

# Ascletis Pharma Inc. 歌禮製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

STOCK CODE: 1672



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## **CORPORATE INFORMATION**

#### **BOARD OF DIRECTORS**

#### **Executive Directors**

Dr. Jinzi Jason WU

(Chairman and Chief Executive Officer)

Mrs. Judy Hejingdao WU

(Vice President)

## **Independent Non-executive Directors**

Dr. Yizhen WEI Mr. Jiong GU Ms. Lin HUA

#### **AUDIT COMMITTEE**

Mr. Jiong GU *(Chairman)*Dr. Yizhen WEI
Ms. Lin HUA

#### **REMUNERATION COMMITTEE**

Ms. Lin HUA *(Chairman)* Dr. Yizhen WEI Mrs. Judy Hejingdao WU

#### **NOMINATION COMMITTEE**

Dr. Jinzi Jason WU *(Chairman)* Dr. Yizhen WEI Ms. Lin HUA

#### **AUTHORISED REPRESENTATIVES**

Dr. Jinzi Jason WU Mrs. Judy Hejingdao WU

#### **COMPANY SECRETARY**

Mr. Lok Kwan YIM

### **REGISTERED OFFICE**

Walkers Corporate Limited 190 Elgin Avenue George Town Grand Cayman KY1-9008 Cayman Islands

#### CORPORATE HEADQUARTERS IN THE PRC

12F, Building D 198 Qidi Road, HIPARK Xiaoshan District Hangzhou Zhejiang Province PRC

#### PRINCIPAL PLACE OF BUSINESS IN HONG KONG

40th Floor Dah Sing Financial Centre No. 248 Queen's Road East Wanchai Hong Kong

## PRINCIPAL SHARE REGISTRAR AND TRANSFER OFFICE IN CAYMAN ISLANDS

Walkers Corporate Limited 190 Elgin Avenue George Town Grand Cayman KY1-9008 Cayman Islands

#### HONG KONG SHARE REGISTRAR

Computershare Hong Kong Investor Services Limited Shops 1712-1716 17th Floor Hopewell Centre 183 Queen's Road East Wanchai Hong Kong

## **CORPORATE INFORMATION**

## HONG KONG LEGAL ADVISER

Kirkland & Ellis 26/F, Gloucester Tower The Landmark 15 Queen's Road Central Hong Kong

## **AUDITOR**

Ernst & Young
Certified Public Accountants
Registered Public Interest Entity Auditor
27/F, One Taikoo Place
979 King's Road
Quarry Bay
Hong Kong

## STOCK CODE

1672

## **COMPANY WEBSITE**

www.ascletis.com

# **FINANCIAL HIGHLIGHTS**

	Un	audited	l	
Six	months	ended	June	30.

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>	Changes %
Revenue			
Promotion service revenue	34,488	30,772	12.1
Collaboration revenue	1,707	_	_
Sale of products	354	1,062	(66.7)
Total	36,549	31,834	14.8
Gross (loss)/profit	(2,560)	20,980	(112.2)
Loss before tax	(110,828)	(51,465)	(115.3)
Loss for the period	(110,828)	(51,465)	(115.3)
Loss attributable to the owners of the parent	(110,828)	(51,465)	(115.3)
Net loss margin	(303.2%)	(161.7%)	_
	RMB	RMB	
Loss per share			
- Basic	(10.09) cents	(4.94) cents	
– Diluted	(10.09) cents	(4.94) cents	

#### **OUR VISION**

Ascletis' vision is to become the most innovative world-class biomedical company addressing global unmet medical needs in the areas of non-alcoholic steatohepatitis (NASH), cancer (lipid metabolism and oral checkpoint inhibitors) and viral diseases.

#### **OVERVIEW**

The total revenue of the Group increased by 14.8% from approximately RMB31.8 million for the six months ended June 30, 2020 to approximately RMB36.5 million for the six months ended June 30, 2021.

The research and development expenses of the Group increased by 43.1% from approximately RMB51.7 million for the six months ended June 30, 2020 to approximately RMB74.0 million for the six months ended June 30, 2021, mainly due to the increased expenses on the clinical development of NASH, HBV and cancer drug candidates.

The loss for the period of the Group increased by 115.3% from approximately RMB51.5 million for the six months ended June 30, 2020 to approximately RMB110.8 million for the six months ended June 30, 2021, primarily attributable to the increased research and development expenses.

