

# 2023 Annual Results

Hangzhou Tigermed Consulting Co., Ltd. 300347.SZ / 3347.HK

March 2024

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#### **Forward-Looking Statements**

The information communicated herein may contain certain "forward-looking statements", which are not historical facts but instead include predictions about future events based on our beliefs and information currently made available to us. Although we believe that these predictions are reasonable on the date hereof, future events are inherently uncertain and these forward-looking statements may turn out to be incorrect. Forward-looking statements involve risk and uncertainty by nature because they relate to events and will depend on circumstances that will occur in the future relating to, inter alia, our ability to compete effectively, our ability to develop and market new service offerings, our ability to expand into new markets, the risks associated with listed subsidiaries of the Company, unforeseeable international tensions, regulatory or governmental scrutiny in certain countries, the impact of emergencies and other force majeure events. We undertake no obligations to update forward-looking statements or to adapt them to future events or developments except as required by applicable laws or listing rules. Any investment in any securities issued by the Company or its subsidiaries will also involve certain risks. There may be additional material risks that are currently not considered to be material or of which the Company and its advisors or representatives are unaware. Against the background of these uncertainties, you should not rely on these forward-looking statements.

#### **Non-IFRS Measure**

To supplement our financial information which are presented in accordance with IFRS, we use adjusted net profit attributable to owners of the Company as an additional financial measure, which is not required by, or presented in accordance with IFRS. We define adjusted net profit attributable to owners of the Company as profit for the year attributable to owners of the Company before certain expenses and amortization. We define adjusted net profit attributable to owners of the Company as profit for the year attributable to owners of the Company before certain expenses and amortization. We define adjusted net profit attributable to owners of the Company as profit for the year attributable to owners of the Company is not an alternative to (i) profit before tax, profit for the year or profit for the year attributable to owners of the Company (as determined in accordance with IFRS) as a measure of our operating performance, (ii) cash flows from operating, investing and financing activities as a measure of our ability to meet our cash needs, or (iii) any other measures of performance or liquidity. We believe that this non-IFRS measure is useful for understanding and assessing underlying business performance and operating items that we do not consider indicative of the performance of our business. However, the presentation of this non-IFRS measure is not intended to, and should not, be considered in isolation from or as a substitute for the financial information prepared and presented in accordance with the IFRS. You should not view the non-IFRS measure on a stand-alone basis or as a substitute for results or a similarly titled financial information prepared and presented in accordance with the IFRS, or as being comparable to results or a similarly titled financial measure reported or forecasted by other companies.





### 2023 Results Overview

### 2023 Business Highlights



Provided services to **22** Class I new drugs and **6** innovative medical devices in China in 2023

Provided services to 61% of all Class I new drug approvals in China from 2004 to 2023

Maintained our leading position in China clinical CRO and increased investments in emerging business and technology, and ecosystem building

Continued to expand overseas, and achieved rapid growth in both revenue and backlog for our US clinical business

Business and profitability demonstrated strong **resilience and sustainability** amid the industry transformation

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### **Ongoing Projects**<sup>(1)</sup>

752 Drug Clinical Trials

253 Overseas Clinical Trials including 59  $\ensuremath{\mathsf{MRCTs}}^{(2)}$ 

465 Medical Device and IVD Projects

1,952 Site Management Projects

826 DMSA<sup>(3)</sup> Projects

4,411 Laboratory Services Projects



#### Corporate Updates<sup>(1)</sup>

**9,701** total employees in **28** countries worldwide, including **1,632** overseas employees

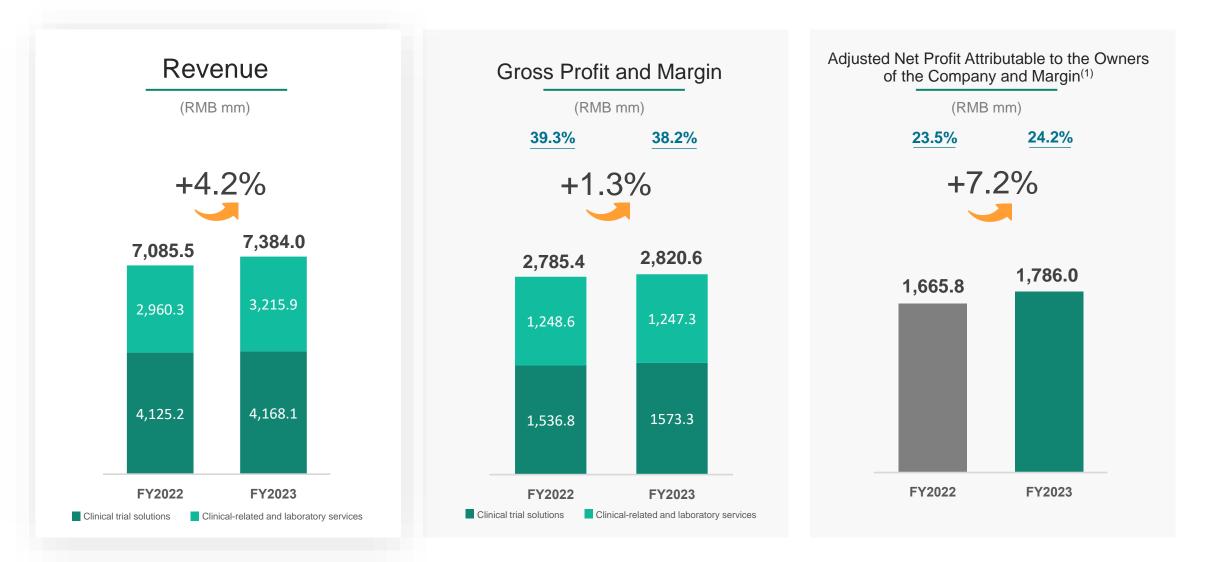
Opened **International Headquarters** in Hong Kong as the main hub for overseas functional support and business development

