



INNOCARE

诺诚健华



InnoCare Pharma (9969.HK) – 2022 Interim Results

August 2022

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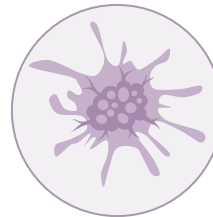
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To Become
a Global Biopharmaceutical Leader
that Develops and Delivers
Innovative Therapies for Patients Worldwide

Oncology



Autoimmune

Our Therapeutic Focus

1

Top-tier Founder & Management Team

- ✓ Experienced founders and strong management team with an excellent track record in drug discovery, clinical development, business development and commercialization

2

Fully-integrated Drug Innovation Platform

- ✓ In-house drug discovery platform and highly efficient clinical development team
- ✓ Well established sales force and novel drug manufacturing facilities

3

A Leading Hema-oncology Franchise

- ✓ Orelabrutinib launched in 2021 with accelerated growth following NDRL inclusion
- ✓ Differentiated approach to hard-to-treat B-cell lymphomas with CD-19, CD20xCD3, E-3 ligase, and BCL-2 molecules
- ✓ Focused and effective sales force expansion

4

Autoimmune Diseases Drugs Covering Both B cell and T cell Pathogenic Pathways

- ✓ Orelabrutinib - Partnered with Biogen in MS; completed Phase II in SLE with positive results and entering further trials
- ✓ Potential best-in-class TYK-2 inhibitors, ICP-332 entered Phase II and ICP-488 initiated Phase I trials
- ✓ A portfolio of compounds targeting different pathways offering a comprehensive coverage of autoimmune disease

5

Competitive Solid Tumor Portfolio

- ✓ Highly selective FGFR, TRK and SHP2 inhibitors in Phase I or II clinical studies in both China and U.S.
- ✓ Advanced solid tumor pipeline covering multiple promising targets i.e. potential first-in-class CCR8, bispecific antibodies

6

Strong Cash Position Providing Safety and Flexibility

- ✓ Continue to expand pipeline through internal and external opportunities
- ✓ M&A opportunities for assets and platforms
- ✓ A shares Listing to provide sufficient funding for growth and expansion

Transforming from Biotech to Biopharma

Snapshot of Achievements in 2022H1

Accelerated Commercialization

- Total revenue reached **RMB 246mn**, including **RMB 217mn of Orelabrutinib sales**, in 2022H1
- Rapid market penetration and hospital coverage after NRDL inclusion
- Tafasitamab 1st prescription landed in Hainan
- Commercial team in expansion

Business Development Progressing

- **Out-licensing:** Orelabrutinib in **MS with Biogen Phase II patient enrollment close to completion**
- **In-licensing:** Tafasitamab pivotal trial patient enrollment initiated in mainland China
- **Collaboration** projects with KeyMed entered clinical stage

Rapidly Maturing Pipeline

- Submitted NDA for WM and MZL
- **SLE moves to further clinical trial in China**
- **Orelabrutinib 1L DLBCL-MCD registrational Phase III trial commenced**
- **ICP-332 Phase II trials initiated in AD and Psoriasis**
- **ICP-488 Phase I initiated**
- **ICP-192 and ICP-723 well positioned** for registrational trials
- 3 NMEs entered clinical stage
- 11 clinical assets in total
- 30+ ongoing global clinical trials

Expanding Infrastructure

- Ready for commercial production of Orelabrutinib in our Guangzhou facility
- Biological drug R&D facility in Beijing

