# JW Therapeutics(2126.HK)

## 2022 Interim Results Presentation

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# Agenda

01 Highlights of 2022 Interim Results

02 Commercialization Progress

03 Product and Pipeline Updates

04 Financial Overview

# Solid Business Performance Continues in Year 2022

**2** 2 Key Progresses: Solid tumor in clinical stage, 3L FL sNDA submitted

**64** Carteyva® completed 64 infusions in 2022 H1

**56.5%** CRR

**66.0** Revenue (RMB' million)

## R&D Progress

- Trials for other B cell malignancies on track, including second-line of LBCL and pALL IND approved, r/r MCL sNDA submission planned for 2023
- Solid tumor development on track: Phase I clinical study of JWATM204 in HCC patients was initiated
- Building discovery capabilities while pursuing BD opportunities

## Commercialization

- Covered by 52 insurance product and 28 local governmental complementary medical insurance programs
- Established with key lymphoma experts the first CAR-T guiding principles to standardize the clinical applications for physicians
- Completed 83 top hospital coverage in China

## Operation Excellence

- Continue high manufacture success rate of 99%
- 100% capacity utilization
- Successfully overcame difficulties caused by COVID-19 pandemic

## Financial Update

- Implemented cost reduction plan and gross margin increased from 29% to 35%
- 2022 H1 Loss RMB429.3m, increased by RMB148.6m compared to 2021 H1, the increase was primarily due to non-operating factors
- RMB1,550m cash balance

*Notes:*
*1.Among 69 assessable patients from 94 infused patients treated by Carteyva® since launch, CRR was 56.5%*
*2.Cash balance is cash and cash equivalents plus highly liquid financial assets*
*Abbreviations: HCC=hepatocellular carcinoma*

# JW Therapeutics – A Leading Cell Therapy Company


One of the Best Teams & Talents in Cell Therapy

A Potential Superior CD19 CAR-T – Carteyva®

Differentiated Pipeline includes Hematological, Solid Tumors and Autoimmune Disease

Proven R&D Capabilities

CMC Manufacturing Excellence

Established Commercialization

# Seasoned Management Team

## Experienced Management Team

**James Li, M.D.**

*Chairman, Executive Director and CEO*

AMGEN · MERCK · KLEINER PERKINS

**Mark Gilbert, M.D.**

*Chief Medical Officer*

JUNO THERAPEUTICS

**Xiaoping Cao, PHD**

*SVP, Head of Tech Ops*

Pfizer · MERCK

**Shaun Paul Cordoba, PHD**

*Chief Scientific Officer*

Autolus

**Xin Fu**

*Chief Financial Officer*

Pfizer · KPMG

**Alex Qiong Wu**

*Chief Commercial Officer*

MERCK · Baxter

**Raymond J. Hage, Jr.**

*SVP, Corporate Development*

Lilly · NOVAVAX

**Karen Xu**

*Head of Quality*

WuXi Biologics · MERCK

## Experienced JW Advisors

**Hans Bishop**

*Senior Advisor to CEO*

**Harry Lam, PHD**

*Senior Technology Advisor*

**Jennifer Wang, PHD**

*Quality Advisor*

# Fully Integrated Cell Therapy Innovation and Commercialization Platform

**Our uniquely designed and fully integrated capabilities range from early research, and analytical development through process development and clinical development to regulatory affairs, with GMP manufacturing facilities and dedicated commercialization capability**

## Early Research

- **Strengthen the existing pipeline** through the development of next-generation platforms
- **Engineer new pipeline products** to hematology and solid tumor indications **with global right**
- **Expand IP portfolio and technical platforms** that enhance the efficacy, robustness and safety of our products

## Clinical Development

- **Comprehensive clinical functions**, which enables the delivery of clinical research with high quality
- **Solid clinical development capabilities** proven by successful approval of Carteyva®

## Regulatory Affairs

- **Viewed as Key Expert driving the development of China's cell therapy**
- Regularly communicates with CDE
- Provided feedback on the drug administration law and the CAR-T GMP inspection guide

