Shenzhen, with a laboratory of approximately 600 sq.m..

We established Acotec Technologies Limited (“**Acotec Technologies**”) in California, U.S. on November 19, 2021. With a group of experienced engineers and scientists in the R&D team, Acotec Technologies is the research and development center of our Company in the U.S. (the “**U.S. R&D Center**”) with a primary focus on the research and development of forward-looking and innovative products.

Our U.S. R&D Center is led by Mr. Wilson who has over 25 years of experience in medical product development. Mr. Wilson is the general manager of Acotec Technologies in the U.S.. Before joining us, Mr. Wilson served as a vice president of R&D at two vascular medical device companies, Medina Medical and Silk Road Medical. Prior to these roles, Mr. Wilson had leadership roles at Concentric Medical, which was acquired by Stryker Neurovascular. Mr. Wilson was the lead director and engineer at Concentric Medical that developed multiple product lines, including Trevo Stentriever, Flow Gate and Distal Access Catheters (DAC).

Mr. Wilson brings to the team over 25 years of medical device engineering experience, with his career including management roles in R&D, manufacturing, marketing, and clinical matters. Mr. Wilson’s career has been split between the neurovascular and peripheral space, including roles at Medina Medical, Silk Road Medical, Stryker Neurovascular, Concentric Medical, and Guidant. Mr. Wilson received a bachelor of science degree in Bioengineering from UC San Diego.

As of the date of this announcement, our U.S. R&D Center has made significant progress with respect to our future product pipeline.

We have also expanded our Scientific Advisory Board (the “**Scientific Advisory Board**”) in October 2021 by inviting four other top physicians, namely Prof. Peter Schneider, Dr. Matthew T. Menard, Dr. Sahil A. Parikh, and Prof. Thomas Zeller to join. The Scientific Advisory Board will provide guidance to and lead the execution of our Company’s global study for BTK DCB products indication expansion in the U.S. and Europe for the purpose of registration with the FDA in the U.S.. Meanwhile, the Scientific Advisory Board will also provide input and feedback to guide our Company’s new product development in peripheral intervention space and will support our Company’s physician education both in China and in global market.

Manufacturing

Our principal manufacturing facility is located at our headquarters in Beijing, China, with an aggregate gross floor area of approximately 6,000 sq.m.. As of December 31, 2021, our facility was primarily used for the production of our balloon catheter products, including DCB and PTA products and product candidates.

We have also extended our manufacturing capacity to the upstream of the manufacturing of micro-extrusions by having a manufacturing facility in Shenzhen (the “**Shenzhen Facility**”). With approximately 2,400 sq.m., our Shenzhen Facility successfully obtained the ISO 13485 certificate qualification and ability to supply the tubes for manufacturing balloon catheters in 2021 and has the maximum annual production capacity of 135 thousand catheters. Our Shenzhen Facility enables us to stabilize the supply of material for catheters, to reduce the impact on us due to the epidemic influence on oversea supply chains, i.e. significant price fluctuation and delay in lead time, and to improve the quality of product by customizing the materials.

The production capacity, actual production volume and utilization rate for our commercialized balloon catheter products in our manufacturing facility for the year ended December 31, 2021 is approximately 84,429, 73,355, and 86.88%, respectively. We conduct all the manufacturing process of our balloon catheter products in-house.

Sales and Marketing

Currently, we primarily sell and market our Core Products, namely AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™, and our PTA balloon products, namely AcoArt Iris™ and AcoArt Lily™ & Rosmarin™, in China. We also sell and market AcoArt Orchid® and AcoArt Tulip™ & Litos™ in several overseas countries. For the year ended December 31, 2021, we generated revenue of approximately RMB299.17 million from the sales of our Core Products and a substantial portion of which is generated from our sales in China. We also launched our Peripheral Aspiration System (AcoStream™) before the end of 2021. As our current products and product candidates receive more marketing approvals in countries and regions outside China, we expect to generate more sales from overseas markets.

We use a combination of our in-house sales and marketing team, our connections with hospitals and a network of independent distributors to sell our products in China. As of December 31, 2021, we had a sales and marketing team of 48 staff members in China, led by the head of our sales and marketing team, Ms. ZHANG Hui, who has vast sales and marketing experience in the medical device industry. We also had sales and marketing staff in India in charge of overseas sales and marketing. Our in-house sales and marketing team tracks and analyzes applicable local laws and regulations and government policies as well as market data of our products in order to formulate national and regional marketing strategies more effectively.

