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TYK Medicines, Inc*

浙江同源康醫藥股份有限公司

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

(Stock Code: 2410)

**INTERIM RESULTS ANNOUNCEMENT
FOR THE SIX MONTHS ENDED JUNE 30, 2024**

FINANCIAL HIGHLIGHTS

	Six months ended June 30,		Changes	
	2024	2023		
	RMB'000	RMB'000	RMB'000	%
	(unaudited)	(unaudited)		
Research and development costs	(137,758)	(119,436)	(18,322)	15.3
Administrative expenses	(40,100)	(22,176)	(17,924)	80.8
Total comprehensive loss for the period	(219,533)	(173,849)	(45,684)	26.3

* For identification purpose only

INTERIM RESULTS

The Board is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2024, together with the comparative figures for the corresponding period in 2023. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the Prospectus.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the six months ended June 30, 2024

		For the six months ended June 30,	
	NOTES	2024 RMB'000 (unaudited)	2023 RMB'000 (unaudited)
Revenue		–	–
Cost of sales		–	–
		<hr/>	<hr/>
Gross profit		–	–
Other income and gains	4	11,285	10,279
Research and development costs		(137,758)	(119,436)
Administrative expenses		(40,100)	(22,176)
Other expenses and losses	5	(70)	(8)
Finance costs	7	(5,431)	(4,483)
Change in fair value of redemption liabilities on equity shares		(47,459)	(38,025)
		<hr/>	<hr/>
LOSS BEFORE TAX	6	(219,533)	(173,849)
Income tax expense	8	–	–
		<hr/>	<hr/>
LOSS FOR THE PERIOD		(219,533)	(173,849)
		<hr/>	<hr/>
Attributable to:			
Owners of the Company		(219,053)	(173,539)
Non-controlling interests		(480)	(310)
		<hr/>	<hr/>
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		(219,533)	(173,849)
		<hr/> <hr/>	<hr/> <hr/>
Attributable to:			
Owners of the Company		(219,053)	(173,539)
Non-controlling interests		(480)	(310)
		<hr/> <hr/>	<hr/> <hr/>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY (expressed in RMB)			
Basic and diluted	9	(0.68)	(0.60)
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INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at June 30, 2024

	<i>NOTES</i>	As at June 30, 2024 <i>RMB'000</i> <i>(unaudited)</i>	As at December 31, 2023 <i>RMB'000</i> <i>(audited)</i>
NON-CURRENT ASSETS			
Restricted bank deposit		4,688	4,683
Property, plant and equipment		156,567	157,510
Right-of-use assets		84,673	92,335
Intangible assets		65,242	68,071
Prepayments and other receivables	10	19,786	16,830
Total non-current assets		330,956	339,429
CURRENT ASSETS			
Prepayments and other receivables	10	40,033	40,387
Financial assets at fair value through profit and loss (“FVTPL”)		53,264	6,001
Restricted bank deposit		–	491
Cash and cash equivalents		105,044	186,830
Total current assets		198,341	233,709
CURRENT LIABILITIES			
Trade and other payables	11	113,330	133,429
Redemption liabilities on equity shares		1,192,783	1,145,324
Interest-bearing bank and other borrowings		80,480	–
Lease liabilities		23,133	22,226
Total current liabilities		1,409,726	1,300,979
NET CURRENT LIABILITIES		(1,211,385)	(1,067,270)
TOTAL ASSETS LESS CURRENT LIABILITIES		(880,429)	(727,841)
NON-CURRENT LIABILITIES			
Deferred income		49,179	48,281
Other long-term payables		95,818	84,408
Lease liabilities		17,105	19,503
Total non-current liabilities		162,102	152,192
Net liabilities		(1,042,531)	(880,033)
DEFICIENCY IN EQUITY			
Equity attributable to owners of the Company			
Share capital		322,956	307,356
Reserves		(1,369,454)	(1,191,836)
Controlling interests		(1,046,498)	(884,480)
Non-controlling interests		3,967	4,447
Total deficits		(1,042,531)	(880,033)

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2024

1. CORPORATE INFORMATION

The Company is a joint stock company with limited liability established in the PRC on November 2, 2017. The registered office address of the Company is Room 1403-2, Floor 14, Tower A, Changxing World Trade Building, No. 1278 Mingzhu Road, Changxing Economic Development Zone, Huzhou, Zhejiang Province, the PRC. During the Reporting Period, the Company and its subsidiaries are principally engaged in the research, development and commercialisation of pharmaceutical products.

The Company was listed on the Main Board of the Stock Exchange on August 20, 2024.

2.1 BASIS OF PREPARATION

Notwithstanding that the Group recorded net liabilities of RMB1,042,531,000 as at June 30, 2024 and incurred recurring losses from operations, the interim condensed financial information has been prepared on a going concern basis. The Group completed its initial public offering on the Stock Exchange on August 20, 2024, raising total gross proceeds of approximately RMB529.2 million. Upon the completion of the Listing, all special rights on equity shares ceased to be effective and the carrying amount of the redemption liabilities on equity shares at that time were transferred to equity, which will result in the change from a net liability position to a net asset position on the statement of financial position. The Directors of the Company are of the opinion that the Group will have sufficient working capital to meet its financial liabilities and obligations as and when they fall due and to sustain its operations for the next twelve months from June 30, 2024.

The interim condensed consolidated financial information for the six months ended June 30, 2024 has been prepared in accordance with HKAS 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements and should be read in conjunction with the Group's consolidated financial statements for each of the years ended December 31, 2022 and 2023 as set out in the accountants' report (the "**Accountants' Report**") included in the prospectus of the Company dated on August 12, 2024 (the "**Prospectus**").

The interim condensed consolidated financial information is presented in Renminbi ("**RMB**"), and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2023, except for the adoption of the following revised Hong Kong Financial Reporting Standards (“HKFRSs”) for the first time for the current period's financial information.

Amendments to HKFRS 16	<i>Lease Liability in a Sale and Leaseback</i>
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-Current</i> (the “2020 Amendments”)
Amendments to HKAS 1	<i>Non-current Liabilities with Covenants</i> (the “2022 Amendments”)
Amendments to HKAS 7 and HKFRS 7	<i>Supplier Finance Arrangements</i>

None of these amendments had a material impact on the financial position or performance of the Group. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

3. OPERATING SEGMENT INFORMATION

Operating segment information

For management purposes, the Group has only one reportable operating segment, which is developing and commercialising pharmaceutical products. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Geographical information

Since all of the Group's non-current assets were located in the PRC, no geographical information in accordance with HKFRS 8 *Operating Segments* is presented.

4. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	Six months ended June 30,	
	2024	2023
	RMB'000	RMB'000
<u>Other income</u>		
Government grants related to income	6,336	4,822
Government grants related to interest-free financing	3,516	2,901
Bank interest income	817	478
	<hr/>	<hr/>
<u>Gains</u>		
Investment income on financial assets at FVTPL	372	2,410
Gain/(loss) on fair value changes of financial assets at FVTPL	263	(473)
Gain on termination of a lease contract	2	–
Foreign exchange gains, net	(21)	141
	<hr/>	<hr/>
	11,285	10,279
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5. OTHER EXPENSES AND LOSSES

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Donation to not-for-profit organisations	–	5
Loss on disposals of property, plant and equipment	–	3
Others	70	–
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	70	8
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6. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging:

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Depreciation of property, plant and equipment	4,702	3,635
Depreciation of right-of-use assets	7,196	7,380
Amortisation of intangible assets	2,829	2,830
	<hr/>	<hr/>
Research and development costs		
Current year expenditure	107,993	88,873
Loss on disposal of items of property, plant and equipment	–	3
Expenses relating to short-term leases	477	449
Listing expenses	12,632	–
	<hr/>	<hr/>
Staff costs (including directors' emoluments):		
– Salaries, discretionary bonuses, allowances and benefits in kind	24,500	26,938
– Pension scheme contributions	1,274	1,477
– Share-based payment compensation	7,035	–
	<hr/>	<hr/>
	32,809	28,415
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7. FINANCE COSTS

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Interest on lease liabilities	816	1,440
Interest expenses of government funding	3,671	3,043
Interest on bank loans	944	–
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	5,431	4,483
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8. INCOME TAX EXPENSE

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

Chinese Mainland

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the Enterprise Income Tax (“EIT”) rate of the PRC subsidiaries was 25% during the six months ended 30 June 2024 except for the Company which was subject to tax concession set out below.

