



康方生物科技(開曼)有限公司
Akeso, Inc.

2020 Interim Results Presentation

August 2020



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1 Company Overview



2 Business and Product Updates



3 Future Milestones and Catalysts



4 Financial Highlights



SECTION 1

Company Overview



We are a clinical-stage biopharmaceutical company committed to in-house discovery, development and commercialization of first-in-class and best-in-class therapies



Visionary and experienced management team
with proven track record of success



ACE⁽¹⁾

- Fully Integrated R&D Platform
- Bi-specific TETRABODY technology
- 20+ products ,with 12 clinical stage, 3 IND Enabling



Large Number of Innovative Products: All Developed In-House

- Penpulimab (PD-1, AK105)
- AK104 (PD-1/CTLA-4)
- AK112 (PD-1/VEGF)
- AK117 (CD47)
- AK119 (CD73)
- AK101 (IL12 / IL 23)
- AK111 (IL17)
- AK120 (IL4R)
- Ebronucimab (PCSK9, AK102)



Synergistic Collaborations

- Co-development and Commercialization of PD-1 with Sino Biopharma (AK105, Penpulimab)



中國生物製藥有限公司
SINO BIOPHARMACEUTICAL LIMITED

- Out-licensing to MSD (AK107, CTLA-4)



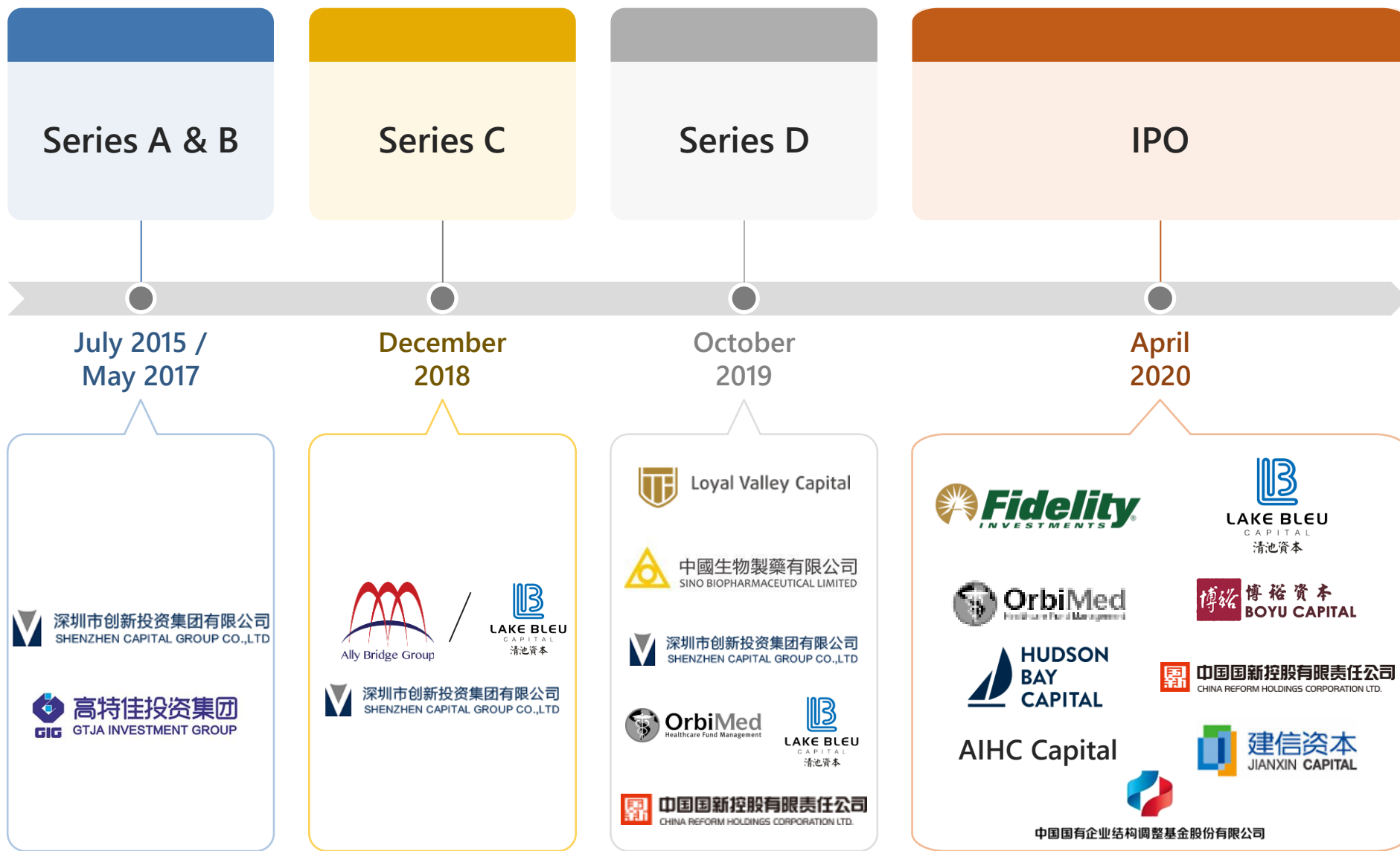
MERCK



Forward-Looking Manufacturing Capacity















- Current: 3,700L
- Guangzhou: to house up to 20,000L capacity by beginning of 2021 (up to 40,000L in total)
- Zhongshan Cuiheng: start to build the facility to house 40,000L capacity

