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Acotec Scientific Holdings Limited

2023 Business Performance Review

Mar. 2024

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01 2023 Financial Performance Review

02 The Progress of CCT Implementation

03 Product Commercialization

04 R&D and Product Approvals

05 Other Important Matters

06 Q&A

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01

2023 Financial Performance Review

2023 Financial Performance Review — Revenue & Gross Profit

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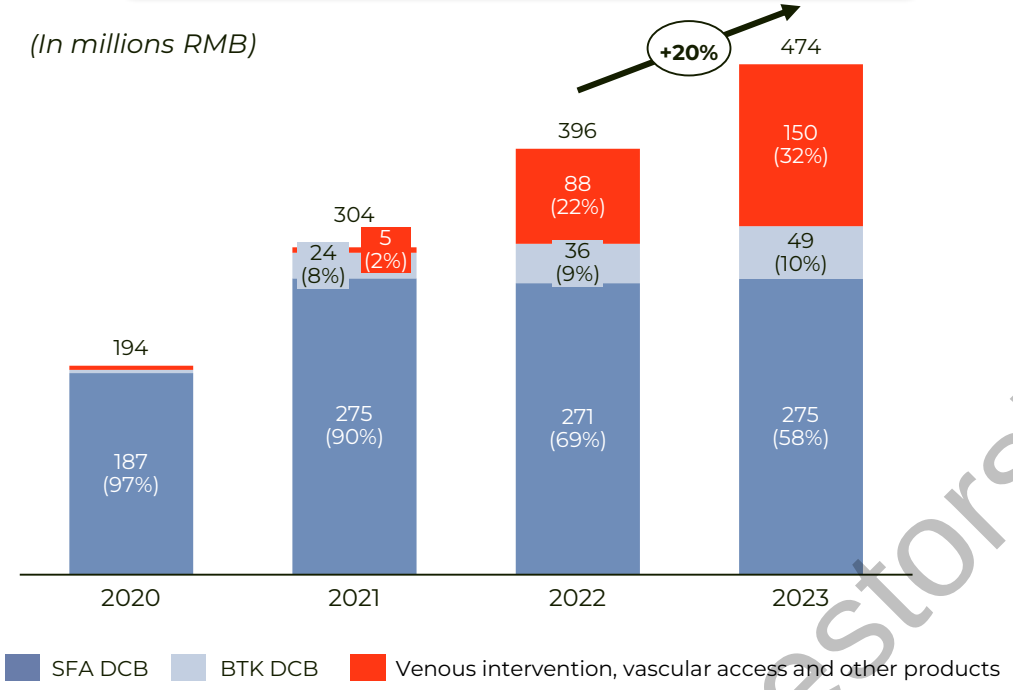
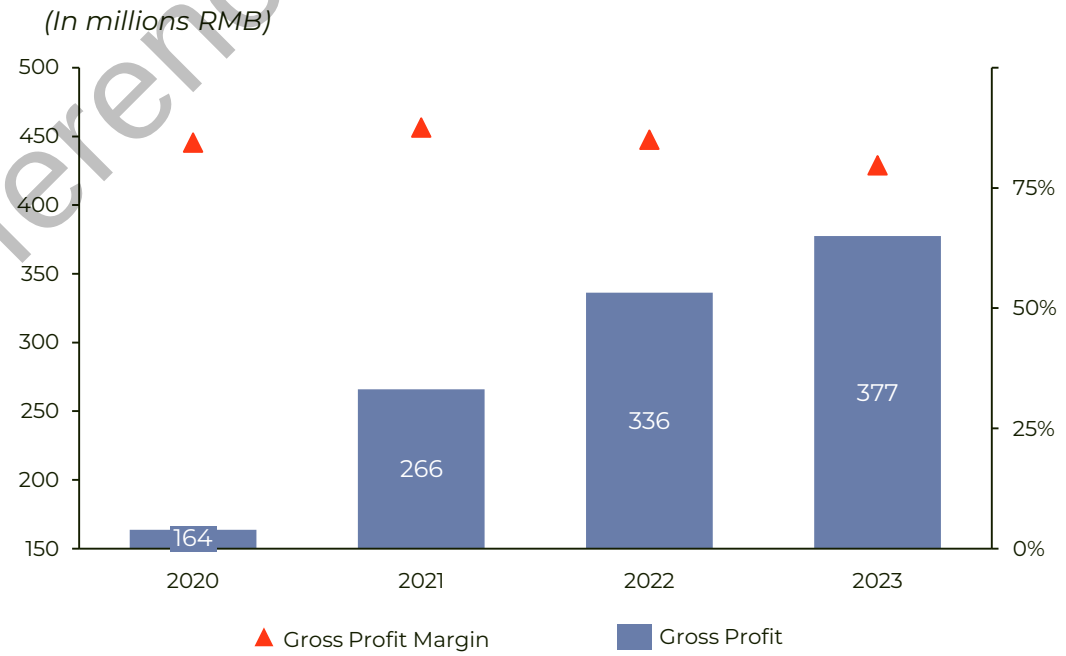
The business sustained rapid growth while achieving a more diversified income



- Acotec achieved a revenue of **RMB 474mn** in 2023, showing robust growth with a **20% increase** over the previous period.
- **Peripheral DCB** contributed **RMB 324 mn** in revenue, accounting **for 68% of total revenue**: SFA DCB revenue remained steady at RMB 275mn, while **BTK DCB** revenue saw a yoy growth of **34% at RMB 49mn**.
- Revenue from **Venous Intervention, vascular access, and other products** reached **RMB 150mn**, marking a **yoy growth of over 70% and contributing 32% of total revenue**, serving as a significant driver for the company's business expansion.

We maintained a high GP level as multiple products enter the commercialization phase



- Acotec attained a **gross profit of RMB 377mn**, with a gross profit margin of approximately **80%**. The GPM has slightly declined compared to the previous year, this change can be attributed to: 1) **Reclassification of certain expenses** from administrative and R&D categories to production costs; and 2) While the **GPM of venous intervention products is lower than DCB**, **the revenue contribution** from venous intervention products **is rapidly increasing**.