The Company was accredited as a “High and New Technology Enterprise” (“HNTE”) in 2022. Therefore, the Company was entitled to a preferential EIT rate of 15% for the six months ended 30 June 2024. The qualification as a HNTE Enterprise is subject to review by the relevant tax authority in the PRC every three years.

9. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE COMPANY

The calculation of the basic loss per share amount is based on the loss for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 320,356,000 (the six months ended June 30, 2023: 287,989,000) in issue during the period, as adjusted to reflect the changes during the period.

The Group had no potentially dilutive ordinary shares in issue during the period.

The calculation of basic and diluted loss per share is based on:

	Six months ended June 30,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Loss		
Loss attributable to ordinary equity holders of the parent	<u>(219,053)</u>	<u>(173,539)</u>
Shares		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation	<u>320,356,000</u>	<u>287,989,000</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (expressed in RMB)		
Basic and diluted	<u><u>(0.68)</u></u>	<u><u>(0.60)</u></u>

10. PREPAYMENTS AND OTHER RECEIVABLES

	As at June 30, 2024 <i>RMB'000</i>	As at December 31, 2023 <i>RMB'000</i>
Non-current:		
Value-added tax recoverable	15,599	14,975
Prepayments for long-term assets	2,554	274
Rental deposits	1,633	1,581
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Total	19,786	16,830
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Current:		
Prepayments for research and development services	29,763	33,202
Deferred listing expense	6,983	5,391
Others	3,287	1,794
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Total	40,033	40,387
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11. TRADE AND OTHER PAYABLES

	As at June 30, 2024 <i>RMB'000</i>	As at December 31, 2023 <i>RMB'000</i>
Trade payables	29,575	32,167
Payroll payables	3,525	10,253
Accrued expenses for research and development services	45,194	36,688
Accrued listing expense	6,822	3,868
Other taxes payables	12	459
Other payables		
– Payables for property, plant and equipment	26,133	32,671
– Payables for transaction cost on issue of redemption liabilities on equity shares	–	13,508
– Others	2,069	3,815
	<hr/>	<hr/>
Total	113,330	133,429
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	As at June 30, 2024 RMB'000	As at December 31, 2023 RMB'000
Within 3 months	18,980	28,406
3 to 6 months	2,591	3,403
6 months to 1 year	7,646	356
Over 1 year	358	2
	<hr/>	<hr/>
Total	29,575	32,167
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12. DIVIDENDS

No dividend was paid or declared by the Company during the six months ended June 30, 2024 (six months ended June 30, 2023: Nil).

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS REVIEW

OVERVIEW

We are a clinical-stage biopharmaceutical company committed to the discovery, acquisition, development and commercialization of differentiated targeted therapies to address unmet medical needs in cancer treatment. Since our inception in 2017, we have built a pipeline with 11 drug candidates, including Core Product TY-9591, seven clinical stage products, and three preclinical stage or early clinical development stage products. We are currently conducting a pivotal Phase II clinical trial of TY-9591 monotherapy as first-line treatment of brain metastases from non-small cell lung cancer (“NSCLC”) with epidermal growth factor receptor (“EGFR”) mutations in China, as well as a registrational Phase III clinical trial of TY-9591 monotherapy as first-line treatment in locally advanced (stage IIIb to IV) or metastatic NSCLC with EGFR L858R mutation in China.

THERE IS NO ASSURANCE THAT WE WILL ULTIMATELY BE ABLE TO DEVELOP AND MARKET OUR CORE PRODUCT OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

The following chart shows our drug candidates as of the date of this announcement:

	Product ⁽¹⁾	Target (Modality)	Indication (Lines of Treatment)	Regimen	Preclinical	IND-Enabling	Ph I/IIa	Ph Ib/II	Registrational Pivotal Ph II/Ph III	Upcoming Milestone/Current Status	Commercial Rights/Partner
Clinical Stage	★ TY-9591	3 rd -Generation EGFR	Brain metastases from NSCLC with EGFR mutations (1L)	Mono	Pivotal Phase II trial ongoing in China					NDA submission in Q1 2025	China
			Advanced (stage IIIb to IV) or metastatic NSCLC with EGFR L858R mutation (1L)	Mono	Registrational Phase III trial ongoing in China					NDA submission in 2H 2026	
			Advanced (stage IIIb to IV) or metastatic NSCLC with EGFR mutations	Combo	IND approval for Phase II and Phase III trials in China					Enter Ph II in 2H 2024	
	☆ TY-302	CDK4/6	Breast cancer (2L+)	Combo	Phase II trial ongoing in China					Enter Registrational Trial in Q1 2025	China
			Prostate cancer (1L)	Combo	Phase II trial ongoing in China					Enter Ph II in 2H 2024	
	☆ TY-2136b	ROSI/NTRK	ROSI/NTRK-mutant solid tumor	Mono	Phase Ib study ongoing in China					Ph Ib ongoing	Livzon (Greater China) ⁽²⁾
			ROSI/NTRK-mutant NSCLC	Mono	Phase I trial ongoing in the U.S.					Ph I ongoing	Ex-Greater China
	TY-2699a	CDK7	SCLC, TNBC	Mono/Combo	Phase I trial ongoing in China					Enter Ph Ib in Q1 2025	Global
					IND approval in the U.S.					IND approved	
	TY-0540	CDK2/4/6	Solid tumor	Mono/Combo	Phase I trial ongoing in China					Enter Ph Ib in Q1 2025	Global
IND approval in the U.S.						IND approved					
TY-1091	RET	RET-fusion positive solid tumor	Mono	Phase I trial ongoing in China					Ph I ongoing	Global	
				IND approval in the U.S.					IND approved		
TY-4028	EGFR Exon 20	EGFR exon 20 insertion NSCLC	Mono	IND approval in China					Enter Ph I in December 2024	Global	
				IND approval in the U.S.					IND approved		
TY-1054	YAP-TEAD	Solid tumor	-	IND approval in the U.S.					IND approved (U.S.)	Global	
				IND approval in China					IND approved (China)		
Preclinical Stage	TY-1210	CDK2	Solid tumor	-	IND approval in China					IND submission in 2H 2025	Global
	TY-0609	CDK4	Solid tumor	-	IND approval in China					IND submission in 2H 2025	Global
	TY-3200	EGFR (PROTAC)	NSCLC	-	IND approval in China					IND submission in 2H 2025	Global

★ Core Product

☆ Key Product

Abbreviations: 1L = first line; 2L+ = third – or later-line; EGFR = epidermal growth factor receptor; CDK = cyclin-dependent kinase; ROS1 = ROS proto-oncogene 1; NTRK = neurotrophic tyrosine receptor kinase; RET = rearranged during transfection; YAP = yes associated protein; TEAD = transcriptional enhanced associate domain; PROTAC = proteolysis-targeting chimera; NSCLC = non-small cell lung cancer; SCLC = small cell lung cancer; TNBC = triple-negative breast cancer; Ph = Phase; NDA = new drug application; 2H = second half; Q1 = first quarter.

Notes:

- (1) The relevant intellectual property rights for TY-9591 and TY-302 were acquired from Changzhou Runnuo and Guangzhou Boji, and Tetranov Pharmaceutical, respectively. We have developed these two drug candidates at our own costs since preclinical stage. Except for these two drug candidates, all other drug candidates were internally discovered and developed by us.
- (2) We have out-licensed the rights to develop, manufacture and commercialize TY-2136b in the Greater China to Livzon. We maintain the rights to develop and commercialize this drug candidate in the rest of the world.

Source: Company Data

Our Business Model

Our core business model involves internally discovering, acquiring, developing, and commercializing small molecule drugs and other innovative drug species related to small molecule drugs to address unmet needs in cancer treatment, especially in lung cancer. We have developed in-house R&D capabilities that cover not only early-stage drug discovery, chemical synthesis and selection, but also clinical development and regulatory affairs. In addition, we have been actively seeking global and regional partnerships with leading pharmaceutical companies to maximize the clinical and commercial value of our drug candidates. As our Core Product TY-9591 enters pivotal clinical trial stage, we are in the process of establishing our in-house cGMP-compliant manufacturing facility in Huzhou, Zhejiang Province, which is expected to commence commercial-scale manufacturing by the end of 2025. We also plan to establish sales and marketing capabilities through a combination of in-house efforts and working with external partners to secure our success in commercializing this product in China.

