

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



Zylox-Tonbridge Medical Technology Co., Ltd.

歸創通橋醫療科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2190)

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

The board (the “**Board**”) of directors (the “**Directors**”) of Zylox-Tonbridge Medical Technology Co., Ltd. (the “**Company**”) is pleased to announce the audited consolidated results of the Company and its subsidiaries (collectively, the “**Group**”) for the year ended December 31, 2021 (the “**Reporting Period**”), together with the audited comparative figures for the year ended December 31, 2020.

FINANCIAL HIGHLIGHTS

	Year ended December 31, 2021 RMB'000	Year ended December 31, 2020 RMB'000	Year-to-year change
Revenue	177,912	27,631	543.9%
Gross Profit	131,881	16,287	709.7%
Gross Profit Margin	74.1%	58.9%	25.8%
Loss before income tax	(199,689)	(100,468)	98.8%
Add:			
Share-based compensation	76,211	23,111	229.8%
Listing expenses	22,733	–	–
Non-IFRS adjusted net loss for the period⁽¹⁾	(100,745)	(77,357)	30.2%

(1) The Company adjusted for RMB76.2 million and RMB23.1 million share-based compensation for the year ended December 31, 2021 and 2020 respectively, and RMB22.7 million listing expense in relation to the Listing for the year ended December 31, 2021. Please refer to section headed “Non-IFRS Measures” in this announcement for more details.

BUSINESS HIGHLIGHTS

In 2021, we achieved significant progress in our R&D pipeline, including (1) receiving regulatory approvals for and successfully launching eight products in China and two products in Europe as planned, (2) submitting registration applications for five products, (3) submitting for type testing for 16 products, and (4) enlarging our product portfolio with another 10 products through in-house R&D and collaboration by leveraging our existing R&D expertise and strength.

In addition, we further enhanced and expanded our sales and marketing team and distribution network to propel the commercialization of our newly approved products. In 2021, we recorded a revenue of RMB177.9 million, representing an increase of 543.9% on a year-over-year basis. In particular, revenue from neurovascular interventional medical device reached RMB112.3 million, which makes us one of the largest domestic manufacturers in the field of neurovascular interventional medical device.

Furthermore, we continue to invest in overseas market by expanding our product portfolio and sales network. In 2021, we obtained CE Mark for two products, while we have successfully commercialized our products in a total of 11 countries, including France, Spain, Italy, and Argentina, etc.

We achieved 100% success rate in obtaining product registration approvals within 2021 as planned in the beginning of 2021.

During 2021, we obtained NMPA registration approvals for eight products, such as intracranial PTA balloon catheter (Rx), balloon guiding catheter (BGC) and neurovascular embolization coils, and CE Marks for two products, namely the aspiration catheter and microcatheter for clot retriever. As of December 31, 2021, we had a total of 14 products with NMPA approval in China and eight products with CE Marks, which made us one of the leading companies with the most comprehensive product portfolio in the vascular interventional medical device market.

We continue to expand product offerings by leveraging our in-house R&D capabilities.

Adhering to our mission to provide complete solution for physicians and patients, we continue to develop new product offerings in our existing and adjacent fields, and improve capabilities of our technology platforms.

In peripheral vascular interventional fields, we identified huge potentials in the venous thromboembolism (VTE) market. Leveraging our technology platforms, we have efficiently developed mechanical thrombectomy device for pulmonary embolism (PE), and submitted it for type testing in 2021. VTE mainly includes PE and deep vein thrombosis (DVT). PE occurs in one to two individuals per 1000 each year. Approximately one-third of all patients with a new diagnosis of VTE have PE, with or without DVT, and it is estimated that up to a quarter of all patients with PE present with sudden death. With the addition of the mechanical thrombectomy device for pulmonary embolism, we have developed one of the most comprehensive portfolios in the venous interventional device market in China. Our portfolio includes retrievable inferior vena cava filter, peripheral thrombectomy system and peripheral venous stent system, etc. In neurovascular interventional fields, leveraging our experience in existing products, we have further developed aspiration pump system and radial access catheter to provide more comprehensive solutions for physicians. Not only do we continuously improve our product portfolio in existing therapeutic areas, but we will also leverage our existing products and advantages to extend to other areas to make full use of our R&D capabilities. For more details of new products, please refer to our pipeline chart on pages 26 and 27.

We enriched our product offerings through collaboration and investment.

In 2021, we expanded our product offerings through collaborations and investments, which we believe is an effective way to enrich our products pipeline in addition to our in-house R&D platform. Through this strategy, we will partner with the top engineers in the industry to accelerate innovation with advanced product offerings by leveraging the R&D capabilities of external experts and our comprehensive R&D, clinical and registration experience.

In November 2021, we entered into a collaboration agreement with Hangzhou Sky Road Medical Instrument Co., Ltd. (杭州天路醫療器械有限公司), which granted us the exclusive license regarding certain proprietary technology for developing intravascular lithotripsy (IVL) system for the treatment of peripheral vascular disease, as a valuable addition to our total solution management for lower limb artery diseases.

In January 2022, we made an investment in Wire Sciences Medical Technology (Suzhou) Co., Ltd. (微亞醫療科技(蘇州)有限公司) (“**Wire Sciences**”) as a strategic investor, a China-based innovative medical device company focusing on development of pan-vascular surgical robots and an independent third party of the Company. Together with the investment, we also entered into a strategic cooperation agreement with Wire Sciences, which granted us priority access to exclusive distribution rights of the products developed by Wire Sciences in selective regions where we have established commercialization strengths. Pan-vascular surgical robots provide greater visualization and enables catheter placement with greater accuracy. In addition, robot-assisted pan-vascular surgery can prevent surgeons from excessive X-ray radiation while the remote-control function will potentially help physicians to conduct remote surgical guidance and education. The R&D team at Wire Sciences has been developing pan-vascular robotics for a few years and we believe this strategic cooperation can promote a standardized, precise and intelligent development of the vascular interventional treatment, and enhance our offering for the pan-vascular interventional treatment solution.

We upgraded key products to address more diversified demand

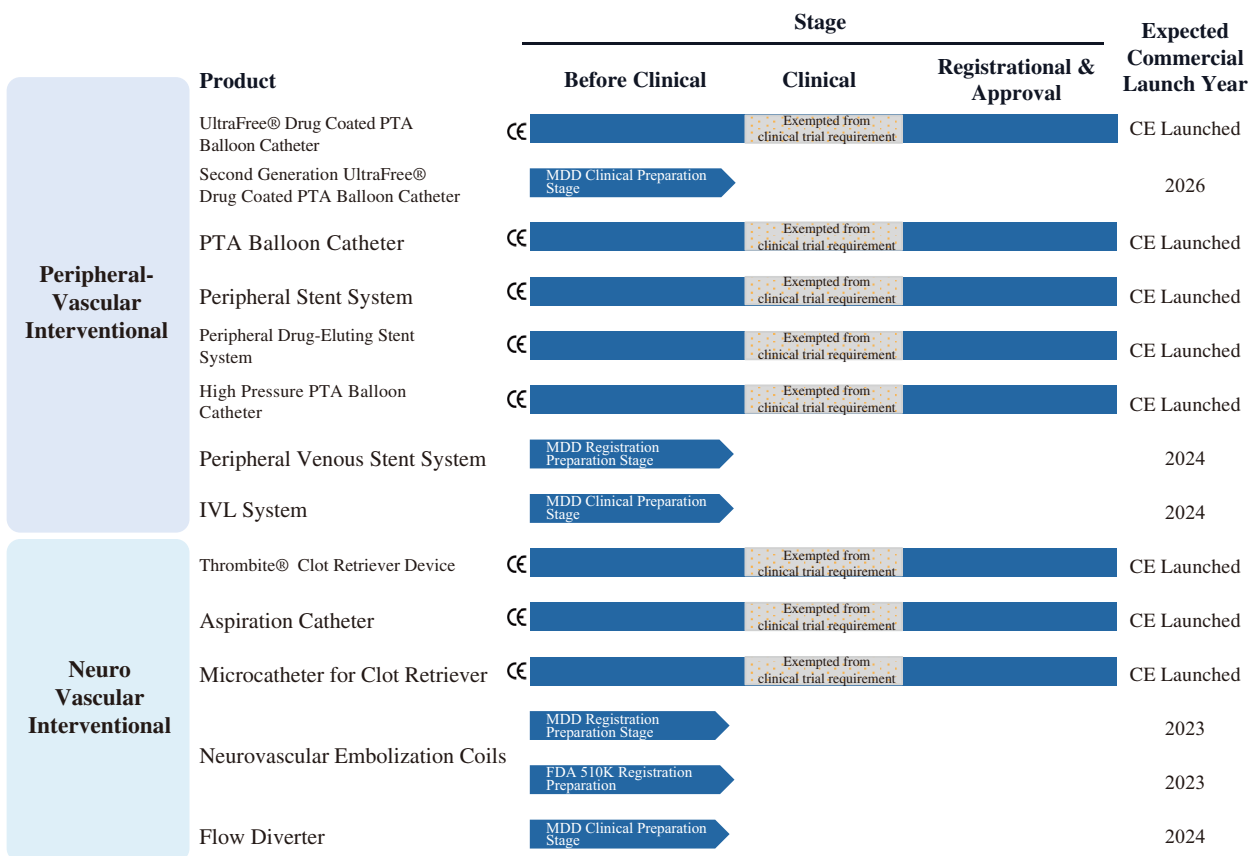
Leveraging our in-house R&D capability, we continue to upgrade our key products with the second generation. We believe the constant optimizing and upgrading of our products is a demonstration of our commitment and R&D capabilities to provide comprehensive portfolio to physicians and patients. Through further R&D efforts, we will continue to improve the clinical performance and manufacturing techniques of our existing products. Shortly after the launch of our key products, we have progressed to upgrade them into the second generation, namely the Clot Retriever Device II (second generation upgraded product of Thrombite® Clot Retriever Device), Mechanical Detachable Coil II (second generation upgraded product of neurovascular embolization coil) and Second Generation UltraFree® DCB, which we plan to launch within one to three years. These upgraded second generation products will allow us to provide more tailored-made device to physicians and patients based on the clinical needs.

We made further investment in overseas markets

In overseas markets, we have made progress in both sales and R&D, and plan to continue the efforts. In 2021, we obtained CE Mark for two new products, bringing us a total of eight products with CE Mark as of December 31, 2021. With the approval of these products, although our overseas sales network is still in early stage and is affected by the COVID-19 pandemic, we are still gradually expanding our overseas sales network. Our products have been successfully commercialized in a total of 11 countries in 2021 across three continents, including France, Spain, Italy and Argentina.

Overseas markets are important to our development strategies, and we will continue to invest in improving our competitiveness. We have commenced the clinical trial designs of key products in overseas markets, including Second Generation UltraFree® DCB, IVL system and flow diverter. We have also launched registration plans for more products, including peripheral venous stent system and neurovascular embolization coils. At the same time, we are preparing to establish a local team in Europe to assist the launch of new products and brand building, and lay a solid foundation for us to build more comprehensive capabilities in Europe and achieve the long-term strategic goals.

In addition to enhancing our own capabilities, we are also looking for partners having advantage on distribution channel and customer resources in Europe and the U.S. markets to accelerate the sales of our products overseas. The following chart summarizes our overseas product R&D development as of the date of this announcement:



CE These products are exempted from clinical trial requirement for obtaining CE marking under the MDD, considering that clinical evaluations were provided

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2021

		Year ended December 31,	
	Note	2021	2020
		RMB'000	RMB'000
Revenue	3	177,912	27,631
Cost of sales		(46,031)	(11,344)
Gross profit		131,881	16,287
Selling and distribution expenses		(95,269)	(20,453)
Administrative expenses		(100,599)	(30,992)
Research and development expenses		(168,100)	(72,065)
Other income		15,286	9,997
Other expenses		(712)	(257)
Other gains/(losses) — net		5,058	(2,679)
Net impairment losses on financial assets		(21)	—
Operating loss		(212,476)	(100,162)
Finance income		13,094	360
Finance costs		(307)	(666)
Finance income/(costs) — net		12,787	(306)
Loss before income tax		(199,689)	(100,468)
Income tax expense	4	—	—
Loss for the year		(199,689)	(100,468)
Loss attributable to:			
— Equity holders of the Company		(199,689)	(100,468)
		(199,689)	(100,468)
Loss and total comprehensive loss for the year attributable to the equity holders of the Company		(199,689)	(100,468)
Loss per share attributable to the equity holders of the Company			
Basic and diluted loss per share (in RMB per share)	5	(0.68)	(0.52)

CONSOLIDATED BALANCE SHEET

AS AT DECEMBER 31, 2021

	<i>Note</i>	As at December 31,	
		2021	2020
		RMB'000	RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment		178,270	105,224
Right-of-use assets		34,115	16,950
Intangible assets		4,889	7,556
Prepayments and other receivables	6	6,804	4,099
Total non-current assets		224,078	133,829
Current assets			
Inventories		57,272	28,993
Prepayments, other receivables and other current assets	6	37,616	23,764
Trade receivables	7	446	129
Financial assets at fair value through profit or loss		10,515	157,700
Term deposits		1,500,000	100,000
Cash and cash equivalents		1,418,359	59,556
Total current assets		3,024,208	370,142
Total assets		3,248,286	503,971
EQUITY AND LIABILITIES			
Equity attributable to equity holders of the Company			
Share capital/paid-in capital		332,401	225,062
Share premium		2,270,033	—
Other reserves		841,007	561,147
Treasury shares		(9,149)	—
Accumulated losses		(289,618)	(361,515)
Total equity		3,144,674	424,694

		As at December 31,	
	<i>Note</i>	2021	2020
		RMB'000	RMB'000
Liabilities			
Non-current liabilities			
Borrowings		—	26,250
Lease liabilities		6,509	1,396
		<hr/>	<hr/>
Total non-current liabilities		6,509	27,646
		<hr/>	<hr/>
Current liabilities			
Trade and other payables	8	86,307	43,658
Contract liabilities	3	3,420	134
Borrowings		—	3,750
Lease liabilities		2,896	2,825
Other current liabilities		4,480	1,264
		<hr/>	<hr/>
Total current liabilities		97,103	51,631
		<hr/>	<hr/>
Total liabilities		103,612	79,277
		<hr/> <hr/>	<hr/> <hr/>
Total equity and liabilities		3,248,286	503,971
		<hr/> <hr/>	<hr/> <hr/>

NOTES TO THE CONSOLIDATED FINANCIAL INFORMATION

1 General information

The Company was incorporated in Hangzhou, Zhejiang Province of the PRC on November 6, 2012 as a limited liability company. On March 2, 2021, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC and changed its registered name from “Zhejiang Zylox Medical Device Co., Ltd.” to “Zylox-Tonbridge Medical Technology Co., Ltd.”