Solid Financial Position

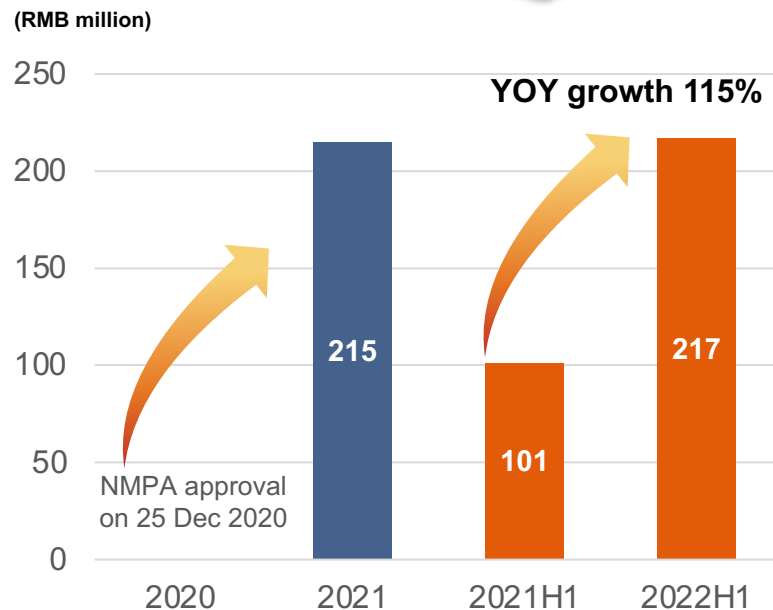
- Over **RMB 5bn** net cash in hand
- CSRC approval obtained for STAR Board listing
- Cost sensitive and cost efficient culture

Commercialization Update

Strong Sales Ramp-up with Orelabrutinib

Robust Net Sales Growth¹

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Successful Commercialization Strategy

- Net sales achieved **RMB 217mn** in 2022H1
- Swift implementation of NRDL at local level
- Experienced and effective in-house commercial team
- Rapid coverage of hematology market in China:
 - Penetrated **260+** Cities
 - Covered **1,000+** Hospitals
 - Educated **5,000+** Doctors
- CSCO Diagnosis and Treatment Guidelines** recommended broad use: r/r CLL/SLL, r/r MCL, r/r DLBCL and PCNSL
- Substantial future growth potential:
 - Indication expansion
 - DOT enhancement
 - Extensive post market clinical studies to strengthen best-in-class profile
 - Tailored-access at different tiered cities

¹ **Indications:** r/r Mantle Cell Lymphoma ("MCL") and r/r Chronic Lymphocytic Leukemia/Small Cell leukemia ("CLL/SLL")

1 Major Program Update

Orelabrutinib (ICP-022) : Comprehensive Coverage in Hematology

- r/r WM NDA accepted by CDE in 2022H1 and site inspection ongoing
- r/r MZL NDA accepted by CDE in 2022H1
- 1L DLBCL - MCD registrational trial enrollment ongoing, promising real world study results posted at ASCO
- 1L CLL/SLL trial more than halfway through patient enrollment
- A comprehensive tool-kit including Orelabrutinib, Tafasitamab, ICP-B02 and ICP-490 offers us a unique position to tackle all stages of DLBCL patients with combination therapies

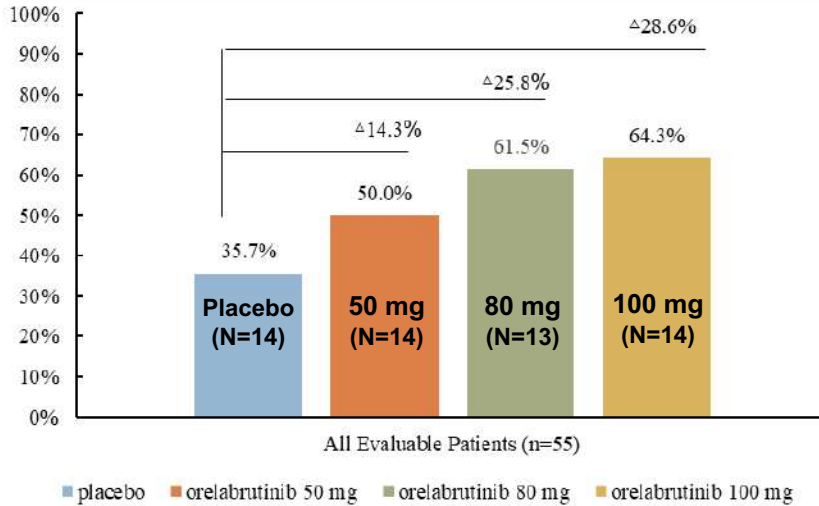


2 Major Program Update

Orelabrutinib (ICP-022) : SLE Phase II Positive Results Lead to Further Development