OUR DRUG CANDIDATES

The field of cancer treatment has developed significantly in the past century. Conventionally, treatment methods such as surgery, radiotherapy, and chemotherapy have been widely utilized to fight against tumor cells, but they have been proven to be deficient due to side effects and limited efficacy. The development of targeted therapies, which target specific molecules, generally proteins, enzymes, a signaling pathway, or genetic changes that play a role in the spread of cancer, has embarked on a new era of cancer treatment with enhanced specificity and efficacy. According to Frost & Sullivan, currently, for early stage patients, the primary treatments are surgery, radiotherapy and chemotherapy. Surgery is often recommended for eligible patients, while radiotherapy and chemotherapy are often used for inoperable patients. For advanced stage patients, surgery is usually not considered due to spread of the tumor and potential metastasis. In addition to radiotherapy and chemotherapy, recommended treatments also include targeted therapy or immunotherapy. The treatments approved for different treatment lines vary depending on the cancer type. For example, for advanced NSCLC patients with driver genes such as EGFR mutations and ALK rearrangement, the first-line treatment is targeted therapy, and the second-line treatment includes targeted therapy and chemotherapy, depending on the types of resistance mutations.

As a company focused on the development of small molecule targeted therapies for cancer treatment, we have built a pipeline with 11 drug candidates. An introduction to these products is listed below:

Core Product TY-9591 — A Third-Generation EGFR-TKI

TY-9591 is a third-generation EGFR-tyrosine kinase inhibitor (“**TKI**”) with antitumor effects on EGFR mutations. It can irreversibly bind to certain EGFR mutants including exon 21 L858R mutation, exon 19 deletion, L858R/T790M mutation, and exon 19 deletion/T790M mutation, and thus inhibit the downstream signaling cascade, such as Ras/Raf/MEK/ERK or phosphoinositide 3-kinase (“**PI3K**”)/protein kinase B (“**AKT**”) pathway, ultimately inhibiting the proliferation and metastasis of cancer cells. TY-9591 was developed through modifications of osimertinib to enhance its safety, allowing for a higher administration dosage and thus, potentially, improved efficacy. Specifically, TY-9591 was modified by replacing certain hydrogens in osimertinib with deuterium to reduce or slow down the breakdown of osimertinib. Such modification may retain the advantages of osimertinib, but also affect the way that osimertinib is metabolized, which may reduce the formation of the metabolite TY-9591-D1 (AZ5104). Based on preclinical studies, TY-9591-D1 (AZ5104) is showed to have much higher affinity to normal cells that express EGFR without mutations, and thus is the major cause of adverse events (“**AEs**”) of TY-9591 and osimertinib. By reducing the production of TY-9591-D1, TY-9591 is expected to be safer than osimertinib and can be administered at a higher dose level, leading to improved antitumor efficacy and a higher level of blood-brain entry. In a Phase I clinical trial in healthy subjects, we investigated the mean drug metabolite concentration-time profiles after a single oral dose of 80 mg TY-9591 and osimertinib in healthy subjects. Compared to osimertinib, the results showed an approximately 50% reduction in metabolite TY-9591-D1 exposure levels after TY-9591 administration, indicating that TY-9591 may have an improved safety profile than osimertinib. In addition, although not a head-to-head comparison, clinical data from our Phase Ib study showed that TY-9591 has demonstrated promising efficacy and safety profile with the median PFS of 21.5 months, confirmed objective response rate (“**ORR**”) of 85.9% and confirmed disease control rate (“**DCR**”) of 94.9% in NSCLC patients with EGFR mutations (L858R/exon 19 deletion).

We are currently investigating TY-9591 in brain metastases from NSCLC with EGFR mutations and in locally advanced (stage IIIb to IV) or metastatic NSCLC with EGFR L858R mutation. While there are a number of third-generation EGFR-TKIs approved for sale in China and worldwide, no drug has been approved and marketed for brain metastases from NSCLC, demonstrating urgent unmet clinical needs. Results from our Phase Ib and Phase II clinical studies of TY-9591 monotherapy in advanced NSCLC have demonstrated a strong clinical efficacy. Among 29 evaluable NSCLC treatment-naïve patients with brain metastases enrolled in these studies, we observed that 25 patients reached intracranial partial response (“**PR**”) and four reached complete response (“**CR**”), with an intracranial ORR of 100%. Although not a head-to-head comparison, this outcome outperformed the confirmed 77% intracranial ORR observed in NSCLC brain metastases patients treated by osimertinib in the Phase III FLAURA trial. In the Phase II study, we observed that the overall incidence of serious adverse events (“**SAEs**”) was only 8.3% and treatment-related SAEs was as low as 8.3%, demonstrating a favorable safety profile.

Furthermore, TY-9591 may deliver improved efficacy compared to osimertinib in NSCLC patients with the EGFR L858R mutation. Osimertinib exhibited a median progression-free survival (“PFS”) of 18.9 months for both EGFR exon 19 deletion and L858R mutation. However, NSCLC patients with EGFR L858R mutation showed significantly shorter PFS of 14.4 months compared to 21.4 months PFS observed in EGFR exon 19 deletion cases, according to the Phase III FLAURA study. Therefore, there exists an unmet clinical need to enhance the clinical outcomes for NSCLC patients with EGFR L858R mutation. Clinical data from our Phase Ib study showed that among NSCLC patients with EGFR L858R mutation, first-line TY-9591 treatment achieved a significantly prolonged median PFS comparing to osimertinib treatment in the Phase III FLAURA trial (19.3 months in 36 patients vs. 14.4 months in 104 patients) based on a non-head-to-head comparison. Since the PFS data for NSCLC patients with EGFR L858R mutation from the FLAURA China cohort is not publicly available, and the efficacy data from the FLAURA global cohort is generally better than that of the China cohort, we compared our clinical results with the data for NSCLC patients with EGFR L858R mutation from the FLAURA global cohort.

We are currently conducting a pivotal Phase II clinical trial of TY-9591 monotherapy as first-line treatment in brain metastases from NSCLC with EGFR mutations in China, for which we expect to complete patient enrollment in the third quarter of 2024. In addition, we are conducting a registrational Phase III clinical trial of TY-9591 monotherapy as first-line treatment in locally advanced (stage IIIb to IV) or metastatic NSCLC with EGFR L858R mutation in China, for which we expect to complete patient enrollment in the fourth quarter of 2024. According to Frost & Sullivan, TY-9591 is the only EGFR-TKI worldwide that is currently undergoing a head-to-head registrational trial directly comparing its efficacy with osimertinib. To fully explore the potential of TY-9591, we also applied for and received IND approval for conducting Phase II and Phase III clinical trials of TY-9591 in combination with pemetrexed and cisplatin or carboplatin as first-line treatment in advanced or metastatic NSCLC with EGFR mutations in March 2024, and expect to commence a Phase II trial in the second half of 2024.

Addressable Markets and Competitive Landscape

NSCLC is any type of epithelial lung cancer other than small cell lung cancer (“SCLC”), accounting for 85% of lung cancer. According to Frost & Sullivan, among all NSCLC patients, EGFR mutation predominantly constitutes 50.2% in China in 2023. Among them, exon 19 deletion and exon 21 L858R mutation account for 85% of EGFR mutations, with exon 19 deletion contributing 44.8% and exon 21 L858R contributing 39.8% to the overall EGFR mutation profile. The EGFR-TKI market focusing on exon 21 L858R mutation increased from RMB1.4 billion in 2017 to RMB5.6 billion in 2023, representing a compound annual growth rate (“CAGR”) of 26.2%, and is projected to further grow to RMB11.9 billion in 2033 with a CAGR of 7.8% from 2023 to 2033. Upon approval of the third-generation EGFR-TKIs for marketing, these drugs rapidly occupied the market with the majority of NSCLC patients with EGFR mutations undergoing treatment with them, leading to a surge in the market size during 2017 to 2023. As market penetration slows down and the prices of third-generation EGFR-TKIs are expected to remain relatively stable, the market size is projected to grow steadily during 2023 to 2033.