2023 Financial Performance Review — Expense and Net Profit

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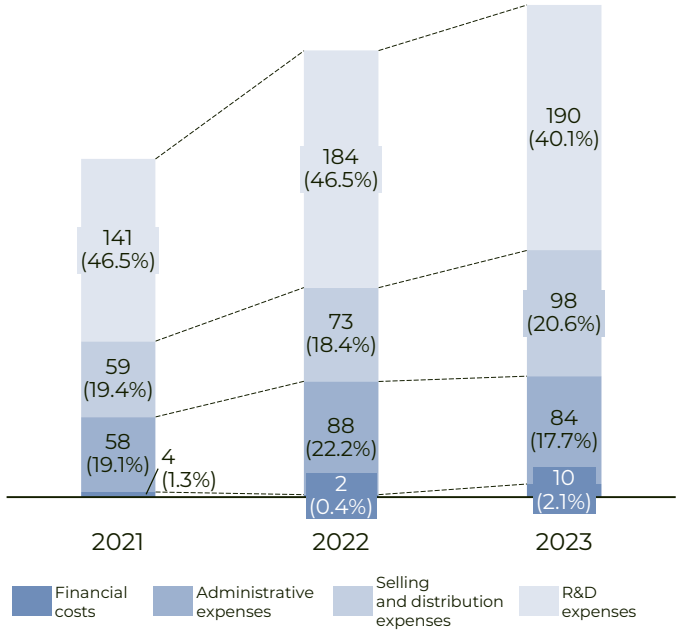
Expenses

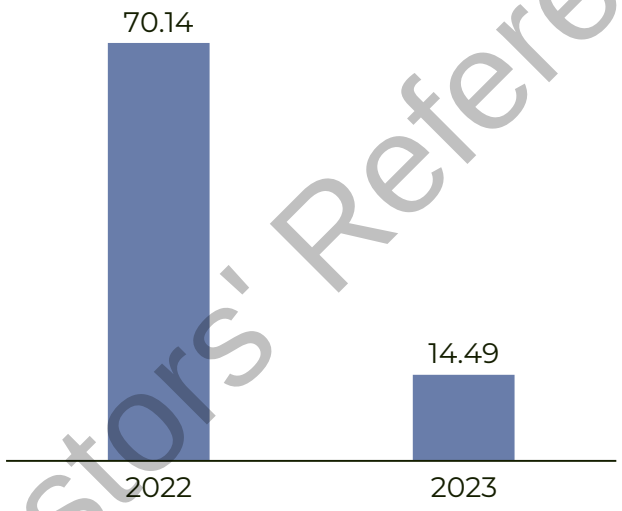
(In millions RMB)



- We prioritized R&D investment to progress pipeline development and clinical work, with R&D expenses around RMB 190mn. **The R&D expense ratio** decreased from 46.5% in 2022 to **40.1% in 2023**.
- Administrative expenses amounted to RMB 84mn, and the **administrative expense ratio** decreased from 22.2% in 2022 to **17.7%** due to **enhanced management and operational capabilities**.
- Sales expenses rose primarily due to increased marketing and offline activities after the pandemic.

Net Profit

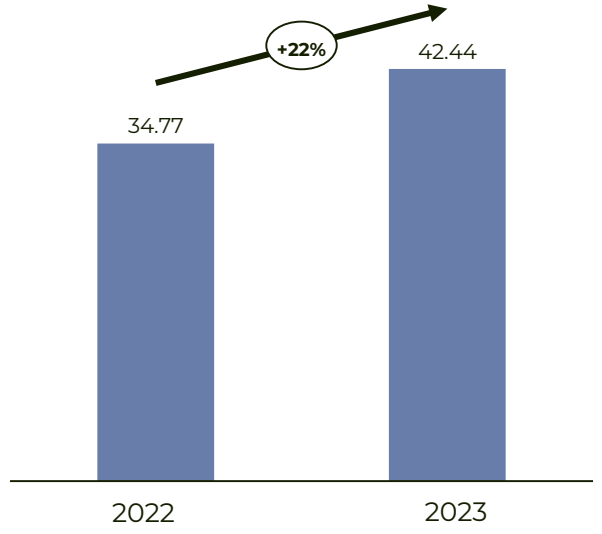
(In millions RMB)



- We achieved a net profit of RMB 14.5mn in 2023.
- In 2022, the company's net profit mainly came from exchange gains.

Adjusted net profit

(In millions RMB)



- In 2023, the adjusted net profit was approximately RMB 42.4mn, showing a yoy increase of 22.1%. The adjusted net profit reflects the company's optional profit capability, excluding the impact of share-based payment, net exchange gains or losses, and one-off transaction cost on net profit.
- The **company has achieved self-sufficiency** in its core operations and possesses sustainable profitability.

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02

The Progress of CCT Implementation

Key Updates on Collaboration with BSC (1/2)