## Commercialization

- Dedicated in-house commercial team to market cell therapy products across China
- Establish a whole process management guidance with top KOLs and physicians to ensure a **higher-quality and safety experience for patient**

## CMC

- **Strong process development**: have developed a single-train manufacturing process platform that allows us to optimize cell product characteristics and consistency
- Process development capabilities based on internal development and optimization of technology in-licensed from Juno
- **Rigorous analytical development, quality control, and quality assurance**, all functions seamlessly coordinated with one another to support our manufacturing capability

## Manufacturing

- Clinical manufacturing and process development at Waigaoqiao and Zhangjiang facilities of approx. 600 sqm
- New **cGMP commercial manufacturing site** in Suzhou covering approx. 10,000 sqm designed to address all of the major challenges associated with scaling up from clinical scale to commercial scale manufacturing

# Our Strategies

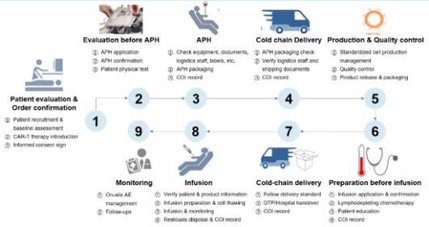
- Drive full-scale commercialization of Carteyva® and build upon our significant first mover advantage
- Solidify our leadership in hematological cancers by continuing to develop Carteyva® for earlier lines of treatment and additional indications, as well as clinical development of other new products
- Leverage our integrated cell therapy platform to expand into the emerging solid tumor market
- Continuously enhance our manufacturing capability and reduce cost through innovation and scale
- Grow our business through in-licensing opportunities, partnerships and selective acquisitions, as well as in-house research and development

# Drive Momentum of Commercialization Pace

| | | | |
|---|---|---|---|
| **64** | Generated 77 prescriptions and completed 64 infusions for patients | **12** | Patients covered by our multi-layer medical care system |
| **56.5%** | CRR among 69 assessable patients from 94 infused patients treated by Carteyva® since launch | **83** | Top hematology hospitals in China that we completed training, dry-run and certification |
| **80** | Listed in 52 commercial insurance products and 28 local governmental complementary medical insurance programs | **99%** | High manufacture success rate |

## Build Eco-system to Provide First-class Service

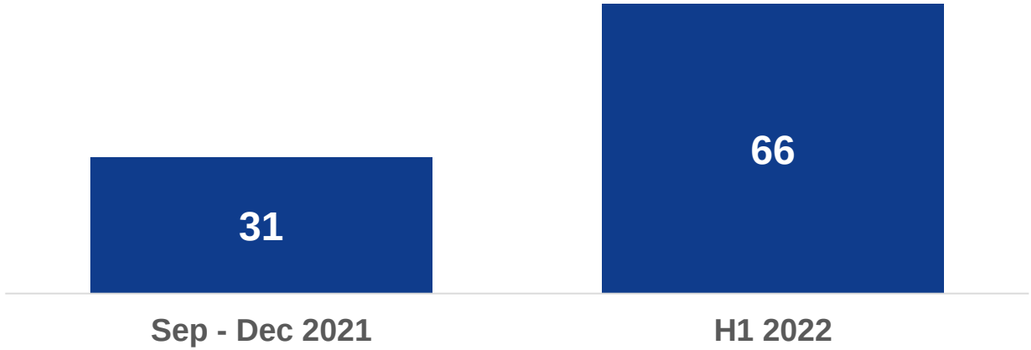
- **Vein to Vein Process**
- **CAR-T Consultant**
- **Multi-layer Medical Care System**
- **Guidance Principle**





## Revenue since launch

**RMB' million**



# JW's R&D Strategies

## In-licensing Opportunities, Partnerships, Selective Acquisitions and In-house Research and Development

**Hematology: Lead CAR-T in hematology cancers leveraging Carteyva® and next generation products. Expand the portfolio and other targets by leveraging new technologies, development collaborations, in-licensing or commercial collaborations.**