SRI-4 Response Rate at 12 Weeks

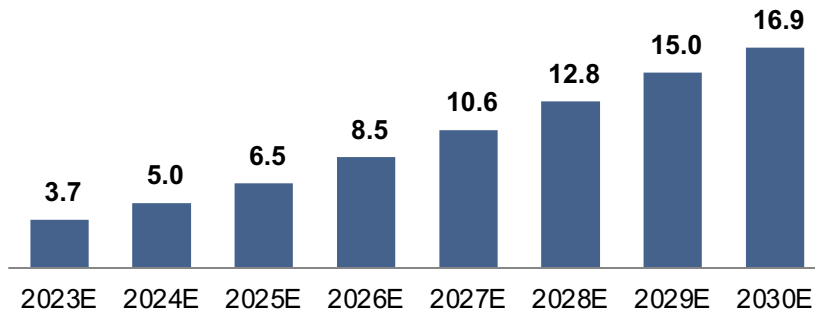


SLE Phase II Study Results¹

- SLE Responder Index (“SRI”)-4 response rates increased in a dose dependent manner
- Trends of reduction in proteinuria level and improvement of immunologic bio-markers²
- The only BTKi ever shown efficacy in Phase II SLE trials
- **Further trial protocol is under final discussion with the CDE**

Worldwide Huge Unmet SLE Market Needs

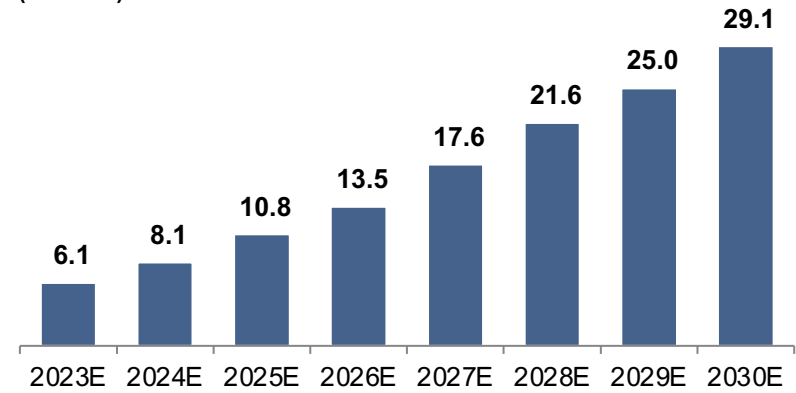
(USD bn)



Source: Frost & Sullivan Analysis 2021

Unmet SLE Potential Market in China

(RMB bn)



Source: Frost & Sullivan Analysis 2021

Currency rate: USD1 :RMB6.7

¹ The Phase II trial evaluated the safety and efficacy of Orelabrutinib plus standard of care verse placebo plus standard of care (“SoC”) in patients with mild to moderate SLE

² Reduced immunoglobulin G and increased complements C3 and C4 were observed

Current Status and Further Development

- Pivotal trial for r/r DLBCL initiated to support approval in mainland China
- 1st prescription landed in Hainan
- NDA submitted in Hong Kong
- NDA to be submitted in Macau, followed by pilot use in GBA
- Potential combination therapy with Orelabrutinib

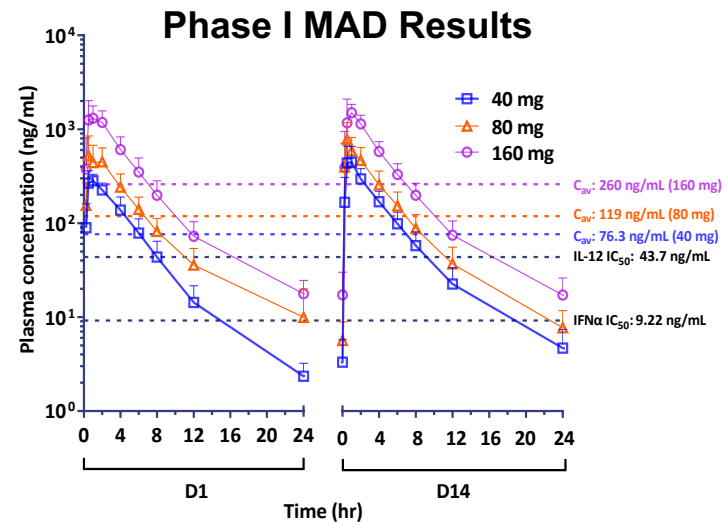
Competitive Landscape: Selected Novel Therapy in r/r DLBCL