The gross profit of the Group decreased for the six months ended June 30, 2021, due to RMB23.0 million impairment provision of inventories. If the impairment provision of inventories were excluded, the gross profit would amount to RMB20.5 million for the six months ended 30 June 2021, representing a gross profit margin of 56.0%.

As of June 30, 2021, the Group has cash and cash equivalents of approximately RMB2,577.8 million.

During the Reporting Period and up to the date of this report, the Group has got five IND approvals (ASC40-NASH; ASC42-NASH; ASC40-recurrent glioblastoma (rGBM); ASC42-HBV; ASC40-acne) from China NMPA and one IND approval (ASC41-NASH) from the U.S. Food and Drug Administration (FDA). In China or the U.S., the Group has advanced (i) ASC40-rGMB into a Phase III clinical trial; (ii) ASC40-NASH into a Phase IIb clinical trial; (iii) ASC42-HBV and ASC40-acne into Phase II clinical trials. The significant progresses of the Group are summarized below:

#### **NASH**

As of the date of this report, the Group's leading NASH drug candidate, ASC40, a first-in-class oral FASN inhibitor, was dosed by its partner Sagimet Biosciences Inc. ("Sagimet") in a randomized, double-blind, placebo-controlled Phase IIb clinical trial of approximately 330 NASH patients with moderate to advanced fibrosis (F2-F3). The Group's second leading NASH drug candidate ASC42, an FXR agonist, has completed a first-in-human, randomized, placebo-controlled, double-blind single-ascending dose (SAD), multiple-ascending dose (MAD), and food effect trial in 64 healthy subjects with positive topline results. The Group dosed ASC41, a THRβ agonist, in the U.S. Phase I clinical study of drug interaction and non-alcoholic fatty liver disease (NAFLD) patient pharmacokinetics. In addition, the Group has developed its first fixed-dose combination ASC43F against two targets (THRβ and FXR) into an IND ready drug candidate.

Our NASH pipeline is shown below:

## Single Agents and Fixed-Dose Combinations Therapy Pipeline<sup>1</sup>

Target	Drug Candidates	Commercial Rights	Pre-IND	IND	Phase I	Phase IIa	Phase IIb/III
FASN	ASC40	Greater China <sup>2</sup>			U.S	S. FDA Fast Track	
THRβ	ASC41	Global					
FXR	ASC42	Global		U.S. F	DA Fast Track		
THRβ + FXR	ASC43F One-Pill, Once-a-Day FDC	Global					
FASN + FXR	ASC44F One-Pill, Once-a-Day FDC	Global <sup>2</sup>					
FASN + THRβ	ASC45F One-Pill, Once-a-Day FDC	Global <sup>2</sup>					

#### Notes:

- Our NASH pipeline is owned by Gannex Pharma Co., Ltd. (甘萊製藥有限公司, "Gannex"), which is a whollyowned subsidiary of the Company.
- 2. ASC40 is licensed from Sagimet the exclusive rights to develop, manufacture and commercialize FASN inhibitors including ASC40 and all related compounds in Greater China.

## CANCER (LIPID METABOLISM AND ORAL CHECKPOINT INHIBITORS)

In March 2021, the Group announced the escalation of the investment in R&D of cancer lipid metabolism and oral checkpoint inhibitors. The Group has made significant progress in advancing its cancer pipeline since then. In July, 2021, China NMPA has approved the Phase III clinical trial application of ASC40 combined with bevacizumab for treatment of patients with rGBM. This is the first Phase III oncology clinical trial of the Group.

Our Cancer (lipid metabolism and oral checkpoint inhibitors) pipeline is shown below:

Target	Drug Candidates	Indication	Commercial Rights	Pre-IND	IND	Phase I	POC	Pivotal
FASN + VEGF	ASC40 (Oral) + Bevacizumab	Recurrent Glioblastoma	Greater China <sup>1</sup>		Phase	III in China ap	pproved	
FASN	ASC40 (Oral)	Multiple Solid Tumors	Greater China <sup>1</sup>					
FASN	ASC60 (Oral)	Multiple Solid Tumors	Greater China <sup>1</sup>					
PD-L1	ASC61 (Oral small molecule)	Multiple Tumors	Global					
PD-L1	ASC63 (Oral small molecule)	Multiple Tumors	Global					

#### Note:

1. ASC40 and ASC60 are licensed from Sagimet.

#### **VIRAL DISEASES**

## Hepatitis B Virus (HBV) Clinical Cure

As a marketed drug of clinically curing chronic hepatitis B (CHB), Pegasys®'s promotion service revenue increased 12.1% from approximately RMB30.8 million for the first half of 2020 to approximately RMB34.5 million for the first half of 2021. The Group announced in July 2021 the completion of 149 patient enrollment and the positive interim results of Phase IIb study on CHB patients in China treated with ASC22 (Envafolimab) – a first-in-class, subcutaneously administered PD-L1 antibody, in combination with nucleos(t)ide analogs (NAs). Furthermore, the Group has completed the FXR Agonist ASC42's bridging study and initiated Phase II clinical trial for CHB indication in China.