**Platform Technologies: Build JW's cell therapy platform including allogeneic, transduction and modules enhancement under new world-class scientific leadership, as well as vector facility throughout life cycle management.**

**In-house Research and Development: Enhance technical innovation capabilities for LSR/ESD. Strengthen the existing pipeline through the development of next-generation platforms. Engineer new pipeline products with global right. Expand IP portfolio and technical platforms.**


**Solid Tumor: Expand JW's solid tumor pipeline building on current product programs and leveraging new in-house capabilities.**

**Business Development: Leverage JW's key strengths in commercial, clinical development and manufacturing to attract new technologies, platforms and partnerships to build the solid tumor pipeline and lead in hematology.**

# Our Robust and Differentiated Cell Therapy Pipeline

| | Product | Target | Indication | Commercial Rights | NMPA Classification | Partner |
|---|---|---|---|---|---|---|
| Hematologic Malignancies | JWCAR029 / Relmacabtagene Autoleucel (relma-cel) [1] | CD19 | 3L LBCL | Mainland China, Hong Kong, Macau* | Category 1 | JUNO, Bristol Myers Squibb Company |
| | | | 3L FL | Mainland China, Hong Kong, Macau* | | |
| | | | 3L MCL | Mainland China, Hong Kong, Macau* | | |
| | | | 1L/2L LBCL | Mainland China, Hong Kong, Macau* | | |
| | | | 3L pALL | Mainland China, Hong Kong, Macau* | | |
| | | | 3L CLL | Mainland China, Hong Kong, Macau* | | |
| | JWCAR129[2] | BCMA | r/r MM | Mainland China, Hong Kong, Macau* | Category 1 | JUNO, Bristol Myers Squibb Company |
| Solid Tumors | JWATM203 | AFP | HCC | Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN* | Category 1 | EUREKA |
| | JWATM213[3] | AFP | HCC | Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN* | Category 1 | EUREKA, Lyell |
| | JWATM204 | GPC3 | HCC | Mainland China, Hong Kong, Macau, Taiwan , and member countries of ASEAN* | Category 1 | EUREKA |
| | JWATM204 | GPC3 | NSCLC/HAS | Mainland China, Hong Kong, Macau, Taiwan , and member countries of ASEAN* | Category 1 | EUREKA |
| | JWATM214[3] | GPC3 | HCC | Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN* | Category 1 | EUREKA, Lyell |
| Other | JWCAR029 / Autoimmune[5] | CD19 | SLE | Mainland China, Hong Kong, Macau* | | JUNO, Bristol Myers Squibb Company |
| | Nex-G | CD19 | NHL | Mainland China, Hong Kong, Macau* | | JUNO, Bristol Myers Squibb Company |


Abbreviations: LBCL = large B-cell lymphoma; FL = follicular lymphoma; MCL = mantle cell lymphoma; ALL = acute lymphoblastic leukemia; CLL = chronic lymphocytic leukemia; MM = multiple myeloma; NHL = non-Hodgkin lymphoma; HCC = hepatocellular carcinoma; NSCLC = non-small cell lung cancer; AFP = alpha-fetoprotein; GPC3 = glypican-3; r/r = relapsed or refractory; 3L = third-line; 2L = second-line; 1L= first-line, HAS= hepatoid adenocarcinoma of the stomach; SLE = systemic lupus erythematosus;

* Mainland China, Hong Kong, Macau and Taiwan refer to Mainland China, Hong Kong (China), Macau (China) and Taiwan (China), respectively.