Company	Target	Therapy	Phase	ORR (%)	CR (%)	mDOR (m)	mPFS (m)	mOS (m)
Incyte/InnoCare	CD19	Tafasitamab + Lenalidomide	Approved ex-China	57.5	40	43.9	11.6	33.5
ADC Therapeutics	CD19 ADC	Loncastuximab tesirine	II	59	41	4.8	5.5	11.6
Roche	CD79b ADC	Polatuzumab vedotin + BR vs BR	II	45 vs 18	40 vs 18	12.6 vs 7.7	9.5 vs 3.7	12.4 vs 4.7
Amgen/Beigene	CD19/CD3	Blinatumomab	II	43	19	11.6	3.7	5.0
Regeneron/Zai Lab	CD20/CD3	Mosunetuzumab	Ib	35	19	N/A	N/A	N/A
Roche	CD20/CD3	Glofitamab	Ib	38	31	N/A	N/A	N/A
Others	BCL2	Venetoclax	I	18	12	N/A	1.0	8.0

Source: Frost & Sullivan Analysis

ICP-332 (TYK-2, JH1)

- Safe and well-tolerated, **no significant decrease of platelet and hemoglobin (JAK2-related AE) observed in Phase I studies**
- Demonstrated a dose proportional and favorable PK profile, no significant food effect observed
- Phase II trials initiated in atopic dermatitis and psoriasis



ICP-488 (TYK-2, JH2)

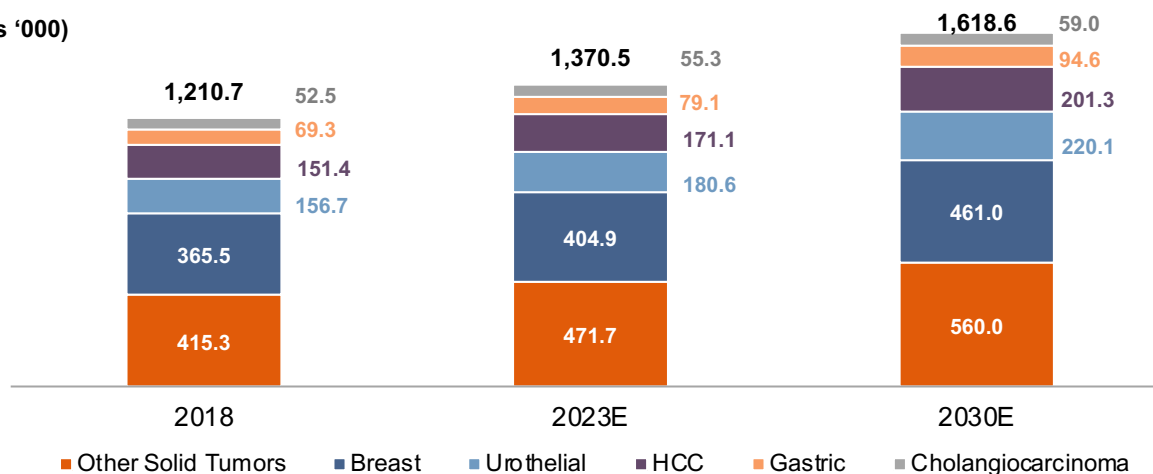
- An oral, potent and allosteric TYK2 inhibitor that selectively binds to the JH2 pseudokinase domain
- Favorable ADME and safety profile **with no activities on JAK1-3**
- Potential to show significant advantages in safety profiles verse other JAK family inhibitors
- Phase I first cohort completed in August 2022

ICP-192 (Gunagratinib, FGFR)

- Finished dose-escalation ranging from **2 mg to 26 mg** and **no DLT observed**
- Safe and well-tolerated in patients with advanced solid tumors
- **20 mg** showed **efficacy in cholangiocarcinoma patients** with **62.5% ORR** and **100% DCR, data posted at ASCO**
- **Well positioned to enter potential registrational trial in cholangiocarcinoma**
- Progressing Phase II trial in urothelial cancer **in China**
- Progressing basket trial, including gastric and head & neck cancer **in China, Australia and the U.S.**