Our HBV clinical cure pipeline is shown below.

Target	Drug Candidates	Commercial Rights	Pre-IND	IND	Phase I	Phase IIa	Phase IIb/III	NDA	Marketed
Interferon receptor	Pegasys® (Peginterferon alfa-2a)	Mainland China <sup>1</sup>							
PD-L1	ASC22	Greater China <sup>2</sup>							
FXR	ASC42	Global							
Undisclosed	Candidate identified	Global							

#### Notes:

- 1. Pegasys® is licensed from Shanghai Roche Pharmaceuticals Ltd.(上海羅氏製藥有限公司) for the exclusive rights in the Mainland China.
- 2. ASC22 is licensed from Suzhou Alphamab Co., Ltd. (蘇州康寧傑瑞生物科技有限公司, "Alphamab") for the exclusive rights in the Greater China.

## **Hepatitis C Virus (HCV)**

Our HCV pipeline is shown below.

Target	Drug Candidates	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III	NDA	Marketed
NS3/4A	GANOVO® (Danoprevir)	Greater China <sup>1</sup>							
NS5A	ASCLEVIR® (Ravidasvir)	Greater China <sup>2</sup>							
Dual Targeted FDC	ASC18	Greater China							

#### Notes:

- 1. GANOVO® is licensed from Roche (F. Hoffmann-La Roche AG) for the exclusive rights in the Greater China.
- 2. ASCLEVIR® is licensed from Presidio Pharmaceuticals, Inc. for the exclusive rights in the Greater China.

#### **HIV/AIDS**

Our HIV/AIDS pipeline is shown below.

Target	Drug Candidates	Commercial Rights	Pre-IND	IND	Phase I	Phase IIa	Phase IIb/III
Protease	ASC09F (ASC09 / Ritonavir FDC)	Mainland China and Macau <sup>1</sup>					
PD-L1	ASC22	Greater China <sup>2</sup>					

#### Notes:

- 1. The Group is developing the tablet formulation of Ritonavir and has completed bioequivalence (BE) studies of the tablets on healthy volunteers. ANDA of Ritonavir was accepted by China NMPA on August 22, 2019.
- 2. ASC22 is licensed from Alphamab.

## OTHER DISEASES

Acne is the eighth most prevalent disease in the world and affects more than 640 million people globally. The Group announced in July 2021 that China NMPA had approved the Phase II clinical trial application of ASC40 for the treatment of patients with moderate to severe acne.

Our ACNE pipeline is shown below.

Target	Drug Candidates	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III
FASN	ASC40	Greater China <sup>1</sup>					

#### Note:

1. ASC40 is licensed for exclusive Greater China rights from Sagimet.

#### **IN-HOUSE DISCOVERY**

The in-house discovery team of the Group has delivered two China NMPA IND approvals (ASC42-NASH and ASC42-HBV) and one U.S. FDA IND approval (ASC41-NASH) in 2021. In addition, the in-house discovery team made significant progress for the oral PD-L1 small molecule inhibitor program for cancer immune modulation.

#### **BUSINESS REVIEW**

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During the Reporting Period and up to the date of this report, the Group has got five IND approvals (ASC40-NASH; ASC42-NASH; ASC40-rGBM; ASC42-HBV; ASC40-acne) from China NMPA and one IND approval (ASC41-NASH) from the U.S. FDA. In China or the U.S., the Group has advanced (i) ASC40-rGMB into a Phase III clinical trial; (ii) ASC40-NASH into a Phase IIb clinical trial; (iii) ASC42-HBV and ASC40-acne into Phase II clinical trials. The significant progresses of the Group are summarized below:

#### **NASH**

#### ASC40

The Group's partner Sagimet dosed the first patient in its FASCINATE-2 Phase IIb clinical trial for NASH. FASCINATE-2 is a randomized, double-blind, placebo-controlled Phase IIb clinical trial of approximately 330 NASH patients with moderate to advanced fibrosis (F2-F3). This trial will evaluate the impact of oral, once-daily doses of TVB-2640 (ASC40) for 52 weeks as assessed by biopsy. Patients will initially be randomized to receive placebo or 50 mg of TVB-2640 (ASC40). A 75 mg dose level of TVB-2640 (ASC40) is planned to be added to FASCINATE-2 following an open-label cohort in the FASCINATE-1 Phase IIa clinical trial.