1. Relma-cel is based on the same chimeric antigen receptor ("CAR") construct as the product lisocabtagene maraleucel (Breyanzi or lisocabtagene or liso-cel) of Juno, which was approved by the U.S. Food and Drug Administration ("FDA") in February 2021.
2. JWCAR129 is based on the same CAR construct as Juno Therapeutics' product orvacabtagene autoleucel (orva-cel).
3. Developing using Lyell technology.
4. JWATM204 is in a Phase I investigator-initiated trial in China. Eureka's products based on the CAR constructs underlying JWATM203 and JWATM204 are currently in Phase I/II trials in the US conducted by Eureka under an IND application. In November 2021, the FDA granted Fast Track Designation to Eureka's counterpart to JWATM203 for the treatment of hepatoblastoma ("HB") and HCC in pediatric patients, as well as "rare pediatric disease designation" for the treatment of HB. In February 2022, the FDA granted Orphan Drug Designation to Eureka's counterparts to JWATM203 and JWATM 204.
5. SLE is a chronic autoimmune disease characterized by the production of autoantibodies and abnormal B-lymphocyte function. To further extend Relma-cel's potential in broader disease area, we are planning a study to evaluate the safety, tolerability, and pharmacokinetic profile of Relma-cel in Chinese patients with moderately or severely active SLE.

# Carteyva®: Potential Superior Anti-CD19 CAR-T Product

- The **first CAR-T therapy approved as a Category 1 biologics** product in China
- In the registrational Phase II clinical trial, Carteyva® demonstrated **superior safety results with comparable efficacy**

## Comparable Efficacy[1]

** Not from a head-to-head comparison study*

| | ORR | CRR |
|---|---|---|
| **Carteyva®** | **77.6%** | **53.5%** |

**Marketed CAR-T**

| | ORR | CR |
|---|---|---|
| Yescarta | 72% | 51% |
| Kymriah | 50% | 32% |
| Breyanzi | 73% | 54% |

## Superior Safety Profile[1]

** Not from a head-to-head comparison study*

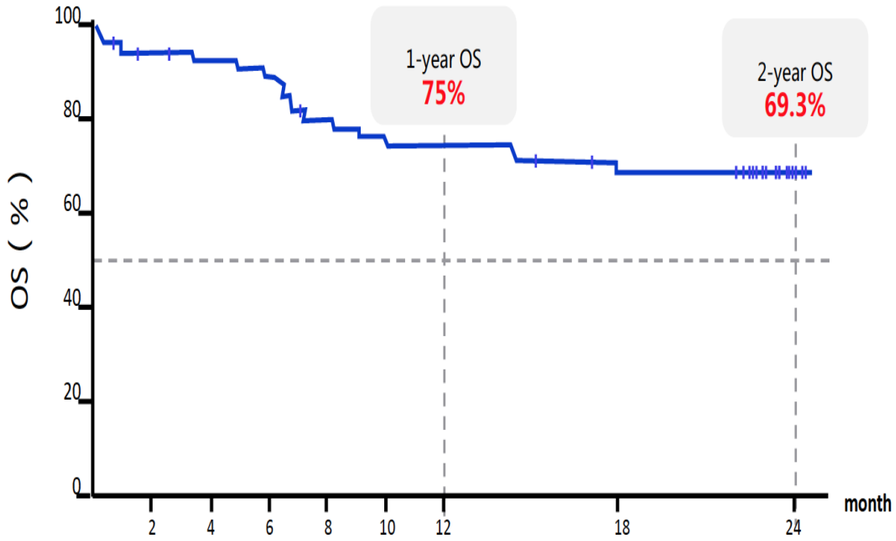
| | Indication | NT (Any) | sNT (≥Grade 3) | CRS (Any) | sCRS (≥Grade 3) |
|---|---|---|---|---|---|
| **Carteyva®** | **r/r LBCL** | **20.3%** | **3.4%** | **47.5%** | **5.1%** |

**Marketed CAR-T**

| | Indication | NT (Any) | sNT (≥Grade 3) | CRS (Any) | sCRS (≥Grade 3) |
|---|---|---|---|---|---|
| Yescarta | r/r LBCL | 87% | 31% | 94% | 13% |
| Kymriah | r/r LBCL | 58% | 18% | 74% | 23% |
| Breyanzi | r/r LBCL | 35% | 12% | 46% | 4% |

## Excellent long-term efficacy: 2Y OS 69.3%

The median follow-up time: 24 months, the median OS was not reached




**month**

The excellent 2 year OS rate and trend of OS KM curve indicate the “curative" potential of Carteyva®.