Strong support from renowned investors



Our senior management team

We are led by a visionary & experienced management team

 <p>Dr. Michelle Xia Ph.D. <i>Chairwoman / President / CEO</i></p>	   	
 <p>Dr. Baiyong Li Ph.D. <i>EVP/CSO</i></p>	  <p>Dr. Max Wang Ph.D. <i>SVP (Clinical Operations, Sourcing)</i></p>	 <p>Dr. Dennis Xia Ph.D. <i>SVP (Manufacturing, Quality and Regulatory)</i></p>
 <p>Michael Xi MBA, M.S. <i>CFO</i></p>	 <p>Dr. Peng Zhang Ph.D. <i>SVP (Corporate Operations)</i></p>	 <p>Dr. Xiaoping Jin Ph.D. <i>SVP (Clinical Science and Development)</i></p>
 <p>Dr. Xinfeng Zhang Ph.D. <i>SVP (CMC, and MST)</i></p>	 <p>Dr. Michael Chen Ph.D. <i>VP (Business Development)</i></p>	

458 employees⁽¹⁾ consist of:

Notes: As of June 30, 2020



111
R&D



122
Clinical



144
Manufacturing

Our business strategies

Our vision is to become a global leader in developing, manufacturing and commercializing innovative, next-generation and affordable therapeutic antibodies for patients worldwide



SECTION 2

Business and Product Updates



Major accomplishments in 1H 2020 – clinical advancement

First NDA Filing

- NMPA accepted the NDA submission of Penpulimab (PD-1) in May 2020

Two Registrational Trials Granted from FDA and NMPA

- FDA granted AK104 for 2L/3L cervical cancer
- NMPA granted AK104 for 3L NPC

FDA Fast Track Designation Granted

- FDA granted AK104 fast track designation for 2L/3L cervical cancer

20 New Clinical Trials Launched

- Penpulimab + Anlotinib for various tumor types
- AK104 + TKI for 1L HCC
- AK 117 (CD47)
- AK120 (IL4R)
- AK109 (VEGFR-2)
- etc.

7 New IND Granted

- AK104 for 2L/3L cervical cancer (US)
- AK112 (China)
- AK117 (US and AU)
- AK120 (AU and New Zealand)
- AK101 for UC (China)

Major accomplishments in 1H 2020 – manufacturing development

Continuous developing strong manufacturing capabilities & expansion of manufacturing capacities



Commercial Manufacturing Base in Guangzhou

- Total area of 58,000 m²
- Phase I capacity, 10*2,000L single use bioreactors, operation expected in Jan 2021
- Two fill/finish lines for vials and pre-filled syringes



Commercial Manufacturing Base in Cuiheng, Zhongshan

- Total area of 110,000 m²
- Designed phase I capacity, 4*10,000L stainless steel bioreactors
- Two fill/finish lines

Strengthened our CMC and manufacturing team with additional key personnel



Yu Xia
Ph.D.
SVP
Manufacturing,
Quality and
Regulatory Affairs



Dr. Xinfeng Zhang
Ph.D.
SVP
CMC and MST



Peng Zhang
Ph.D.
SVP
Corporate
Operations



Jin Jiang
Director
Head of Akeso's
manufacturing
• 15 years of experience
in biopharmaceutical
industry



Jianjun Zhan
Associate Director
Head of Process
Development
• 12 years of experience in
biopharmaceutical industry.



Shuquan Xia
Director
Head of Corporate
Operations,
Guangzhou
• 16 years of experience
in FMCG industry



Major accomplishments in 1H 2020 – key hires



Dr. Xinfeng Zhang

*SVP, CMC
Development & MST*

- Responsible for CMC Development and MST
- Extensive experience and track records in global biopharmaceutical CMC and MST operations, including biologics process and product development, manufacturing operation, CMC technology transfer, regulatory filings, quality system, and supply chain management
- Further strengthen Akeso's layout in CMC development and manufacturing science and technology, and expedite the development and global filings of new drug



Dr. Michael Chen

*VP, Business
Development*

- Responsible for global business development of the Company
- Extensive experience in external innovation, pipeline collaboration and business development in global pharmaceutical industry
- Further strengthen Akeso's pipeline collaboration and business expansion, accelerate the commercialization of our innovative drug pipeline, enhance our core competitiveness and improve our global business layout