A Glance at FGFR Mutation by Solid Tumor Types Worldwide

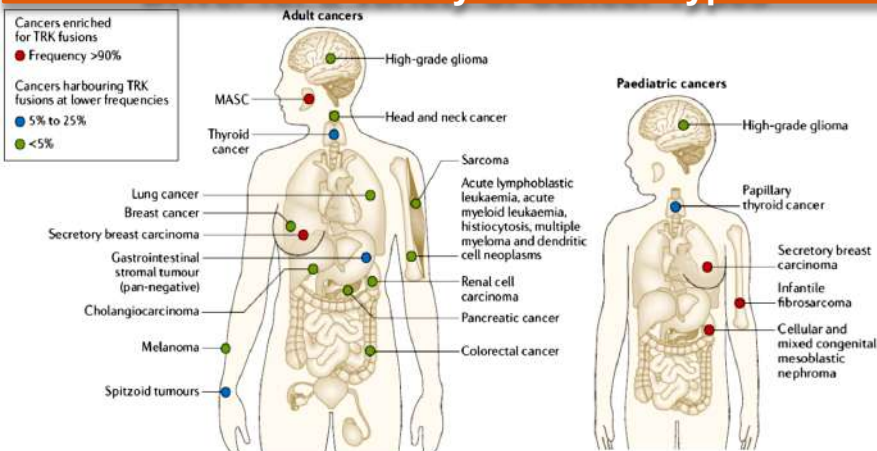
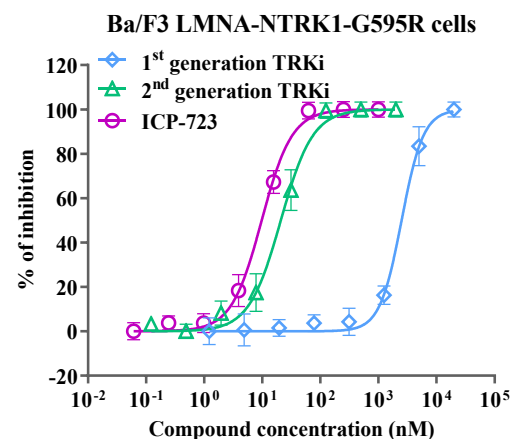
(No. of Patients '000)



ICP-723 (TRK)

- **2nd generation TRKi overcomes acquired resistance to 1st generation TRKi**
- **No DLTs** observed in Phase I (1-16 mg)
- Phase I study demonstrated favorable PK profile and anti-tumor activity
- **100% ORR** observed in various types of solid tumors carrying NTRK fusion at dosages of 4 mg and above
- Well positioned to enter potential registrational trial in China soon
- Study to expand potential use in adolescent and pediatric patients
- Clinical trial initiated in the U.S.

NTRK Gene Fusion Mutation is an Oncogenic Driver for a Variety of Cancer Types


 Pre-clinical Results


ICP-723 showed excellent activities against TRK resistance mutations including gatekeeper, xDFG and solvent front mutations.



Entering Phase I


















- **ICP-B02 / CM355 (CD3 x CD20)**
 - First patient enrolled in Feb 2022 and Phase I trial ongoing in China
- **ICP-189 (SHP2)**
 - First patient enrolled in June 2022 and Phase I trial ongoing in China
- **ICP-033 (DDR1, VEGFR)**
 - First patient enrolled in March 2022 and Phase I trial ongoing in China
- **ICP-490 (E3-Ligase)**
 - IND approved in July 2022 and Phase I initiated in China



IND Being Approved

- **ICP-248 (BCL-2)**
 - IND submitted in June 2022 and accepted by CDE in July 2022
- **ICP-B05 / CM365 (CCR8)**
 - IND submitted in May 2022 and accepted by CDE in 2022Q2