*Source:*

*[1] All clinical data above comes from specification of each marketed product, the data for Carteyva® is from ASCO 2022 annual meeting Abstract #7529 presentation with data cut off 22 Dec, 2021*

*.Abbreviations: ORR=Overall Response Rate；CRR=Compete Response Rate；NT=Neurotoxicity；sNT=severe Neurotoxicity；CRS=Cytokine Release Syndrome；sCRS=severe Cytokine Release Syndrome；; r/r = relapsed or refractory；LBCL = large B-cell lymphoma*

# Carteyva® Expected to Be The First CAR-T Product Approved for Treatment of 3L FL Patient in China

- **Granted Breakthrough Therapy Designation by the NMPA in September 2020**
- **Ph2 pivotal trial has completed in mid-2021**
- **sNDA application was accepted by NMPA in Q1 2022**

## Efficacy Comparison

** Not from a head-to-head comparison study*

| | ORR | CRR |
|---|---|---|
| **Carteyva®** | **100%** | **92.6%** |

| | ORR | CRR |
|---|---|---|
| Yescarta | 91% | 60% |
| Kymriah | 86% | 68% |

## Safety Profile Comparison

** Not from a head-to-head comparison study*

| | Indication | NT (Any) | sNT (≥Grade 3) | CRS (Any) | sCRS (≥Grade 3) |
|---|---|---|---|---|---|
| **Carteyva®** | **3L FL** | **18%** | **4%** | **43%** | **0** |

| | Indication | NT (Any) | sNT (≥Grade 3) | CRS (Any) | sCRS (≥Grade 3) |
|---|---|---|---|---|---|
| Yescarta | 3L FL | 77% | 21% | 84% | 8% |
| Kymriah | 3L FL | 43% | 6% | 53% | 0 |

*Source: data from ASH 2021 Annual Meeting Abstract #2434 presentation and r/r Follicular Lymphoma indication in the May 2022 product specification for Kymriah and iNHL indicication in the April 2022 product specification for Yescarta*

*Abbreviations: ORR=Overall Response Rate；CRR=Compete Response Rate ；NT=Neurotoxicity；sNT=severe Neurotoxicity；CRS=Cytokine Release Syndrome；sCRS=severe Cytokine Release Syndrome；r/r = relapsed or refractory；FL = follicular lymphoma；3L=third line*

# Carteyva®: Exploring the Further Clinical Potential in Early Line Treatment and Other Indications

- **To fully explore the clinical potential of Carteyva®, we intend to develop Carteyva® for a number of other hematological indications, including early line LBCL ,MCL, pALL and CLL**

**1st/2nd line LBCL**

- **IND for 2L treatment was approved in March 2022**
- Multi-center, randomized Phase II registrational clinical trial comparing Carteyva® to 2nd line stand of care therapy
- **Intend to begin a Ph1 IIT trial for frontline or treatment-naïve patients**
- Aim to establish new standard of care and impact clinical practice for early line LBCL population

**MCL**

- Carteyva® was granted Breakthrough Therapy Designation in patients with MCL by NMPA
- Historically has been resistant to standard therapy, or therapies have provided only short periods of response
- Will evaluate MCL patients for whom the use of BTK inhibitors has failed
- **Single arm Ph2 pivotal trial started, sNDA expected to submit in 2023**

**pALL**

- Relapse after initial induction chemotherapy carries a very poor prognosis with median survival rates in adults being less than one year
- **First registration trial to execute in pediatric population**
- **IND was approved in April 2022 and competed first patient dose**

**CLL**

- Certain subtypes of CLL have a much worse prognosis
- Will evaluate high risk CLL patients for whom the use of BTK inhibitors has failed

# Carteyva® in Moderate-Severe Systemic Lupus Erythematosus

- **To further extend Relma-cel's potential in broader disease area, we are planning a study to evaluate the safety, tolerability, and pharmacokinetic profile of Relma-cel in Chinese patients with moderately or severely active SLE**