Brain metastases occur when cancer cells spread from their original site to the brain. Lung cancer is among the cancer types that most likely cause brain metastases. The annual incidence of lung cancer in China is 1,015.5 thousand in 2023 and the incidence of brain metastases in patients with advanced NSCLC can be nearly 25% at diagnosis, approximately 30% to 55% of NSCLC patients develop brain metastases during treatment. From 2017 to 2023, the number of new patients with brain metastases from lung cancer in China increased from 137.6 thousand to 166.3 thousand, and is estimated to reach 218.0 thousand in 2033. The natural average survival of NSCLC patients with brain metastases, i.e. the average survival period for NSCLC patients with brain metastases without any treatment, is only one to two months, and the prognosis is poor, which seriously jeopardizes patients' lives and quality of life.

The last three columns of the table below set forth a summary of the targeted patient population of TY-9591 by indications:

Summary of Targeted Patient Population of TY-9591

	Lung Cancer	NSCLC	NSCLC with EGFR Mutations	Advanced or Metastatic NSCLC with EGFR Mutations	Brain Metastases from NSCLC with EGFR Mutations	Advanced or Metastatic NSCLC with EGFR L858R Mutation
Patient Population (in 2023 in China)	1,015.5 thousand	863.2 thousand	433.3 thousand	201.9 thousand	112.9 thousand	80.4 thousand
Patient Percentage	100%	Approximately 85% of all lung cancer patients	Approximately 50.2% of all NSCLCs patients	Approximately 46.6% of all NSCLC patients with EGFR mutations**	Approximately 47.5% to 66.3% of all advanced or metastatic NSCLCs patients*	Approximately 39.8% of all NSCLC patients with EGFR mutations

Notes:

* According to Frost & Sullivan, specific data for brain metastases in NSCLC patients with EGFR mutations is not available. However, it is believed that percentage of NSCLC patients with brain metastases may also apply to brain metastases in NSCLC patients with EGFR mutations as there is no reliable evidence of a significant discrepancy.

** According to the Treatment Guidelines for Stage IV Primary Lung Cancer in China (2023), about 46.6% of patients are diagnosed with stage IIIb to IV at the time of initial diagnosis. However, according to interviews with industry experts, approximately 50% are stage IV patients, as disclosed in the "Industry Overview." There is a gap between literature statistics and empirical data.

Source: Frost & Sullivan Analysis

As of June 30, 2024, there were six third-generation EGFR-TKIs approved for NSCLC with EGFR exon 19 deletion, exon 21 L858R and exon 20 T790M in China, and only befotertinib, furmonertinib, almonertinib, and osimertinib were approved as first-line treatment. None of these drugs were indicated for brain metastases from lung cancer. The third-generation EGFR-TKI market is highly competitive. The tables below illustrate the efficacy and the competitive landscape of marketed third-generation EGFR-TKIs for NSCLC in China:

Efficacy of EGFR-TKIs Approved by the NMPA

Drug Name	Brand Name	Target	Generation	Company	Indications	mPFS (month)			Line	Approval Date	2023 Global Sales (million USD)
						Ex19del	L858R	Overall			
Rilertinib	Sanrisso	EGFR	3 rd -generation	Sanhome Pharmaceutical	NSCLC	13.8	9.7	12.6	2 nd line	2024-06-17	NA
Rezivertinib	Undisclosed	EGFR	3 rd -generation	Betta Pharma	NSCLC	12.4	10.3	12.2	2 nd line	2024-05-20	NA
Befotertinib	Surmana	EGFR	3 rd -generation	Betta Pharma	NSCLC	NE	17.9	22.1	1 st line	2023-10-12	Undisclosed
Furmonertinib	Ivesa	EGFR	3 rd -generation	Allist Pharmaceutical	NSCLC	20.8	13.4	19.3	1 st line	2022-06-28	274.0
Almonertinib	Ameile	EGFR	3 rd -generation	Hansoh Pharma	NSCLC	Undisclosed		20.8	1 st line	2021-12-16	Undisclosed
Osimertinib	Tagrisso	EGFR	3 rd -generation	Astrazeneca	NSCLC	21.6	14.2	18.9	1 st line	2019-08-30	5,799

Abbreviation: NE = not evaluated.

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of EGFR-TKIs Approved by the NMPA

Drug Name	Brand Name	Target	Mutation Subtype	Monotherapy or Combined Therapy	Whether enter the NRDL	End User Price (RMB/box)	Treatment Cost (RMB/month)
Rilertinib	Sanrisso	EGFR	T790M	Monotherapy	No	NA	NA
Rezivertinib	Undisclosed	EGFR	T790M	Monotherapy	No	NA	NA
Befotertinib	Surmana	EGFR	Ex19del, L858R, T790M	Monotherapy	Yes	2,862.4	8,587.2
Furmonertinib	Ivesa	EGFR	Ex19del, L858R, T790M	Monotherapy	Yes	2,494.5	4,989.0
Almonertinib	Ameile	EGFR	Ex19del, L858R, T790M	Monotherapy	Yes	2,016.0	5,345.4
Osimertinib	Tagrisso	EGFR	Ex19del, L858R, T790M	Monotherapy	Yes	4,966.2	4,966.2

Source: NMPA, Frost & Sullivan Analysis

As of June 30, 2024, nine third-generation EGFR-TKI candidates were in clinical development for NSCLC and two of them were indicated for NSCLC with brain metastases, among which TY-9591 was the most clinically advanced EGFR-TKI candidate. The table below illustrates the competitive landscape of clinical-stage third-generation EGFR-TKIs for NSCLC in China:

Drug Name/Code	Target	Mutation Subtype	Company	Control	Clinical Stage	Indications	First Posted Date
TY-9591	EGFR	L858R	TYK Medicines, Inc	Osimertinib	III	NSCLC	2022-05-19
		Ex19del, L858R, T790M			II (Pivotal)	NSCLC with Brain metastases	2021-11-16
Abivertinib	BTK, EGFR	Ex19del, L858R, T790M	Sorrento/Essex Pharmaceutical	Gefitinib	III	NSCLC	2019-04-09
FHND9041	EGFR	Ex19del, L858R, T790M	Chia Tai Fenghai Pharmaceutical	Afatinib	III	NSCLC	2021-08-31
Limertinib	EGFR	Ex19del, L858R, T790M	Aosaikang Pharmaceutical	Gefitinib	III	NSCLC	2019-08-29
Kenitinib	EGFR	Ex19del, L858R	Suzhou Teligene	NA	II	NSCLC with Brain metastases	2020-05-12
TQB3456	EGFR	Ex19del, L858R, T790M	Chia Tai-tianqing Pharmaceutical	NA	I	NSCLC	2018-08-31
QLH11811	EGFR	Ex19del, L858R, T790M	Qilu Pharmaceuticals	NA	I	NSCLC	2022-09-22
YZJ-0318	EGFR	Ex19del, L858R, T790M	Yangtze River Pharmaceutical	NA	I	NSCLC	2018-01-28
DZD6008	EGFR	Ex19del, L858R, T790M	Dizal Pharma	NA	I	NSCLC	2024-05-24

Source: CDE, Frost & Sullivan Analysis

TY-302

TY-302 is a potent, selective oral cyclin-dependent kinase 4/6 (“**CDK4/6**”) inhibitor developed for the treatment of advanced solid tumors, including breast cancer and prostate cancer. Targeting CDK4/6, a key cell cycle regulator, TY-302 suppresses the phosphorylation of the retinoblastoma protein (“**Rb**”), preventing proliferation of cancer cells. TY-302 was modified by H/D exchange of palbociclib, the best-selling CDK4/6 inhibitor in the world. Based on the preliminary safety data collected through our current Phase I/II clinical trial, TY-302 achieved an improved safety profile in respect of AEs in general, especially AEs related to infectious disease, skin and subcutaneous tissue and GI system, based on a non-head-to-head comparison. In addition, TY-302 has achieved encouraging efficacy in breast cancer. We observed that TY-302 achieved a DCR of 71.4% in 14 recruited breast cancer patients who had failed prior two or more lines of treatments. We expect to further investigate the combination therapy of TY-302 with toremifene in third – or later-line estrogen receptor positive (“**ER+**”)/human epidermal growth factor receptor 2-negative (“**HER2-**”) breast cancer that has progressed after second-line endocrine therapy. In addition, we plan to commence a Phase II clinical trial of TY-302 in prostate cancer in the second half of 2024, exploring TY-302 in combination with abiraterone for the treatment of metastatic castration – resistant prostate cancer (“**mCRPC**”), which is an advanced prostate cancer that is challenging to treat with no responding to the standard of care treatment, endocrine therapy.