We employ a strategic marketing model to promote and sell our products. Under this model, we promote our products to hospitals in China through academic marketing, by establishing research and clinical collaboration and training relationships with hospitals and by leveraging our network with KOLs.

Intellectual Property Rights

We have built a comprehensive intellectual property portfolio in China and overseas to protect our technologies, inventions and know-how and ensure our future success with commercializing our products. As of December 31, 2021, we had 27 registered patents and 26 registered trademarks, as well as 13 pending patent applications and nine pending trademark applications in China and overseas. There is no material legal impediment for us to obtain the approvals for these pending patents and trademarks.

Impact of the COVID-19 Outbreak

Although we experienced slight delays in the patient enrollment, data collection and data analysis processes for certain of our clinical trials, we had resumed the normal patient enrollment and data analyses for our clinical trials in China since April 2020. Moreover, the sales of our DCB products in China for 2020 have been significantly affected by the COVID-19 pandemic, but the sales amount of AcoArt Orchid® & Dhalia™ gradually bounced back since April 2020. As of December 31, 2021, we had not encountered any material long-term impact on our clinical trials or our overall clinical development plans, nor had we experienced any significant impact on product sales. Further, since the outbreak of the COVID-19 in December 2019 and as of December 31, 2021, we had no suspected or confirmed COVID-19 cases on our premises or among our employees. We had not experienced any material difficulties in procuring our major raw materials and had not experienced significant fluctuations in the prices of our supplies since the outbreak of COVID-19 and as of December 31, 2021.

FINANCIAL REVIEW

Overview

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

Revenue

During the Reporting Period, all our revenue was generated from sales of medical devices. Sales of DCB products, our Core Product, have comprised the major portion of our revenue since its first commercialization in China in 2016. Our revenue primarily comprised of the sales of Orchid[®] & Dhalia[™], two of our Core Products, launched in China in 2016. In January 2021, we launched another Core Product, AcoArt Tulip[™] & Litos[™] in China. We expect that sales of our Core Products will continue to account for a substantial portion of our total revenue in the near future.

The Group's revenue for the year ended December 31, 2021 was approximately RMB303.8 million, representing an increase of approximately 56.6% compared to approximately RMB194.0 million for the year ended December 31, 2020. The increase was primarily attributable to (i) an increase in the number of surgeries performed with our medical devices, (ii) New core product AcoArt Tulip[™] & Litos[™] launched in China since January 2021, and, and (iii) the normalization of COVID-19 epidemic prevention and control has enabled patients to seek medical treatment normally. It is noted that such number of surgeries performed with our medical devices recorded a sharp increase compared to the year ended December 31, 2020. For the year ended December 31, 2021, revenue from sales of DCB products accounted for approximately 98.5% of our total revenue, as compared to approximately 98.1% for the year ended December 31, 2020.

The following table sets forth a breakdown of our revenue by product:

Revenue	Year ended December 31, 2021		Year ended December 31, 2020	
	RMB'000	Proportion	RMB'000	Proportion
DCB products	299,165	98.5%	190,279	98.1%
AcoArt Orchid [®] & Dhalia [™]	275,071	90.5%	187,246	96.5%
AcoArt Tulip [™] & Litos [™]	24,094	8.0%	3,033	1.6%
PTA balloon products	4,581	1.5%	3,696	1.9%
Others	67	0.0%	—	—
Total	<u>303,813</u>	<u>100.0%</u>	<u>193,975</u>	<u>100.0%</u>

Cost of Sales

The cost of sales primarily consists of staff costs, raw material costs, depreciation and amortization, utility costs and others.

The Group's cost of sales for the year ended December 31, 2021 was approximately RMB37.9 million, representing an increase of approximately 25.5% compared to approximately RMB30.2 million for the year ended December 31, 2020. The increase was primarily attributable to (i) increase of sales volume of the Orchid® & Dhalia™, (ii) cost of sales of AcoArt Tulip™ & Litos™ in China was just included since 2021 due to new launch, and (iii) scale effect of production.