Major accomplishments in 1H 2020 – global clinical team key hires

Reputable and experienced KOLs leading our trials globally

With very rich experience developing trials with MNC drug candidates



Wee 1 inhibitor
AstraZeneca

Ralimetinib



Zalypsis



Balstilimab: PD-1

agenus

Pazopanib



Oxaliplatin



MEK1/2 inhibitor



MEK1/2 inhibitor



Etigilimab



AMG386

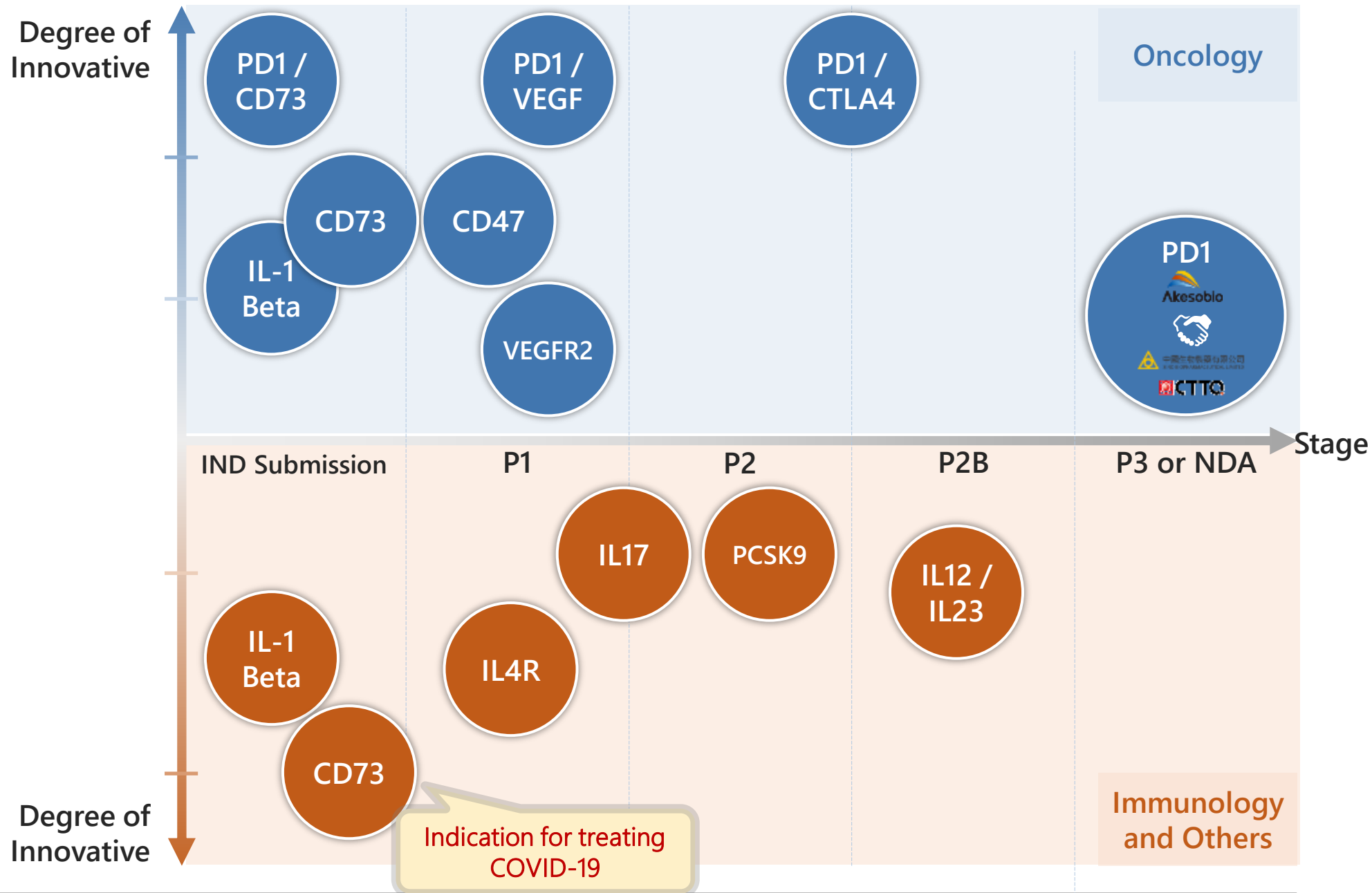


Highly experienced global clinical operation and development team

With very rich experience running clinical trials in leading pharmaceutical companies



Akeso clinical pipeline landscape



Diversified and robust pipeline

As of August 17, 2020

	Drug Candi	date	Target	Comm Rights	Status (Most Advanced Program)					Expected Earliest NDA Submission Date	Major Indications
					Dose Esc Ph 1a	Dose Exp Ph 1b	Ph 2	Pivotal			
Oncology	AK104		PD-1/CTLA-4	Global	China/Global(FDA Fast Track Designation)					2H2021	Cervical Cancer, HCC, ESCC, GC, NSCLC, Melanoma, Adv.Solid Tumors, PTCL
	AK105		PD-1	Global	China/Global					Submitted in May	Combo with Anlotinib / Chemo (SQ NSCLC, non-SQ NSCLC, HCC), R/R cHL, NPC, Adv. solid tumors
	AK112		PD-1/VEGF	Global	Global					-	Adv. solid tumors
	AK1117		CD47	Global	Gloabl					-	Adv. solid tumors
	AK109		VEGFR-2	Global	China					-	Adv. solid tumors
Immunology	AK101		IL-12/ IL-23	Global	China					-	Moderate-to-severe plaque psoriasis, Moderate-to-severe UC, SLE
	AK111		IL-17	Global	China					-	Moderate-to-severe plaque psoriasis, AS
	AK120		IL-4R	Global	Global					-	Atopic dermatitis
Others	AK102		PCSK9	Global	China					-	Hypercholesterolemia, HoFH, HeFH

 Key products that are near term priorities of the company

Our selected IND-enabling drug candidates

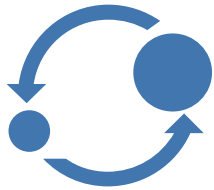
In addition to our clinical-stage drug candidates, as of June 30, 2020, we are also developing over five drug candidates in IND-enabling stage, including but not limited to:

Assets	Target(s)	Comm. Rights	Therapeutic Areas
AK114	IL-1beta	Global	Oncology/ Inflammatory disease
AK119	CD73	Global	Oncology/ Immunology
AK123	PD-1 / CD73	Global	Oncology
AK127	TIGIT	Global	Oncology
AK129	PD-1 / LAG3	Global	Oncology

1

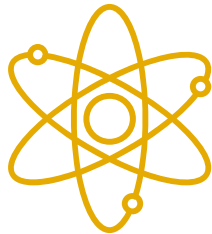
AK104 (first-in-class PD-1/CTLA-4 bi-specific) - Next-generation immune-oncology backbone drug

- AK104 is a bi-specific antibody drug candidate that simultaneously targets both PD-1 and CTLA-4
- Currently in Phase Ib/II and Phase II clinical trials in US, China, New Zealand and Australia for multiple indications.