Commercialization Collaboration Progress

Overseas Market

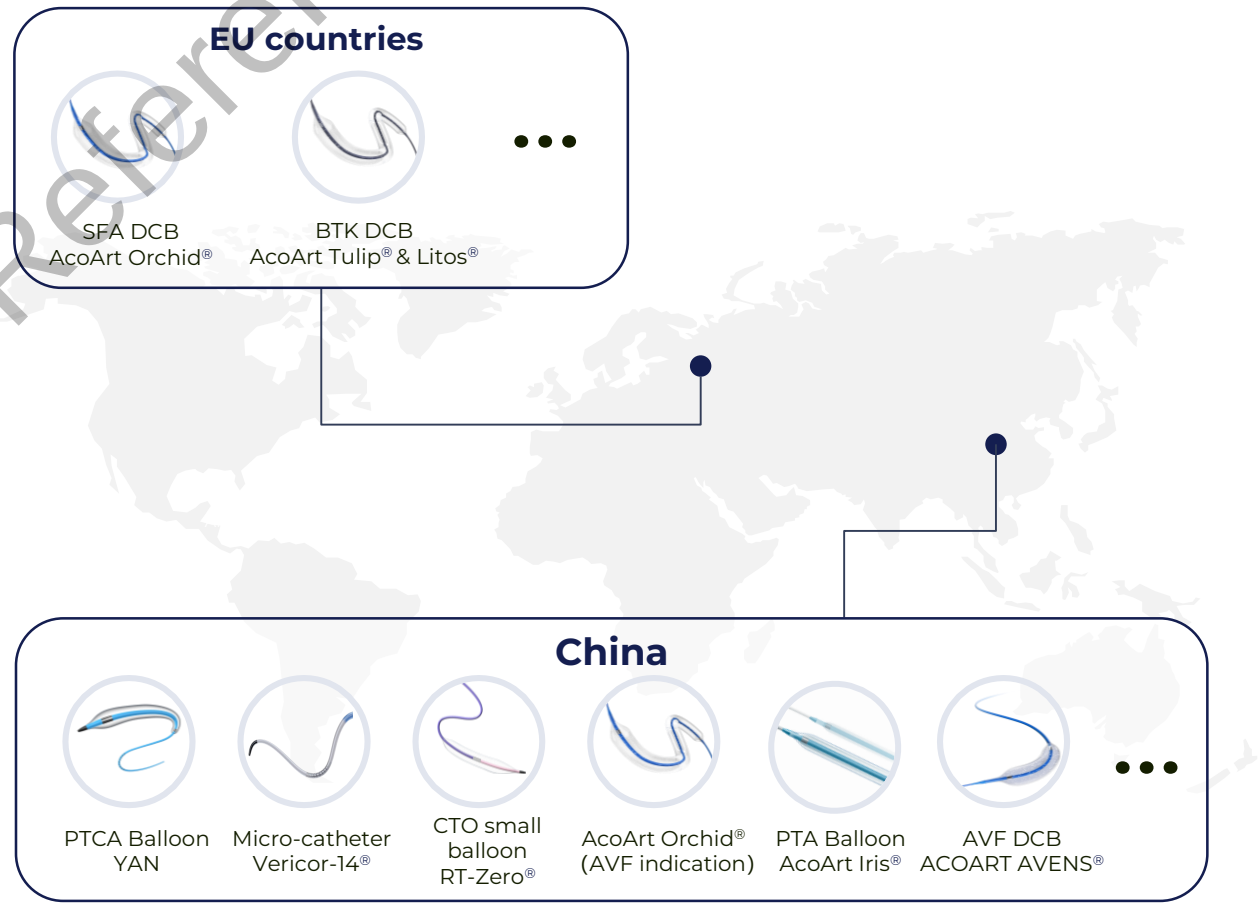
- **Distribution Agreement signed** for **SFA & BTK DCB sales in EU market** in 2023.
- By the end of 2023, BSC has commenced selling Acotec products overseas.

Chinese Market

- **Distribution Agreement signed** for Approved **Coronary Products**(YAN, RT-Zero® and Vericor-14®), and **AVF Products** (AcoArt Orchid® (AVF indication), ACOART AVENS®, etc.) in 2023. BSC has commenced selling Acotec products.
- **The collaboration scope will broaden** with the expected approval of several new products in 2024.

Global Expansion landscape of Collaborative Products

With the launch of additional products in China and globally, the scope and geographical coverage of collaboration is continuing to expand.



Key Updates on Collaboration with BSC (2/2)

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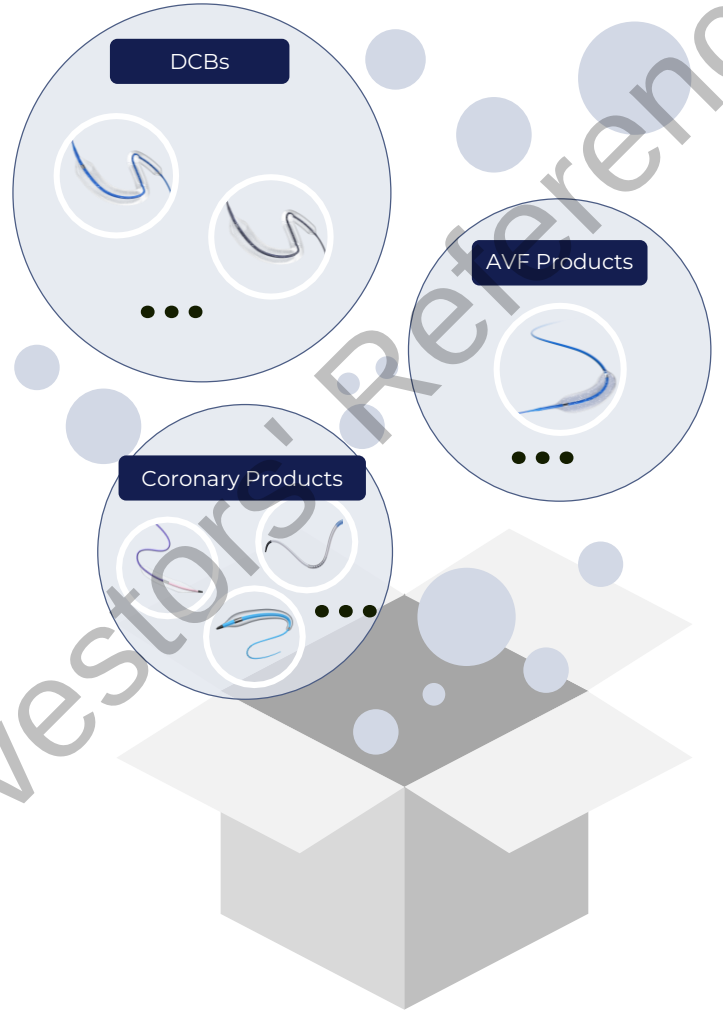
Internal Process Alignment and Qualification Completed in 2023

- **Qualified Supplier**
- **Supply Chain Integration**

- Acotec is **accelerating the overseas product registration process** to meet the increasing sales demands of BSC.