Gross Profit and Gross Profit Margin

As a result of the aforementioned factors, the gross profit of the Group increased by approximately 62.4% from approximately RMB163.8 million for the year ended December 31, 2020 to approximately RMB265.9 million for the year ended December 31, 2021. Gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group increased from approximately 84.4% for the year ended December 31, 2020 to approximately 87.5% for the year ended December 31, 2021, mainly due to an increase in sales volume of DCB.

Other Income

The Group recorded other income for the year ended December 31, 2021 was approximately RMB11.4 million, representing an increase of approximately 147.8% compared to approximately RMB4.6 million for the year ended December 31, 2020, primarily attributable to an increase in government grants received and an increase in interest income due to increase in balance of bank deposits.

Other Gains and Losses, Net

The net other gains and losses primarily consisted of gain on fair value change of financial assets measured at fair value through profit or loss, net exchange gain or loss, gain or loss on disposal of property, plant and equipment, and others.

The Group recorded net other gains and losses for the year ended December 31, 2021 was a loss of approximately RMB8.8 million, representing a decrease compared to a gain of approximately RMB0.7 million for the year ended December 31, 2020. The decrease was mainly due to foreign exchange loss.

Gain (loss) on fair value change of preferred shares

The Group recorded loss on fair value change of preferred shares of approximately RMB33.5 million for the year ended December 31, 2021, compared to a gain of approximately RMB0.4 million for the year ended December 31, 2020. All the then existing preferred shares were converted to ordinary shares upon the global offering.

Impairment Losses on expected credit loss model, net of reversal

The Group had a reversal of impairment losses on expected credit loss model amounting to approximately RMB0.8 million during the year ended December 31, 2021 compared to loss with approximately RMB1.1 million for the year ended December 31, 2020. The reversal was primarily due to the recovery of non-credited impaired trade receivables.

Selling and Distribution Expenses

The Group's selling and distribution expenses for the year ended December 31, 2021 were approximately RMB58.8 million, representing an increase of approximately 80.4% compared to approximately RMB32.6 million for the year ended December 31, 2020. The increase was primarily attributable to (i) employee stock ownership plan (“ESOP”) expense in January 2021, (ii) to the fact that fewer conferences were held in the first half of 2020 due to the impact of COVID-19, and (iii) an increase in the number of sales staff and therefore an increase in staff cost.

R&D Costs

The Group's R&D costs for the year ended December 31, 2021 were approximately RMB141.3 million, representing an increase of approximately 69.2% compared to approximately RMB83.5 million for the year ended December 31, 2020. The increase was primarily attributable to (i) the research and development expense of the Shenzhen R&D center which was acquired in May 27, 2020 and was consolidated in the comprehensive financial statement of the Group from the acquisition date onwards for the year ended December 31, 2020; (ii) increase in staff cost; (iii) ESOP expense in 2021, and (iv) the increased investments in the on-going research and development projects.

The following table sets forth the components of our research and development expenses for the period indicated.

	Year ended December 31,			
	2021		2020	
	RMB'000	%	RMB'000	%
Employee benefits expenses	50,950	36.0%	21,941	26.3%
Third-party contracting expenses	35,405	25.1%	15,115	18.1%
Depreciation and amortisation	4,326	3.1%	1,809	2.2%
Material consumed	30,550	21.6%	27,783	33.3%
Consultancy fee	9,487	6.7%	10,592	12.7%
Others	10,570	7.5%	6,247	7.5%
	<u>141,288</u>	<u>100.0%</u>	<u>83,487</u>	<u>100.0%</u>

Administrative Expenses

The Group's administrative expenses for the year ended December 31, 2021 were approximately RMB58.1 million, representing a decrease of approximately 19.4% compared to approximately RMB72.1 million for the year ended December 31, 2020. The decrease was primarily due to share-based compensation decreased in 2021.

Finance Costs

The Group's finance costs for the year ended December 31, 2021 were approximately RMB3.8 million, representing an increase of approximately 171.4% compared to approximately RMB1.4 million for the year ended December 31, 2020. The increase was primarily attributable to the interest expense on bank borrowings.

Income Tax Expense

The Group's income tax expense for the year ended December 31, 2021 was approximately RMB11.8 million, representing a decrease of approximately 7.8% compared to the income tax expense of approximately RMB12.8 million for the year ended December 31, 2020. The decrease was primarily attributable to more additional tax deduction for R&D expenses compared with the previous year.