Primary efficacy endpoints are:

- 1. ≥ 2-point improvement in NAFLD activity score (NAS) that results from reduction of necro-inflammation (inflammation or ballooning); or
- 2. improvement in fibrosis.

The U.S. FDA accepted these two endpoints for Phase IIb studies in NASH. Liver biopsy data will also be evaluated to assess NASH resolution without worsening of fibrosis and/or improvement in fibrosis without worsening of NASH, both of which are endpoints accepted by the U.S. FDA for accelerated approval following Phase III studies.

#### **BUSINESS REVIEW** (Continued)

## **NASH** (Continued)

#### ASC41

ASC41 is a liver-targeted prodrug. The active metabolite of ASC41 is a potent and selective THRβ agonist. In April 2021, the Group announced the dosing of the first cohort in the U.S. Phase I clinical study of drug interaction and NAFLD patient pharmacokinetics for ASC41 oral tablets. This clinical study consists of two cohorts: the first cohort is a drug-drug interaction study to evaluate the effect of itraconazole and phenytoin on the pharmacokinetics of ASC41 oral tablets in healthy volunteers, and the second cohort is a study to evaluate the pharmacokinetics, safety and tolerability of ASC41 oral tablets in patients with NAFLD.

#### ASC42

ASC42 is a novel non-steroidal, potent and selective FXR agonist with the best-in-class potential. In June 2021, the Group announced positive topline results of safety and pharmacodynamic biomarkers from the U.S. Phase I trial of NASH drug FXR agonist ASC42.

The ASC42 Phase I trial in the U.S. was a first-in-human, randomized, placebo-controlled, double-blind SAD, MAD, and food effect trial in 64 healthy subjects receiving ASC42 or matching placebo. Doses in the SAD portion ranged from 5 to 200 mg doses and in the MAD portion ranged from 5 to 50 mg administered once-daily for 14 days. The food effect on ASC42 pharmacokinetics was studied with a dose of 15 mg. The primary objective was to evaluate the safety, pharmacokinetics and pharmacodynamics of ASC42 versus placebo. Biomarkers for FXR target engagement were assessed through measurement of  $7\alpha$ -hydroxy-4-cholesten-3-one (C4), a blood biomarker of bile acid synthesis that decreases with FXR activation, and Fibroblast Growth Factor 19 (FGF19), a hormone produced after FXR activation in the intestine that regulates bile acid synthesis as well as glucose and lipid metabolism.

Based on both mouse and rat NASH animal models, the predicted human therapeutic dose was 15 mg once-daily. ASC42 Phase I topline data showed that during 14-day treatment with 15 mg once-daily, Day 1 and Day 14 FGF19 levels increased 1,195% and 1,632% from the pre-dose level, respectively; Day 1 and Day 14 C4 levels decreased 88% and 93% from the baseline, respectively. Based on these data, 15 mg once-daily dose has been selected as one of three doses to be studied in the Phase II trial in patients with NASH, which will be initiated by the end of 2021. The magnitude of FGF19 increase and/or C4 decrease may be used to project potential levels of liver fat reduction in patients with NASH, with a  $\geq$  30% relative liver fat reduction on magnetic resonance imaging proton density fat fraction (MRI-PDFF) potentially correlating with an increased likelihood of histologic benefit.

Overall, ASC42 was safe and tolerated and there were no study drug related serious adverse events (SAEs) or premature discontinuations. Notably, there was no pruritus, mean low density lipoprotein cholesterol (LDL-C) values remained within normal limits and there were no treatment-emergent alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevations for 14-day, once daily dosing with 15 mg (therapeutic dose).

#### **BUSINESS REVIEW** (Continued)

## **NASH** (Continued)

#### **Fixed-Dose Combinations**

With three single agents against three distinct but complementary targets, the Company has made significant progress in formulation development and preclinical toxicology studies of three fixed dose combinations (FDCs) to take advantage of synergies among these targets (see below).