More countries,
More products...



Estimated Revenue from Collaboration in 2024

¥40 Million

1. FX: 7.19
2. The estimated revenue for collaborative products, including signed and pending contracts.

03

Product Commercialization

We maintained market competitiveness through our reliable products and first-mover advantage.

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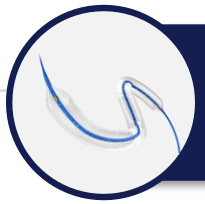

SFA DCB
AcoArt Orchid® & Dhalia®/ Orchid Plus

1600

Hospital Admitted

- The first approved product in China, with early-mover advantage and outstanding clinical performance, established a strong competitive edge;
- Still the leading brand in market share.

冀 HEBEI

- Winning bids in Hebei+ Sanming VBP;
- The VBP is gradually being implemented in various regions and cities.

BTK DCB
AcoArt Tulip® & Litos®

770

Hospital Admitted

- Exclusive products in China;
- We strive to enhance doctors' treatment philosophies and skills.

Peripheral Aspiration System
AcoStream®

1300

Hospital Admitted

- 2 generations of products consolidate our market competitiveness;
- Huge and Urgent demand in lower-tier markets;
- A vital growth driver for the company.

豫 HENAN

- Winning the bid in Henan's VBP has accelerated product admissions in hospitals and increased implanting volumes.

RFA System
AcoArt Cedar®

350

Hospital Admitted

- Continuously expanding hospital coverage, conducting training programs to enhance doctors' skills and knowledge, promoting therapy transformations.

豫 HENAN

- Winning the bid in Henan's VBP has accelerated product admissions in hospitals and increased implanting volumes.

04

R&D and Product Approvals

Multiple products have been approved for market domestically and internationally in 2023

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15
Approved Products
(24/02/29)

15
Overseas countries where we have launched products
(24/02/29)

2 Products obtained approvals overseas

Vascular Surgery

Vericor®
Peripheral Support Catheter

Cardiology

Vericor-14®
Coronary CTO Antegrade Micro-Catheter

4 Products obtained NMPA Approvals

Vascular Surgery

Upgrade

2 Gen AcoStream®
Peripheral Aspiration System

Nephrology

Upgrade

AcoArt Avens®
Paclitaxel Coated High-pressure Balloon

Cardiology

RT-Zero®
Coronary CTO Recanalization Balloon

Vericor-14®
Coronary CTO Antegrade Micro-Catheter

2 Products update registration

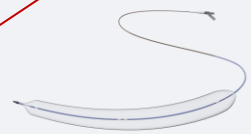
Vascular Surgery

Upgrade

AcoArt Iris®
PTA Balloon

- Added large diameter balloon specifications.
- Product structure upgrade.

Upgrade



P-Conic®
Tapered PTA Balloon

- Added the specification of diameter above 4.0 mm, which is unique domestically.

Products and Pipeline-Overview

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15 Commercialized Products

9 Vascular surgery

Artery

Vascular Treatment:
(1) SFA DCB
(2) BTK DCB

Vessel Preparation :
(1) AcoArt Iris® & Jasmin®
(2) AcoArt Lily® & Rosmarin®
(3) P-Conic®

Vascular Access:
(1) Vericor ®

Vein

- Venous Thrombosis
  1st & 2nd Gen AcoStream®
- Varicose Vein:
  RFA Syatem AcoArt Cedar®