Non-IFRS Measures

To supplement our audited consolidated statement of profit or loss and other comprehensive income which is presented in accordance with the IFRS, we also use adjusted net loss as a non-IFRS measure, which is not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measure 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 period to period by eliminating potential impact of certain non-recurring or one-off expenses that do not affect the Group's ongoing operating performance, including listing expenses, loss on fair value change of preferred shares, net exchange loss on the translation of listing proceeds, deferred tax asset reversal and share-based payments expenses. Such non-IFRS measure allows investors to consider metrics used by our management in evaluating our performance.

The following table shows our adjusted net loss and its reconciliation to loss for the periods indicated:

	Year ended December 31, 2021 RMB'000	Year ended December 31, 2020 RMB'000
Loss for the year	(79,077)	(44,292)
add:		
Share-based payments ⁽¹⁾	33,356	51,956
Net exchange loss on the translation of listing proceeds ⁽²⁾	9,350	–
Loss (gain) on fair value change of preferred shares ⁽³⁾	33,458	(447)
Listing expenses ⁽⁴⁾	41,129	10,317
Deferred tax asset reversal ⁽⁵⁾	4,174	–
Adjusted Net Profit for the year ⁽⁶⁾	42,390	17,534

Notes:

- (1) Share-based payments are non-operational expenses arising from granting shares to selected executives, employees, 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.
- (2) The amounts represent the net exchange loss on the translation of listing proceeds was included in the net exchange loss under other gain and losses, which was primarily arised from re-translation of net balances of listing proceeds.
- (3) Loss (gain) on fair value change of preferred shares are one-off expenses arising from when the preferred shares were converted to ordinary shares upon the global offering. The fair value loss of preferred shares is a non-cash item, and there will be no further gains or losses on fair value changes from these preferred shares after the conversion into ordinary shares upon the closing of the global offering.
- (4) Listing expenses are one-off expenses in relation to the listing of the Company's shares on the Main board of the Stock Exchange.
- (5) Deferred tax reversal due to deductible temporary difference and tax losses cannot be utilized by future tax profit.
- (6) We consider share-based payments, net exchange loss on the translation of listing proceeds, loss on fair value change of preferred shares, listing expenses and deferred tax asset derecognition as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the share-based payments, net exchange loss on the translation of listing proceeds, loss on fair value change of preferred shares, listing expenses and deferred tax asset reversal provides useful information to investors in facilitating a comparison of our operating performance from period to period.

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 measure may be defined differently from similar terms used by other companies and therefore may not be comparable to similar measures presented by other companies.

Capital Management

The primary goal of the Group's capital management is to maintain the Group's stability and growth, safeguard its normal operations and maximize shareholders' value. The Group reviews and manages its capital structure on a regular basis, and makes timely adjustments to it in light of changes in economic conditions. To maintain or realign our capital structure, the Group may raise capital by way of bank loans or issuance of equity or convertible bonds.

Liquidity and Financial Resources

The Group's cash and cash equivalents as at December 31, 2021 were approximately RMB1,137.2 million, representing an increase of approximately 673.1% compared to approximately RMB147.1 million as at December 31, 2020. The increase was primarily attributable to the offering of Shares on the Main Board of the Stock Exchange.

We rely on capital contributions by our shareholders and bank loans as the major sources of liquidity. We also generate cash from our sales revenue of existing commercialized products, including PTA balloons and DCB. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue of existing commercialized products and by launching new products, as a result of the broader market acceptance of our existing products and our continued efforts in marketing and expansion, improving cost control and operating efficiency.

Borrowings and Gearing Ratio

The Group's bank borrowings, as at December 31, 2021 were RMB6.0 million, representing a decrease of 70.0% compared to RMB20.0 million as at December 31, 2020. The decrease was primarily attributable to repayment of principal and interest of such borrowings by the Group at the beginning of 2021.

Gearing ratio is calculated by dividing total liabilities by total equity and multiplying the result by 100%. As at December 31, 2021, the gearing ratio of the Group decreased to approximately 8.3% from approximately -197.1% as at December 31, 2020.

Net Current Assets

The Group's net current assets, as at December 31, 2021 were approximately RMB1,155.4 million, representing an increase of approximately 721.5% compared to net current liabilities of approximately RMB185.9 million as at December 31, 2020.

Foreign Exchange Exposure

We have transactional currency exposures. Certain of our bank balances, trade receivables, other receivables and trade and other payables, are dominated in foreign currencies and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise.