Global team with **950+** CRAs, **2,700+** CRCs, **850+** DMSA experts and **1,700+** laboratory services personnels

MSCI ESG Rating upgraded to AA

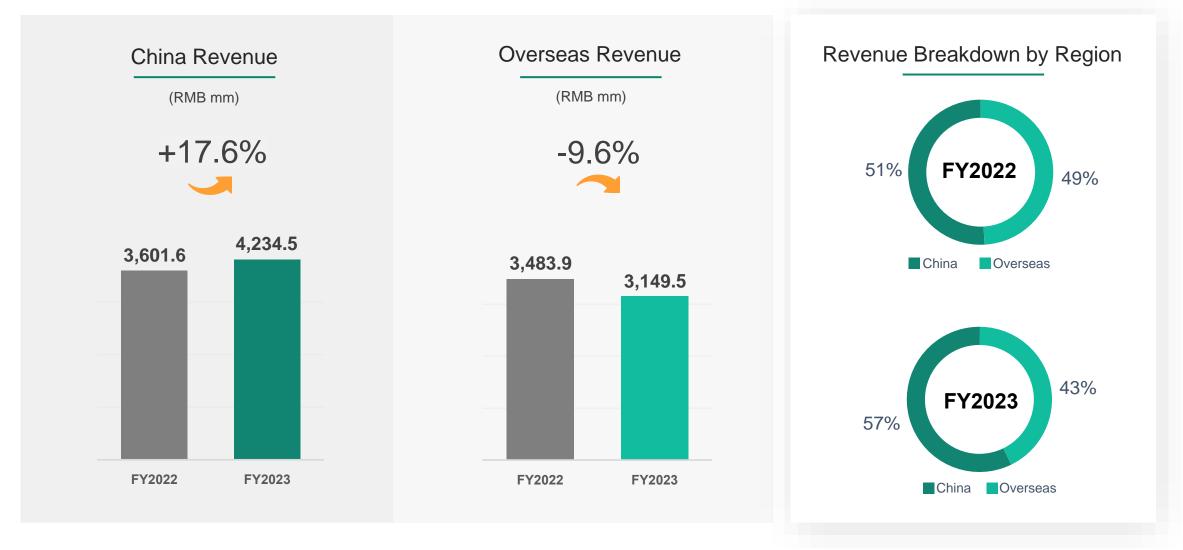
As of December 31, 2023
 Multi-regional Clinical Trials
 Data Management and Statistical Analysis