3 Cardiology
- YAN
- RT-Zero®
- Vericor-14®

1 Nephrology
- ACOART AVENS®
- SFA DCB for AVF
- Pridge®

1 Neurology
- Neo-Skater®

11 Product Candidates under Development & Clinical Trail

3 Indication Expansion for Core Products

6 Vascular surgery

4 Cardiology

1+1 Neurology

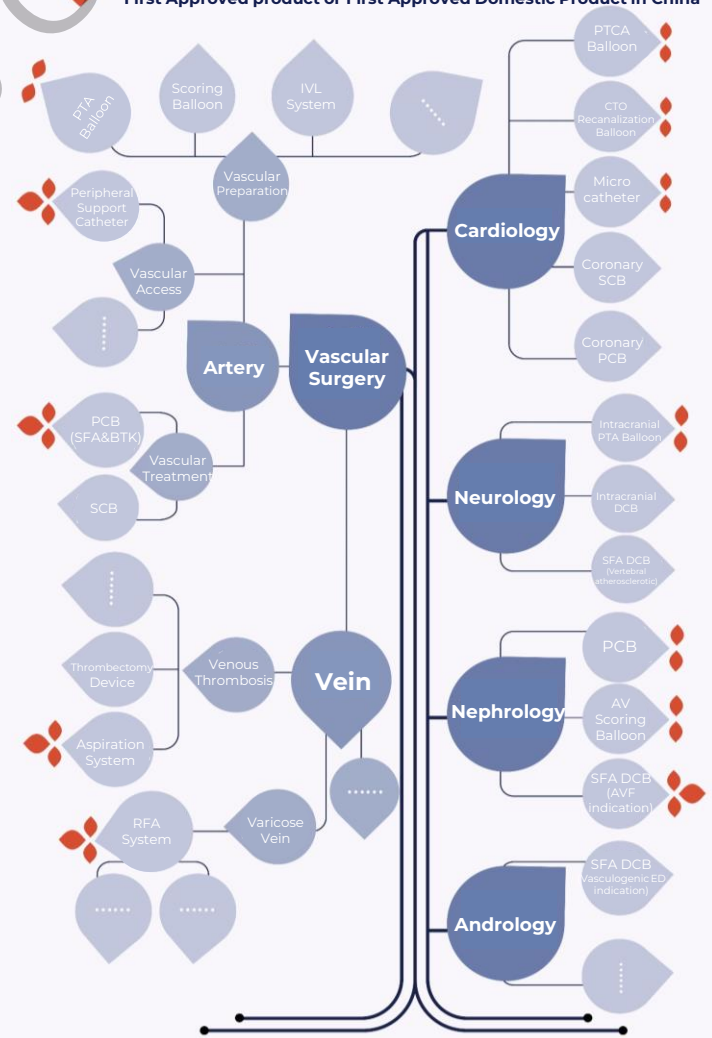
2 Andrology

15 Overseas countries where we have launched products or have products received marketing approvals

Product Pipeline

Approved products

First Approved product or First Approved Domestic Product in China



Comprehensive Solution for Vascular Diseases

We have launched several first & best-in-class products, and the approval process is accelerating both in domestic and international market

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2016-2021	2022	2023	2024	2025-2026
5	5 + 1	4 + 2	1 + 6	4 + 1

2016-2021 (5)

- SFA DCB
- BTK DCB
- 1st Gen Peripheral Aspiration System
- PTA Balloon
- PTA Balloon

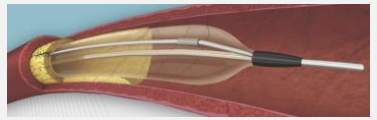
2022 (5 + 1)

- RF Ablation System
- Peripheral Support Catheter
- AVF DCB (indication expansion)
- Intracranial PTA Balloon
- Tapered PTA Balloon
- Semi-compliant PTCA Balloon

2023 (4 + 2)

- 2nd Gen Peripheral Aspiration System
- AVF DCB
- Coronary CTO Antegrade Micro-Catheter
- Coronary CTO Recanalization Balloon
- PTA Balloon
- Tapered PTA Balloon
- BTK DCB — **FDA IDE Approval**

2024 (1 + 6)

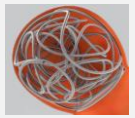


Peripheral Scoring Balloon (Approved)

DCBs

- Intracranial Paclitaxel coated Balloon
- SFA DCB & BTK DCB (Indication expansion for Vertebral atherosclerotic stenosis)
- Coronary Sirolimus coated Balloon
- Coronary Paclitaxel coated Balloon

Submitted registration application



Peripheral Coil

Coronary Micro-catheter

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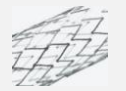
2025-2026 (4 + 1)

DCB Product

- Peripheral Sirolimus coated Balloon

IVL System (Peripheral &Coronary)



Spot Stent

.....

The First Approved Product in China
The First Approved Domestically Manufactured Product in China
Approved Product(s)
Indication Expansion for DCB
Products ready for approval
Products with added specifications approved
Product Candidate
DCB Indication Expansion

Products and Pipeline-Full Product Portfolio

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Department	Products and Product Candidates	Indications / Applications	Key Technologies	Phase				Upcoming Milestone
				Area	Pre-clinical Studies	Clinical Studies	Registration	
Vascular Surgery	AcoArt Orchid® & Dhalia®/Orchid Plus★ Note 1	Superficial femoral artery (SFA) and popliteal artery (PPA) disease	Drug coating technology	China			NMPA Approval★	/
				EU			CE★	/
	AcoArt Tulip®& Litos®★	Below-the-knee (BTK) artery disease	Drug coating technology	China			NMPA Approval★	/
				EU			CE★	/
				U.S.		FDA IDE Approval		
	AcoArt Iris® & Jasmin®	PTA Balloon applied in PTA procedure	Polymer materials	China			NMPA Approval★	/
				EU			CE★	/
	AcoArt Lily® & Rosmarin®	PTA Balloon applied in PTA procedure	Polymer materials	China			NMPA Approval★	/
				EU			CE★	/
	Peripheral Aspiration System (AcoStream®)▲	DVT, ALI	Aspiration platform	China		Exempted from clinical trial	NMPA Approval★	/
				Brazil			ANVISA Approval★	/
	Radiofrequency Ablation System (AcoArt Cedar®)	Saphenous varicose veins	RF platform	China			NMPA Approval★	/
	Peripheral Support Catheter (Vericor®)▲	Peripheral CTO lesion	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	/
				U.S.			FDA Approval★	/
				Brazil			ANVISA Approval★	/
				Thailand			TFDA Approval★	/
				Japan			MHLW Approval★	/
	PTA Balloon (P-Conic®)	PTA	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	/
	2nd Gen Peripheral Aspiration System (2nd Generation AcoStream®)▲	DVT, ALI	Aspiration platform	China		Exempted from clinical trial	NMPA Approval★	/
	Peripheral Spot Stent	SFA and PPA disease	Polymer materials	China				2026
	Lower Limb Sirolimus DCB	SFA and PPA disease	Drug coating technology	China				2026
	Peripheral Scoring Balloon	SFA and PPA disease	Polymer materials	China				2024
	Peripheral Coil	Embolization	Polymer materials	China				2024
	Peripheral Thrombectomy Device	DVT, ALI and PE	Polymer materials	China				2025
	Peripheral IVL System	Intravascular calcium	Polymer materials	China				2026

★Core product ☆ Indication expansion of core product ★Commercialization

▲ 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.