Significant Investments, Material Acquisitions and Disposals

As of December 31, 2021, we did not hold any significant investments. For the Reporting Period, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Capital Expenditure

For the year ended December 31, 2021, the Group's total capital expenditure amounted to approximately RMB21.9 million, which was used in (i) purchase of property, plant and equipment; (ii) Payment of rental deposits; (iii) purchase of intangible assets.

Charge on Assets

As at December 31, 2021, there was no charge on assets of the Group.

Contingent Liabilities

As at December 31, 2021, we did not have any contingent liabilities.

Future Investment Plans and Expected Funding

The Group will continue to expand its markets in the PRC and globally in order to tap its internal potential and maximize shareholders' interest. The Group will continue to push products development in our pipeline. The Group will continue to grow through self-development, mergers and acquisitions, and other means. We will employ a combination of financing channels to finance capital expenditures, including but not limited to internal funds and bank loans. Currently, the bank credit lines available to the Group are adequate.

COVID-19 Impact and Response

The outbreak of COVID-19 had an adverse impact on our product sales, financial condition and results of operations. Delays have been caused to our animal studies, clinical trials and product registration, since medical resources of hospitals in China were allocated to addressing COVID-19. However, we believe that we have sufficient cash position and other available financial resources to cover our costs for normal operations for at least the next 12 months from the date of this announcement.

It is uncertain when, and whether, COVID-19 could be contained. The above analysis is made by our management team based on currently available information concerning COVID-19. Management of the Company cannot guarantee that the outbreak of COVID-19 will not further escalate or have a material adverse effect on our results of operations.

Employees and Remuneration Policies

As of December 31, 2021, we had 362 employees in total. Most of them are stationed in China. We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We assess our employees based on their performance to determine their salary, promotion and career development.

In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. These employment contracts typically have terms of three to five years.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and stock incentive plans to our employees, especially key employees.

Subsequent Events

On January 27, 2022, the Company granted 1,540,000 restricted share units to 55 eligible employees under the restricted share units scheme adopted by the Company on January 8, 2021. The granted restricted share units have a vesting period of two years and are subjected to non-market performance vesting conditions.

Save as disclosed above, there is no material subsequent event undertaken by the Group from December 31, 2021 to the date of this announcement.

USE OF NET PROCEEDS FROM LISTING

Net proceeds from the Global Offering and the full exercise of the over-allotment option, after deduction of the underwriting fees and commissions and expenses of the Company in connection with the Global Offering, was approximately RMB1,294.0 million. The Group would apply such proceeds in a manner consistent with the intended use of proceeds as disclosed in the Prospectus.

The table sets forth the utilization of the net proceeds from the Global Offering and the unutilized amount as at December 31, 2021:

Intended use of proceeds as stated in the Prospectus	Percentage to total amount %	Net proceeds RMB'000	Utilised amount as at December 31, 2021 RMB'000	Unutilised amount as at December 31, 2021 RMB'000	Expected timeline for unutilized amount
Development and commercialization of our Core Products	32	414,067	33,705	380,362	Year 2027
Development and commercialization of other 24 products	23	297,611	40,425	257,186	Year 2024
Expand our production capacity and strengthen our manufacturing capabilities	7	90,577	852	89,725	Year 2023
Expand our product portfolio through in-house research and development, collaboration, mergers and acquisitions, in-licensing or equity investments	24	310,550	–	310,550	Year 2024
Working capital and other general corporate purposes	8	103,517	–	103,517	Year 2025
Repay the Loan	6	77,638	77,638	–	N/A
Total	100	1,293,960	152,619	1,141,341	

OUTLOOK

Our goal is to become a global leader that provides full-suite of interventional solutions for vascular diseases.

In August 2021, our peripheral vacuum aspiration pump was approved to launch. Our Peripheral Aspiration System (AcoStream™) was approved to launch three months later. As of December 31, 2021, all of our products under the peripheral thrombus aspiration system had been launched, which made us become the first Chinese enterprise possessing originated technologies and ability to provide comprehensive solution in such sector. We also plan to further promote peripheral aspiration system awareness among doctors and patients in China in order to broaden the doctor and patient base.