The Group are providing solutions to patients and physician with the product portfolio covering peripheral-vascular interventional devices and neurovascular interventional devices in the PRC and other countries.

The Company’s shares have been listed on the Main Board of the Stock Exchange on July 5, 2021.

These consolidated financial information are presented in thousands of Renminbi (“**RMB’000**”), unless otherwise stated. These consolidated financial statements have been approved for issue by the Board of Directors on March 15, 2022.

2 Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with all applicable International Financial Reporting Standards (“**IFRSs**”) issued by International Accounting Standards Board (“**IASB**”) and the disclosure requirements of the Hong Kong Companies Ordinance Cap. 622. The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through profit or loss, which are carried at fair value.

The preparation of the consolidated financial statements in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group’s accounting policies.

(a) Amended standards adopted by the Group

The following amended standards have been adopted by the Group for the first time to financial reporting period commencing on or after January 1, 2021:

- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16-Interest Rate Benchmark Reform — Phase 2

The amendments listed above did not have any impact on the amounts recognised in prior periods and are not expected to significantly affect the current or future periods.

(b) New Standards, amendments to standards and interpretations not yet adopted

Certain new accounting standards, amendments and interpretations that have been issued but not yet effective and not been early adopted by the Group for the reporting period are as follows:

	New standards, amendments	Effective for annual periods beginning on or after
Amendments to IFRS 3	Reference to the Conceptual Framework	January 1, 2022
Amendments to IAS 37	Onerous Contracts — Cost of Fulfilling a Contract	January 1, 2022
Annual Improvements to IFRSs 2018–2020 Cycle	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41	January 1, 2022
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended Use	January 1, 2022
Amendments to Accounting Guideline 5	Merger Accounting for Common Control Combinations	January 1, 2022
IFRS 17	Insurance contracts	January 1, 2023
Amendments to IAS 1	Classification of Liabilities as Current or Non-current	January 1, 2023
Amendments to IFRS 4	Extension of the temporary exemption from applying IFRS 9	January 1, 2023
Amendments to IAS 8	Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	January 1, 2023
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	To be determined

The Group has already commenced an assessment of the related impact of the above standards and amendments to standards which are relevant to the Group's operation. There are no other standards that are not yet effective and that are expected to have a material impact on the Group's financial performance and position.

3 Segment and revenue information

(a) *Description of segments and principal activities*

The management of the Company has determined the operating segment based on the reports reviewed by the chief operating decision-maker (the "CODM"). The CODM, who is responsible for allocating resources and assessing performance of the operating segment, has been identified as the executive Directors. On this basis, the Group has determined that it only has one operating segment which is the production and sales of neurovascular and peripheral-vascular interventional surgical devices during the year.

(b) *The amount of each category of revenue is as follows:*

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Revenue from sales of goods		
— at a point in time	<u>177,912</u>	<u>27,631</u>
	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Revenue from sales of goods		
— Neurovascular interventional devices	<u>112,271</u>	<u>19,940</u>
— Peripheral-vascular interventional devices	<u>65,641</u>	<u>7,691</u>
	<u>177,912</u>	<u>27,631</u>

- (c) *The Group recognised the following liabilities related to the contracts with customers:*

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Contract liabilities	<u>3,420</u>	<u>134</u>

Contract liabilities represent advance from customers and are recognised when payments are received before the transfer of goods. As at December 31, 2021 and 2020, there are no material unsatisfied performance obligations resulting from contracts.

- (d) *Revenue recognised that was included in the balance of contract liabilities at the beginning of the year:*

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Revenue from sales of goods	<u>134</u>	<u>19</u>

- (e) *Geographical information*

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
The PRC	174,450	24,284
Others	<u>3,462</u>	<u>3,347</u>
	<u>177,912</u>	<u>27,631</u>

The geographical information above is based on the locations of the customers. All of the non-current assets of the Group are physically located in the PRC.

4 Income tax expense

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Current income tax expense	—	—
Deferred income tax expense	—	—
	<u>—</u>	<u>—</u>
	<u>—</u>	<u>—</u>

The Group's principal applicable taxes and tax rates are as follows:

(a) *Mainland China*

Pursuant to the PRC Corporate Income Tax Law and the respective regulations (the "CIT Law"), the Group is subject to enterprise income tax at a rate of 25% on the taxable income.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 onwards, the enterprises engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their taxable income for that year. Pursuant to the relevant tax regulations, effective from 2021 onwards, manufacturing enterprises are entitled to claim 200% of their research and development expenses incurred as tax deductible expenses.

No deferred tax asset has been recognised in respect of the tax losses and temporary differences due to the unpredictability of future profit streams.

The tax losses will normally expire within five years. The Company's subsidiary Zhuhai Tonbridge Medical Technology Co., Ltd. ("**Zhuhai Tonbridge**") was qualified as Small and Medium-sized Technological Enterprises in 2018. Pursuant to the relevant regulations on extending the expiry date of tax losses of High-Tech Enterprises and Small and Medium-sized Technological Enterprises issued in July 2018, which retrospectively effects from January 1, 2018, the expiry date of the unused tax losses extended from five years to 10 years from then on.

(b) *Hong Kong*

Hong Kong profits tax rate is 8.25% for assessable profits on the first HKD2 million and 16.5% for any assessable profits in excess. No Hong Kong profit tax was provided for as there was no estimated assessable profit that was subject to Hong Kong profits tax during the year ended December 31, 2021.

According to the Hong Kong tax laws and regulations, the tax losses would be carried forward and deducted for income tax purposes, without expiry date.

A reconciliation of the expected income tax calculated at the applicable tax rate and loss before income tax, with the actual income tax is as follow:

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Loss before income tax	<u>(199,689)</u>	<u>(100,468)</u>
Tax calculated at statutory tax rates applicable to each Group entity	(49,657)	(25,117)
Tax effect of:		
Expenses not deductible for tax purpose	689	352
Extra deduction for research and development expenses	(31,439)	(11,540)
Temporary differences not recognised as deferred tax assets	11,784	3,988
Tax losses not recognised as deferred tax assets	<u>68,623</u>	<u>32,317</u>
Income tax expense	<u> —</u>	<u> —</u>

(c) *Unrecognised tax losses and temporary differences*

The Group has not recognised any deferred tax assets in respect of the following items:

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Deductible losses (i)	275,552	129,267
Deductible temporary differences	47,136	15,952
	<u>322,688</u>	<u>145,219</u>

(i) Deductible losses that were not recognised as deferred tax assets will be expired as follows:

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
2023	5,528	5,528
2024	66,582	66,582
2025	115,313	115,313
2026	232,097	31,813
2027	39,529	39,529
2028	107,797	107,797
2029	44,108	44,108
2030	24,568	24,568
2031	72,150	—
Indefinite	3,118	—
	<u>710,790</u>	<u>435,238</u>
Unused tax losses carried forward	<u>710,790</u>	<u>435,238</u>

5 Loss per share

In March 2021, the Company was converted to a joint stock limited liability company and total 263,401,001 ordinary shares with par value of RMB1.00 each were issued and allotted to the respective equity holders of the Company according to the paid-in capital registered under these equity holders on that day. The conversion to ordinary shares with par value of RMB1.00 each issued after the conversion is applied retrospectively for the years ended December 31, 2021 and 2020 for the purpose of computation of basic loss per share.

Basic loss per share is calculated by dividing the loss of the Group attributable to equity holders of the Company by weighted average number of ordinary shares outstanding during the financial year excluding treasury shares.

For the years ended December 31, 2021 and 2020, the Group has potential dilutive shares related to the shares held for the Pre-IPO Share Option Scheme. Due to the Group's losses, the potential ordinary shares are not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, the diluted loss per share is the same as basic loss per share.

The calculations of basic and diluted loss per share are based on:

	Year ended December 31,	
	2021	2020
Loss attributable to equity holders of the Company (RMB'000)	(199,689)	(100,468)
Weighted average number of ordinary shares in issue during the year (thousand)	<u>294,595</u>	<u>194,766</u>
Basic and diluted loss per share (RMB)	<u><u>(0.68)</u></u>	<u><u>(0.52)</u></u>

6 Prepayments, other receivables and other current assets

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Included in non-current assets		
Prepayments:		
Prepayments for purchase of property, plant and equipment	5,790	4,099
Other receivables:		
Deposits for leases	1,014	—
	<u>6,804</u>	<u>4,099</u>
Total	<u>6,804</u>	<u>4,099</u>
Included in current assets		
Prepayments:		
Prepayments for purchase of goods	23,636	10,694
Prepayments for purchase of service	5,764	2,854
Other receivables:		
Deposits for industrial land project performance guarantee and leases	3,147	3,446
Staff advances	68	75
Others	131	321
	<u>3,346</u>	<u>4,842</u>
Less: loss allowance	(9)	—
	<u>3,337</u>	<u>4,842</u>
Others:		
Value-added tax recoverable	3,112	6,374
Accrued interest receivable	1,767	—
	<u>4,879</u>	<u>6,374</u>
Total	<u>37,616</u>	<u>23,764</u>

7 Trade receivables

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables from contracts with customers	458	129
Less: loss allowance	(12)	—
	<u>446</u>	<u>129</u>

The Group applies the IFRS 9 simplified approach to measure expected credit losses which use a life time expected loss allowance for all trade receivables.

As at December 31, 2021 and 2020, the ageing analysis of the trade receivables based on invoice date were as follows:

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Up to 3 months	458	128
Over 6 months	—	1
	<u>458</u>	<u>129</u>

The carrying amounts of the Group's trade receivables are denominated in RMB and approximate their fair values. The maximum exposure to credit risk at the reporting date is the carrying value of trade receivables mentioned above.

As at December 31, 2021, a provision of RMB12,000 was made against the gross amounts of trade receivables.

8 Trade and other payables

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables (a)	14,114	4,604
Staff salaries and welfare payables	35,396	18,595
Payables for purchase of property, plant and equipment	22,450	18,717
Payables to suppliers of service	7,463	839
Accrued taxes other than income tax	4,468	665
Listing expenses	1,762	—
Others	654	238
	<u>86,307</u>	<u>43,658</u>

- (a) The ageing analysis of trade payables based on invoice date at the respective balance sheet dates is as follows:

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	14,114	4,513
Between 1 and 2 years	—	91
	<u>14,114</u>	<u>4,604</u>

9 Dividend

No dividend has been paid or declared by the Company during each of the years ended December 31, 2021 and 2020, respectively.

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW

We are a leading player in the neuro- and peripheral-vascular interventional medical device market in China. As an integrated medical device company supported by our in-house research and development (R&D) and manufacturing capabilities, proprietary technological platforms, and commercialization capabilities, we provide physicians and patients in China and overseas with medical devices to treat and manage neuro- and peripheral-vascular diseases. We strive to provide all patients, regardless of their race, age and affluence, with accessible medical devices and services.

BUSINESS HIGHLIGHT

In 2021, we achieved significant progress in our R&D pipeline, including (1) receiving regulatory approvals for and successfully launching eight products in China and two products in Europe as planned, (2) submitting registration applications for five products, (3) submitting for type testing for 16 products, and (4) enlarging our product portfolio with another 10 products through in-house R&D and collaboration by leveraging our existing R&D expertise and strength.

In addition, we further enhanced and expanded our sales and marketing team and distribution network to propel the commercialization of our newly approved products. In 2021, we recorded a revenue of RMB177.9 million, representing an increase of 543.9% on a year-over-year basis. In particular, revenue from neurovascular interventional medical device reached RMB112.3 million, which makes us one of the largest domestic manufacturers in the field of neurovascular interventional medical device.