### 2023 Key Financials



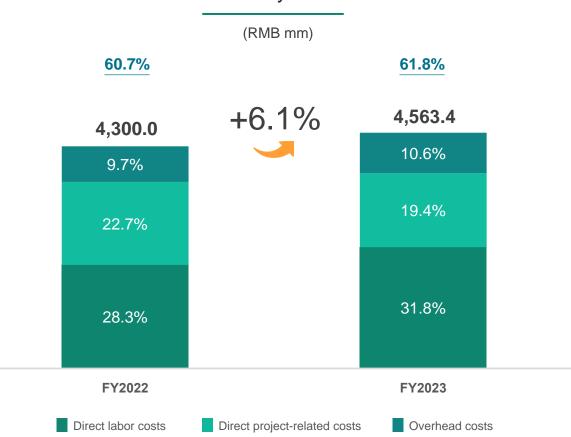


### Revenue Breakdown by China and Overseas Markets





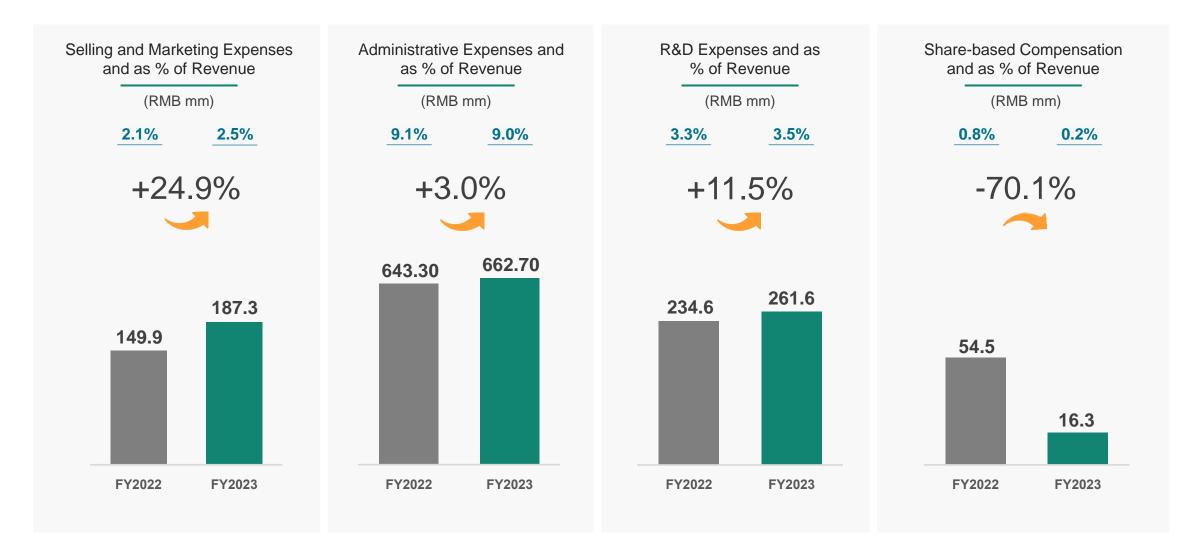
### **Cost of Services**



#### Cost of Services Breakdown by Nature and as % of Revenue



### **Operating Expenses**



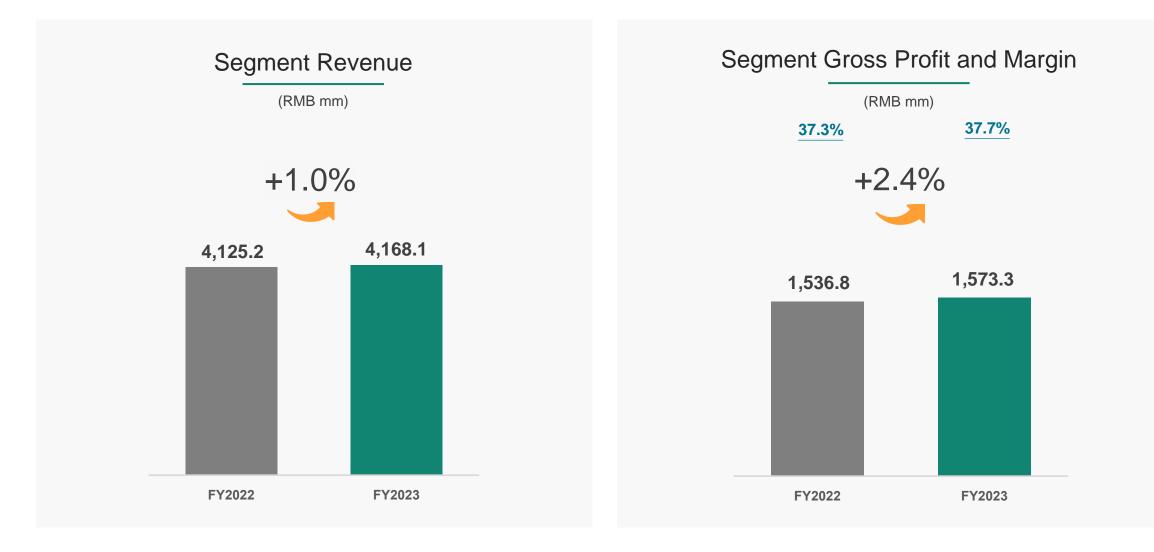




### **Business Updates**

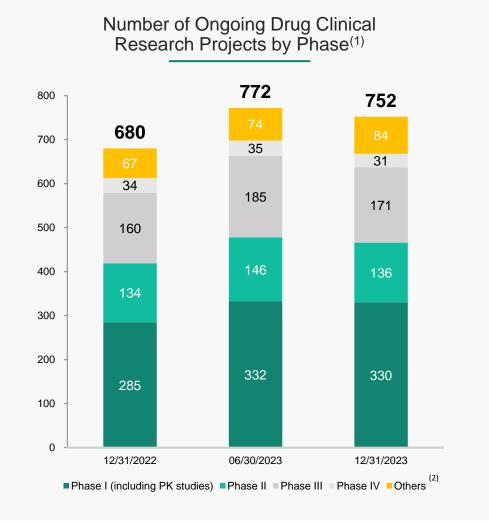
**Clinical Trial Solutions** 

### Clinical Trial Solutions ("CTS")

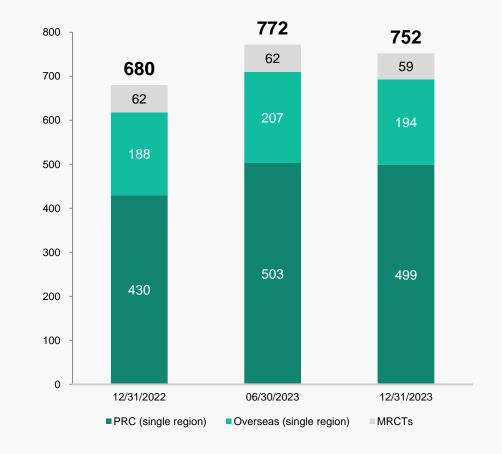




### **CTS Key Business Updates**



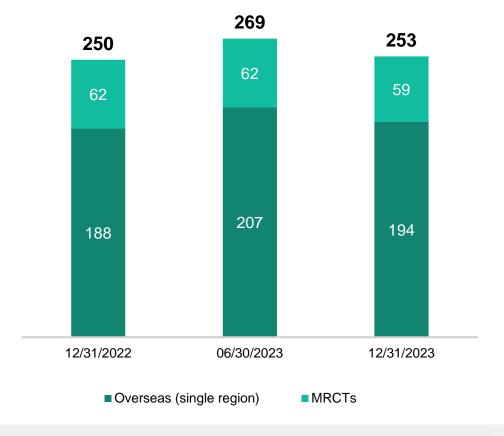






#### **Overseas Clinical Operation Business Updates**

Number of Ongoing Overseas Drug Clinical Research Projects<sup>(1)</sup>



**194** ongoing single region overseas clinical trials as of December 31 2023, primarily in South Korea, Australia and the United States

**59** ongoing MRCTs as of 31 December 2023, being conducted in countries across North America, Asia Pacific, Europe and Africa

The slight decline in number of ongoing overseas drug projects as of December 31, 2023 was mainly due to the closing of certain projects during 2H2023 in South Korea and Latin America (including certain COVID-19 related projects)

Initiated a first-of-its-kind Phase I trial of a Chinese vaccine program (herpes zoster vaccine) in the United States in 2023

Added **15** newly signed MRCT projects in 2023, with a cumulative experience of handling over **127** MRCT projects as of December 31, 2023

**Overseas Clinical Operation Business Updates** 

#### North America

Our US clinical operation business saw **rapid growth of revenue and backlog in 2023**, mainly covering oncology, vaccines, ophthalmology, central nervous system, and medical devices

As of December 31, 2023, our US clinical operation business run on a well-supported integrated platform covering **site initiation**, **project management**, **clinical operation**, **regulatory affairs**, **biometrics and medical monitoring** etc., and a growing team with over **110** PMs and CRAs in **42** cities across North America

As of December 31, 2023, our US team had accumulated know-how from over **100** clinical trials, working with over **500** clinical sites in **45** states

#### EMEA

Our EMEA team completed the integration of Marti Farm in Croatia and Opera in Romania in 2023