Research & Development Product Pipeline – Liquid Cancer

Drug	Target	Indication(s)	Worldwide Rights	Pre-clinical Development	IND	Phase I	Phase II	Phase III	Launched	
Liquid Cancer	BTK	r/r CLL/SLL		NDA approved: 25 Dec 2020					★	
		r/r MCL		NDA approved: 25 Dec 2020					★	
		r/r WM		NDA accepted by NMPA In 2022Q1					☑	
		r/r MZL		NDA accepted by NMPA In 202208					☑	
		ICP-022/ Orelabrutinib	1L: CLL/SLL							★
		1L: MCL								★
		1L: DLBCL - MCD								★
		r/r MCL			US Development Status					★
		r/r CNSL								
		Combo w/ MIL-62 (basket)								
ICP-B04/ Tafasitamab	CD19	DLBCL/Hematology						 ★		
ICP-B02	CD3 x CD20	Hematology								
ICP-490	E3 Ligase	Hematology			IND was approved in 202207					
ICP-248	BCL-2	Hematology			IND was accepted by CDE in 202207					

★ Listed drug
 ★ Registrational trials
 ☑ NDA
 ■ Clinical Stage
 ■ Pre-clinical Stage
 ■ Commercial Product
 ■ Clinical Asset

Research & Development

Product Pipeline – Solid Tumors and Autoimmune Diseases



Anticipated Milestones & Catalysts in Next 12 Months

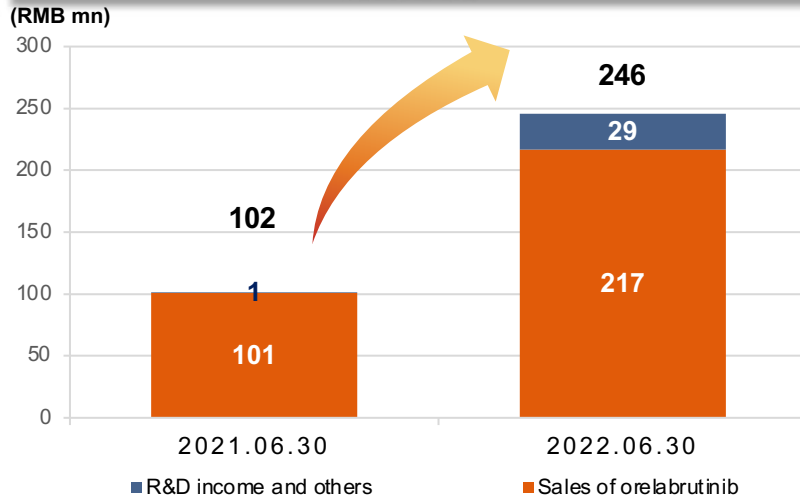
<p>Liquid Cancer</p>	<ul style="list-style-type: none"> ■ Orelabrutinib □ r/r WM NDA approval □ r/r MZL NDA approval □ Complete 1L DLBCL-MCD enrollment □ Complete 1L CLL/SLL enrollment □ Complete r/r MCL enrollment in U.S. ■ TafaTafasitamab (CD19) □ NDA approval in HK/Macau □ Commence pilot use in GBA □ Complete r/r DLBCL pivotal trial enrollment in China 	<p>Auto-immune Diseases</p>	<ul style="list-style-type: none"> ■ Orelabrutinib □ SLE further trial initiation in China □ MS Phase II global trial result □ ITP Phase II preliminary result ■ ICP-332 (TYK2 - JH1) □ Phase II in AD efficacy and safety result □ Global Phase II enrollment completed ■ ICP-488 (TYK2 - JH2) □ Complete Phase I trial
<p>Solid Tumors</p>	<ul style="list-style-type: none"> ■ ICP-192 (FGFR) □ Expanding into iCCA registrational trial in China ■ ICP-723 (TRK) □ Initiate registrational trial in China ■ ICP-189 (SHP2) □ Phase I trial result ■ B05 (CCR8) □ Phase I commences first patient enrollment 	<p>Discovery</p>	<ul style="list-style-type: none"> ■ 2-3 NMEs entering clinical stage
		<p>Capital Market</p>	<ul style="list-style-type: none"> ■ A share listing on STAR Board
		<p>Production</p>	<ul style="list-style-type: none"> ■ Commence commercial production at Guangzhou site