Breast cancer is the most common cancer in women, and its incidence rises with age, increasing year by year as women age. The number of new breast cancer cases in China increased from 315.2 thousand in 2017 to 345.5 thousand in 2023, and is projected to reach 376.9 thousand in 2033. ER+/HER2 – breast cancer is the most common breast cancer subtype, representing approximately 70% of patients.

Prostate cancer is an epithelial malignant tumor that occurs in the prostate. It is the most common malignant tumor of the male genitourinary system. The number of new cases of prostate cancer in China grew from 97.3 thousand in 2017 to 132.7 thousand in 2023. This number is expected to continue to grow and reach 189.1 thousand in 2033. Almost all advanced prostate cancer patients, after undergoing hormonal therapy, will eventually progress to CRPC, with mCRPC being the primary cause of patient death. The main goal for treating mCRPC is to control symptoms and slow progress.

As of June 30, 2024, there were five cyclin-dependent kinase (“**CDK**”) inhibitors approved and marketed globally, namely, palbociclib, abemaciclib, dalpiciclib, trilaciclib and ribociclib, all of which targeted CDK4/6. Among these, four were approved for combination use with endocrine therapy. The global CDK4/6 inhibitors market has grown from US\$3.2 billion in 2017 to US\$10.7 billion in 2023 at a CAGR of 22.2%. With an increasing number of CDK4/6 inhibitors coming to market, the market size will continue to expand in the future, and the global CDK4/6 inhibitors market is expected to reach approximately US\$16.1 billion and US\$26.2 billion in 2027 and 2033, respectively, with a CAGR of 10.6% from 2023 to 2027 and at a CAGR of 8.5% from 2027 to 2033.

As of June 30, 2024, there were 26 CDK inhibitor candidates under development in China, among which TY-302 was the only CDK4/6 inhibitor indicated for prostate cancer.

TY-2136b

TY-2136b is an internally developed, oral ROS proto-oncogene 1 (“**ROS1**”)/neurotrophic tyrosine receptor kinase (“**NTRK**”) inhibitor for the treatment of solid tumors. It was designed to efficiently bind with the active kinase conformation and avoid steric interference from a variety of clinically resistant mutations. The compact structure is believed to allow TY-2136b to precisely and efficiently bind into the adenosine triphosphate (“**ATP**”) binding pocket of the kinase, and potentially circumvent the steric interference that results in resistance to bulkier kinase inhibitors. Our current primary focus lies on NSCLC with ROS1 or NTRK mutation, a demographic estimated to reach 56.2 thousand new cases worldwide in 2033, according to Frost & Sullivan.

TY-2136b has demonstrated encouraging safety profile in preclinical studies. Also according to our preclinical data, TY-2136b is not only effective against ROS1/NTRK oncogenic gene mutations, but also exhibits high selectivity of ROS1 and NTRK mutations such as ROS1 G2032R mutation and NTRK G595R, which commonly contribute to resistance against existing ROS1/NTRK drugs. Specifically, despite its targeting multiple mutations, TY-2136b does not interfere with JAK/STAT signaling pathway, inhibit Ba/F3 cells overexpressing ABL1 (H396P) mutant kinase, or disrupt SRC kinase activity. In addition, its preliminary efficacy against ROS1 and NTRK mutations has been demonstrated across multiple animal models, showcasing its potential to address drug resistance against existing ROS1/NTRK drugs. As a result, the FDA has granted Orphan Drug Designation to TY-2136b for the treatment of ROS1-positive, NTRK fusion-positive, anaplastic lymphoma kinase (“**ALK**”)-positive or leukocyte receptor tyrosine kinase (“**LTK**”)-positive NSCLC. Furthermore, its potential has been recognized and endorsed by Livzon and we have out-licensed the Greater China rights of TY-2136b to Livzon.

Livzon is currently conducting a Phase Ib clinical trial of TY-2136b in China under IND approval from the National Medical Products Administration of the PRC (“**NMPA**”) obtained in February 2022 and we are conducting a Phase I clinical trial in the U.S. under FDA’s implied IND approval obtained in November 2021. Leveraging Phase I clinical data collected both in China and the U.S., we will communicate with the FDA and carefully design our future clinical development plan of TY-2136b in the U.S.

Addressable Markets and Competitive Landscape

According to Frost & Sullivan, the global ROS1/NTRK-TKI market grew from US\$70.7 million in 2017 to US\$332.0 million in 2023, reflecting a CAGR of 29.4%. The global ROS1/NTRK-TKI market is forecasted to reach US\$602.0 million in 2027 and ultimately to US\$1,052.9 million in 2033, representing a CAGR of 16.0% from 2023 to 2027 and a CAGR of 9.8% from 2027 to 2033. The ROS1/NTRK-TKI market in China has developed at a faster pace, increasing from RMB15.7 million in 2017 to RMB252.6 million in 2023, demonstrating a CAGR of 58.8%. The ROS1/NTRK-TKI market in China is projected to further grow to RMB514.2 million in 2027 and RMB860.5 million in 2033, with a CAGR of 19.4% from 2023 to 2027 and a CAGR of 9.0% from 2027 to 2033.

In China, ROS1 mutation accounts for approximately 1.5% of all NSCLC patients, while NTRK mutation accounts for approximately 1.0% of all NSCLC patients. From 2017 to 2023, the number of new cases of NSCLC with ROS1 or NTRK mutation worldwide increased from 36.8 thousand to 43.3 thousand, representing a CAGR of 2.7%. It is estimated that the number of new patients of NSCLC with ROS1 or NTRK mutation worldwide will reach 56.2 thousand in 2033. From 2017 to 2023, the number of new cases of NSCLC with ROS1 or NTRK mutation in China increased from 17.9 thousand to 21.6 thousand, representing a CAGR of 3.2%. It is estimated that the number of new cases of NSCLC with ROS1 or NTRK mutation in China will reach 28.3 thousand in 2033.

As of June 30, 2024, four ROS1/NTRK-TKIs had secured approval from the FDA, including entrectinib by Roche, crizotinib by Pfizer, repotrectinib by BMS, and larotrectinib by Bayer, and there were five ROS1/NTRK-TKIs that secured approval from the NMPA. As of June 30, 2024, there were 29 ROS1/NTRK-TKI candidates under clinical development globally. Among them, there were four candidates that simultaneously target both ROS1 and NTRK with the most clinically advanced candidate in the Phase II clinical stage.

Other Pipeline Products

Our clinical products include the followings:

- TY-2699a is a selective CDK7 inhibitor designed for the treatment of advanced/metastatic solid tumors. Our preclinical studies showed that TY-2699a potentially has improved safety window with blood-brain barrier penetration capability. TY-2699a received implied IND approval from the FDA and IND approval from the NMPA in February 2023 and May 2023, respectively. We are currently conducting a Phase I clinical trial of TY-2699a monotherapy or combination therapy in locally advanced or metastatic solid tumors (especially in SCLC and triple-negative breast cancer (“TNBC”)) in China. We expect to commence Phase Ib clinical trial in the first quarter of 2025.
- TY-0540 is a selective CDK2/4/6 inhibitor intended for the treatment of advanced/metastatic solid tumors. Despite the transformative impact of CDK4/6 inhibitors on HR+/HER2 – breast cancer treatment, significant challenges persist, notably primary and acquired resistance. According to Frost & Sullivan, approximately 20% of patients exhibit primary resistance to CDK4/6 inhibitors, rendering initial therapy ineffective, while others develop resistance within approximately 25 months. Once resistance occurs, treatment options often entail higher toxicity and limited clinical benefit, such as mammalian target of rapamycin inhibitors, leading to the emergence of CDK2/4/6 inhibitors as a novel therapeutic avenue to curb cancer cell proliferation. We received implied IND approval from the FDA and the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of TY-0540 for the treatment of advanced solid tumors in June 2023 and September 2023, respectively. We are currently conducting a Phase I clinical trial of TY-0540 monotherapy or combination therapy in solid tumors in China, and expect to commence Phase Ib clinical trial in the first quarter of 2025.
- TY-4028 is a potent, irreversible, oral exon 20 insertion-TKI, targeting locally advanced or metastatic NSCLC with EGFR exon 20 or HER2 exon 20 insertions. EGFR exon 20 insertion is the third common mutation in NSCLC, according to Frost & Sullivan, and among NSCLC patients with EGFR mutation, approximately 7.7% of patients have EGFR exon 20 insertion in China. Patients with exon 20 insertions are associated with primary resistance to targeted EGFR-TKIs and correlate with a poor patient prognosis. TY-4028 presents an innovative, targeted therapy for this specific subset of NSCLC patients. We received implied IND approval from the FDA and the IND approval from the NMPA in April 2023 and June 2023, respectively. We plan to initiate a Phase I trial of TY-4028 in NSCLC with exon 20 insertion in China in December 2024.