## Systemic Lupus is Common and Associated with Fatal Organ Damage

- SLE is a debilitating, autoimmune disease affecting the soft tissues and organs of the body
- Incidence in China among the highest in the world, 270k[1] cases patient-year with Lupus
- 40% of patients develop organ damage by 1 year, 50% develop irreversible damage by 5 years
- Risk of dying is 3 times higher than normal rates

## B Cells Play Critical Role in SLE Pathogenesis & Unmet Need is Very High

- B Cell Depletion Therapy with antibodies is most important approach to treat Lupus
- Currently available therapies are Inadequate and can worsen organ damage over time
- We estimates that over 15,000 patients may be eligible for B cell depletion CAR T therapy

## Carteyva® May Potentially Stop the Disease Process in Patients

- Anti-CD19 CAR T [~1M cells/kg after Flu/CY lymphodepletion] rapidly induced remission of a patient's severe SLE
- JW is planning to begin an SLE Ph1 trial in early 2023 for dose optimization and early safety/efficacy assessments
- JW believes we are the only company worldwide actively pursuing this indication in the clinic with CAR T cells

*Source:*

*[1]Rees F, Doherty M, Grainge MJ, et al. The Worldwide Incidence and Prevalence of Systemic Lupus Erythematosus: A Systematic Review of Epidemiological Studies. Rheumatology. 2017;56(11): 1945–1961. Applied 30cases/100K and assuming 900m as China adult population.in 2017*

*Data from CD19-Targeted CAR T Cells in Refractory Systemic Lupus Erythematosus; The New England Journal of Medicine 2021; 385:567-569*

*Abbreviations: SLE = systemic lupus erythematosus; HCC=hepatocellular carcinoma*

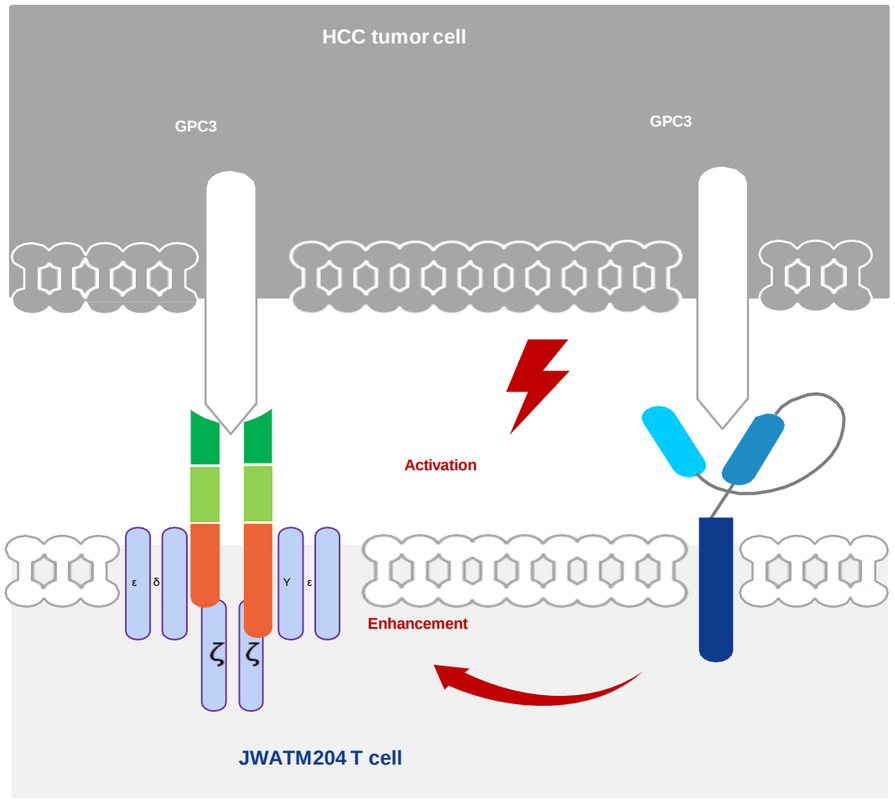
# JWATM204 and JWATM214 Programs

## Overview

**JWATM204: A novel TCR-T therapy using ARTEMIS 3.0 technology and targeting GPC3 may benefit many HCC patients and other solid tumor patients. JWATM214 combines ARTEMIS 3.0 technology with Lyell's cJun technology to potentially add better persistence and anti-tumor activity**