Established a **new medical device team** in 2023 and supported over **10** device clinical trials in EMEA

#### Asia Pacific

As of December 31, 2023, our team in South Korea (DreamCIS) reached **369** people, up by 28% YoY. DreamCIS had over **100** ongoing clinical trials as of December 31, 2023

As of December 31, 2023, our presence in Southeast Asia was a team of over **70**, with **24** ongoing clinical trial projects in Indonesia, Philippines, Singapore, Thailand, Vietnam, Malaysia and Laos

Added **20** new clinical trials in Australia with expanded collaboration with Australian sites



#### Regulatory Affairs ("RA")

- As of December 31, 2023, we have a total of **1,009** accumulated RA project experience
- Added 29 new US FDA IND projects in 2023, of which 16 of them have been cleared for clinical trial as of December 31, 2023
- Assisted 9 products to receive approvals in China in 2023, as well as 40 MRCT IND applications in multiple countries and regions
- The number of customers increase to 720 as of December 31, 2023, from 649 as of December 31, 2022

#### Medical Device & IVD

- Assisted 6 innovative medical device products to receive China launch approvals in 2023
- Realized rapid growth of multi-regional device projects in 2023 covering regions including Europe, South Korea, the United States and Southeast Asia etc. Also expanded medical device registrational services to the United States, Southeast Asia and Saudi Arabia
- Accelerated the capacity buildup of our device testing lab and the existing lab qualifications covered 343 industry standards and the technical capabilities of 185 testing objects and 2,913 parameters as of December 31, 2023
- Announced the acquisition of NAMSA's China business in February 2024 and reached an exclusive strategic cooperation agreement with NAMSA in China, expanding our existing team and the global reach, including general consulting, regulatory affairs, quality consulting and clinical research, etc



#### Decentralized Clinical Trials ("DCT"s)

- In 2023, our in-house DCT technology has been widely used in various projects including pivotal clinical trials, post-marketing studies, real-world studies, investigator-initiated trials etc., covering therapeutic areas including oncology, haematology, central nervous system, respiratory and endocrine etc.
- As of December 31, 2023, **13%** of Tigermed's ongoing clinical trials had adopted the DCT hybrid model
- Deeply involved in building China's DCT ecosystem in 2023 and published the landmark report on the DCT Industry Best Practice (数字化/去中心化临床 研究行业实践调研), and authored Tigermed DCT Global Regulatory Handbook
- Tigermed DCT team involved in the Phase III trial of Pfizer's Nurtec<sup>®</sup> in both China and South Korea to collect primary efficacy data using ePRO system, leading to its China approval in 2023

#### **Real World Studies**

- Worked with Sanofi on the submission of the NDA to NMPA of its Isatuximab (accepted by NMPA in December 2023) as one of the first three pilot drugs to conduct real world studies in Hainan Boao Hope City (海南博鳌乐城国际医疗旅游先行区), marking the first ever NDA application acceptance of a haematological cancer drug using real world data generated in Boao Hope City
- In 2023, our real-world study projects have been further expanded to multiple therapeutic areas including oncology, rare diseases, orthopaedics, diabetes, respiratory, cardiovascular, ophthalmology and aesthetics etc.
- Plan to collaborate with DCT team to further increase the adoption of DCT technology and applications in our real world studies

#### Pharmacovigilance ("PV")

- Completed the integration of Marti Farm's PV teams with our existing PV team in China in 2023 with a team of c. **150**, providing global safety monitoring solutions to both pre-NDA and post-market projects for drugs, medical devices, vaccines and aesthetics etc.
- Added 134 new PV customers and 152 new PV projects in 2023
- Signal management tool in final testing phase as of December 31, 2023 and already in touch with potential PV customers for signal management projects

#### **Medical Translation**

- According to CSA Research, our medical translation business ranked 7th globally (1<sup>st</sup> in Chinese Mainland and 3<sup>rd</sup> in Asia Pacific) in the 2023 CSA The Top Life Sciences Language Service Providers Ranking
- Added **86** new customers in 2023, including 45 pharmaceutical companies and 41 medical device companies
- As of December 31, 2023, annual translation volume reached **380 million** words relying on our integrated medical translation platform covering business development, systems (TMS/EPS/TEP/TQC), project management, quality control, translation and algorithm optimization etc.
- Became the Asia Pacific regional supplier and/or global supplier for multiple global pharmaceutical companies in 2023
- Plan to develop automated models dedicated to life science translations and enhance our intelligent medical translation and document management platform leveraging industry leading large language model