Furthermore, we continue to invest in overseas market by expanding our product portfolio and sales network. In 2021, we obtained CE Mark for two products, while we have successfully commercialized our products in a total of 11 countries, including France, Spain, Italy, and Argentina, etc.

We achieved 100% success rate in obtaining product registration approvals within 2021 as planned in the beginning of 2021.

During 2021, we obtained NMPA registration approvals for eight products, such as intracranial PTA balloon catheter (Rx), balloon guiding catheter (BGC) and neurovascular embolization coils, and CE Marks for two products, namely the aspiration catheter and microcatheter for clot retriever. As of December 31, 2021, we had a total of 14 products with NMPA approval in China and eight products with CE Marks, which made us one of the leading companies with the most comprehensive product portfolios in the vascular interventional medical device market.

We continue to expand product offerings by leveraging our in-house R&D capabilities.

Adhering to our mission to provide complete solution for physicians and patients, we continue to develop new product offerings in our existing and adjacent fields, and improve capabilities of our technology platform.

In peripheral vascular interventional fields, we identified huge potentials in the venous thromboembolism (VTE) market. Leveraging our technology platform, we efficiently developed mechanical thrombectomy device for pulmonary embolism (PE), and submitted it for type testing in 2021. VTE mainly includes PE and deep vein thrombosis (DVT). PE occurs in one to two individuals per 1000 each year. Approximately one-third of all patients with a new diagnosis of VTE have PE, with or without DVT, and it is estimated that up to a quarter of all patients with PE present with sudden death. With the addition of mechanical thrombectomy device for pulmonary embolism, we have developed one of the most comprehensive portfolios in the venous interventional device market in China. Our portfolio includes retrievable inferior vena cava filter, peripheral thrombectomy system and peripheral venous stent system, etc. In neurovascular interventional fields, leveraging our experience in existing products, we further developed aspiration pump system and radial access catheter to provide more comprehensive solutions for physicians. Not only do we continuously improve our product portfolio in existing therapeutic areas, we will also leverage our existing products and advantages to extend to other areas to make full use of our R&D capabilities. For more details of new products, please refer to our pipeline chart on pages 26 and 27.

We enriched our product offerings through collaboration and investment.

In 2021, we expanded our product offerings through collaborations and investments, which we believe is an effective way to enrich our products pipeline in addition to our in-house R&D platforms. Through this strategy, we will partner with the top engineers in the industry to accelerate innovation with advanced product offerings by leveraging the R&D capabilities of external experts and our comprehensive R&D, clinical and registration experience.

In November 2021, we entered into a collaboration agreement with Hangzhou Sky Road Medical Instrument Co., Ltd. (杭州天路醫療器械有限公司), which granted us the exclusive license regarding certain proprietary technology for developing intravascular lithotripsy (IVL) system for the treatment of peripheral vascular disease, as a valuable addition to our total solution management for lower limb artery diseases.

In January 2022, we made an investment in Wire Sciences Medical Technology (Suzhou) Co., Ltd. (微亞醫療科技(蘇州)有限公司) (“**Wire Sciences**”) as a strategic investor, a China-based innovative medical device company focusing on development of pan-vascular surgical robots and an independent third party of the Company. Together with the investment, we also entered into a strategic cooperation agreement with Wire Sciences, which granted us priority access to exclusive distribution rights of the products developed by Wire Sciences in selective regions where we have established commercialization strengths. Pan-vascular surgical robots provide greater visualization and enables catheter placement with greater accuracy. In addition, robot-assisted pan-vascular surgery can prevent surgeons from excessive X-ray radiation while the remote-control function will potentially help physicians to conduct remote surgical guidance and education. The R&D team at Wire Sciences has been developing pan-vascular robotics for a few years and we believe this strategic cooperation can promote a standardized, precise and intelligent development of the vascular interventional treatment, and enhance our offering for the pan-vascular interventional treatment solution.

We upgraded key products to address more diversified demand

Leveraging our in-house R&D capability, we continue to upgrade our key products with the second generation. We believe the constant optimizing and upgrading of our products is a demonstration of our commitment and R&D capabilities to provide comprehensive portfolio to physicians and patients. Through further R&D efforts, we will continue to improve the clinical performance and manufacturing techniques of our existing products. Shortly after the launch of our key products, we have progressed to upgrade them into the second generation, namely the Clot Retriever Device II (second generation upgraded product of Thrombite® Clot Retriever Device), Mechanical Detachable Coil II (second generation upgraded product of neurovascular embolization coil) and Second Generation UltraFree® DCB, which we plan to launch within one to three years. These upgraded second generation products will allow us to provide more tailored-made device to physicians and patients based on the clinical needs.

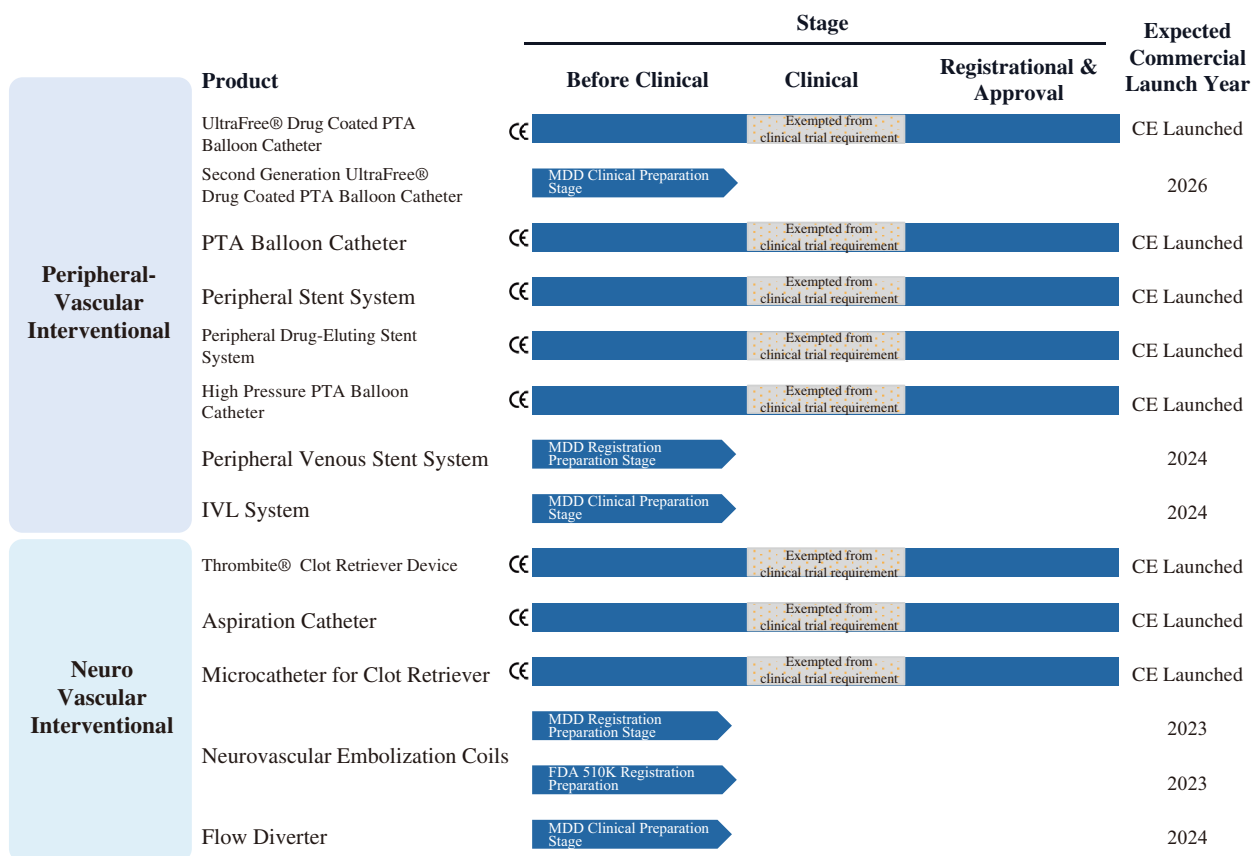
We made further investment in overseas markets

In overseas markets, we have made progress in both sales and R&D, and plan to continue the efforts. In 2021, we obtained CE Mark for two new products, bringing us a total of eight products with CE Mark as of December 31, 2021. With the approval of these products,

although our overseas sales network is still in early stage and is affected by the COVID-19 pandemic, we are still gradually expanding our overseas sales network. Our products have been successfully commercialized in a total of 11 countries in 2021 across three continents, including France, Spain, Italy and Argentina.

Overseas markets are important to our development strategies, and we will continue to invest in improving our competitiveness. We have commenced the clinical trial designs of key products in overseas markets, including Second Generation UltraFree® DCB, IVL system and flow diverter. We have also launched registration plans for more products, including peripheral venous stent system and neurovascular embolization coils. At the same time, we are preparing to establish a local team in Europe to assist the launch of new products and brand building, and lay a solid foundation for us to build more comprehensive capabilities in Europe and achieve the long-term strategic goals.

In addition to enhancing our own capabilities, we are also looking for partners having advantage on distribution channel and customer resources in Europe and the U.S. markets to accelerate the sales of our products overseas. The following chart summarizes our overseas product R&D development as of the date of this announcement:



CE These products are exempted from clinical trial requirement for obtaining CE marking under the MDD, considering that clinical evaluations were provided

INDUSTRY OVERVIEW

Vascular diseases generally refer to the conditions that affect the circulatory system, typically consisting of neurovascular, coronary vascular and peripheral-vascular diseases. According to Frost & Sullivan, neurovascular disease is one of the leading causes of death in China which accounted for over 20% of the total mortality in 2019 in China and such percentage continues to rise. Peripheral-vascular diseases can lead to severe neuro- and cardio-vascular conditions such as heart attacks and strokes. Driven by a pressing clinical need for less invasive treatment to patients and more convenience to physicians, technology breakthroughs have been made in terms of minimally invasive endovascular interventional therapies, which generally involve transcatheter technique with fewer post-operative complications, which allows faster recovery and shorter hospital stay.

In recent years, interventional therapies are progressing quickly as a replacement of traditional surgeries. Within the domain of interventional therapy, neuro-intervention and peripheral-intervention markets in China are at emerging stage and are expected to experience rapid growth with accelerated expansion and technology evolvement, driven by the increasing health awareness, escalating incidence of cardiovascular diseases, enhancing patient affordability, improving clinical practice of physicians, and favorable policies to promote domestic products.

From 2020 to 2022, the total number of neuro- and peripheral-interventional vascular procedures are estimated to be 482.1 thousand, 605.5 thousand and 750.5 thousand, respectively, according to Frost & Sullivan.

Overview of Neurovascular Disease and China Neurovascular Device Market

The neurovascular diseases mainly include ischemic neurovascular diseases and hemorrhagic stroke, which nowadays can be treated with neuro-interventional procedural methods as a result of technology innovation. Neuro-interventional procedure is normally performed with intravascular surgery technology to diagnose and treat neurovascular diseases through selective angiography, embolization, dilation, mechanical clearance, drug delivery, and other specific methods.

The market size of China neuro-interventional medical device is expected to increase from RMB4.9 billion in 2019 to RMB37.1 billion in 2030 at a CAGR of 20.2%, according to Frost & Sullivan.

Overview of Peripheral-vascular Disease and China Peripheral-vascular Device Market

The peripheral-vascular disease includes peripheral artery diseases and peripheral venous diseases. Peripheral artery disease (PAD) refers to diseases of blood vessels located outside of the heart or brain, which develops when plaque clogs or narrows arteries that deliver blood to the arms, legs and internal organs such as the stomach or kidneys. PAD is the third leading cause of atherosclerotic vascular morbidity after coronary heart disease and stroke. In China, there is an increasing prevalence of PAD driven by the aging population and increasing public awareness. Along with the improvement on the diagnostic technology and knowledge, it is projected that the total number of prevalence of PAD in China will reach 62.3 million in 2030. Peripheral venous diseases are divided into two categories including chronic venous disease (CVD) and acute venous disease. The most common peripheral venous diseases consist of DVT, iliac compression syndrome and varicose vein.

The market size of the China PAD interventional device is expected to increase from RMB2.4 billion in 2019 to RMB12.2 billion in 2030 at a CAGR of 15.7%.

Among peripheral venous diseases, PE has significant market potential as a part of venous thromboembolism (VTE). PE occurs in 1 to 2 individuals per 1000 each year. Approximately 1/3 of all patients with a new diagnosis of VTE have PE, with or without DVT, and it is estimated that up to a quarter of all patients with PE present with sudden death, according to Frost & Sullivan.

In China, the number of DVT incidence is estimated to increase to 3.3 million in 2030 at a CAGR of 7.3% from 2019 to 2030. PE incidence in China is expected to reach 2,340.58 thousand in 2030 with a CAGR of 8.14% from 2019 to 2030.

In the U.S., researchers estimate that approximately 668,000 new patients are diagnosed with DVT and approximately 400,000 new patients are diagnosed with PE each year.

OUR PRODUCTS AND PRODUCT PIPELINE

As China's leading interventional medical device company in developing minimally invasive vascular interventional medical devices, we have built a comprehensive product portfolio including neurovascular and peripheral-vascular interventional surgical devices.