Leveraging the synergistic effects from our four core technologies, we will further expand our product offerings. To fuel our long-term growth, we plan to further expand our coverage in the domain of vascular interventional therapies. We plan to cover five therapeutic areas consisting of vascular surgery, cardiology, nephrology, neurology and andrology primarily by leveraging our four technology platforms. We also plan to expand our product offerings from therapeutic devices, procedural devices to other ancillary devices for vascular interventional procedures in each of the five therapeutic areas.

We will continue to grow sales of AcoArt Orchid® & Dhalia™ through increasing our sales efforts to deepen the penetration in hospitals to which we currently sell AcoArt Orchid® & Dhalia™ and expanding into new hospitals in China by leveraging our direct access to KOLs in vascular interventional therapy, providing systematic training to physicians, and increasing DCB awareness among hospitals, physicians and patients.

To enjoy early-mover advantage, we will rapidly advance the clinical development and commercialization of our late-staged product candidates. We will also broaden our sales and expand our presence globally, especially in Europe and the United States. To execute our global expansion strategy, we will continue to participate in international vascular intervention conferences and academic events, such as Leipzig Interventional Course (LINC), to further promote our products and brand name. We also plan to conduct clinical trials for some product candidates in China and Europe simultaneously. We believe our existing brand name in Europe will contribute to our future expansion in the United States and other emerging markets.

DIVIDEND

The Board does not recommend the payment of a final dividend for the year ended December 31, 2021.

CLOSURE OF THE REGISTER OF MEMBERS

The Company will hold the AGM on Thursday, May 26, 2022. The register of members of the Company will be closed from Monday, May 23, 2022 to Thursday, May 26, 2022, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend the AGM, during which period no share transfers will be registered. To be eligible to attend the AGM, all properly completed transfer forms accompanied by the relevant share certificates must be lodged for registration with the Company's branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong no later than 4:30 p.m. on Friday, May 20, 2022.

CORPORATE GOVERNANCE

The Group is committed to maintaining high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability. The Company has adopted the CG Code as its own code of corporate governance. The Company has complied with all applicable code provisions of the CG Code during the period from the Listing Date to December 31, 2021, save for the following deviations. The Company will continue to review and monitor its corporate governance practices to ensure compliance with the CG Code.

Code provision C.2.1 of the CG Code stipulates that the roles of chairman and chief executive should be segregated and should not be performed by the same individual. According to the current structure of the Board, the positions of the Chairperson and Chief Executive Officer of the Company are held by Ms. Jing LI.

The Board believes that this structure will not impair the balance of power and authority between the Board and the management of the Company, given that: (i) decision to be made by the Board requires approval by at least a majority of the Directors and that the Board comprises three independent non-executive Directors out of seven Directors, and the Board believes there is sufficient check and balance on the Board, (ii) Ms. Jing LI and the other Directors are aware of and undertake to fulfil their fiduciary duties as Directors, which require, among other things, that they act for the benefit and in the best interests of the Company and will make decisions of the Group accordingly, and (iii) the balance of power and authority is ensured by the operations of the Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of the Group. Moreover, the overall strategic and other key business, financial and operational policies of the Group are made collectively after thorough discussion at both the Board and senior management levels. Finally, as Ms. Jing LI is our principal founder, the Board believes that vesting the roles of both chairman and chief executive officer in the same person has the benefit of ensuring consistent leadership within the Group and enables more effective and efficient overall strategic planning for the Group. The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairman and chief executive officer is necessary.

Code provision C.5.1 of the CG Code provides that Board meetings should be held at least four times a year at approximately quarterly intervals with active participation of the majority of the Directors, either in person or through electronic means of communication. As the Company was only listed on the Stock Exchange on August 24, 2021, only two Board meetings were held during the period from the Listing Date to December 31, 2021. The Company expects to continue to convene at least four regular meetings in each financial year at approximately quarterly intervals in accordance with code provision C.5.1 of the CG Code.

Code provision F.1.1 of the CG Code provides that the issuer should have a policy on payment of dividends. As the Company expects to retain all future earnings for use in the operation and expansion of the business and does not have any dividend policy to declare or pay any dividends in the near future. The Board will review the Company's status periodically and consider adopting a dividend policy if and when appropriate.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding directors' securities transactions. Having made specific enquiries of all Directors, each of the Directors has confirmed that he/she has complied with the required standards as set out in the Model Code during the period from the Listing Date to December 31, 2021.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

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

SCOPE OF WORK OF MESSRS. DELOITTE TOUCHE TOHMATSU

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2021 as set out in the preliminary announcement have been agreed by the Group's auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the audited consolidated financial statements of the Group for the year as approved by the Board of Directors on March 29, 2022. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by Messrs. Deloitte Touche Tohmatsu on the preliminary announcement.