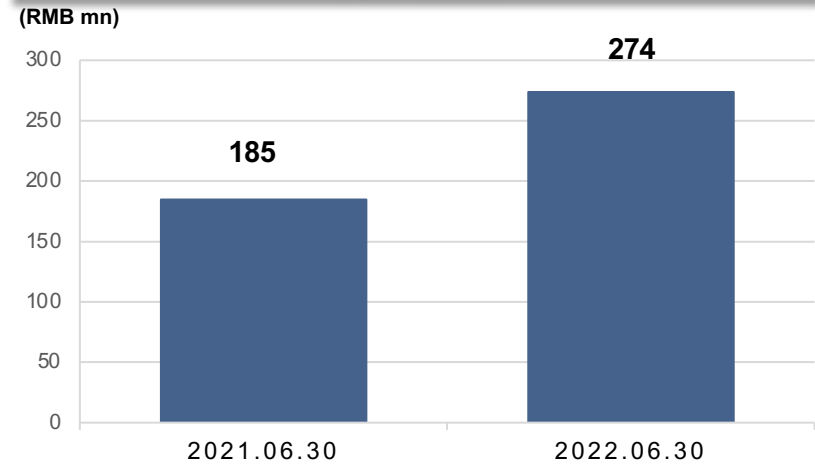
Financial Update

Key Financials for 2022H1

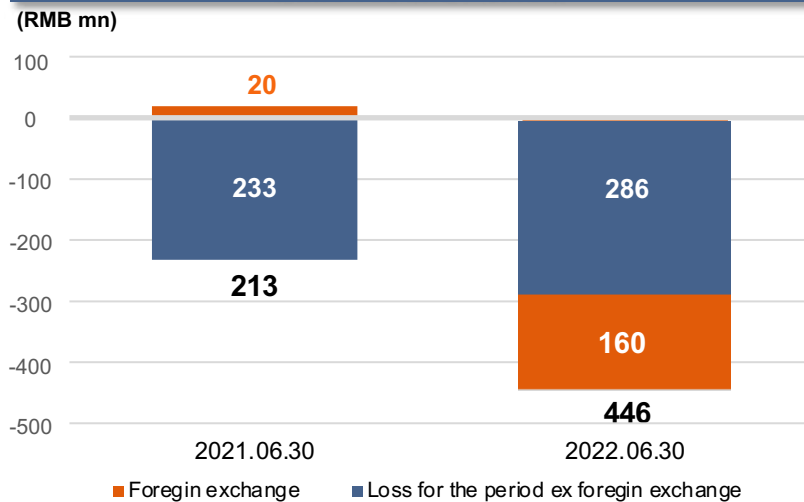
Revenue



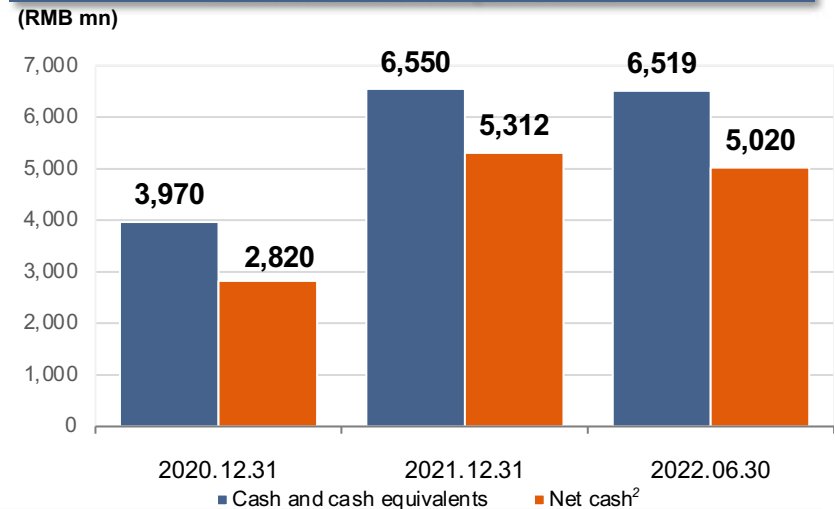
R&D Costs



Loss for the Period



Cash and Cash Equivalents¹



¹ Cash and cash equivalents = investments measured at fair value investments, cash and bank balance

² Net cash = cash balance – convertible loan – loans and borrowings – loans from a related party

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Science Drives Innovation for the Benefit of Patients