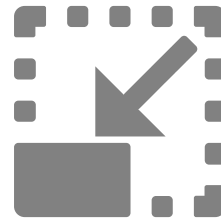


Higher avidity by design

for PD-1 and CTLA-4
in tumor micro-
environment versus
normal peripheral
sites

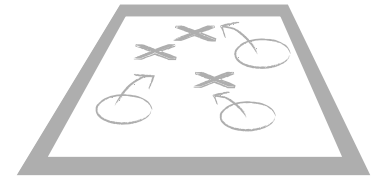


Robust manufacturing process



Favorable safety profile

lower toxicity than PD-
1 and CTLA-4
combination therapy,
observed in clinical
trials



Clear and focused clinical development path

1 AK104 – clinical development plan

Fast to market strategy

- 2L/3L Cervical cancer: single-arm registrational trials in China and US, **expected to file NDA/BLA in 2H 2021**
 - FDA granted fast track designation status
- ≥3L NPC: a single-arm registrational trial ongoing in China
 - NMPA granted registrational status

Combo strategy for large indications

- 1L GC: initiated a Phase 1b/2 trial to evaluate AK104 in combination with chemo
- 1L HCC: initiated a Phase 1b/2 trial to evaluate AK104 in combination with TKI
- 1L NSCLC: Planning to conduct studies to evaluate AK104 in combination with chemo or angiogenesis inhibitor
- Planning to conduct combo studies with other internally developed drugs, e.g. AK109, AK119, AK114

Resistance to anti-PD-1/PD-L1 therapies

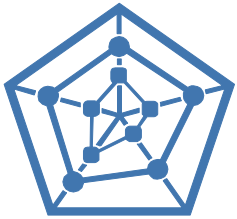
- NSCLC (R/R to anti-PD-1/L1): Planning a Phase 2 trial to evaluate AK104 in combination with angiogenesis inhibitor
- Pancreatic cancer (R/R to anti-PD-1/L1): Planning a Phase 1 trial to evaluate AK104 in combination with anti-CD73 antibody AK119

Global strategy

- Single-arm registrational trial for 2L/3L cervical cancer for speed to market
- AK104 in combination with angiogenesis inhibitors for large indications
- Actively exploring collaboration opportunities globally

2 AK105 - Registrational stage PD-1 mAb penpulimab targeting large indications

- Penpulimab (AK105) is a late-stage, differentiated and potentially best-in-class PD-1 monoclonal antibody drug candidate



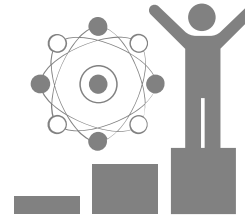
Differentiated structure & characteristics

- (i) Fc-receptor-mediated effector function removed to increase anti-tumor activities
- (ii) leads to slower off-rate and better receptor occupancy



Strong efficacy data and favorable safety profile

Observed in clinical trials



Focus on combo studies with Anlotinib

Potential chemo-free therapeutic approach with better efficacy



Commercialization in partnership with Sino Biopharm

Leverage Sino Biopharm's strong sales team of about 12,000 professionals.

2 AK105 – clinical development plan

Fast to market strategy

- Single-arm registrational trials for Penpulimab for the treatment of cHL and NPC
 - NDA filed for 3L R/R cHL in May 2020
 - Expected to file NDA for $\geq 3L$ NPC in 1H 2021

Combo strategies for large indications

- Phase III trial: combination of chemo for SQ NSCLC, expected to file NDA in 2021
- Phase III trial initiated: combination of Anlotinib or chemo for 1L non-SQ NSCLC
- Phase III trial initiated: combination of Anlotinib for 1L HCC
- Phase III trial initiated: combination of Anlotinib for 2L Gastric/GEJ cancer
- Phase II trials initiated: combination of Anlotinib for various cancer types to explore various indication opportunities

Global strategy

- IND for Penpulimab (AK105) was granted from the FDA
- Actively exploring collaboration opportunities globally

3 AK101 – Potentially first anti-IL-12/IL-23 mAb developed in China

- AK101 is potentially the first domestically developed monoclonal antibody drug in the market that targets IL-12/IL-23
- AK101 has the same target as Johnson & Johnson's Stelara (ustekinumab), which is currently one of the major treatments for psoriasis, psoriatic arthritis, Crohn's disease, and UC worldwide



Market leader
in the treatment of
psoriasis and UC in
China



Potentially best-in-class dosing profile





Differentiated safety profile
versus anti-TNF-alpha agents



Improved efficacy and less frequent dosing schedule
to enhance patient compliance

3 AK101 – clinical development plan

Our development of AK101 is aimed at the treatment of autoimmune diseases with unmet medical needs, including psoriasis and UC.