The following chart summarizes the development status of our products and product candidates as at the date of this announcement:

	Product	Stage				Expected Commercial Launch Year
		Design	Type Testing	Clinical	Registrational & Approval	
Neuro Vascular Interventional Portfolio	Intracranial Ischemic Stroke	Thrombite® Clot Retriever Device (Thrombite® CRD) ★				Launched
		Clot Retriever Device II			CE Marking: Exempted from clinical trial requirement	2023
		Balloon Guiding Catheter (BGC) ▲			Exempted from clinical trial requirement	Launched
		Aspiration Catheter ★			CE Marking: Exempted from clinical trial requirement	Launched
		Aspiration Pump System			Exempted from clinical trial requirement	2023
	Intracranial Stenosis	Intracranial PTA balloon catheter (Rx) ▲			Exempted from clinical trial requirement	Launched
		Intracranial PTA balloon catheter (OTW)			Exempted from clinical trial requirement	2023
		Microcatheter for Intracranial Stent ▲			Exempted from clinical trial requirement	2023
		Intracranial Drug Coated Balloon Catheter				2024
		Intracranial Stent				2025
	Intracranial Hemorrhagic Stroke	Neurovascular Embolization Coils				Launched
		Mechanical Detachable Coil II			Exempted from clinical trial requirement	2023
		Microcatheter for Coiling ▲			Exempted from clinical trial requirement	Launched
		Microcatheter for Flow Diverter ▲			Exempted from clinical trial requirement	2023
		Flow Diverter				2024
	Self-expandable Intracranial Stent				2025	
	Intracranial Access	SilverSnake® Intracranial Support Catheter ▲			Exempted from clinical trial requirement	Launched
		Microcatheter for Clot Retriever ▲			Exempted from clinical trial requirement	Launched
		Distal Access Catheter ▲			CE Marking: Exempted from clinical trial requirement	Launched
		SilverSnake® Standard Intracranial Support Catheter			Exempted from clinical trial requirement	Launched
Neurovascular Guidewire ▲				Exempted from clinical trial requirement	2022	
Radial Access Catheter				Exempted from clinical trial requirement	2024	
Carotid Artery Stenosis		Carotid RX PTA Balloon Catheter ▲			Exempted from clinical trial requirement	2022
	Embolic Protection System ▲			Exempted from clinical trial requirement	2023	
	Carotid Stent				2025	

★ Core Product; further R&D includes post-approval study, product improvement and indication expansion

▲ Among our product candidates, these devices are exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials (《免於進行臨床試驗醫療器械目錄》) promulgated by the NMPA, as amended.

■ These devices are exempted from clinical trial requirement for obtaining CE marking under the MDD, considering that clinical evaluation reports were provided.

 Commercialized
  China status
  Overseas status

★ The devices will be subject to a clinical evaluation with peer products in accordance with relevant regulations while the clinical trial be conducted as planned.

	Product	Stage				Expected Commercial Launch Year
		Design	Type Testing	Clinical	Registrational & Approval	
Peripheral-Vascular Interventional Portfolio	UltraFree® Drug Coated PTA Balloon Catheter (UltraFree® DCB) ★				CE Marking: Exempted from clinical trial requirement	Launched
	Second Generation UltraFree® Drug Coated PTA Balloon Catheter				Exempted from clinical trial requirement	2022
	PTA Balloon Catheter ▲				Exempted from clinical trial requirement CE Marking: Exempted from clinical trial requirement	Launched
	Second Generation PTA Balloon Catheter				Exempted from clinical trial requirement	2022
	Peripheral Stent System ▲				CE Marking: Exempted from clinical trial requirement	Launched
	Peripheral Drug-Eluting Stent System				CE Marking: Exempted from clinical trial requirement	Launched
	Endovascular Snare ▲				Exempted from clinical trial requirement	Launched
	PTA Scoring Balloon Catheter					2024
	Multi-spot Stent System					2024
	Drug Coated PTA Balloon Catheter-BTK ★					2024
	IVL System					2025
	Snare Retrieval Kit for IVC Filter ▲				Exempted from clinical trial requirement	Launched
	Endovenous Radiofrequency Ablation (RFA) Catheter					2022
	Radiofrequency Generator					2023
	PTA Balloon Catheter Large Diameter ▲				Exempted from clinical trial requirement	2022
	Infusion Catheter ▲				Exempted from clinical trial requirement	2023
	Peripheral Venous Stent System					2023
	Varicose Vein Closure System					2024
	Peripheral Thrombectomy System					2024
	Retrievable Inferior Vena Cava Filter					2022
	Mechanical Thrombectomy Device					2025
	High Pressure PTA Balloon Catheter ▲				Exempted from clinical trial requirement CE Marking: Exempted from clinical trial requirement	Launched
	Second Generation High Pressure PTA Balloon Catheter				Exempted from clinical trial requirement	2022
	Drug Coated PTA Balloon Catheter-AV Fistula ★					2024
	Thoracic Aorta Stent Graft System					2025
	Peripheral Detachable Embolization Coils					2024
	TIPS Access Set ▲				Exempted from clinical trial requirement	2023
	TIPS Endoprosthesis					2024
	Suture-mediated Closure System					2023
	Vascular Closure System					2024

★ Core Product; further R&D includes post-approval study, product improvement and indication expansion

★ UltraFree® DCB indication extension

▲ Among our product candidates, these devices are exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials (《免於進行臨床試驗醫療器械目錄》) promulgated by the NMPA, as amended.



Commercialized



China status



Overseas status



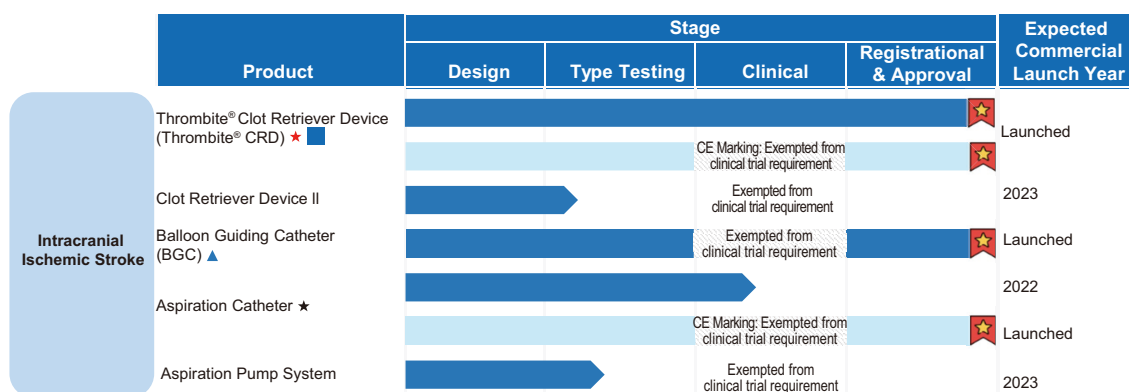
These devices are exempted from clinical trial requirement for obtaining CE marking under the MDD, considering that clinical evaluation reports were provided.

Our Neurovascular Products

Our current neurovascular product portfolio covers a full suite of products for five major categories, namely ischemic, hemorrhagic, stenosis, carotid artery, vascular access device, and according to Frost & Sullivan, we are the only domestic company in China that has developed a neurovascular product portfolio covering all these five major categories. We have obtained Class III registration certificates for nine neurovascular interventional products and one product is at the registration stage and four are at clinical stage as at the date of this announcement. We expect to have 16 more neurovascular interventional products approved by the end of 2025.

Intracranial Ischemic Stroke Treatment

In the field of ischemic neurovascular diseases, in particular intracranial ischemic stroke, we have five product offerings, among which we have launched Thrombite® CRD, BGC and aspiration catheter successfully as a complete three-piece solution to physicians, the details of which are illustrated in the chart below:



BADDASS Clot-retrieval Approach

We have strategically developed a suite of products covering the full procedure cycle for major vascular diseases, offering seamless treatment solutions with better prognosis.

We are actively promoting our BADDASS (i.e. BALloon guide with large bore Distal access catheter with Dual Aspiration with Stent-retriever as Standard approach) clot-retrieval modality. Multiple academic papers in China and overseas have confirmed the superior clinical application of our BADDASS approach — as compared to mainstream clot-retrieval methods using stent retriever or aspiration catheter only, or stent in combination with intracranial support catheter, our BADDASS approach with three-piece suite of Thrombite® CRD, intracranial support catheter and BGC results in higher first-time recanalization rate of intracranial blood vessels, shorter recanalization time and lower escape rate at the distal end of the thrombus, which can effectively improve the procedure success rate, reduce operation

time and incidence of post procedure complications. Our three key products in BADDASS, namely Thrombite® CRD, intracranial support catheter and BGC, have all received marketing approvals from the NMPA. We are one of the few domestic interventional device companies that can provide a complete three-piece solution.

Thrombite® Clot Retriever Device (Thrombite® CRD)

Our Thrombite® CRD is a minimally invasive device to capture and remove clots blocking blood vessels to treat neurovascular diseases such as AIS. We commenced the clinical trial for Thrombite® CRD in October 2016 and completed such clinical trial in October 2019. We received the registration certificate of Class III medical device from the NMPA in September 2020. We commercialized Thrombite® CRD in China in September 2020. We currently mainly target the China market for Thrombite® CRD. We also obtained CE Mark in January 2020 and started commercialization of Thrombite® CRD in Europe in May 2020.

Clot Retriever Device II (Second Generation Upgraded Product of Thrombite® CRD)

Clot Retriever Device II that we are developing has a similar product structure with the first generation Thrombite® CRD, the multi-segment radiopaque markers of which are expected to deliver better fluoroscopic visualization. We will add more specifications of CRDs, offering physicians more choices when dealing with occluded blood vessels of different diameters and thrombus sizes. The smallest specification of the Clot Retriever Device II is designed to be compatible with 0.017” micro-catheter, which allows physicians to push the clot retriever to the distal end of target blood vessels when necessary.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CLOT RETRIEVER DEVICE II SUCCESSFULLY.

Balloon Guiding Catheter (“BGC”)

Our BGC is a large lumen catheter with a compliance balloon at the distal tip of the catheter. It is designed to facilitate the insertion and guidance of an intravascular catheter. It features various stiffness in different parts of the catheter which provides a combination of sufficient support and flexibility allowing the catheter to navigate through torturous vessel to the target site. High compliance balloon at tip helps to stop blood flow at low inflating pressure, which is critical in neuro intervention procedure. The optimized three-layer coaxial catheter wall design with a mixture of braided wire and polymer jacket enables catheter to have a sufficient large lumen while keeping the outside diameter at low profile to accommodate 8F and 9F sheath. We have obtained NMPA approval for our BGC in June 2021 and have started commercialization in China subsequently.

Aspiration Catheter

Our aspiration catheter is designed for the aspiration and removal of intracranial neurovascular blood clots. It features 4F-8F multiple size options to meet the aspiration needs of different vessel segments. The nitinol spiral and stainless-steel braided structure provides better flatness resistance. We obtained CE Mark for aspiration catheter in April 2021 and started commercialization of aspiration catheter in Europe in May 2021.

Aspiration Pump System

Our aspiration pump system is designed for thrombectomy, with a brand-new impulse aspiration mechanism by implementing automatic valve control. This new feature provides stronger suction effect, which can greatly reduce aspiration time.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR ASPIRATION PUMP SYSTEM SUCCESSFULLY.

Intracranial Stenosis Treatment

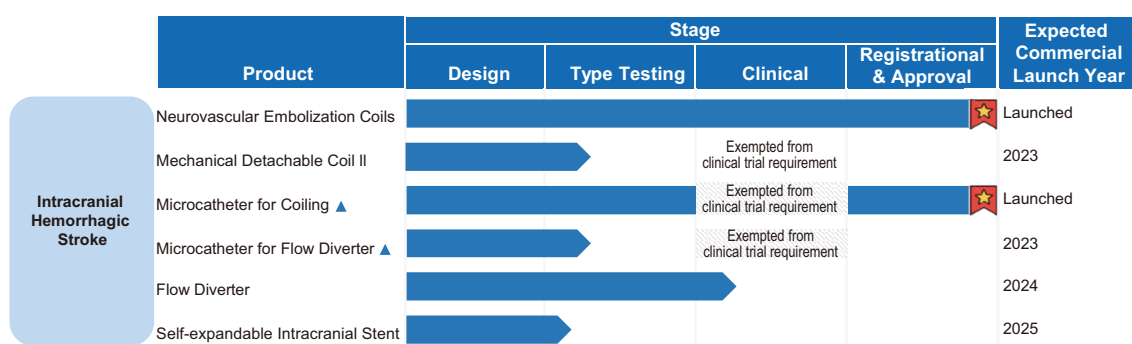
With the development of imaging technology and the increasing social awareness of stroke prevention, intracranial stenosis has attracted great clinical attention and been under rapid development in recent years. Our intracranial stenosis treatment portfolio consists of five products as below:

	Product	Stage				Expected Commercial Launch Year
		Design	Type Testing	Clinical	Registrational & Approval	
Intracranial Stenosis	Intracranial PTA balloon catheter (Rx) ▲			Exempted from clinical trial requirement		Launched
	Intracranial PTA balloon catheter (OTW)			Exempted from clinical trial requirement		2023
	Microcatheter for Intracranial Stent ▲			Exempted from clinical trial requirement		2023
	Intracranial Drug Coated Balloon Catheter					2024
	Intracranial Stent					2025

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR INTRACRANIAL STENOSIS TREATMENT PRODUCTS SUCCESSFULLY.