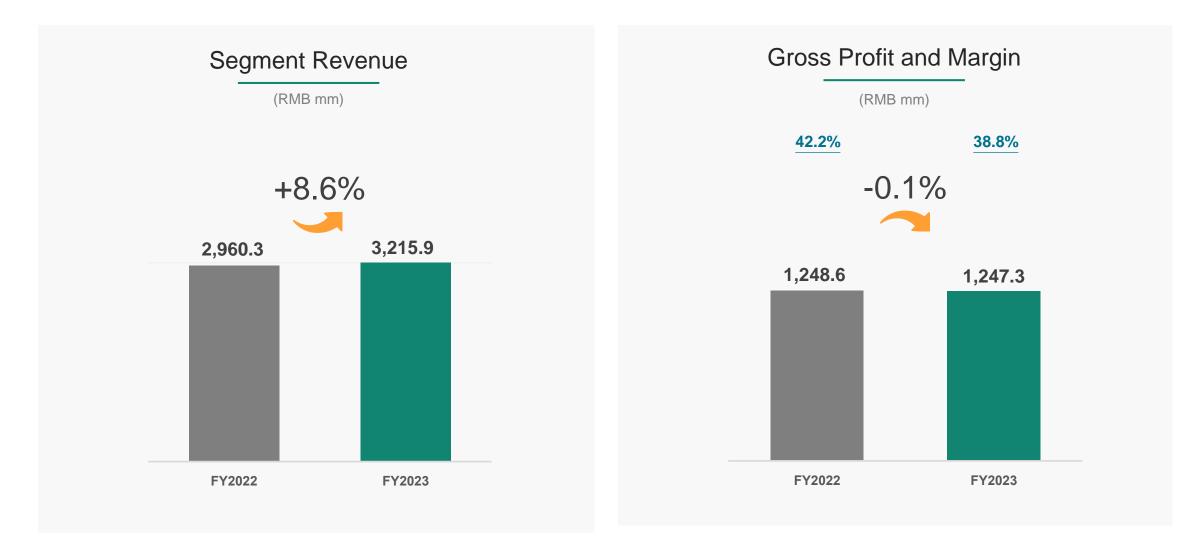




### **Business Updates**

Clinical-related and Lab Services

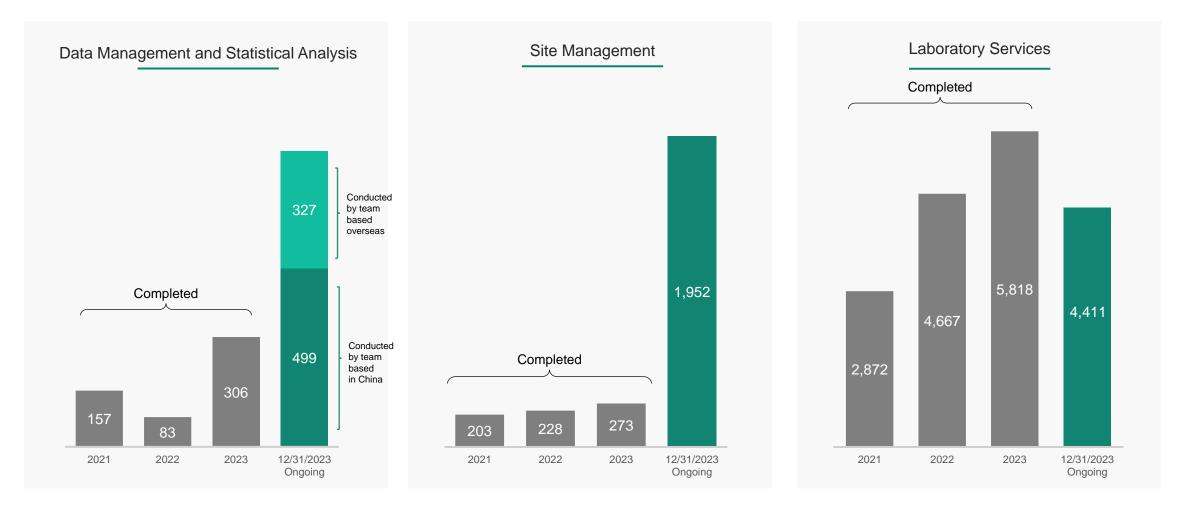
### Clinical-related and Lab Services ("CRLS")





### **CRLS Key Business Updates**

#### Project Status for Key CRLS Services



#### Data Management & Statistical Analysis ("DMSA")

- Provided DMSA services to multiple new drug approvals in China, including Pfizer's Nurtec<sup>®</sup> and Cejemly<sup>®</sup> and oral-dose COVID-19 drug
- As of December 31, 2023, our DMSA team had over 850 professionals based in China, South Korea, the United States and India
- Total number of DMSA customers increased to 340 as of December 31, 2023 from 259 as of December 31, 2022
- Number of ongoing DMSA projects increased to 826 as of December 31, 2023 from 776 as of December 31, 2022

#### Laboratory Services

- Frontage completed the acquisition of Nucro-Technics Holdings, Inc. and its subsidiary, Nucro-Technics, Inc, adding lab space of over 5,574 square meters with enhanced analytical chemistry, microbiology, toxicology, bioanalytical and sample storage and stability testing services in North America
- The new **8,000** square meters clinical trial manufacturing facility in Suzhou was officially put into operation, further improving our capacity in Good Manufacturing Practice ("GMP") clinical trial manufacturing and meeting the more diversified customer needs
- The Wuhan R&D center of ACME Biopharma, a subsidiary of Frontage, was officially opened on May 15, 2023. With a total space of **18,000** square meters, the first phase of the R&D center has a capacity of **50** chemical pharmacology laboratories, **4** formulation development laboratories, and a testing and analysis center, providing one-stop R&D from target screening to pre-clinical pharmacology research
- On June 6, 2023, Frontage Suzhou Safety Assessment Center obtained the GLP (Good Laboratory Practice) certification issued by the NMPA



#### Site Management ("SMO")

- Had **1,952** ongoing SMO projects as of December 31, 2023 and completed **273** SMO projects in 2023
- Team size of over **2,700** Clinical Research Coordinators ("CRC"s) as of December 31, 2023. covering over **1,100** clinical sites in over **140** cities across China through **25** offices
- As of December 31, 2023, has provided SMO services to support 50 Class I innovative drug approvals in China accumulatively

#### Clinical Trial Sites of Excellence ("E-Site")

- As of December 31, 2023, our E-Site Program had 224 core collaborative sites and 74 green channel sites in 19 regions across China. 7 co-sites has been established by the end of 2023, forming a diversified and win-win strategic cooperation model
- As of December 31, 2023, Tigermed has further formed strategic alliance with **52** E-Sites, to jointly incubate industry leading clinical research management system