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

Products and Pipeline-Full Product Portfolio

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Department	Products and Product Candidates	Indications / Applications	Key Technologies	Phase				Upcoming Milestone
				Area	Pre-clinical Studies	Clinical Studies	Registration	
Cardiology	Semi-compliant PTCA Balloon (YAN)	PTCA	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	/
	Coronary CTO Recanalization Balloon (RT-Zero®)▲	Coronary CTO	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	/
	Coronary CTO Antegrade Micro-Catheter (Vericor-14®) ▲	Coronary CTO	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	/
				Japan			MHLW Approval★	/
				Thailand			TFDA Approval★	/
	Coronary Retrograde Micro-Catheter (Vericor-RS®) ▲	Coronary CTO	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	
	Coronary High-Pressure Balloon (YIYAN)	PTCA	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	
	AcoArt Camellia® (DCB)	Coronary small vessel diseases	Drug coating technology	China				2024
	Coronary Sirolimus DCB	Bifurcation lesions	Drug coating technology	China				2024
	Coronary IVL System	Coronary lesion calcium	Polymer materials	China				2026
Nephrology	AcoArt Orchid®& Dhalia®/Orchid Plus☆(DCB)	Arteriovenous fistula stenosis	Drug coating technology	China			NMPA Approval★	/
	Paclitaxel Coated High-pressure Balloon ACOART AVENS®▲	AVF PTA procedure	Drug coating technology	China			NMPA Approval★	/
	AV Scoring Balloon (Peridge®) Note 2	AVF PTA procedure	Polymer materials	China			NMPA Approval★	/
Neurology	Intracranial PTA Balloon (NEO-Skater®)▲	Intracranial PTA procedure	Polymer materials	China		Exempted from clinical trial	NMPA Approval★	/
	AcoArt Orchid®& Dhalia®/Orchid Plus☆(DCB)	Vertebral atherosclerotic stenosis	Drug coating technology	China				2024
	AcoArt Daisy®	Intracranial atherosclerotic stenosis	Drug coating technology	China				2024
Andrology	AcoArt Orchid®& Dhalia®/Orchid Plus☆(DCB)	Vasculogenic erectile dysfunction	Drug coating technology	China				2026
	AcoArt Tulip®& Litos®☆	Vasculogenic erectile dysfunction	Drug coating technology	China				2026

★Core product ☆ Indication expansion of core product ★Commercialization

Note 2: AV Scoring Balloon (Peridge®) obtained the registration approval from the NMPA on January 30, 2024.

AcoArt Litos® Received FDA IDE Approval, Clinical Trials are scheduled to commence in the U.S.

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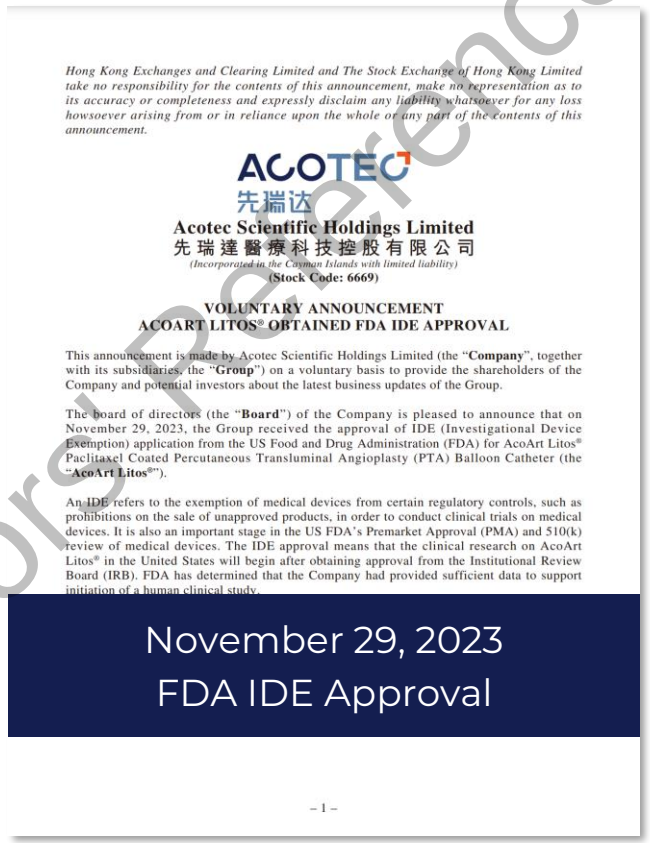
Peripheral DCB (BTK)
AcoArt Litos®



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(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 6669)

VOLUNTARY ANNOUNCEMENT
ACOART LITOS® OBTAINED FDA IDE APPROVAL

This announcement is made by Acotec Scientific Holdings Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to provide the shareholders of the Company and potential investors about the latest business updates of the Group.

The board of directors (the "**Board**") of the Company is pleased to announce that on November 29, 2023, the Group received the approval of IDE (Investigational Device Exemption) application from the US Food and Drug Administration (FDA) for AcoArt Litos® Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (the "**AcoArt Litos®**").

An IDE refers to the exemption of medical devices from certain regulatory controls, such as prohibitions on the sale of unapproved products, in order to conduct clinical trials on medical devices. It is also an important stage in the US FDA's Premarket Approval (PMA) and 510(k) review of medical devices. The IDE approval means that the clinical research on AcoArt Litos® in the United States will begin after obtaining approval from the Institutional Review Board (IRB). FDA has determined that the Company had provided sufficient data to support initiation of a human clinical study.

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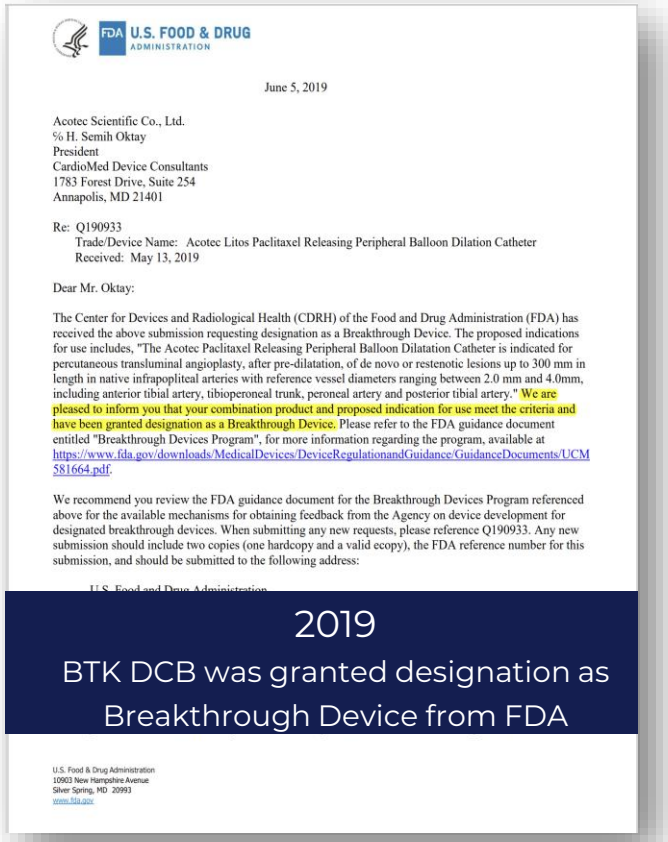
November 29, 2023
FDA IDE Approval