### Mechanism of Action

**JWATM204 Program (JWATM204 and JWATM214)**




### Our Advantages

- ✓ **GPC3** expressed in **~80% HCC patients** and also high expression in other solid tumors including subtype of gastric cancer and NSCLC
- ✓ Use of ARTEMIS technology could potentially create **more effective and safer** T-cell therapy
- ✓ Combination of Lyell's technology for JWATM214 may increase **T-cell functionality and reduce T-cell exhaustion**

### Our Clinical Development Plan

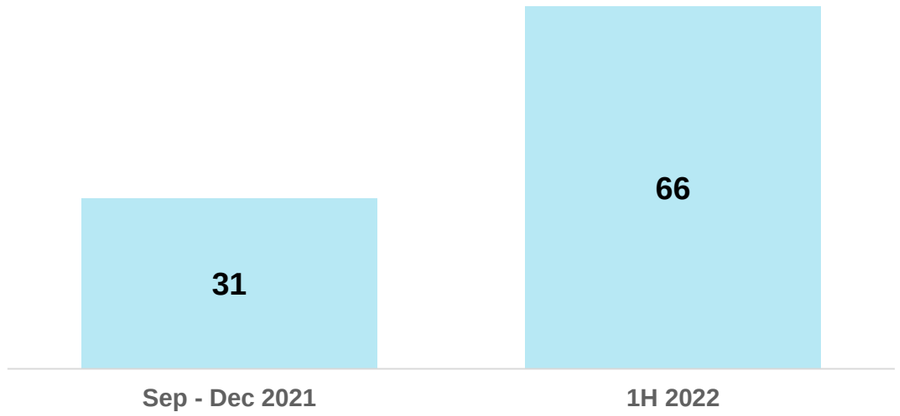
- A Ph I dose escalation study of JWATM204 has been initiated in late stage HCC patients
- Another phI dose escalation study will also be initiated in solid tumor patients to identify alternative indications. FPI is expected around 2022 year's end
- A Ph I dose escalation study of JWATM214 is also planned to start in 1Q2023
- Further development plan is to select the lead development product and expand to earlier lines of treatment of HCC as either monotherapy or combinations of TKI and CPI agents, and conduct pivotal studies in other solid tumor types.

| 2021 | | 2022 | | | | 2023 | |
|---|---|---|---|---|---|---|---|
| Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 |
| CMC process lock | | | Manufactory ready and FPI for JW204 HCC ph I study | | FPI for basket design ph I study | JW214 ph I dose escalation study | |

# Key Financial Update

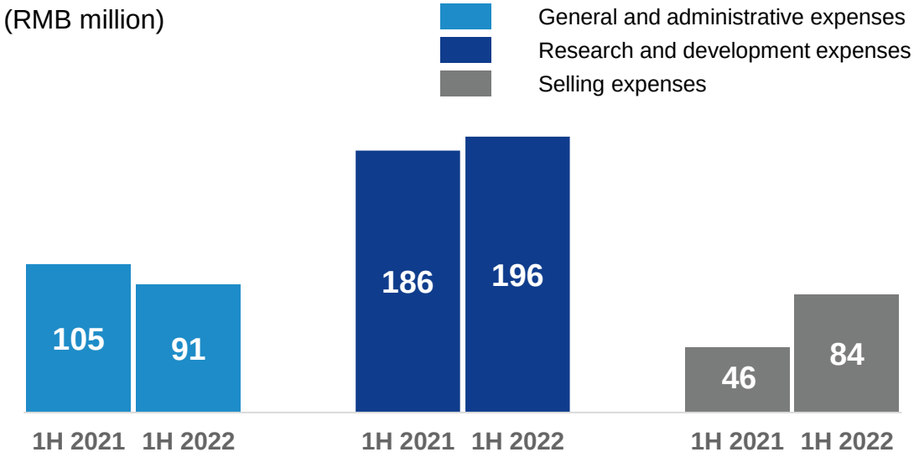
## Revenue

(RMB million)