Intracranial Hemorrhagic Stroke Treatment

In the field of intracranial hemorrhagic stroke, we have two launched products and are developing four product candidates, including four treatment products (the neurovascular embolization coils, the Mechanical Detachable Coil II, the flow diverter, and the self-expandable intracranial stent (previously named as stent for stent assisted coiling)) and two microcatheters (microcatheter for coiling and microcatheter for flow diverter), the details of which are illustrated in the chart below:



Neurovascular Embolization Coils

Our neurovascular embolization coils are a set of flexible coils used in the endovascular coiling procedure, which is a minimally invasive technique using a catheter to reach the aneurysm in the brain, displace the coils to block the blood flowing into the aneurysm, thus reducing the risk of aneurysm rupture. We have received NMPA approval in the fourth quarter of 2021 as expected and have started commercialization in China subsequently. We are in preparation of the CE Mark and FDA 510K registration.

Mechanical Detachable Coil II (Second Generation Upgraded Product of Neurovascular Embolization Coils)

We are upgrading our neurovascular embolization coils to improve their basket-forming performance. More specifications and sizes will be introduced, offering more options for physicians when dealing with different size of intracranial aneurysms. We are also working to optimize the design of delivery system.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP OR MARKET OUR MECHANICAL DETACHABLE COIL II SUCCESSFULLY.

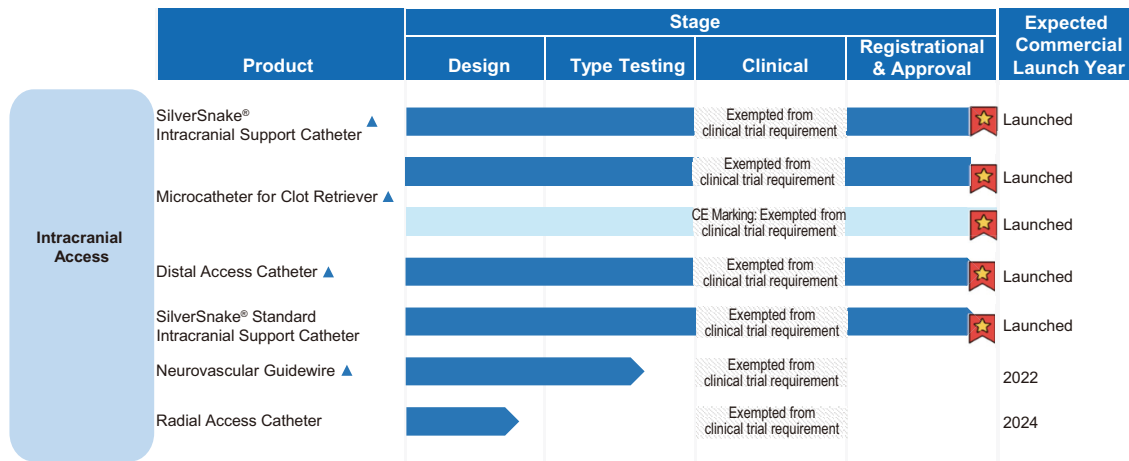
Flow diverter

Our flow diverter is important in endovascular treatment of intracranial aneurysms. It has an optimized metal and mesh coverage, which is capable of changing the hemodynamics in the target artery and promoting formation of the thrombosis inside the tumor cavity and repair of the vascular intima at the tumor neck. Pre-clinical data has supported feasibility, safety and preliminary efficacy of our flow diverter on rabbits. We have initiated the patient enrollment for two clinical trials for two indications, including treatment of both small and giant unruptured intracranial aneurysms in China. In November 2021, we completed the patient enrollment of a prospective, multi-center, single-arm objective performance criteria clinical trial, which is designed to evaluate the efficacy and safety of our flow diverter. The trial achieved significant progress in less than five months since the first patient enrollment initiated in July 2021. Meanwhile, we expect to complete another clinical trial by the end of 2023 for the giant unruptured intracranial aneurysms in China. We will use domestic clinical trial data, combined with European clinical data as a supplement, to apply for CE Mark and support further commercialization of our flow diverter in European market in the future.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR FLOW DIVERTER SUCCESSFULLY.

Intracranial Access

Our intracranial access pipeline includes six products and products candidates, and is as illustrated below:



Our intracranial access products are designed to work together with other treatment products with high compatibility to offer seamless treatment solutions with better prognosis.

Intracranial support catheter

Our intracranial support catheter is one of the important products in our intracranial access product portfolio, and it is designed for delivery of interventional/diagnostic devices in intracranial nerves and blood vessels. It features a nitinol spiral and stainless-steel braided structure with better flatness resistance as compared with similar products on the market, which leads to better abilities to capture the thrombus. The nitinol spiral and stainless-steel braided structure carries a better crossability to reach the M1 segment of the middle cerebral artery. Our intracranial support catheter also features a strengthened arch support design to provide stronger stability and support than its competitors, to effectively prevent the occurrence of catheter separation during the operation. In addition, our intracranial support catheter offers a comprehensive code selection from 95cm to 135cm, ensuring its compatibility with other devices during the procedure. These clinical advantages of our intracranial support catheters have been evidenced by clinical trial results. We obtained NMPA approval for our intracranial support catheter in September 2020 and it was successfully launched in October 2020. The superior clinical performance of intracranial support catheter led to its significant revenue contribution in 2021.

Carotid Artery Stenosis Treatment

Our carotid artery stenosis pipeline includes three products and products candidates, and is as illustrated below:

	Product	Stage				Expected Commercial Launch Year
		Design	Type Testing	Clinical	Registrational & Approval	
Carotid Artery Stenosis	Carotid RX PTA Balloon Catheter ▲			Exempted from clinical trial requirement	▶	2022
	Embolic Protection System ▲			Exempted from clinical trial requirement		2023
	Carotid Stent					2025

Our carotid artery stenosis treatment products are designed to be used in combination, which can ensure product compatibility and improve operational safety through reducing the risk of device retrieval failure and medical accidents caused by product incompatibility during carotid artery revascularization procedures.

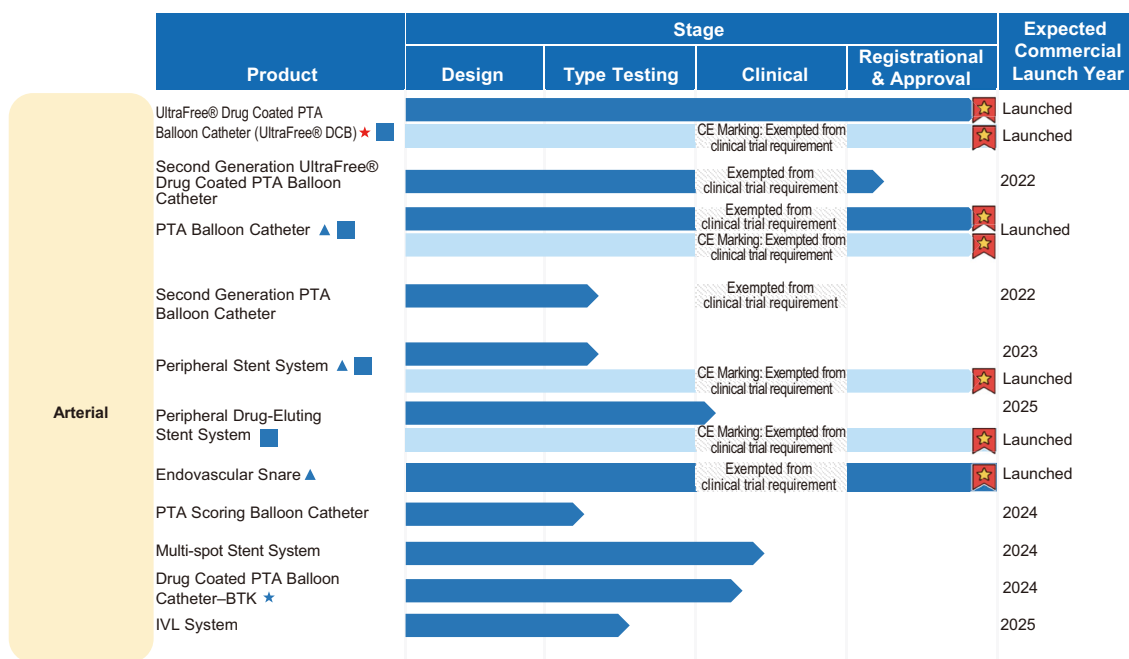
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CAROTID ARTERY STENOSIS TREATMENT PRODUCTS SUCCESSFULLY.

Our Peripheral-Vascular Products

We are one of the first companies that developed a portfolio of peripheral-vascular interventional products in China. With five approved products and 23 product candidates, we have the most comprehensive peripheral-vascular interventional product portfolio among domestic players in China covering a full spectrum of arterial and venous products including stents, balloons, catheters and filters, according to Frost & Sullivan. We have obtained Class III registration certificates for five peripheral-vascular interventional products and four products are at the registration stage and seven are at clinical stage as at the date of this announcement. We expect to have 23 more peripheral-vascular interventional products approved by the end of 2025. According to Frost & Sullivan, we are the first and only domestic player that commercialized peripheral stent system, which is one of the primary products for peripheral vascular disease treatment, in the European market.

Peripheral Arterial Vascular Diseases Treatment

Our peripheral arterial vascular diseases treatment pipeline includes a total of 11 products and product candidates as illustrated below:



UltraFree® Drug coated PTA balloon catheter (UltraFree® DCB)

UltraFree® DCB is an interventional device designed for percutaneous transluminal angioplasty for patients with stenosis or occlusion in femoral artery and popliteal artery (except inferior knee artery). We commenced the clinical trial for UltraFree® DCB in November 2014 and completed such clinical trial in July 2019. We received the registration certificate of Class III medical device from the NMPA in November 2020. We subsequently commercialized UltraFree® DCB in China in December 2020. We currently mainly target the China market. We also obtained CE Mark in October 2020 and commercialized UltraFree® DCB in Europe in the second half of 2021.

The indication expansion of UltraFree® DCB include the following:

- Drug Coated PTA Balloon Catheter — BTK: We initiated the clinical trial preparation in the second half of 2021 and expect to start the patient enrollment in the first half of 2022, and to launch Drug Coated PTA Balloon Catheter — BTK in 2024.
- Drug Coated PTA Balloon Catheter — Dialysis Access: We commenced a clinical trial in February 2021 and are still in the process of patient enrollment. We expect to launch Drug Coated PTA Balloon Catheter — Dialysis Access in 2024.

Second Generation UltraFree® DCB

We have been continuously improving the performance of our UltraFree® DCB, by increasing its flexibility for better crossing, navigation, and dilatation performance. For the second generation of UltraFree® DCB, we have improved the materials of the balloon and optimized the structural design of the catheter, strengthening the support of the catheter lumen and enhancing the pushability and bending resistance of the catheter. We are currently discussing with the NMPA on the registration pathway of the second generation UltraFree® DCB. In addition, it is expected that in 2022, we will initiate a clinical trial in Europe to obtain local clinical trial data to support further development and commercialization of UltraFree® DCB in the European market.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR SECOND GENERATION ULTRAFREE® DCB SUCCESSFULLY.

IVL System

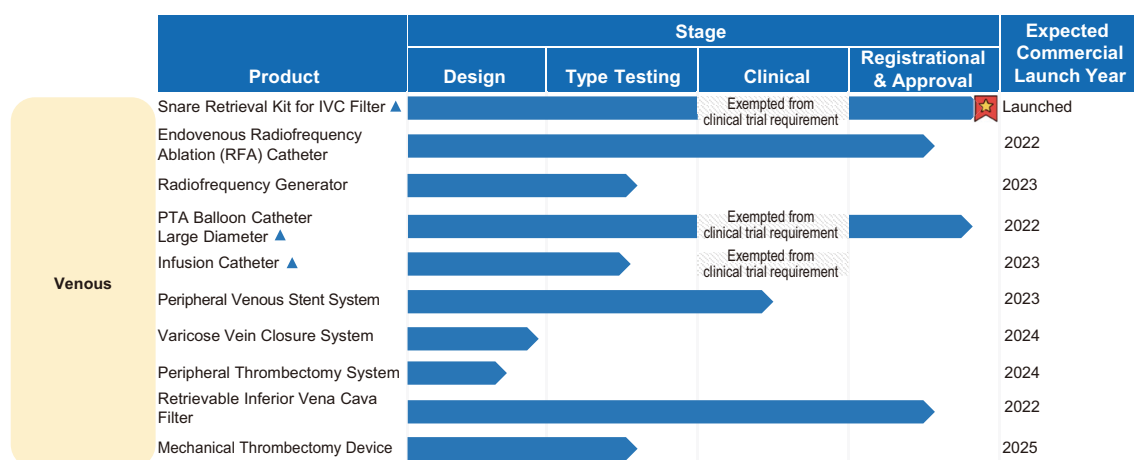
In November 2021, we entered into a collaboration agreement with Hangzhou Sky Road Medical Instrument Co., Ltd. (杭州天路醫療器械有限公司) (“**Sky Road**”), an independent third party of the Company, which granted us the exclusive license regarding certain proprietary technology for developing intravascular lithotripsy (IVL) system for the treatment of peripheral vascular disease, as a valuable addition to our total solution management for lower limb artery diseases.