Drug Candidate	Target	Comm. Rights	Indication	Status				
				Phase I		Phase II	Pivotal	NDA Submitted
				Phase Ia	Phase Ib			
AK101	IL12 / IL23	Global	Moderate-to-severe plaque psoriasis					
			Moderate-to-severe UC					

 = Completed;
  = Completed Patient Enrollment;
  = In Progress;
  = To Be Initiated within Next Quarter

■ Moderate to severe Psoriasis

- Two Phase IIb dose-ranging studies are in progress to evaluate AK101 optimal dose and dosing schedule
- Expected to initiate Phase III in 2021

■ UC

- Plan to initiate Phase Ib for UC in 2H 2020
- FDA IND was granted in October 2019. We are actively exploring co-development/licencing opportunities globally

- Ebronucimab (AK102) is potentially the first domestically-developed PCSK9 drug for the significant cardiovascular patient population
- It is being developed for the treatment of acquired or inherited hyperlipidemias, including hypercholesterolemia (high cholesterol), HoFH and HeFH patients with atherosclerotic cardiovascular disease.



Market leader

in the treatment of
hyperlipidemias, HoFH, HeFH
and hypercholesterolemia in
China



Superior elimination of low- density lipoprotein cholesterol (LDL-C)




in patients compared to
published data of Evolocumab



JV with Dawnrays Pharma

to co-develop and
commercialize AK102

We have initiated three Phase II trials in patients for various indications in China

Drug Candidate	Target	Comm. Rights	Mono / Combo	Indication	Status				
					Phase I		Phase II	Pivotal	NDA Submitted
					Phase Ia	Phase Ib			
<u>Ebronucimab (AK102)</u>	PCSK9	Global	+Statin / Ezetimibe	HoFH					
			+Statin / Ezetimibe	HeFH					
			+Statin / Ezetimibe	Hypercholesterolemia					

 = Completed;
  = Completed Patient Enrollment;
  = In Progress;
  = To Be Initiated within Next Quarter

■ Hypercholesterolemia

- Enrolled the first patient in Phase II trial for hypercholesterolemia with high cardiovascular risk in 2020

■ Heterozygous Familial Hypercholesterolemia (HeFH)

- Enrolled the first patient in Phase II trial for HeFH in 2020

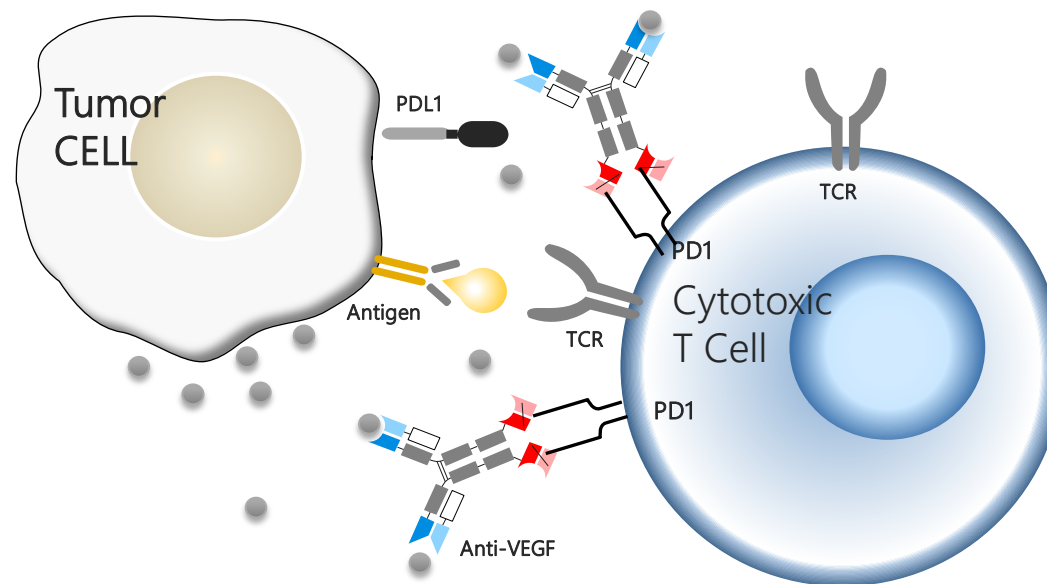
■ Homozygous Familial Hypercholesterolemia (HoFH)

- Initiated Phase II trial in patients with HoFH in 2019

5 AK112 (first-in-class PD-1/VEGF bi-specific) – Potential next-generation immune-oncology backbone drug

- **Dual blockade of PD1 and VEGF pathways** have clinical **proven activity** in major tumor types: **NSCLC, HCC, RCC etc**
- AK112 blocks **PD-1 binding to PD-L1 and PD-L2**, and blocks **VEGF binding to VEGF receptors**, thus inhibiting tumor cell proliferation and tumor angiogenesis
- AK112 exploits **co-expression of PD-1 and VEGF in the TME** by using a tetrameric structure to facilitate tumor enrichment of drug
- Among numerous drug classes that have been tested for **combination with PD-1 antibody, anti-angiogenic agents stood out as a top winner**




Mechanism of Action



5 AK112 (PD-1/VEGF) – clinical development plan

We are executing a global clinical development strategy for AK112. Started Phase I trial for the treatment of advanced solid tumors in Australia in October 2019.