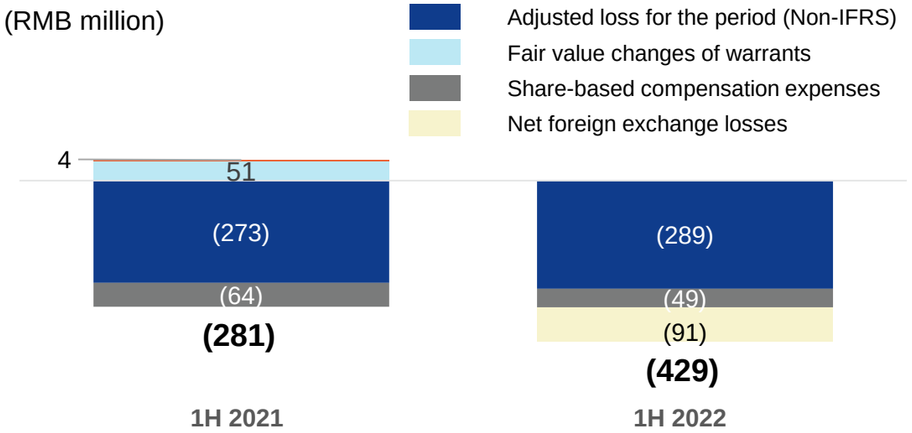

## Operating expenses

(RMB million)



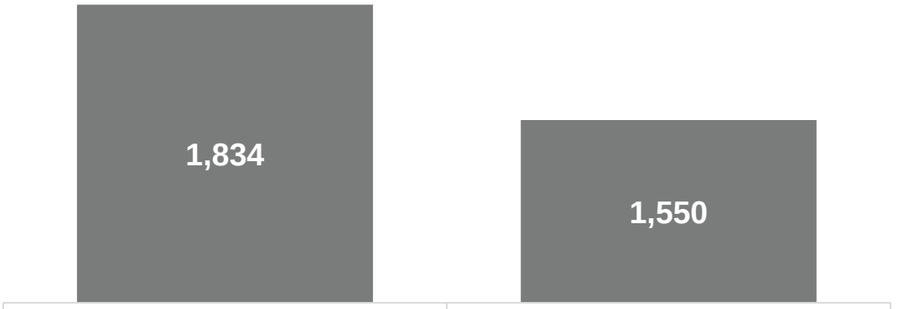

## Loss for the period

(RMB million)




## Cash balance *

(RMB million)




** Cash balance is cash and cash equivalents plus highly liquid financial assets*

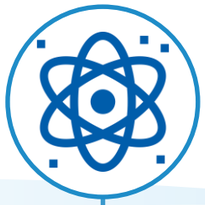
# Manufacturing & Technology Evolution - from Cost Reduction to Value Creation

**Near-Term**
**Completed**

**Realize cost reduction** by implementing **technologies and procedures to reduce raw material wastes and scraps**

Realize **further cost reduction** by replacing imported materials with **domestic supplies**

**Mid-Term**
**2 – 3 years**



**Long-Term**
**3 – 5 years**

Implement new technologies to simplify and/or replace/combine unit operations and enable the **next generation** CAR-T product with:

- High quality
- Better product characterization
- Improved product efficacy and safety
- Lower cost
- Shorter production cycle

药明巨诺 JW Therapeutics

# Become an Innovation Leader in Cell Immunotherapy

# 以创新为先导 成为细胞免疫治疗引领者