FDA U.S. FOOD & DRUG ADMINISTRATION

June 5, 2019

Acotec Scientific Co., Ltd.
% H. Semih Oktay
President
CardioMed Device Consultants
1783 Forest Drive, Suite 254
Annapolis, MD 21401

Re: Q190933
Trade/Device Name: Acotec Litos Paclitaxel Releasing Peripheral Balloon Dilation Catheter
Received: May 13, 2019

Dear Mr. Oktay:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission requesting designation as a Breakthrough Device. The proposed indications for use includes, "The Acotec Paclitaxel Releasing Peripheral Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 300 mm in length in native infrapopliteal arteries with reference vessel diameters ranging between 2.0 mm and 4.0mm, including anterior tibial artery, tibioperoneal trunk, peroneal artery and posterior tibial artery." We are pleased to inform you that your combination product and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

We recommend you review the FDA guidance document for the Breakthrough Devices Program referenced above for the available mechanisms for obtaining feedback from the Agency on device development for designated breakthrough devices. When submitting any new requests, please reference Q190933. Any new submission should include two copies (one hardcopy and a valid ecopy), the FDA reference number for this submission, and should be submitted to the following address:

U.S. Food and Drug Administration

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

2019
BTK DCB was granted designation as Breakthrough Device from FDA

Acotec Intracranial DCB, AcoArt Daisy®, achieves excellent clinical trial results

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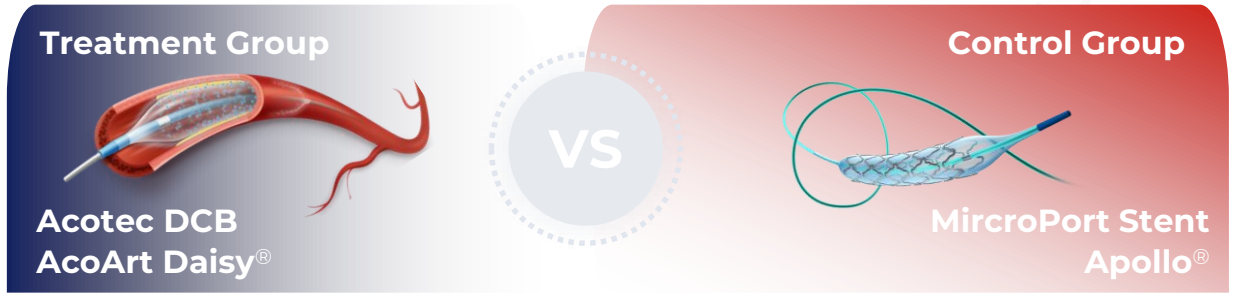
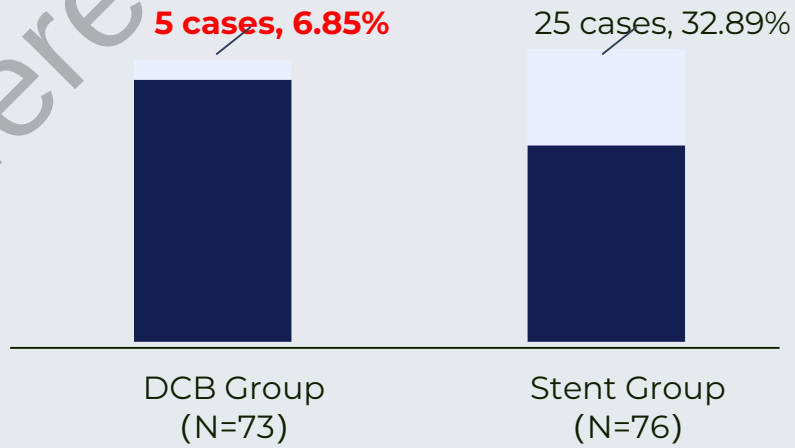
Clinical Trial Design



Study Objective	To verify the efficacy and safety of intracranial DCB in the endovascular treatment of symptomatic intracranial atherosclerotic stenosis.
Study Design	Prospective, multicenter, randomized controlled non-inferiority trial
Patients Enrollment	180 patients 1:1 allocate to the DCB group and the Stent group.
Primary Study Endpoints	6-month follow-up: Restenosis rate of the target lesion

DCB demonstrates superior vessel patency maintenance at the 6-month post-operation

The restenosis rate at 6-month follow-up



Superior efficacy clinical trial results

The target lesion restenosis rate at 6-month

	DCB Group	Stent Group	Rate difference and 95% CI
Number of Follow-up Cases	73	76	NA
Number of Cases with Lesion Restenosis	5	25	NA
Restenosis Rate	6.85% (5/73)	32.89% (25/76)	-19.02% (-27.42, -6.18%)

The launch of the Acotec intracranial DCB will fill a domestic and international gap, bringing better clinical benefits to patients