- Dose escalation phase (Phase Ia) to determine the maximum tolerated dose (MTD)
- Dose expansion phase (Phase Ib) in subjects with selected tumor types with AK112 at the MTD or RP2D

Drug Candidate ⁽¹⁾	Target	Comm. Rights	Mono / Combo	Indication	Status				
					Phase I		Phase II	Pivotal	NDA Submitted
					Phase Ia	Phase Ib			
AK112*	PD-1 / VEGF	Global	Mono 	Adv. solid tumors					
			Mono	Adv. solid tumors					

 = Completed;
  = Completed Patient Enrollment;
  = In Progress;
  = To Be Initiated within Next Quarter

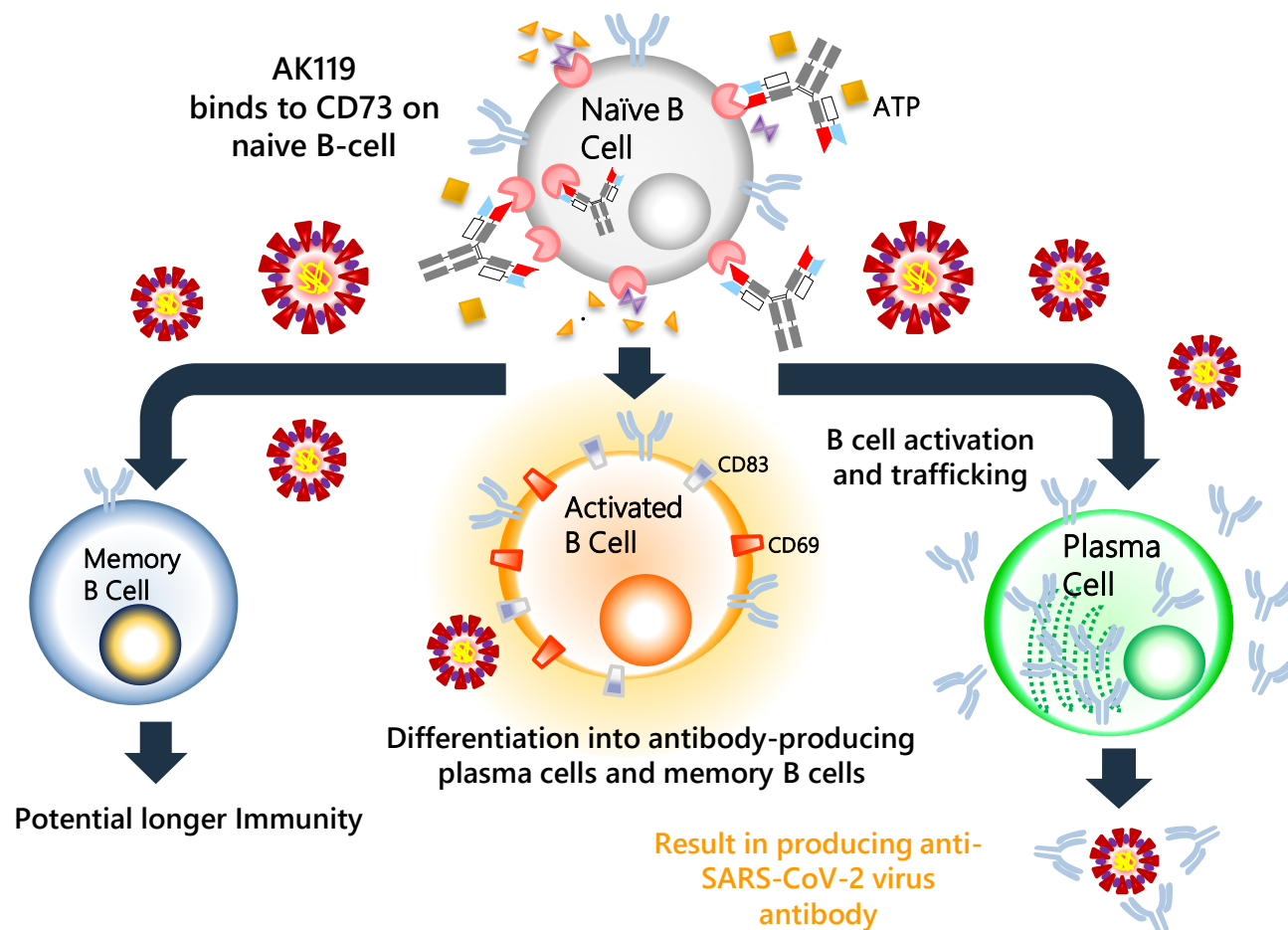
 Global trial

- We have obtained IND approval from NMPA in Aug 2020, will initiate Phase Ib in China, and expect to enroll patients in 2H 2020

6 AK119 – Anti-CD73 antibody drug for COVID-19 treatment

We want to contribute to the fight against COVID-19 by leveraging our immunology assets to find solutions to this pandemic as matter of priority

- AK119 activates the immune system to fight COVID-19 via binding to immune cells and stimulating B cell activation and humoral immunity
- AK119 could enhance antibody production against SAR-CoV-2 virus in Humans
- **Completed regulatory and ethics submissions in New Zealand for AK119 for a COVID-19 trial in HV**



- CD73 expressed on immune cells in various tissue and in the vasculature creates an immune suppressive environment through adenosine generation