## Fixed-Dose Combinations: Synergies among ASC40, ASC41 and ASC42

Treatment Goals	Monotherapy			FDC One-Pill, Once-a-Day			
	ASC40 FASN	ASC41 THRβ	ASC42 FXR	ASC43F THRβ + FXR	ASC44F FASN + FXR	ASC45F FASN + THRβ	
Liver fat reduction	***	***	**	***	***	***	
Anti-inflammation	**	**	**	**	**	**	
Anti-fibrosis	**	**	***	***	***	**	
Lowering LDL-C and TG		***		***		***	

## CANCER (LIPID METABOLISM AND ORAL CHECKPOINT INHIBITORS)

The Group has been focused on discovery and development of therapeutics in the areas of cancer (lipid metabolism and oral checkpoint inhibitors) since we have unique competitive edges against our competitors. In 2017, the U.S. FDA approved Agios' and Celgene's enasidenib for acute myeloid leukaemia (AML) as the first-in-class cancer metabolism drug, validating metabolism-modulating drugs as a means of killing cancer cells.

Lipid metabolism has been reported to play a critical role in various cancers. FASN is one of the most important enzymes which regulates lipid metabolism. Many solid and hematopoietic tumors overexpress FASN, including glioblastoma (GBM, Grade IV astrocytoma), non-small cell lung, breast, ovarian, prostate, colon, pancreatic cancers, and non-Hodgkin lymphoma.

GBM represents the most common and devastating primary brain tumor. There is no standard of care after patients have progressed on chemo-radiation. An investigator sponsored Phase II trial of TVB-2640 in combination with bevacizumab in patients with first relapse of high-grade astrocytoma (including GBM) was completed in the United States. The data have shown that the overall response rate (ORR) for TVB-2640/bevacizumab was 65% including the complete response (CR) of 20% and partial response (PR) of 45%. Furthermore, the data indicate that the progression-free survival at six months (PFS6) observed for TVB-2640 plus bevacizumab was 47%, representing a statistically significant improvement in PFS6 over historical bevacizumab monotherapy (BELOB 16%, p=0.01). TVB-2640 in combination with bevacizumab was safe and well tolerated in such patient population.

In July 2021, the Group announced that China NMPA had approved the Phase III clinical trial application of ASC40 combined with bevacizumab for treatment of patients with rGBM.

#### **BUSINESS REVIEW** (Continued)

## CANCER (LIPID METABOLISM AND ORAL CHECKPOINT INHIBITORS) (Continued)

The Phase III registrational study is a randomized, double-blind, placebo-controlled, multi-center clinical trial in China to evaluate progression-free survival (PFS), overall survival (OS) and safety of patients with rGBM. Approximately 180 patients will be 1:1 randomized to Cohort 1 (oral ASC40 tablet QD + Bevacizumab) and Cohort 2 (matching placebo tablet QD + Bevacizumab).

Based on published data, in China, glioblastoma (GBM) represents 46.1% of gliomas and has an incidence rate of approximately 2.85 to 4.56 per 100,000 population per year, suggesting approximately 40,000 to 64,000 new cases of GBM per year. More than 90% GBM patients will relapse after surgery, radiation and chemotherapies. In the United States, GBM represents 56.6% of gliomas and has an incidence rate of approximately 3.21 per 100,000 population per year.

Bevacizumab was the only drug which has been approved for rGMB indication in China as of September, 2020. The data of BELOB Trial indicated that median PFS was three months for patients with rGBM after bevacizumab treatment (Clinical Trials.gov Identifier: NCT03032484).

ASC60 is a next generation oral FASN inhibitor, which may be combined with other therapies for various solid tumors.

Our oral PD-L1 small molecule inhibitors discovered in-house have shown favorable anti-tumor activities in animal model compared to the marketed anti-PD-L1 antibody. The Company believes that oral PD-L1 small molecule inhibitors are next generation checkpoint inhibitors as cancer immune therapies and have potential to be combined with oral FASN small molecule inhibitors.

#### **VIRAL DISEASES**

#### **HBV**

According to WHO¹, there were 257 million people worldwide in 2015, including 86 million people in China, infected by HBV.

Note:

1. WHO. Global Hepatitis Report 2017. Geneva; 2017.

## **Pegasys®**

As a marketed drug of clinically curing CHB, Pegasys® promotion service revenue increased 12.1% from approximately RMB30.8 million for the first half of 2020 to approximately RMB34.5 million for the first half of 2021.

#### ASC22

As T cell exhaustion in HBV infections is an important factor in immune tolerance, blocking the PD-1/PD-L1 pathway could be an effective immunotherapy approach to improve specific T cell function and lead to an effective clinical cure for CHB.