The technology developed by Sky Road with pending global patents will allow us to develop IVL system for the treatment of medium and heavy calcified arteries in China and globally. The design with innovative intellectual properties realizes safe and intelligent energy control through self-developed algorithms and the preliminary animal study demonstrated superior efficacy and safety as compared to that its comparable products on the market, which is expected to reduce dissection of the blood vessels. The IVL catheter can also be used in combination with our DCB to treat patients with complex calcified vessels. We plan to start the clinical trial in China in the second half of 2022 and expect to obtain the NMPA approval in 2025. We also plan to apply for CE registration for the IVL system, and potentially to obtain approval by the end of 2024 depending on registration pathway which are being discussed with relevant regulatory authorities.

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

Peripheral Venous Vascular Diseases Treatment

Our peripheral venous vascular diseases treatment pipeline includes a total of 10 products and product candidates, including our retrievable inferior vena cava filter and peripheral venous stent system, as illustrated below:



Venous thromboembolism (VTE) refers to a group of diseases in which blood is abnormally coagulated in the venous system due to various causes (such as venous blood stagnation, venous intima injury, or hypercoagulable blood). VTE includes PE and DVT, which are the manifestations of the same disease in different stages and different places.

Retrievable Inferior Vena Cava (“IVC”) Filter

For the prevention of pulmonary embolism (PE), we provide patients with our retrievable inferior vena cava filter. A retrievable IVC filter traps large clot fragments and prevents them from traveling through the vena cava to the heart and lungs, where they could cause severe complications such as pain, difficulty breathing, shortness of breath or even death. We commenced the patient enrollment in March 2020 and completed enrollment of 188 patients in February 2021. We completed the clinical trial in the third quarter of 2021 and submitted the registration application to NMPA in the fourth quarter of 2021. We currently do not have immediate plan to develop this product outside the China market.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR RETRIEVABLE INFERIOR VENA CAVA FILTER SUCCESSFULLY.

Mechanical Thrombectomy Device

Together with IVC filter, which is expected to receive NMPA approval in 2022, we are striving to provide physicians and patients with full solution for treatment of VTE. We have submitted type testing for our latest product, the Mechanical Thrombectomy Device to treat pulmonary embolism (PE). The device is designed based on catheter-directed techniques, which is a pure mechanical method used to remove embolisms and thrombosis from pulmonary vessels through both large-bore aspiration and mechanical retraction, without the need for thrombolytics.

We submitted for type testing in the fourth quarter of 2021 and expect to launch the product in China market in 2025.

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

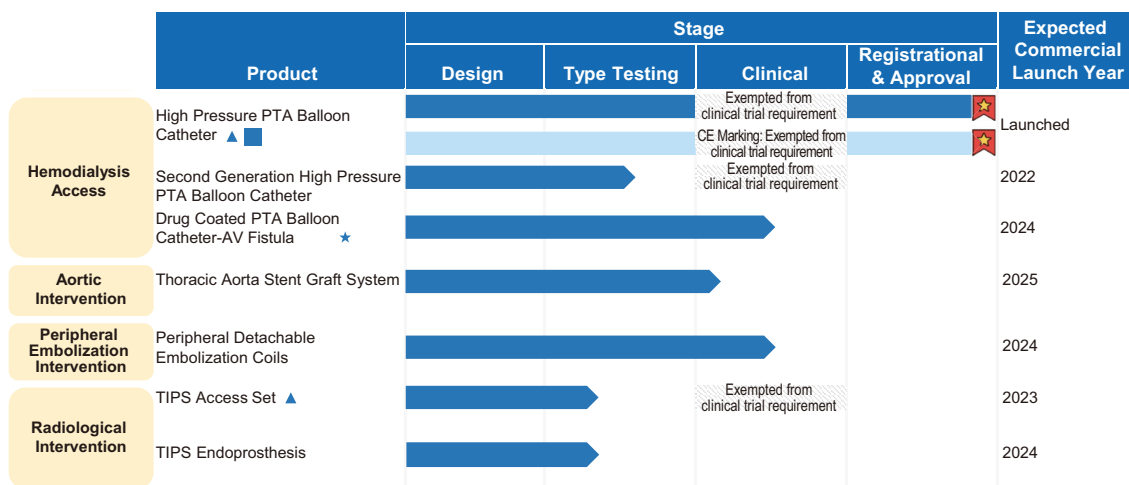
Peripheral Venous Stent System

Our peripheral venous stent system is designed for the treatment of iliac vein stenosis or occlusive disease such as IVCS. We obtained approval from the ethics committee of the principal investigator hospital of a multi-center, randomized and non-inferiority clinical trial in China to investigate the efficacy and safety of our peripheral venous stent system and initiated patient enrollment in October 2020. We completed the patient enrollment process for the clinical trial of peripheral venous stent system in July 2021. We plan to submit the registration application for our peripheral venous stent system with NMPA in early fourth quarter of 2022 after the 12-month follow-up, and expect to receive NMPA approval for peripheral venous stent system in 2023. We are in the process of preparing the registration documents for CE mark and expect to launch this product in CE market in 2024.

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

Other Peripheral-Vascular Products

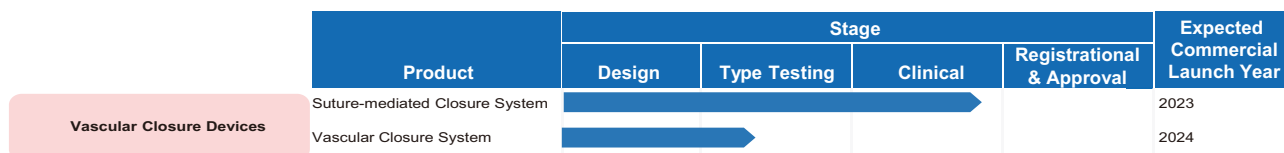
In addition to the peripheral arterial and venous products above, our peripheral-vascular portfolio also covers hemodialysis access, aortic intervention, peripheral embolization intervention and radiological intervention, as illustrated below:



WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OTHER PERIPHERAL-VASCULAR PRODUCTS SUCCESSFULLY.

Our Vascular Closure Product

In addition, our product portfolio also includes two vascular closure device candidates which makes us the first domestic medical device company that has developed suture-mediated vascular closure device candidate.



Suture-mediated Closure System

Our suture-mediated closure system is used to suture the femoral artery access site after diagnostic/therapeutic interventional procedures and is applicable to procedures with bore size ranging between 5F and 29F. We have obtained approval from the principal investigator hospital of a multi-center, randomized and non-inferiority clinical trial in China to investigate the efficacy and safety of our suture-mediated closure system, and started patient enrollment in June 2020. We are in the process of patient enrollment with a target of 228 patients in total according to current clinical trial plan. We currently do not have immediate plan to develop this product outside the China market.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR SUTURE-MEDIATED CLOSURE SYSTEM SUCCESSFULLY.

Vascular Closure System

We are developing another VCD product, the vascular closure system, and is applicable to procedures with bore size no more than 8F. We submitted the type testing in the fourth quarter of 2021 and expect to start patient enrollment in the second half of 2022. We expect to launch this product in China in 2024 and currently do not have immediate plan to develop this product outside the China market.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR VASCULAR CLOSURE SYSTEM SUCCESSFULLY.

Our Platform

As we build our pipeline, we have developed an integrated platform for the discovery, development, manufacture and commercialization of interventional medical devices including neurovascular and peripheral-vascular interventional surgical devices for neurovascular and peripheral-vascular diseases.

Research and Development

We have established in-house R&D capabilities which are manifested by our product innovations, our proprietary technologies and efficient product development process. Leveraging our strong research and development capabilities, we have developed a portfolio of innovative products and product candidates with advanced features that are comparable in performance to imported products by established international brands in the industry. We have developed our R&D capabilities, combined with our extensive registration experience and established strong collaboration with leading physicians and hospitals, also helping improve our clinical trial efficiency and expedite our product advancement. For example, our patient enrollment timeline reduced by half from 25 months in our first

large scale clinical trial to around one year, which is at the top level for similar product in the industry according to Frost & Sullivan. Recently, we completed patient enrollment for peripheral venous stent system and flow diverter for small unruptured intracranial aneurysms in 10 months and less than five months respectively. As of December 31, 2021, we had 12 products in the process of clinical trial. Our track record has demonstrated that we have established capability to push forward a large number of products efficiently and effectively, which is essential for a medical device platform company.

Manufacturing

The manufacturing process of vascular interventional products is complex and technologically challenging. Over the years, we have accumulated extensive expertise and know-how in developing and manufacturing vascular interventional products and obtained a number of patents for our proprietary technologies. Our manufacturing expertise and know-how combined with advanced technologies applied during our manufacturing process help ensure both high quality and efficiency of our production. We had built manufacturing facilities of an aggregate area of approximately 3,800 sq.m. in Hangzhou and Zhuhai. In addition, we are in the process of expanding our production capacity with additional aggregate area of approximately 13,000 sq.m. in Hangzhou and plan to establish a new manufacturing site in Zhuhai with an aggregate area of approximately 20,000 sq.m in preparation for the commercialization of our further expanded product portfolio.

Commercialization

We have a proven track record of commercializing 14 products domestically and eight products in the Europe since our inception in 2012. We employ a strategic offline and online integrated marketing model with a focus on academic promotion to increase market and physician awareness and penetration of our products. We have a dedicated in-house sales team led by Mr. Yang Xie with a focus on academic marketing driven by our extensive expertise and clinical resources. We had also established an extensive distribution network covering over 2,100 hospitals across 22 provinces, four autonomous regions and four municipal cities in China as at December 31, 2021. Over the years, we have developed strong collaborations with and established a well-recognized brand among KOLs, leading physicians and hospitals in China in the field of neuro and peripheral-vascular intervention.

Impact of the COVID-19 Pandemic

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand globally. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. The Chinese government has again implemented significant regional travel restrictions in response to the outbreak of the Delta variant since July 2021 and the Omicron variant since November 2021.

Despite of the foregoing, our revenue for the year ended December 31, 2021, being RMB177.9 million, increased by 543.9% as compared to RMB27.6 million for the year ended December 31, 2020. The pandemic did not have material adverse effect on the Group's commercialization in China and Europe for 2021. As the future impact of COVID-19 in China and Europe is still uncertain, we expect our business operations, planned regulatory process and commercialization in China and Europe will be subject to the impact of the COVID-19 pandemic.

As at the date of this announcement, we had no suspected or confirmed active COVID-19 cases on our premises or among our employees. We will continue to implement our remedial measures and may implement additional measures as necessary to ease the impact of the COVID-19 outbreak on our operations. However, we cannot guarantee you that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial position or prospects.

II. 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, our revenue was mainly generated from sales of our nine commercialized products including Thrombite® CRD, UltraFree® DCB, SilverSnake® intracranial support catheter, intracranial PTA balloon catheter (Rx), PTA balloon catheter, neurovascular embolization coils, snare retrieval kit for IVC filter, high pressure (HP) PTA balloon catheter and distal access catheter.

The Group's revenue for the year ended December 31, 2021 was RMB177.9 million, representing an increase of 543.9% compared to RMB27.6 million for the year ended December 31, 2020. The increase was primarily attributable to (i) the sales revenue from products approved before December 31, 2020, including Thrombite® CRD, UltraFree®DCB and intracranial support catheter, increased 441.5% for the year ended December 31, 2021, as compared to the year ended December 31, 2020; and (ii) since December 31, 2020, we have obtained approvals from the NMPA for eight more products, among which we have successfully launched six products in China as at December 31, 2021. Those launched products, mainly including neurovascular embolization coils and intracranial PTA balloon catheter (RX), contributed more than 15.8% of total revenue for the year ended December 31, 2021.

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

Revenue	Year ended December 31, 2021 (Audited)		Year ended December 31, 2020 (Audited)	
	<i>RMB'000</i>	<i>Proportion</i>	<i>RMB'000</i>	<i>Proportion</i>
Neurovascular interventional devices	112,271	63.1%	19,940	72.2%
Peripheral-vascular interventional devices	65,641	36.9%	7,691	27.8%
Total	<u>177,912</u>	<u>100.0%</u>	<u>27,631</u>	<u>100.0%</u>

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

Revenue	Year ended December 31, 2021 (Audited)		Year ended December 31, 2020 (Audited)	
	<i>RMB'000</i>	<i>Proportion</i>	<i>RMB'000</i>	<i>Proportion</i>
The PRC	174,450	98.1%	24,284	87.9%
Others	3,462	1.9%	3,347	12.1%
Total	<u>177,912</u>	<u>100.0%</u>	<u>27,631</u>	<u>100.0%</u>

Cost of Sales

Our cost of sales primarily consists of raw materials and consumables used, employee benefits expenses, depreciation of right-of-use assets, depreciation of property, plant and equipment, utilities and office expenses and others.