- TY-1091 is a potent and selective rearranged during transfection proto-oncogene (“**RET**”) inhibitor. It is intended for the treatment of advanced NSCLC with RET gene fusion, advanced medullary thyroid cancer (“**MTC**”) with RET gene mutation and other advanced solid tumors with RET gene alterations. We received implied IND approval from the FDA and the IND approval from the NMPA in August 2022 and December 2022, respectively. We are currently conducting a Phase I clinical trial of TY-1091 in RET fusion-positive solid tumors in China.

In addition, we are developing a number of drug candidates in preclinical or early clinical development stage, including TY-1054, TY-1210, TY-0609 and TY-3200.

Our Technology Platforms

We have established four proprietary and fully-integrated technology platforms centered around the development of new small molecule drugs, which enable us to direct our efforts towards candidates with the best potential to become clinically active, cost-effective and commercially viable drugs:

- Drug design and screening platform: Our drug design and screening platform is a small molecule drug discovery platform, currently focusing on kinase. This platform comprises two important functions, namely, kinase biology and small molecule drug discovery. Notably, all our drug candidates (except TY-9591 and TY-302) were conceived and synthesized within this platform, and have garnered recognition from domestic pharmaceutical companies. For example, we out-licensed the Greater China rights of TY-2136b to Livzon when it was in the preclinical stage.
- Druggability evaluation platform: Equipped with a druggability evaluation platform, we are capable to conduct a wide range of R&D activities in-house, including drug metabolism and pharmacokinetics (“**DMPK**”) studies, *in vivo* and *in vitro* bioactivity studies (including animal modeling), toxicity studies, physicochemical characterization, and chemistry, manufacture, and controls processes (“**CMC**”) of drug candidates. We are capable to evaluate the efficacy of our drug candidates including kinase inhibitors in-house.
- Translational medicine platform: Our translational medicine platform enables us to conduct research on the pathogenesis of tumors and neurological disorders, and systematically search for and identify potential biomarkers and new drug targets. Using genomics, transcriptomics and proteomics methods, we can systematically assess drug effects.
- CADD/AIDD platform: Our computer-aided drug design (“**CADD**”)/artificial intelligence drug design (“**AIDD**”) platform is dedicated to aiding our internal drug discovery team. This platform has yielded several pipeline products. For example, TY-2136b, designed to target tyrosine kinases ROS1/NTRK, emerged during lead optimization in CADD. TY-2699a, a CDK7 inhibitor, employed CADD/AIDD in compound design, highlighting the value of AIDD in identifying overlooked aspects to improve therapeutic window.

RESEARCH AND DEVELOPMENT

We consistently devote resources to research and development to pave way for long-term growth. Our research and development costs in 2022, 2023 and six months ended June 30, 2024 amounted to RMB229.8 million, RMB249.3 million and RMB137.8 respectively. Our in-house R&D capabilities, built on our proprietary technology platforms, are backed by our R&D centers in Huzhou, Zhejiang and Zhengzhou, Henan. Our R&D centers are equipped with advanced laboratories and state-of-art equipment and instruments such as liquid chromatography, liquid chromatography mass spectrometer, and nuclear magnetic resonance. We believe that our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through rapidly changing market needs, enable us to improve pipeline viability and expedite the product development cycle at a lower cost.

As of June 30, 2024, we had 107 members in our R&D team, around 56% of whom held master's or doctoral degrees in relevant fields. The expertise of our team members spans the entire spectrum of drug development, encompassing drug discovery, medicinal chemistry design and virtual screening, preclinical pharmaceutical research, drug testing and purification, formulation development, clinical research, regulatory submissions and platform construction.

COMMERCIALIZATION

To capture market demand under fierce competition, we will not only build our in-house sales and marketing capabilities progressively, but also engage contract sales organizations in China to leverage their sales and marketing expertise and well-established networks and resources.

II. FINANCIAL REVIEW

Revenue

The Group did not generate any revenue for the six months ended June 30, 2024 and 2023. The Group's revenue basically depends on the exclusive license agreement (the "**Livzon Agreement**") with Livzon Pharmaceutical Group Inc. ("**Livzon**") to research, develop, improve, manufacture, use, sell, contract and commercialize ROS1/NTRK/ALK multi-target small molecule broad-spectrum tyrosine kinase inhibitor ("**TY-2136b**") in Great China. The next milestone that would trigger payment obligation of Livzon had not been reached as of June 30, 2024.

Cost of Sales

The Group did not incur any cost of sales for the six months ended June 30, 2024 and 2023.

Other Income and Gains

During the Reporting Period, our other income and gains primarily consisted of government grants, investment income on financial assets at FVTPL, bank interest income and fair value changes of financial assets at FVTPL.

The Group's other income and gains for the six months ended June 30, 2024 was RMB11,285,000, representing an increase of RMB1,006,000 compared to RMB10,279,000 for the six months ended June 30, 2023, mainly due to the increase in government grants and increase in fair value changes of financial assets at FVTPL, partially offset by the decrease in investment income on financial assets at FVTPL.

Research and Development Costs

During the Reporting Period, our research and development costs consisted of (i) trial and testing expenses for our drug candidates, primarily in relation to the engagement of CROs, CDMOs, principal investigators, and other service providers; (ii) staff costs mainly relating to salaries, bonus and other welfare for our research and development personnel; (iii) depreciation and amortization expenses in relation to our research and development equipment and instruments, as well as intangible assets which were used for research and development purpose; (iv) costs of materials consumed in the course of our research and development activities; and (v) other research and development costs, mainly comprising travelling and transportation expenses of our research and development personnel, utilities incurred for our research and development activities and other miscellaneous expenses.

The Group's research and development costs for the six months ended June 30, 2024 was RMB137,758,000, representing an increase of 15.3% compared to RMB119,436,000 for the six months ended June 30, 2023. The increase was primarily attributable to the increase in trial and testing expenses, especially in relation to the development of our core product.

	Six months ended 30 June	
	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Trial and testing expenses	99,601	83,915
Staff costs	20,295	21,651
Depreciation and amortization expenses	9,470	8,912
Materials consumed	1,342	3,079
Others	7,050	1,879
Total	<u>137,758</u>	<u>119,436</u>

Administrative Expenses

During the Reporting Period, our administrative expenses primarily consisted of (i) staff costs mainly relating to salaries, bonus and other welfare for our administrative personnel; (ii) general office expenses mainly comprising office expenses, hospitality expenses, travelling and transportation expenses, and utilities used for administrative purpose; (iii) depreciation and amortization expenses for offices, equipment and other assets which were used for administrative purpose; (iv) professional service fees mainly paid to legal advisors, auditors, asset valuers and recruitment consultants; (v) listing expenses; and (vi) other administrative expenses mainly including tax and surcharges and other miscellaneous expenses.

The Group's administrative expenses for the six months ended June 30, 2024 was RMB40,100,000, representing an increase of 80.8% compared to RMB22,176,000 for the six months ended June 30, 2023. The increase was primarily attributable to the increase in listing expenses.