AUDIT COMMITTEE

The Audit Committee has reviewed the Group's audited consolidated financial statements for the year which have been agreed by the Company's auditor, and is of the view that the Group's audited consolidated financial statements for the year are prepared in accordance with the applicable accounting standards, laws and regulations, and appropriate disclosures have already been made. The Audit Committee has also reviewed the annual results for the year.

PUBLICATION OF THE ANNUAL RESULTS AND 2021 ANNUAL REPORT ON THE WEBSITES OF THE STOCK EXCHANGE AND THE COMPANY

This annual results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.acotec.cn), and the 2021 Annual Report containing all the information required by the Listing Rules will be dispatched to the Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

DEFINITIONS AND GLOSSARY

In this annual results announcement, unless the context otherwise requires, the following expressions shall have the following meanings.

“AGM”	the annual general meeting of the Company to be held on Thursday, May 26, 2022
“Audit Committee”	the audit committee of the Board
“AVF”	arteriovenous fistula, an abnormal connection between an artery and a vein, bypassing some capillaries. It is usually surgically created for hemodialysis treatments
“Board of Directors” or “Board”	the board of Directors
“CAD”	coronary artery disease
“CG Code”	the “Corporate Governance Code” as contained in Appendix 14 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, which, for the purpose of this interim results announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
“Company”, “our Company”, or “Acotec”	Acotec Scientific Holdings Limited (先瑞達醫療科技控股有限公司), an exempted company with limited liability incorporated under the laws of the Cayman Islands on December 3, 2020
“Core Product”	AcoArt Orchid® & Dhalia™ and AcoArt Tulip™ & Litos™, the designated “core product” as defined under Chapter 18A of the Listing Rules
“DCB”	drug-coated balloon, an angioplasty balloon used in PCI procedures with anti-proliferation drug coated on its surface. The drug can inhibit smooth muscle cell proliferation and migration, thereby further reducing the chance of artery restenosis

“Director(s)”	the director(s) of the Company or any one of them
“FDA”	the U.S. Food and Drug Administration
“Global Offering”	the Hong Kong Public Offering and the International Offering each as defined in the Prospectus
“Group”, “our Group”, “our”, “we”, or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“KOLs”	key opinion leaders, being renowned physicians that are able to influence their peers’ medical practice
“IDE”	investigational device exemption, an approval granted by the FDA that allows a medical device to be used in a clinical research study that involves human subjects or human specimens
“IFRS”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“LEAD”	lower extremity artery disease, the narrowing or blockage of leg arteries
“Listing”	the listing of the Shares on the main board of the Stock Exchange
“Listing Date”	August 24, 2021, on which the Shares were listed and from which dealings therein were permitted to take place on 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” set out in Appendix 10 to the Listing Rules

“NMPA”	the National Medical Product Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“PAD”	peripheral artery disease, the narrowing or blockage of arteries outside the heart or brain
“Prospectus”	the prospectus of the Company dated August 12, 2021
“Reporting Period”	the year ended December 31, 2021
“RCT”	randomized controlled clinical trial, a study in which people are allocated at random (by chance alone) to receive one of several clinical interventions
“RMB”	Renminbi, the lawful currency of the PRC
“Share(s)”	ordinary share(s) with nominal value of US\$0.00001 each in the share capital of the Company
“Shareholder(s)”	holder(s) of the Share(s)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$”	United States dollars, the lawful currency of the United States
“vasculogenic ED”	vasculogenic erectile dysfunction, the inability to achieve and maintain an erection due to defects in the blood flow
%	per cent

By order of the Board
Acotec Scientific Holdings Limited
Jing LI

*Chairperson of the Board, Executive Director and
Chief Executive Officer*

Hong Kong, March 29, 2022

As at the date of this announcement, the executive Directors are Ms. Jing LI and Mr. Silvio Rudolf SCHAFFNER, the non-executive Directors are Mr. Ke TANG and Mr. Chen CHEN, and the independent non-executive Directors are Dr. Yuqi WANG, Ms. Hong NI and Ms. Kin Yee POON.