#### Independent Central Imaging

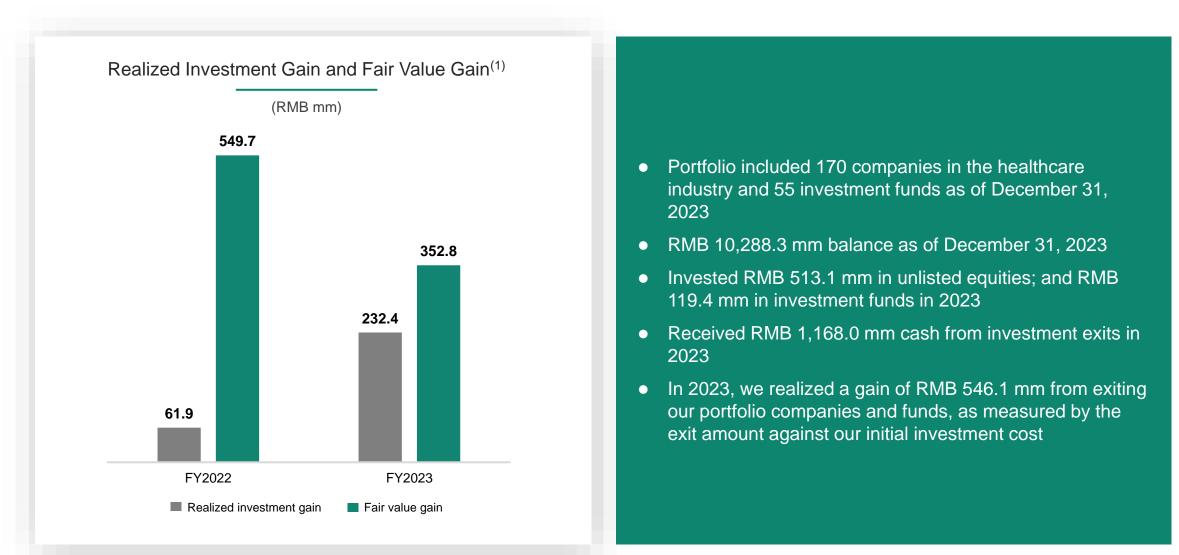
- Provided independent imaging evaluation services for 6 new drug approvals in China in 2023. 20 NMPA inspections in 2023 with zero findings
- As of December 31, 2023, has provided imaging services for over 280 clinical trials accumulatively with 25 products approved
- Established integrated business platform covering central imaging, oncology imaging, pathology, ECG, and imaging consulting etc., and expanded into new therapeutic areas including respiratory system, skin diseases, and orthopaedics in 2023





**Other Updates** 

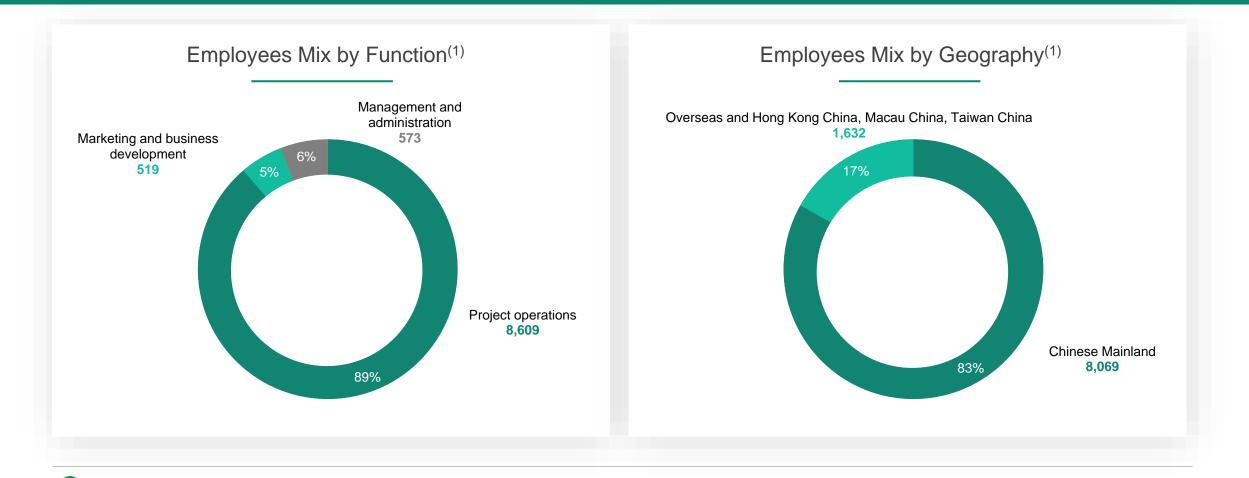
### Updates of Investment Activities





### Employee Base

#### Total employees increased to 9,701 as of December 31, 2023 from 9,455 as of June 30, 2023

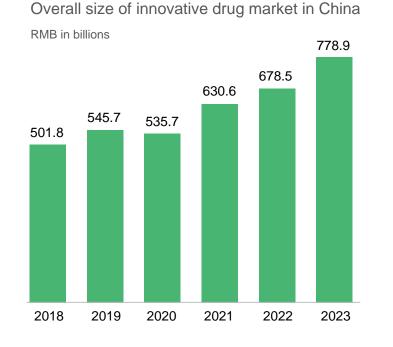




### Industry Trends and Growth Strategies

### Innovative Drug Market in China is Growing...

#### Growing Overall Market

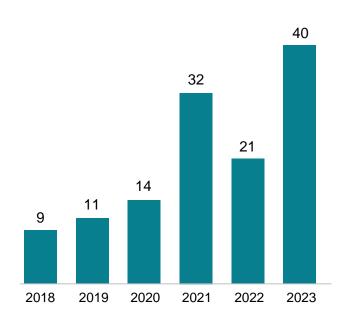


Domestic Innovative Drugs Continued to Ramp Up

Historical sales of select domestic innovative

drugs in China<sup>(1)</sup> RMB in millions 20,750 16,155 12,441 3,820 719 2018 2019 2020 2021 2022 2023 More Innovative Drug Approvals

Class-1 innovative drug approvals by NMPA (2)



(1) Selected domestic innovative drugs include: Tislelizumab, Anlotinib, Sintilibab, Almonertinib, Zanubrutinib, Furmonertinib, Cadonilimab, Serplulimab, Fruquintinib, Toripalimab; all approved after 2018