Finance Costs

During the Reporting Period, our finance costs primarily consisted of (i) interest on lease liabilities; (ii) interest expenses of government funding, representing deemed interest expenses recorded in relation to Changxing Investment; and (iii) bank loan interests.

The Group's finance costs for the six months ended June 30, 2024 was RMB5,431,000, representing an increase of 21.1% compared to RMB4,483,000 for the six months ended June 30, 2023. The increase in finance costs was primarily attributable to the increase in interests on bank loans and interest expenses of government funding, partially offset by the decrease in interest on lease liabilities.

Income Tax Expense

The Group did not generate any profits, therefore, there was no income tax for the six months ended June 30, 2024 and 2023.

Loss for the Period

Based on the factors described above, our loss for the Reporting Period increased by 26.3% from RMB173,849,000 for the period ended June 30, 2023 to RMB219,533,000 for the six months ended June 30, 2024.

Capital Management

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Reporting Period.

Liquidity and Capital Resources

As at June 30, 2024, the Group had cash and cash equivalents of RMB105,044,000, including term deposits with initial terms of 6 months of RMB60,000,000 in total. The balance of cash and cash equivalents decreased by 43.8% from RMB186,830,000 as at December 31, 2023. The decrease was primarily arising from the followings:

- For the six months ended June 30, 2024, our net cash used in operating activities was RMB136,281,000, primarily attributable to (i) our loss before tax of RMB219,533,000, as adjusted to reflect non-cash and/or non-operating items, which principally included fair value loss on redemption liabilities on equity shares of RMB47,459,000, depreciation and amortization of RMB14,727,000, listing expenses of RMB12,632,000, share-based payment compensation expenses of RMB7,035,000, finance costs of RMB5,431,000; and (ii) an increase in trade and other payables of RMB1,659,000.
- For the six months ended June 30, 2024, our net cash used in investing activities was RMB120,136,000, primarily attributable to (i) purchase of financial assets of RMB138,000,000; and (ii) purchase of time deposits of RMB60,000,000, partially offset by the disposal of financial assets at FVTPL of RMB91,372,000.

- For the six months ended June 30, 2024, our net cash generated from financing activities was RMB114,652,000, primarily as a result of new bank loans of RMB80,400,000 and net proceeds from the issue of shares of RMB50,000,000.

Borrowings

As at June 30, 2024, our borrowings were RMB80,480,000 and there was no borrowing as at December 31, 2023. The borrowings were unsecured short-term bank loans with various commercial banks, with effective interest rates ranging from 3.6% to 3.9% per annum. As at June 30, 2024, the Group has unutilized bank facilities of RMB20,000,000.

The loan agreements in relation to such bank loans contained standard terms, conditions and covenants that are customary for commercial bank loans.

Net Current Liabilities

The Group's net current liabilities, as at June 30, 2024 were RMB1,211,385,000, representing an increase of 13.5% compared to the net current liabilities of RMB1,067,270,000 as at December 31, 2023 primarily because of the increase in the redemption liabilities on equity shares.

Currency Risk

The Group was not exposed to significant currency risk, and did not experience any material impact on our operations resulting from fluctuation in exchange rates during the Reporting Period. However, our management monitors our foreign currency risk exposure and will review and adjust our currency risk measures in accordance with our needs.

Pledge of Shares

As of June 30, 2024, the Group did not have any major assets pledged.

Contingent Liabilities

As of June 30, 2024, the Group did not have any material contingent liabilities.

Significant Investments, Material Acquisitions and Disposals

Save as disclosed in this announcement and the Prospectus, as at June 30, 2024, we did not hold any significant investments. For the Reporting Period, except for the potential disposal of the entire equity interest in a subsidiary to an Independent Third Party with a consideration of RMB34,900,000 which we are still in the process of completing this transaction, the Group did not have material acquisitions or disposals.

Capital Expenditure

During the Reporting Period, the Group's total capital expenditure amounted to approximately RMB18,268,000, which was mainly used in purchases of items of property, plant and equipment.

We regularly incur capital expenditures to purchase and maintain our property, plant and equipment in order to enhance our research and development capabilities and expand our business operations. Historically, we have funded our capital expenditures mainly through equity financing and bank borrowings.

Employees and Remuneration Policies

As at June 30, 2024, we had 144 employees in total. The remuneration package of our employees includes basic salaries, bonuses, and employee benefits. In addition, we provide relevant training to our employees in order to improve their skills and knowledge.

Future Plan of Significant Investment or Acquisition of Assets

Save as disclosed in the Prospectus, the Group did not have detailed future plans for any significant investment or acquisition of capital assets as of the date of this announcement.

III. PROSPECTS

OUR STRATEGIES

Accelerate the clinical development of our product candidates

We intend to accelerate the clinical development of our Core Product and Key Products to achieve commercialization, while continuing to explore potential combination therapy opportunities to fully unlock the commercial and clinical value of our product pipeline. In particular:

- **TY-9591.** We are currently conducting a pivotal Phase II clinical trial of TY-9591 monotherapy as first-line treatment in brain metastases from NSCLC with EGFR mutations. We plan to complete patient enrollment for this clinical trial in the third quarter of 2024, and submit an application to the NMPA for conditional marketing approval in the first quarter of 2025. In addition, we are conducting a registrational Phase III clinical trial of TY-9591 monotherapy as first-line treatment in locally advanced or metastatic NSCLC with EGFR exon 21 L858R mutation. We plan to complete patient enrollment for this clinical trial in the fourth quarter of 2024, and submit a NDA in the second half of 2026. To fully explore the potential of TY-9591, we also applied for and obtained the IND approval for conducting Phase II and Phase III clinical trials of TY-9591 in combination with pemetrexed and cisplatin or carboplatin as first-line treatment in advanced or metastatic NSCLC with EGFR mutations in March 2024, and expect to commence a Phase II trial in the second half of 2024. We expect to complete patient enrollment of the Phase II trial in the first half of 2026.
- **TY-302.** We are currently conducting a Phase II clinical trial of TY-302 in breast cancer. We expect to initiate a registrational Phase III clinical trial of TY-302 in combination with toremifene citrate as third- or later-line treatment in breast cancer in the first quarter of 2025, and we anticipate to submit a NDA in the second half of 2028. In addition, we plan to commence a Phase II clinical trial of TY-302 in combination with abiraterone as first-line treatment in prostate cancer in the second half of 2024 and we expect to commence a registrational Phase III clinical trial of TY-302 in the second half of 2026.

- TY-2136b. Livzon is currently conducting a Phase Ib clinical trial of TY-2136b in China and we are conducting a Phase I clinical trial in the U.S. Leveraging Phase I clinical data collected both in China and the U.S., we plan to communicate with the FDA and carefully design our future clinical development plan of TY-2136b in the U.S.

We also plan to rapidly advance the clinical development of our other clinical-stage and preclinical-stage drug candidates either as monotherapies or combination therapies to address unmet clinical needs. In particular:

- TY-2699a. We are currently in Phase Ia clinical stage of investigating TY-2699a monotherapy or combination therapy in locally advanced or metastatic solid tumors (especially in SCLC and TNBC) in China, and expect to commence Phase Ib study in the first quarter of 2025. We anticipate to commence a pivotal Phase II clinical trial in the second half of 2026.
- TY-0540. We are currently in Phase Ia clinical stage of investigating TY-0540 monotherapy or combination therapy in solid tumors in China, and expect to commence Phase Ib study in the first quarter of 2025. We anticipate to commence a Phase II clinical trial in the second half of 2026.

Continue enhancing R&D capabilities and expanding our pipeline

Our core competencies lie in our understanding of diseases and the mechanisms of action of drugs. We have made remarkable achievements so far, and in the future, we will continue to strengthen these capabilities. At the same time, we recognize that drugs with novel targets and mechanisms of action will enhance our competency in the pharmaceutical industry. Therefore, we have developed several innovative drug candidates, such as TY-1054, TY-1210, and TY-0609, and plan to continue the development of these candidates. Furthermore, we plan to actively invest in in-house discovery to seize market opportunities and to identify and develop innovative compounds.

Additionally, we intend to leverage Dr. Wu's experience in the development of innovative drugs for central nervous system diseases and pursue opportunities to expand into other therapeutic areas, such as central nervous system diseases, autoimmune diseases, and cardiovascular diseases.