The Group's cost of sales for the year ended December 31, 2021 was RMB46.0 million, representing an increase of 305.8% compared to RMB11.3 million for the year ended December 31, 2020. The increase was primarily attributable to increase in raw materials and consumables used for sales of our products in line with increased commercialization of our marketed products in 2021, and the increase in employee benefits expenses as a result of increase in the number of our employees for expanded production and operation.

Gross Profit and Gross Profit Margin

As a result of the aforementioned factors, the gross profit of the Group increased by 709.7% from RMB16.3 million for the year ended December 31, 2020 to RMB131.9 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 58.9% for the year ended December 31, 2020 to 74.1% for the year ended December 31, 2021, mainly due to (i) since December 31, 2020, we have obtained approvals from the NMPA for eight products, among which we have successfully launched six products in China as at December 31, 2021, and most of them have overall gross profit margin higher than those products commercialized before December 31, 2020; and (ii) we achieved significant progress in the commercialization of our products in China, and domestic sales that have higher gross profit margin as compared to sales overseas contributed much higher percentage of overall revenue for the year ended December 31, 2021 than that for the year ended December 31, 2020.

Research and Development Expenses

The Group's research and development expenses for the year ended December 31, 2021 was RMB168.1 million, representing an increase of 133.3% compared to RMB72.1 million for the year ended December 31, 2020. The increase was primarily attributable to (i) increased number of R&D personnel and share-based payment increased from RMB6.7 million for the year ended December 31, 2020 to RMB39.5 million for the year ended December 31, 2021; and (ii) increased testing, clinical trial, professional service fees and raw material and consumables used from RMB28.1 million for the year ended December 31, 2020 to RMB73.4 million for the year ended December 31, 2021, primarily due to more research and development projects and development of these projects.

Research and development expenses	Year ended December 31, 2021 (Audited)		Year ended December 31, 2020 (Audited)	
	<i>RMB'000</i>	<i>Proportion</i>	<i>RMB'000</i>	<i>Proportion</i>
Employee benefits expenses	85,262	50.7%	35,062	48.7%
Testing and clinical trial fees for research and development	41,386	24.6%	13,109	18.2%
Raw materials and consumables used	24,897	14.8%	9,853	13.6%
Depreciation and amortization	6,549	3.9%	7,319	10.2%
Professional services	7,120	4.2%	5,185	7.2%
Others	2,886	1.8%	1,537	2.1%
Total	<u>168,100</u>	<u>100.0%</u>	<u>72,065</u>	<u>100.0%</u>

Selling and Distribution Expenses

The Group's selling and distribution expenses for the year ended December 31, 2021 was RMB95.3 million, representing an increase of 365.8% compared to RMB20.5 million for the year ended December 31, 2020. The increase was primarily attributable to (i) increased marketing and product education activities along with increasing number of newly launched products and associated expansion of our sales and marketing team; and (ii) increased relevant share-based payment from RMB4.2 million for the year ended December 31, 2020 to RMB15.9 million for the year ended December 31, 2021. The sales and distribution expense, excluding share-based payment, as percentage of overall revenue has been decreased from 58.9% for the year ended December 31, 2020 to 44.6% for year ended December 31, 2021.

Administrative Expenses

The Group's administrative expenses for the year ended December 31, 2021 was RMB100.6 million, representing an increase of 224.6% compared to RMB31.0 million for the year ended December 31, 2020. The increase was primarily attributable to (i) RMB22.7 million of fees in relation to our financing activities, such as IPO and series C+ round of financing; and (ii) increase in our employee benefit expenses, office and utility expenses due to our business growth, in particular, increased relevant share-based payment from RMB11.8 million for the year ended December 31, 2020 to RMB20.7 million for the year ended December 31, 2021.

Other Expenses

The Group's other expenses for the year ended December 31, 2021 was RMB0.7 million, representing an increase of 177.0% compared to RMB0.3 million for the year ended December 31, 2020. The increase was primarily attributable to increased leased area.

Other Income

The Group's other income for the year ended December 31, 2021 was RMB15.3 million, representing an increase of 52.9% compared to RMB10.0 million for the year ended December 31, 2020. The increase was primarily attributable to an increase of government grants in 2021.

Other Gains/(Losses)

The Group's other gains for the year ended December 31, 2021 was a net gain of RMB5.1 million, representing an increase of 288.9% compared to a net loss of RMB2.7 million for the year ended December 31, 2020. The increase was primarily attributable to an increase in interest income on financial assets at fair value through profit or loss.

Finance Income/(Costs) — net

The Group's finance income — net for the year ended December 31, 2021 was RMB12.8 million, representing an increase from a finance cost — net of RMB0.3 million for the year ended December 31, 2020. The increase in finance income/(costs) — net was primarily attributable to an increase in bank interest income in 2021.

Income Tax Expense

The Group did not incur income tax expense for the year ended December 31, 2020 and 2021 as our Group had no assessable profit.

Non-IFRS Measures

To supplement our consolidated statements of profit or loss which are presented in accordance with IFRS, we also use adjusted net loss as non-IFRS measures, which are not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measures when shown in conjunction with the corresponding IFRS measures facilitates a comparison of our operating performance from period to period by eliminating potential impacts of items that our management does not consider to be indicative of our operating performance. Such non-IFRS measures allow investors to consider metrics used by our management in evaluating our performance. From time to time in the future, there may be other items that we may exclude in reviewing our financial results. The use of the

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

The following table shows its reconciliation to loss for the periods indicated:

	Year ended December 31, 2021 (RMB'000) (Audited)	Year ended December 31, 2020 (RMB'000) (Audited)
Loss for the period	(199,689)	(100,468)
Add:		
Share-based compensation ⁽¹⁾	76,211	23,111
Listing expenses ⁽²⁾	22,733	—
Adjusted net loss for the period⁽³⁾	(100,745)	(77,357)

Notes:

- (1) Share-based compensation is non-operational expenses arising from granting shares through the Employee Incentive Platforms and Pre-IPO Share Option Scheme to eligible employees of the Group, 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) Listing expenses are one-off expenses in relation to the IPO and the Global Offering.
- (3) We consider the share-based compensation and listing expenses as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the share-based compensation and listing expenses 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.

Liquidity and Financial Resources

The Group's cash and cash equivalents as at December 31, 2021 were RMB1,418.4 million, representing an increase of 2,281.6% compared to RMB59.6 million as at December 31, 2020. Term deposits as at December 31, 2021 were RMB1,500.0 million as compared to RMB100.0 million as at December 31, 2020. Financial assets measured at fair value were RMB10.5 million as at December 31, 2021 as compared to RMB157.7 million as at December 31, 2020.

We rely on capital contributions by our shareholders as the major sources of liquidity. We also generate cash from our sales revenue of existing commercialized products, including Thrombite® CRD, UltraFree®DCB, SilverSnake® intracranial support catheter, intracranial PTA balloon catheter (Rx), PTA balloon catheter, neurovascular embolization coils, snare retrieval kit for IVC filter, high pressure (HP) PTA balloon catheter and distal access catheter. 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 and accelerating the turnover of trade receivables by tightening our credit policy.

Borrowings and Gearing Ratio

As at December 31, 2021, our borrowings were fully repaid.

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group decreased from 8.1% for the year ended December 31, 2020 to 0.3% for the year ended December 31, 2021 primarily because the Company repaid all the outstanding bank loans and the completion of the series C+ round of financing and initial public offering took place in 2021 and the remaining debt is purely for house leasing.

Net Current Assets

The Group's net current assets, as at December 31, 2021 were RMB2,927.1 million, representing an increase of 819.0% compared to net current assets of RMB318.5 million as at December 31, 2020 primarily due to the IPO and series C+ financing of the Company.

Foreign Exchange Exposure

We have transactional currency exposures. Certain of our bank balances, other receivables, other financial assets, other payables and other financial liabilities 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.

Pledge of Shares

We do not have any pledging of shares by our Single Largest Group of Shareholders.

Significant Investments, Material Acquisitions and Disposals

As at 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.

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.

Events after the Reporting Period

H Share Full Circulation

On November 26, 2021, the Company received a formal official approval from the China Securities Regulatory Commission regarding the implementation of the full circulation of H shares of the Company (“**H Share(s)**”), pursuant to which up to 194,099,746 domestic unlisted shares of the Company (“**Domestic Unlisted Share(s)**”) can be converted into H Shares, and their listing thereof on the Stock Exchange. On January 18, 2022, the Stock Exchange granted approval for the listing of and permission to deal in 194,099,746 H Shares, representing the maximum number of Domestic Unlisted Shares to be converted to H Shares. On March 3, 2022, the conversion of 194,099,746 Domestic Unlisted Shares into H Shares has been completed, and listing of such shares on the Stock Exchange commenced on March 4, 2022. For more related details, please refer to the Company’s announcements dated November 26, 2021, February 28, 2022 and March 3, 2022.

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

Employees and Remuneration Policies

As at December 2021, we had 487 employees in total.

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

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 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 limit to internal funds and bank loans.

III. PROSPECTS

We plan to implement the following strategies to achieve our mission and vision:

Further strengthen our commercialization capabilities to solidify our leadership in China

We plan to further strengthen our commercialization capabilities to accelerate sales of our approved product and late-stage product candidates. We will further deepen our collaboration with KOLs and physicians and continue to actively participate in academic promotion such as providing product education to physicians to further increase adoption of our products, and enhance recognition for our product offering and innovation. To increase penetration among our covered hospitals and enter into new hospitals, we expect to further expand the distribution network for both of our existing and future commercialized products by cooperating with additional distributors who have impressive sales records in high-growth regions in China. We plan to coordinate our sales and marketing team to support these distributors to reach their sales targets. In preparation for the sales expansion of our marketed products and upcoming commercialization of our product candidates at registration stage, we intend to further scale up our sales and marketing team by hiring additional experienced sales personnel.

We also endeavor to enhance our manufacturing capabilities to support the sales of our approved products and expedite the commercialization of our products candidates. We believe that the ability to cost-effectively manufacture high-quality products on a commercial scale is key to meeting the fast-growing market needs and capturing additional growth opportunities. We have completed construction of our new headquarters manufacturing facilities in Hangzhou with aggregate area of approximately 13,000 sq.m. As of the date of this announcement, the new facilities in Hangzhou have preliminary been used to manufacture sample of our candidates, and are expected to be in full operation by the end of 2022. In addition, we plan to expand the manufacturing facilities in Zhuhai to capture the market demand of our products, including Thrombite® CRD. We intend to build a new manufacturing site in Zhuhai with an aggregate area of approximately 20,000 sq.m., which is expected to enter into full operation by the end of 2022. We also plan to further enhance our manufacturing capacities by investment in automation to meet growing market needs.

Continue to accelerate product development and expand our product portfolio to provide total solutions

We believe our leadership is, and will continue to be, attributable to our successful development of a robust portfolio of complementary and advanced products. We will continue to accelerate product development and expand our product portfolio.

We currently have an extensive portfolio with 55 products and product candidates in different development stages. We plan to obtain NMPA approvals for nine products in 2022 and obtain NMPA approvals for other candidates by 2025. We plan to accelerate the clinical trial and registration of such product candidates. We currently have 12 products in the clinical trial stage. We will leverage our close relationships with KOLs and leading hospitals to accelerate patient enrollment for our clinical trials. Some of our product candidates are eligible for clinical trial exemption under the Catalogue of Medical Devices Exempted from Clinical Trials (《免於進行臨床試驗醫療器械目錄》) issued by the NMPA. We will further enhance our development efforts in type testing, animal study and product registration for these exempted product candidates in order to further enrich our product portfolio.

In addition, we plan to expand our portfolio to cover more indications in neuro- and peripheral vascular areas and provide more effective solutions to patients and physicians, gradually increasing our market penetration. We plan to conduct further studies on our approved products, such as product improvements to realize whole-device imaging and longer treatment window for Thrombite® CRD, as well as material upgrade and indication expansion to cover BTK indications, dialysis fistulae for UltraFree® DCB. On the back of the breadth of our portfolio, we are confident to provide total solutions to the full spectrum of neuro- and peripheral-vascular diseases.

To further enhance our product development capabilities, we plan to expand our R&D team and improve execution efficiency throughout the development processes. We expect to hire additional R&D members with solid academic background and extensive industry experience in order to further accelerate our product development pace and expand our portfolio.

Further advance R&D capabilities to support our long-term growth

We plan to further enhance our R&D capability focusing on interventional solutions tailored for neuro- and peripheral-vascular diseases in China. We will continue to invest in technology innovations to support the development of next generation products. We also plan to improve our R&D efficiency leveraging our synergistic technology platforms in neuro- and peripheral-vascular fields.

To advance our R&D efforts, we plan to recruit more talents to strengthen our internal R&D teams. We intend to strengthen our collaboration with KOLs and leading physicians and hospitals to gain first-hand knowledge of current and unmet clinical needs, surgeons' preferences and clinical trends, in order to enhance the clinical utility of our products and therefore increase the market potential of our product candidates.