- AK119 is a full antagonist of CD73 activity, thus causing full scale B cell activation

7 Other clinical stage products

Oncology

AK109

Anti-VEGFR-2



- First patient was dosed with AK109 in Phase I study in China (June 2020)
- Plan to conduct combo studies with AK104 in 2021
- Expect data readouts in next 12 months

AK117

Anti-CD47

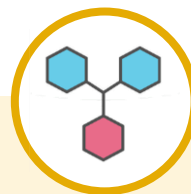


- First patient was dosed with AK117 in Phase I study in Australia (May 2020)
- IND was submitted to NMPA
- Expect data readouts in next 12 months

Immunology

AK111

Anti-IL-17



- First patient with moderate-to-severe plaque psoriasis was dosed with AK111 in Phase Ib study in China (June 2020)
- Expect data readouts in next 12 months

AK120

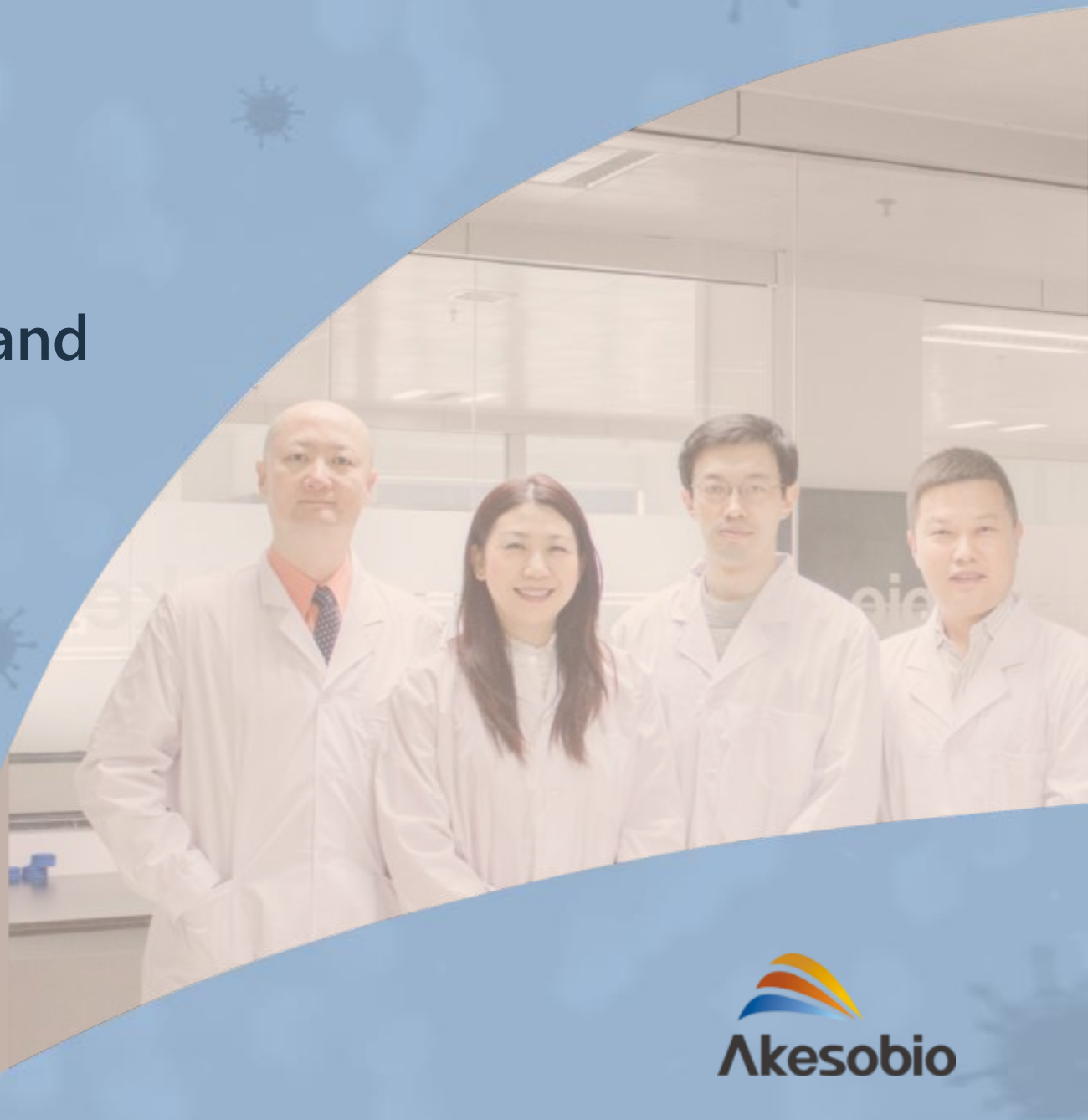
Anti-IL-4R



- Dupixent developed by Sanofi/Regeneron is expected to realize Euro2bn revenue in 2019
- First healthy subject was dosed with AK120 in Phase I study in New Zealand (June 2020)
- Expect data readouts in next 12 months