Enhance manufacturing capability and establish commercialization capability

We plan to continue to enhance manufacturing capability by procuring additional manufacturing equipment and scaling up our manufacturing capacity when necessary, which we believe will prepare us for the commercialization of more pipeline products in the foreseeable future.

In addition, we plan to explore opportunities to vertically integrate our supply chain to secure upstream resources and improve our profitability by investment in or partnerships with selective and qualified raw material suppliers.

We also intend to establish sales and marketing capabilities through a combination of in-house efforts and working with external partners to leverage their sales and marketing expertise and well-established networks and resources.

Explore partnership opportunities to maximize the value of our drug candidates and further expand our product pipeline

We plan to continue to actively explore business collaboration opportunities with leading industry participants to accelerate our development timelines and maximize the clinical and commercial value of our drug candidates in other key international markets. For example, we will consider forging partnerships with multinational corporations to out-license the overseas rights of our assets when appropriate opportunities arise.

Meanwhile, we plan to enhance our business development team, which will continue to closely monitor and keep abreast of the evolving clinical demands, to pursue global opportunities to in-license new drug candidates. We may also selectively acquire or invest in innovative technologies to enhance our research and development capabilities or explore potential combination therapy partners for TY-9591. In addition, we may collaborate with leading universities or research institutions to develop new technologies or drug candidates. We will emphasize on assets that have potential synergies with our current pipeline and technology pipeline, and/or have best-in-class and/or first-in-class potential.

OTHER INFORMATION

INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend for the Reporting Period.

CORPORATE GOVERNANCE

The Directors recognize the importance of incorporating elements of good corporate governance in the management structures and internal control procedures of the Group so as to achieve effective accountability.

The Company has committed to achieving high standards of corporate governance with a view to safeguarding the interest of the Shareholders and adopted the principles and code provisions set out in the CG Code as its own code to govern its corporate governance practices.

The CG Code was not applicable to the Company for the Reporting Period, as the Company had not been listed on the Stock Exchange as at June 30, 2024. Since the Listing Date and up to the date of this announcement, the Company has complied with all the applicable code provisions set out in Part 2 of the CG Code, other than disclosed below:

The code provision C.2.1 of CG Code requires that the roles of chairperson and chief executive should be separate and should not be performed by the same individual to ensure there is a clear division of responsibilities between the running of the Board and the executives who manage the business. Dr. WU Yusheng (“**Dr. Wu**”) is the chairperson of the Board and the chief executive officer of the Company. With experience in the pharmaceutical industry and having served in the Company since its establishment, Dr. Wu is in charge of overseeing the overall management, business operation and strategies of the Group. Despite the fact that the roles of the chairperson of the Board and the chief executive officer of the Company are both performed by Dr. Wu which constitutes a deviation from the CG Code, the Board considers that vesting the roles of both the chairperson of the Board and the chief executive officer of the Company all in Dr. Wu has the benefit of ensuring consistent leadership and more effective and efficient overall strategic planning of the Company. The balance of power and authority is ensured by the operation of the Board and the senior management, each of which comprises experienced and diverse individuals. The Board currently comprises two executive Directors, five non-executive Directors and four independent non-executive Directors. Therefore, the Board possesses a strong independence element in its composition.

The Company will continue to regularly review and monitor its corporate governance practices to ensure compliance with the CG Code and maintain a high standard of corporate governance practices.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors and Supervisors.

The Model Code was not applicable to the Company for the Reporting Period, as the Company had not been listed on the Stock Exchange as at June 30, 2024. Upon specific enquiries, all Directors and Supervisors confirmed that they have complied with the Model Code since the Listing Date and up to the date of this announcement.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY

Disclosure on the particulars of purchase, sale or redemption by the Company or any of its subsidiaries of the listed securities of the Company is not applicable to the Company for the Reporting Period as the Company was not listed on the Stock Exchange during the Reporting Period. Since the Listing Date and up to the date of this announcement, none of the Company or any of its subsidiaries has purchased, sold or redeemed any of the Company’s listed securities.

EVENTS AFTER THE REPORTING PERIOD

On August 20, 2024, the Company was successfully listed on the Stock Exchange following the completion of the issue of 47,880,000 H Shares at the price of HK\$12.10 per share. The total gross proceeds arising from the listing amounted to approximately HK\$579.3 million. The Group will utilize the net proceeds in accordance with the intended purposes as set out in the Prospectus. The Board is not aware of any material change to the planned use of the net proceeds as at the date of this announcement.

Upon the completion of the Listing on August 20, 2024, all special rights on Shares has ceased to be effective and the carrying amount of the redemption liabilities on equity shares has transferred to equity accordingly.

Save as disclosed above, the Group did not have any other material subsequent events after the Listing Date and up to the date of this announcement.

REVIEW OF INTERIM RESULTS

The Board has established the Audit Committee which consists of one non-executive Director, namely, Dr. LI Jun and two independent non-executive Directors, namely, Mr. ZHANG Senquan Dr. LENG Yuting. The chairperson of the Audit Committee is Mr. ZHANG Senquan, who holds the appropriate professional qualifications as required under Rules 3.10(2) of the Listing Rules.

The Audit Committee has reviewed and considered that the unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2024 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

The Company's independent auditor, Ernst & Young, has performed an independent review of the Group's interim financial information for the Reporting Period in accordance with Hong Kong Standard on Review Engagements 2410, *Review of Interim Financial Information performed by the Independent Auditor of the Entity* issued by the Hong Kong Institute of Certified Public Accountants.

PUBLICATION OF THE 2024 CONDENSED CONSOLIDATED INTERIM RESULTS AND INTERIM REPORT

This interim results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.tykmedicines.com). The 2024 interim report of the Company containing all the information required by the Listing Rules will be published on the respective websites of the Stock Exchange and the Company in due course.

DEFINITIONS

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

“Audit Committee”	the audit committee of the Board
“Board”	the board of Directors
“CG Code”	the Corporate Governance Code as set out in Appendix C1 to the Listing Rules
“China” or “the PRC”	the People’s Republic of China excluding, for the purposes of this announcement, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“Company” or “the Company”	TYK Medicines, Inc* (浙江同源康醫藥股份有限公司), a joint stock company incorporated in the PRC with limited liability on November 2, 2017
“Director(s)”	the director(s) of the Company
“Global Offering”	has the meaning as ascribed to it in the Prospectus
“Group”, “our Group”, “our”, “we”, or “us”	the Company and its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“H Share(s)”	ordinary share(s) in the share capital of the Company with a nominal value of RMB1.00 each, which are subscribed for and traded in Hong Kong dollars and listed on the Stock Exchange
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“Listing”	listing of the H Shares on the Main Board of the Stock Exchange
“Listing Date”	August 20, 2024, on which the H Shares were listed and dealings in the H Shares first commenced on the Stock Exchange

“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange (as amended, supplemented or otherwise modified from time to time)
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules
“Main Board”	the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange
“Prospectus”	the prospectus of the Company dated August 12, 2024
“Reporting Period”	the six months ended June 30, 2024
“RMB”	renminbi, the lawful currency of the PRC
“Share(s)”	ordinary share(s) in the capital of the Company with a nominal value of RMB1.00 each, including both Unlisted Share(s) and H Share(s)
“Shareholder(s)”	holder(s) of the Share(s)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary(ies)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	member(s) of the Supervisory Committee
“Supervisory Committee”	the supervisory committee of the Company
“Unlisted Share(s)”	ordinary share(s) issued by the Company with a nominal value of RMB1.00 each and are not listed on any stock exchange
“USD”	United States dollars, the lawful currency of the United States
“%”	per cent

By Order of the Board
TYK Medicines, Inc*
(浙江同源康醫藥股份有限公司)
Dr. WU Yusheng

Chairman, Executive Director and Chief Executive Officer

Hong Kong, August 30, 2024

As at the date of this announcement, the Board comprises Dr. WU Yusheng and Dr. JIANG Mingyu as executive Directors, Dr. LI Jun, Dr. GU Eric Hong, Dr. MENG Xiaoying, Mr. HE Chao and Dr. DING Zhao as non-executive Directors, and Mr. ZHANG Senquan, Dr. LENG Yuting, Dr. XU Wenqing and Dr. SHEN Xiuhua as independent non-executive Directors.