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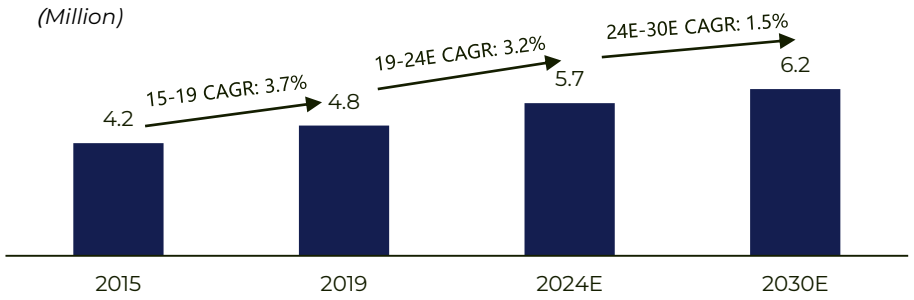
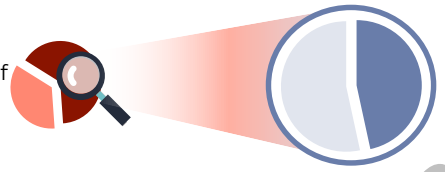
Stroke poses a serious threat, with a rising number of cases in China



- Stroke is the second leading cause of death and the third leading cause of disability globally.
- The CAGR of Chinese stroke cases was at 3.7% from 2015 to 2019, with nearly **5mn strokes recorded in 2019.**
- The incidence of strokes is increasing, ranking as **the top cause of death** among Chinese residents in 2017.

Treatment of ICAS holds significance in stroke prevention

Ischemic strokes account for **70.2%** of all strokes



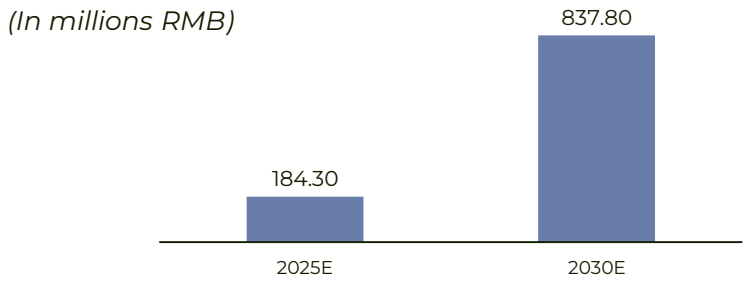
Ischemic strokes combined with ICAS account for **46.6%**

- Intracranial arterial stenosis (ICAS) is a significant factor in ischemic stroke occurrence and recurrence.
- In China, the incidence of ICAS among stroke and Transient Ischemic Attack (TIA) patients is as high as 46.6%.
- ICAS treatment is crucial in stroke prevention.

Forecasted volume of ICAS interventional procedures

- With an recorded 5mn stroke cases in 2019, including around 3.5mn ischemic strokes, approximately 1.6mn cases involve ICAS.
- Considering the rising patient awareness and the advancing maturity of intracranial vascular disease intervention, the projected volume of interventional surgeries is expected to **reach 287.3 thousand per year by 2030.**

Market size forecast for DCB in treating ICAS



- Based on data analysis, after the approval and introduction of Acotec intracranial DCB, the market size for intracranial DCB (ICAS indication) is forecasted to reach approximately **RMB 837.8mn by 2030**.

Data sources: Anand Alurkar et al.; Stroke. 2013; 44:2000-2003; Jiang Weijiang et al.; Multicenter analysis of symptomatic intracranial atherosclerotic stenting; Endovascular Treatment of Symptomatic Intracranial Atherosclerotic Stenosis - Chinese Expert Consensus (2018); Drug-Coated Balloon for Treatment of Symptomatic Intracranial Atherosclerosis: Initial Experience and Follow-Up Results; Neuro Elutax SV Drug-Eluting Balloon vs. Wingspan Stent System in Symptomatic Intracranial High-Grade Stenosis: Single-Center Experience; DOI: 10.3969/j.issn.1673-5765.2018.06.012; Endovascular Treatment of Symptomatic Intracranial Atherosclerotic Stenosis - Chinese Expert Consensus (2018); WANG YJ, ZHAO XQ, LIU LP et al. Prevalence and outcomes of symptomatic intracranial large artery stenoses and occlusions in China: the Chinese Intracranial Atherosclerosis (CICAS) study [J]. Stroke, 2014, 45(3): 663-669.; Frost Sullivan Analysis.

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Other Important Matters

We are enhancing manufacturing capacity in Beijing & Shenzhen to meet increasing market demand

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2+M Units/Year

One-shift Production Capacity, can double by working in two shifts
(After Beijing & Shenzhen New Facility put in use)

1+M Units/Year

Production Capacity for OEM, can double by working in two shifts
(After Beijing & Shenzhen New Facility put in use)

The gross floor area of production facilities

35,000m²	9,100m²
Beijing	Shenzhen

Production Capacity

760,043	307,412	40.4%
Production Capacity	Actual Production Volume	Utilization Rate


Lab


Manufacturing Area


Office


Clean Room

Beijing Manufacturing Facility

Shenzhen Manufacturing Facility

In 2023, we aim to improve the team's quality and offer ample career development opportunities for employees.

Supplementing fresh blood through campus recruitment

- In 2023, the company conducted campus recruitment at top-tier universities, bringing in high-quality new talents to our team.
- We established a management trainee program for fresh graduates and offered comprehensive training courses to cultivate high-potential talents for the company.

- By the end of 2023, We have a strong in-house R&D team of 120+ members base in Beijing, Shenzhen and California.
- Our team has experts in various fields such as materials science, biomedical engineering, automation, computer programming, etc., helping to advance the rapid development of products.

- In 2023, our frontline sales and regional marketing teams continued to facilitate hospital coverage expansion, physician education, and accelerated product commercialization.

- The construction of our manufacturing team is the fundamental pillar for ensuring product supply. We remain committed to maintaining the stability of our team to ensure optimal production efficiency.

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06

Q&A

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THANKS!

谢谢！

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