(2) Including Covid-19 vaccines and Covid019 related diagnostic products

Source: Frost & Sullivan, Center for Drug Evaluation of NMPA, PharmaCube, Tigermed Analysis; May Not Be Exhaustive



### ...with Multiple Milestones and Highlights in 2023

### 40

#### A record-high number of Class-1 innovative drug approvals in 2023<sup>(1)</sup>

Surpassing historical record of 32 approvals in 2021

### 80

### Out-licensing transactions in 2023<sup>(2)</sup>

Billion-dollar out-licensing deals kept happening across the year

### 41.1 billion USD

Total potential out-licensing deal size<sup>(3)</sup>

US\$3.2 billion upfront payments also hit a record high

### 1 st

### Listed China biotech fully acquired by global pharma<sup>(4)</sup>

Gracell Biotechnologies (China) announced in Dec 2023 to be acquired by AstraZeneca

### 1 st

## China originated and manufactured new molecule approved by US FDA<sup>(5)</sup>

Junshi Biosciences' PD-1 inhibitor LOQTORZI<sup>™</sup> is the first and only FDA-approved treatment for Nasopharyngeal Carcinoma (NPC)

### 67

ICH guidelines fully implemented in China<sup>(6)</sup>

Full harmonization of regulatory regime with global standards

(1) Source: Center for Drug Evaluation of NMPA(2) Source: PharmaCube(3) Source: PharmaCube

(4) Source: Gracell Press Release, PharmaCube
(5) Source: Junshi Biosciences Press Release, PharmaCube
(6) Source: Center for Drug Evaluation of NMPA presentation at DIA China 2023



### A New Cycle of Innovation is Emerging

Stage 1	Stage 2	Stage 3
Catching Up	A Closer Gap	Global Recognition
2010-2017	2017-2021	2021 onwards
<ul> <li>Majority of pipeline are pure followers</li> <li>Large gap between global first PoC and China first PoC</li> <li>No or limited clinical development strategy</li> <li>Accumulating core technology and capability for engineering-based innovation</li> <li>Emerging of abundant high-quality talents and suppliers along industry value chain</li> </ul>	<ul> <li>Leaders started to pursue fast- following strategy with speed and profile differentiation</li> <li>Pipeline with a more complexity of modalities</li> <li>Strong engineering-based innovation capability</li> <li>More savvy on clinical development</li> </ul>	<ul> <li>Wave of out-licensing transactions to global MNCs:</li> <li>Represents 27% of global ADC out-licensing deals since 2021<sup>(1)</sup></li> <li>Co-developments with global leaders in developed markets</li> <li>Started to develop assets with global first-wave potential: <ul> <li>15% of first-in-class MoAs are currently developed by Chinese companies<sup>(2)</sup></li> </ul> </li> </ul>

(1) Source: McKinsey analysis as of Nov 2023. ADC deals from China only include out-licensing transactions to US and EU markets; acquisitions excluded

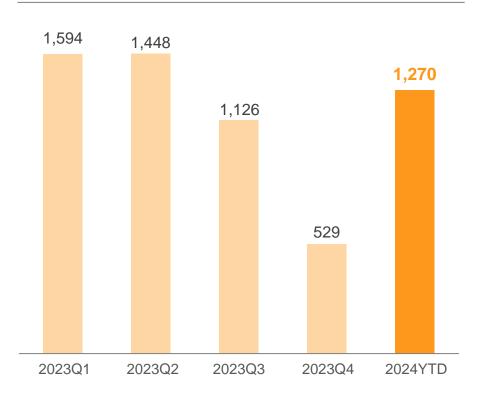
(2) Source: McKinsey analysis as of Nov 2023. Including MoAs at Phase I–III clinical and pre-NDA stages. MoA numbers are counted by modality and target pairs, i.e. for small molecule, ADC, and mAbs, the MoA is counted by targets; for multivalent mAbs and CGT, the MoA is counted by combinations



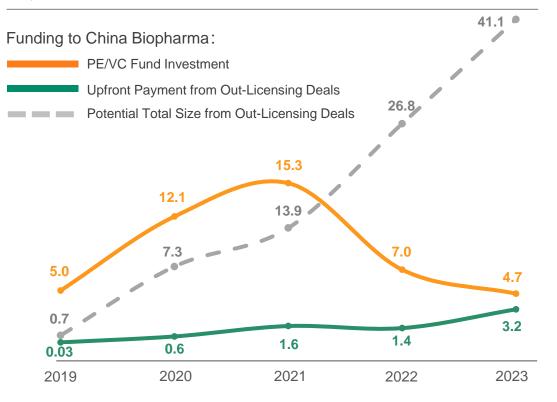
### Light at the End of the Tunnel

Potential Recovery of PE/VC Funding Environment with Additional Funding Sources

**PE/VC financing in China's biopharma industry has shown sign of improvement**<sup>(1)</sup> US\$ in millions



Out-licensing payment emerging as a new R&D funding source<sup>(1)</sup> US\$ in billions



May Not Be Exhaustive

### **CRO Industry Outlook**

### A Growing CRO Market in China<sup>(1)</sup>

- China's CRO market is expected to reach RMB 165 billion in 2026, accounting for 21.0% of the global CRO market
- China's CRO industry is expected to grow faster than total R&D spending, and the clinical CRO segment is expected to grow faster than the overall CRO market

#### Funding Environment Likely Improving<sup>(2)</sup>

- PE/VC financing in China's innovative drug industry in 2024YTD has shown sign of recovery and exceeded 2023Q3 and Q4
- The boom in out-licensing transactions is expected to continue and become a new source of funding for innovative drug R&D in China

#### Foreign Sponsors Continue to invest in China<sup>(3)</sup>

- Number of clinical trials initiated by foreign sponsors in China has seen a year-on-year increase of 18.5% in 2023
- Foreign sponsors continue to expand R&D pipelines in China
- Multiple global pharmas have achieved fast growth of their China business and increased their investment in local innovation