In addition, we may strategically collaborate with academic institutions or medical associations on developing new products to broaden our product portfolio. We also plan to complement our organic growth with prudent investment, acquisition or partnership. Particularly, we plan to opportunistically acquire product candidates which have advanced technologies or have synergies with our existing research and development infrastructure. To pursue such opportunities, we will explore suitable investment and partnership arrangements, including establishing strategic alliances, joint ventures and in-licensing relationships. We believe that our extensive industry knowledge and R&D expertise, and proven product development speed will not only empower us to promptly identify and capture potential targets to enhance our R&D capabilities, but also make us a more desirable acquirer or partner than our competitors.

Further develop our integrated platform and enhance operational efficiency

We plan to further streamline our integrated platform with comprehensive R&D, manufacturing and commercialization capabilities. With our continuously growing operation scale, we will further centralize and unify our management in procurement, clinical trial, registration, manufacturing and quality control, in order to enhance our overall operational efficiency.

We believe that manufacturing capability and quality control are critical to the expansion of our product portfolio. Our new manufacturing facilities in Hangzhou are expected to be in full operation by the end of 2022, which will enhance our manufacturing capacity and help further centralize our procurement and production processes. We plan to strengthen our production efficiency by streamlining supply chain management, quality control systems and reducing raw material and processing costs. We intend to continue in-house production for all our future marketed products.

With the successful registrations for 17 products and our regulatory experience with the NMPA registration process and CE Mark, we plan to further implement centralized product registration management which allows us to share such experience among various registration processes and to reduce the costs and time involved in the clinical trial and product registration for our product candidates.

We plan to enhance the core competency of every aspect of our integrated platform, from R&D, manufacturing to commercialization, which in turn will further promote the overall competitiveness of our Company. We aim to upgrade from an R&D-driven company to a full-powered integrated platform. We will maximize the synergy effect of our integrated platform to rely on the revenue from our commercialized products and other resources to support the development and commercialization of our other product candidates, which in turn will generate more revenue thereby mitigating the uncertainties and risks involved in the development of innovative medical devices and ensure sustainable growth.

Selectively expand our global footprint

As of the date of this announcement, we have obtained CE Mark for eight products and commercialized all products in Europe, including Thrombite® CRD, peripheral stent system, PTA balloon catheter and HP PTA balloon catheter. Leveraging our successful overseas registration and sales experiences, we intend to pursue geographical expansion in selected markets based on different product demands, adopting tailored strategies to commercialize our products in different target jurisdictions, including joint development, granting commercial rights to third parties and cooperation with distributors. We hold global rights of our products and product candidates through patent registration and protection over proprietary technologies. We may enter into partnership arrangements to expand our market coverage and maximize the global value of our products. In particular, we have considered the geographical distance, disease similarity, regional competitive landscape of medical device, and local regulatory conditions for our plan to expand geographical coverage.

To promote our brand name overseas, we plan to become a regular and long-term participant of LINC and join more prominent international medical conferences and industry exhibitions such as World Live Neurovascular Conference, and conferences held by European Stroke Organization and World Stroke Organization. We plan to leverage our brand name in China and high product quality to promote our brand awareness and build our reputation among influential KOLs and major medical associations globally. Led by our management team's global vision and leveraging our proven R&D, manufacturing and commercialization capabilities, we may also strategically import advanced technologies, invention patents and product prototypes from overseas or collaborate with overseas companies to co-develop products to expand our global footprint.

CORPORATE GOVERNANCE RELATED INFORMATION

Compliance with the Corporate Governance Code

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in the Corporate Governance Code as contained in Appendix 14 to the Listing Rules as its own code of corporate governance practices. The Board is of the view that during the Relevant Period, the Company has complied with all the applicable code provisions as set out in the Corporate Governance Code, except for the code provision C.2.1 as explained below.

Pursuant to code provision C.2.1 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between the chairman and the chief executive officer should be segregated and should not be performed by the same individual. Up to the date of this announcement, the roles of chairman and chief executive officer were performed by Dr. Jonathon Zhong Zhao, which may be inconsistent with code provision C.2.1. Nevertheless, the Board considers that this arrangement is proper and beneficial to the Group as the stability and efficiency of the Company's operations, as well as the continuity of the Company's policies and strategies, can be maintained. Going forward, the Board will periodically review the effectiveness of this arrangement and considers appointing another individual as the chief executive officer when it thinks appropriate.

The Board will continue to review and monitor the code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

Compliance with the Model Code

The Company has adopted the Model Code set out in Appendix 10 to the Listing Rules as its code of conduct regarding dealings in the securities of the Company by the Directors, the Supervisors and the Group's employees who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company's securities. Specific enquiries have been made to all Directors and Supervisors and the Directors and the Supervisors have confirmed that they have complied with the Model Code throughout the Relevant Period.

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

Purchase, Sale or Redemption of the Company's Securities

During the Relevant Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed the Company's listed securities.

Audit Committee

The Audit Committee has three members comprising all independent non-executive Directors, being Ms. Yun Qiu (chairman of the Audit Committee), Dr. Jian Ji and Mr. Hongze Liang, with terms of reference in compliance with the Listing Rules. The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Company and the Group and discussed matters in relation to internal control, risk management and financial reporting with the management. The Audit Committee reviewed the annual financial results for the year ended December 31, 2021 and considers that the annual financial results are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Scope of Work of the Company's Auditors

The figures in respect of the Group's consolidated balance sheet, consolidated statement of 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, PricewaterhouseCoopers, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by PricewaterhouseCoopers in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by PricewaterhouseCoopers on the preliminary announcement.

FINAL DIVIDEND

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

ANNUAL GENERAL MEETING

An announcement containing information in relation to the latest registration date and the period of closure of share register for attending 2021 annual general meeting of the Company (expected to be held before June 30, 2022) will be published separately when the date of 2021 annual general meeting of the Company is fixed.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (<http://www.zyloxtb.com>).

The annual report of the Company for the year ended December 31, 2021 containing all the information required by the Listing Rules will be despatched to the Company's shareholders and published on the websites of the Stock Exchange and the Company in due course.

DEFINITIONS

“AIS — acute ischemic stroke”	one subtype of ischemic intracranial vascular diseases, which is caused by thrombotic or embolic occlusion of an intracranial artery
“Audit Committee”	the audit committee of the Board
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“BGC — balloon guiding catheter”	a large lumen catheter with a compliance balloon at the distal tip of the catheter. intending to facilitate the insertion and guidance of an intravascular catheter
“Board”	the board of Directors
“CE Mark”	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
“China” or “PRC”	the People's Republic of China, which for the purpose of this Prospectus and for geographical reference only, excludes Hong Kong, Macao and Taiwan

“Company”, “our Company”, “Group”, “our Group”, “We” “our” or “us”	Zylox-Tonbridge Medical Technology Co., Ltd. (歸創通橋醫療科技股份有限公司), a limited liability company incorporated in the PRC on November 6, 2012 and converted into a joint stock limited liability company incorporated in the PRC on March 2, 2021, whose predecessor was Zhejiang Zylox Medical Device Co., Ltd. (浙江歸創醫療器械有限公司), and the H Shares of which are listed on the Hong Kong Stock Exchange (stock code: 2190), which includes its subsidiaries (from time to time) as required by the context
“Core Products”	Thrombite® CRD and UltraFree® DCB, the designated “core products” as defined under Chapter 18A of the Listing Rules
“Corporate Governance Code”	the “Corporate Governance Code” as contained in Appendix 14 to the Listing Rules
“CRD — clot retriever device”	a minimally invasive device to capture and remove the clot blocking blood vessels to treat neurovascular diseases such as acute ischemic stroke
“DCB — drug-coated balloon”	angioplasty balloons (usually semi-compliant) coated with a cytotoxic chemotherapeutic agent
“Director(s)”	the director(s) of the Company
“DVT — deep vein thrombosis”	occurring when a blood clot forms in one or more of the deep veins in the body, usually in the leg
“Employee Incentive Platforms”	Hangzhou Fujiang Investment Partnership (Limited Partnership) (杭州涪江投資合夥企業(有限合夥)), Zhuhai Guichuang Equity Investment Center (Limited Partnership) (珠海歸創股權投資中心(有限合夥)), Zhuhai Tongqiao Investment Center (Limited Partnership) (珠海通橋投資中心(有限合夥)) and Huzhou Guiqiao Enterprise Management Partnership (Limited Partnership) (湖州歸橋企業管理合夥企業(有限合夥))
“Frost & Sullivan”	Frost & Sullivan International Limited, an independent market, research and consulting company

“Global Offering”	the Hong Kong Public Offering and the International Offering (each as defined in the Prospectus)
“H Share(s)”	the overseas listed foreign shares in the share capital of our Company with nominal value of RMB1.00 each, which are listed on the Stock Exchange
“HKD” or “HK\$”	Hong Kong dollars and cents, both are the lawful currency of Hong Kong
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“ischemic stroke”	a stroke caused by a blockage in an artery that supplies blood to the brain
“IVC — inferior vena cava”	a large vein that carries the deoxygenated blood from the lower and middle body into the right atrium of the heart
“IVCS — iliac vein compression syndrome”	a syndrome in which the iliac vein is compressed by the iliac artery that spans from its front, resulting in changes such as intraluminal adhesion, luminal stenosis, or occlusion of the vein, which in turn causes obstruction of the iliac vein flow, producing a range of clinical symptoms
“KOL(s)”	Key Opinion Leader(s), renowned physicians that are able to influence their peers’ medical practice
“LINC”	Leipzig Interventional Course, an interdisciplinary live course widely regarded as one of the most authoritative industry events for the discussion of advanced technologies used in endovascular interventions
“Listing” or “IPO”	the listing of the H Shares on the Main Board of the Stock Exchange on July 5, 2021
“Listing Date”	the date on which our H Shares are listed and from which dealings are permitted to take place on the Stock Exchange, being July 5, 2021
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time

“Main Board”	the stock exchange (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with Growth Enterprise Market of the Hong Kong Stock Exchange
“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 Products Administration of the People’s Republic of China
“non-inferiority clinical trial”	a clinical trial that tests whether a new treatment is not worse than an active treatment it is being compared to
“PE — pulmonary embolism”	a blockage in one of the pulmonary arteries in the lungs. Caused by blood clots that travel to the lungs from deep veins in the legs or, rarely, from veins in other parts of the body
“Pre-IPO Share Option Scheme”	the pre-IPO share option scheme of our Company approved and adopted by our Board on January 18, 2021, as amended from time to time
“Prospectus”	the prospectus issued by the Company dated June 22, 2021
“PTA — percutaneous transluminal angioplasty”	a percutaneous interventional procedure that can open up blocked peripheral arteries using a catheter with a balloon at the end of it, allowing blood to circulate unobstructed
“Relevant Period”	the period from the Listing Date to December 31, 2021
“Reporting Period”	the one-year period from January 1, 2021 to December 31, 2021
“RMB”	Renminbi, the lawful currency of the PRC
“Share(s)”	the ordinary shares in the capital of our Company with a nominal value of RMB1.00 each
“Shareholder(s)”	the holder(s) of the Shares

“Single Largest Group of Shareholders”	refers to Dr. Jonathon Zhong Zhao (趙中), Dr. Shengping Sam Zhong (鍾生平), Dr. Zheng Li (李崢), Ms. Na Wei (衛娜), Zhuhai Tongqiao Investment Center (Limited Partnership) (珠海通橋投資中心(有限合夥)), Hangzhou Fujiang Investment Partnership (Limited Partnership) (杭州涪江投資合夥企業(有限合夥)), Zhuhai Guichuang Equity Investment Center (Limited Partnership) (珠海歸創股權投資中心(有限合夥)), Huzhou Guiqiao Enterprise Management Partnership (Limited Partnership) (湖州歸橋企業管理合夥企業(有限合夥)), WEA Enterprises, LLC and Huzhou Yuyihui Investment Partnership (Limited Partnership) (湖州語意慧投資合夥企業(有限合夥)) (formerly known as Nanjing Yuyihui Investment Partnership (Limited Partnership) (南京語意慧投資合夥企業(有限合夥)))
“Stock Exchange” or “Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary(ies)”	has the meaning ascribed thereto under the Listing Rules
“USD”	United States dollars, the lawful currency of the United States of America
“Supervisor(s)”	member(s) of the supervisory committee of the Company
“U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“vascular intima”	the inner layer of the blood vessel that is in contact with blood flow

“VCD — vascular closure device”

a medical device used to achieve hemostasis of the small hole in the artery after a cardiovascular procedure of endovascular surgery requiring a catheterization

“%”

percent

By order of the Board
Zylox-Tonbridge Medical Technology Co., Ltd.
Dr. Jonathon Zhong Zhao
Chairman and Executive Director

Hong Kong, March 15, 2022

As of the date of this announcement, the Board comprises Dr. Jonathon Zhong Zhao, Mr. Yang Xie and Dr. Zheng Li as executive Directors, Mr. Stephen Hui Wang, Dr. Hai Lu and Dr. Steven Dasong Wang as non-executive Directors, and Dr. Jian Ji, Mr. Hongze Liang and Ms. Yun Qiu as independent non-executive Directors.