SECTION 3

Future Milestones and Catalysts



Clinical Advancement

- 1 **Receive NDA approval** for Penpulimab in 3L R/R cHL in 2021
- 2 **File NDA** for Penpulimab in \geq 3L NPC in 1H 2021
- 3 **File NDA** for Penpulimab in combination with chemotherapy for 1L squamous NSCLC in 2021
- 4 **File NDA** for AK104 (PD-1/CTLA-4) in 2L/3L cervical cancer in 2021
- 5 **Data readouts for various clinical development programs** in the next 12 months
- 6
 - AK119 (CD73): **First-in-human** in 2H 2020
 - AK114 (IL-1beta): **First-in-human** in 1H 2021

Early Stage Assets

7

Advance at least one pre-clinical compound in our pipeline into clinic in 2021

Commercialization

8

Commercialization of Penpulimab with CTTQ in 2021

9

Actively explore value-accretive strategic partnerships both in China and globally

10

Build an experienced and strong commercial team of approximately 300-500 personnel in 2021

Manufacturing

11

Complete the phase 1 installation of Guangzhou manufacturing facility, which expects to house up to 20,000L bioreactor capacity, and commence operation by 1H 2021

12

Start the construction of the new manufacturing facility to add 40,000L bioreactor capacity in Zhongshan in 2H 2020

SECTION 4

Financial Highlights



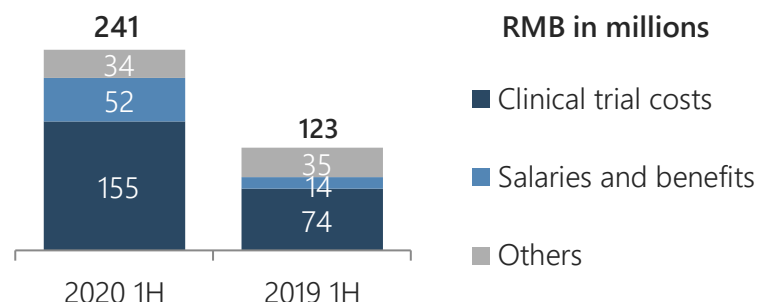
Income statement

	As of June 30,	
	2020	2019
	(RMB in thousands)	
1 Other income and gains, net	41,012	22,917
2 Research and development expenses	(240,708)	(123,218)
3 Administrative expenses	(99,521)	(13,602)
Other expenses, net	(230)	(267)
4 Fair value changes on convertible redeemable preferred shares	(412,421)	–
Finance costs	(6,471)	(1,570)
Loss before tax	(718,339)	(115,740)
Income tax expense	–	–
Loss for the periods	(718,339)	(115,740)
Total comprehensive loss for the periods*	(728,709)	(115,550)
Added:		
Fair value changes	412,421	–
Listing expenses	45,492	350
Share award expenses	54,051	–
Adjusted total comprehensive loss for the periods*	(216,745)	(115,200)

1 Other income and gains, net

The increase was primarily attributable to interests earned on the proceeds from the IPO and the increase in subsidies from government for R&D activities.

2 Research and development expenses



The increase was primarily attributable to (i) clinical trial advancement and the increased expenses incurred for additional clinical trials for more drug candidates, and (ii) increase in headcount of R&D.

3 Administrative expenses

The increase was primarily attributable to the increase in listing expenses, and the increase in employee salaries and benefits mainly caused by share award expense and increase in headcount of non-R&D personnel.

4 Fair value changes on convertible redeemable preferred shares

Such loss represents an increase in fair value of convertible redeemable preferred shares, which will not incur on going forward since all of the Group's preferred shares were converted to ordinary shares upon the listing date.

* Adjusted total comprehensive loss for the periods represents the loss for the periods excluding the effect brought by fair value changes³³ in preferred shares, listing expenses and share award expenses.

Balance sheet and cash flow statement

Summary of Combined Statements of Financial Position

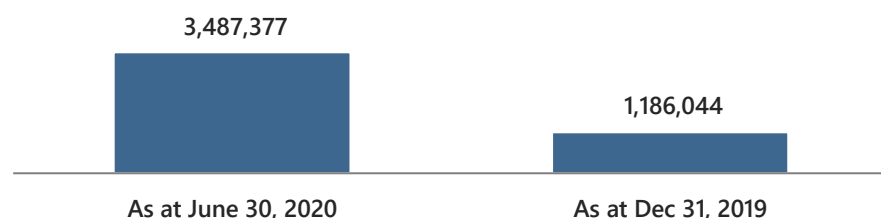
	As of June 30, 2020	As of December 31, 2019
	(RMB in thousands)	
Non-current assets	588,126	416,975
Current assets	3,888,454	1,255,964
Current liabilities	230,244	119,761
Net current assets	3,658,210	1,136,203
Non-current liabilities	265,190	1,337,473
Net assets	3,981,146	215,705

Cash Flow Statement

	As of June 30, 2020	As of June 30, 2019
	(RMB in thousands)	
Net cash generated used in operating activities	(201,992)	(154,229)
Net cash used in investing activities	(477,300)	(56,349)
Net cash generated from financing activities	2,975,972	100,310
Net increase/(decrease) in cash and cash equivalents	2,296,680	(110,268)
Cash and cash equivalents at end of the periods	3,487,377	203,364

❖ Cash and cash equivalents

RMB in thousands



The increase in cash and cash equivalents was primarily as a result of the proceeds from the Company's IPO, partially offset by an increase in purchases of financial assets.

❖ Total capital expenditure

RMB in thousands



The increase in capital expenditure was primarily attributable to progress made in the construction of manufacturing facilities including the construction of Guangzhou facility to enhance development capabilities and expand business operations.