#### Recovery in Overseas Markets<sup>(4)</sup>

- Company 1 expects revenue to pick up in 2024Q2
- Company 2 raised its guidance for the fourth consecutive year
- Company 3 and Company 4
   raised its guidance
- Company 5 seen backlog increased by 10% in 2023

(1) Source: Frost & Sullivan

(2) Source: PharmaCube, Tigermed Analysis; as of March 25, 2024

(3) Source: PharmaCube, Tigermed Analysis

(4) IQVIA Q42023 Earning Conference Call / Medpace Q42023 Earnings Presentation / Charles River 2023 earnings and 2024 guidance conference call / Q4 and Full Year 2023 Laboratory Corporation of America Holdings Earnings Conference Call /

ICON Q4 2023 Earnings Conference Call & Webcast



### Our Clinical Services are Evolving

#### **Regulatory Change**

Keep abreast of the latest regulatory regime and position for potential future changes – allowing us to adapt to changes quickly and preempt business opportunities

#### **Technology Innovation**

Navigate technology and launch new services in the highly regulated clinical development market – allowing us to rampup market share as first mover in emerging areas and improve our service efficiency

#### **Global Expansion**

Sense the needs from our customers and establish a growing global team in both developed markets and key emerging countries – allowing us to provide global solutions and win cross-border business

#### Increased competitiveness and resilience

**Growth Opportunities** 

Reinforce leading position on core services

Grow revenue and market share on emerging services

Go-to partner from China to the world and vice versa



### Our Near Term Business Development Focus and Growth Strategy

Strengthen BD<sup>(1)</sup> coverage of global and local big pharmas Continue to enhance our integrated service platform to drive higher igermed customer conversion rate from earlier stage to later stage services Monitor inorganic opportunities in key overseas markets to increase our global market share

Establish operational business units by therapeutic area and modality to expand capabilities for more customized specialty solutions

> Form clinical operation strategy committee to pool resources and expertise for more in-depth advice to clients

Further investments in BD and operation capabilities in the US and Europe for more overseas clinical trial exposure and to maintain high growth rate for our US clinical operation business



# Appendix

### **Consolidated Statement of Profit or Loss**

	Year ended December 31,	
(RMB 000s)	2022	2023
Revenue	7,085,471	7,384,039
Cost of services	(4,300,027)	(4,563,378)
Gross profit	2,785,444	2,820,661
Other income	284,961	311,707
Other gains and losses, net	620,322	552,201
Impairment losses	(24,575)	(68,098)
Selling and marketing expenses	(149,890)	(187,315)
Administrative expenses	(643,315)	(662,696)
Research and development expenses	(234,619)	(261,555)
Share of losses of associates	39,763	105,183
Finance costs	(83,179)	(119,897)
Profit before tax	2,594,912	2,490,191
Income tax expense	(313,652)	(338,606)
Profit for the year	2,281,260	2,151,585
Profit attributable to owners of the Company	2,016,086	2,026,507
Adjusted for:		
Share-based compensation expense	37,542	5,712
Net foreign Exchange loss/(gain)	(16,952)	111
Amortization of intangible assets arising from acquisitions	15,448	13,876
Goodwill impairment	-	23,286
Change in fair value of financial assets at FVTPL	(386,254)	(283,372)
Adjusted net profit attributable to owners of the Company <sup>(1)</sup>	1,665,870	1,786,120

### **Consolidated Statement of Financial Position**

(RMB 000s)	As of December 31, 2022	As of December 31, 2023
NON-CURRENT ASSETS	16,341,353	18,338,740
Property, plant and equipment	976,679	1,190,992
Intangible assets	276,147	309,852
Goodwill	2,485,018	2,764,189
Right-of-use assets	622,354	556,645
Interests in associates	1,799,825	2,977,028
Other financial assets at amortized cost	27,607	-
Deferred tax assets	121,353	134,791
Financial assets at fair value through profit or loss ("FVTPL")	9,963,853	10,231,702
Financial assets at fair value through other comprehensive income ("FVTOCI")	3,864	14,508
Restricted bank deposits	2,089	2,137
Other non-current assets	62,564	156,896
CURRENT ASSETS	11,105,157	11,342,003
Inventories	22,204	23,398
Trade, bills and other receivables and prepayments	1,186,273	1,428,206
Contract assets	1,997,311	2,364,435
Other financial assets at amortised cost	-	40,995
Financial asset through P&L - Current	24,946	42,138
Prepaid income tax	15,136	24,977
Restricted bank deposits	19,115	6,885
Time deposit with original maturity over three months	54,194	11,028
Cash and cash equivalents	7,782,741	7,399,941
Assets classified as held for sales	3,237	-



### Consolidated Statement of Financial Position (Cont'd)

(RMB 000s)	As of December 31, 2022	As of December 31, 2023
CURRENT LIABILITIES	3,729,569	4,138,737
Trade and other payables	717,950	845,110
Contract liabilities	939,765	680,489
Bank borrowings	1,868,215	2,366,380
Income tax payables	85,875	123,877
Lease liabilities/obligations under finance leases	117,764	122,881
NON-CURRENT LIABILITIES	1,035,913	1,088,444
Non-current Bank borrowing	244,641	434,223
Lease liabilities/obligations under finance leases - non current	488,976	423,109
Deferred government grant	14,786	14,594
Pension obligations	425	719
Other long-term liabilities	72,692	1,820
Deferred tax liabilities	214,393	213,979
NET ASSETS	22,681,028	24,453,562
TOTAL EQUITY	22,681,028	24,453,562
Share capital	872,419	872,419
Treasury shares	(869,340)	(869,340)
Retained earnings	19,625,366	21,066,063
Equity attributable to owners of the Company	19,628,445	21,069,142
Non-controlling interests	3,052,583	3,384,420





# Hangzhou Tigermed Consulting Co., Ltd. 300347.SZ / 3347.HK