In July 2021, the Group announced the completion of 149 patient enrollment and the positive interim results of Phase IIb study on CHB patients in China treated with ASC22 (Envafolimab) - a first-in-class, subcutaneously administered PD-L1 antibody, in combination with NAs.

#### **BUSINESS REVIEW** (Continued)

#### VIRAL DISEASES (Continued)

#### **HBV** (Continued)

#### **ASC22** (Continued)

The ASC22 Phase IIb study is a randomized, single-blind, placebo-controlled, multi-center clinical trial in China which evaluates the safety and efficacy of treating patients with CHB for 24-week treatment of 1 mg/kg or 2.5 mg/kg ASC22 or matching placebo given once every two weeks (Q2W) in combination with NAs. Patients enrolled in the study were hepatitis B surface antigen (HBsAg) < 10,000 IU/mL, HBV DNA < 20 IU/mL and negative hepatitis B e-antigen (HBeAg). A total of 149 patients with CHB were enrolled. Among them, 75 patients were 2:1 randomized to 1 mg/kg ASC22 Q2W dosed subcutaneously plus NAs and placebo Q2W dosed subcutaneously plus NAs and placebo Q2W dosed subcutaneously plus NAs and placebo Q2W dosed subcutaneously plus NAs.

As of July 20, 2021, for the 1 mg/kg ASC22 Q2W plus NAs group, 37% of patients completed 24-week treatment per protocol; 35% of patients completed 14 to 22-week treatment and 28% of patients completed 1 to 12-week treatment; for the 2.5 mg/kg ASC22 Q2W plus NAs group, 7% of patients completed 14 to 24-week treatment and 93% of patients completed 1 to 12-week treatment. Based on the safety data available as of July 20, 2021, the interim analysis indicated the 1 mg/kg ASC22 Q2W plus NAs group had a rate of any adverse events of 75% which was comparable to that (73%) of the placebo Q2W plus NAs group. The rate of grade 3 and 4 adverse events (7%) for the 1 mg/kg ASC22 Q2W plus NAs group was also comparable to that (7%) of the placebo Q2W plus NAs group.

Based on the efficacy data available as of July 20, 2021, the interim analysis indicated that HBsAg reduction was observed for 1 mg/kg ASC22 Q2W plus NAs with more HBsAg reduction observed in patients with HBsAg  $\leq$  500 IU/mL at baseline while no HBsAg reduction was observed for placebo plus NAs.

Based on the pharmacokinetic data of the Phase IIb study in patients with 1 mg/kg or 2.5 mg/kg ASC22 Q2W plus NAs, the minimum concentrations ( $C^{min}$ ) of ASC22 at steady state are predicted to be > 3 µg/mL one month after both 1 and 2.5 mg/kg dosing, indicating > 90% receptor occupancy in CHB patients over one month after dosing. These data suggest that ASC22 has the potential to be given once a month, which will enhance the compliance and convenience of patients with CHB.

#### ASC42

In June, 2021, the Group announced that China NMPA has approved the IND application for its drug candidate ASC42 to conduct clinical trials for CHB indication. In August, 2021, the Group announced the completion of the clinical bridging study and initiation of Phase II trial of ASC42 in China for CHB indication.

ASC42 is an in-house developed, selective, potent FXR agonist. ASC42 is an oral tablet formulation developed with in-house proprietary technology and is stable at room temperature.

Both *in vitro* primary human hepatocyte (PHH) cells and *in vivo* AAV/HBV mouse studies demonstrated that ASC42 significantly inhibited serum HBsAg and HBV pregenomic RNA (pgRNA), indicating that ASC42 has therapeutic potential to functionally cure CHB.

Nucleot(s)ide analogues (direct antiviral drugs) inhibit only reverse transcription of HBV RNA into HBV DNA and do not inhibit the transcription of HBV cccDNA (covalently closed circular DNA) into HBV RNA, thus have no inhibitory effect on HBsAg. As an FXR agonist, ASC42 has unique mechanism of action against HBV: ASC42 inhibits the transcription of HBV cccDNA into HBV RNA, which in turn inhibits the translation of HBV RNA into HBsAg. ASC42 may also reduce HBV cccDNA stability.

#### **BUSINESS REVIEW** (Continued)

#### OTHER DISEASES

Acne is the eighth most prevalent disease in the world and affects more than 640 million people globally. The onset of acne often coincides with pubertal hormonal changes, and the condition affects approximately 85% of adolescents and young adults aged 12 to 25 years. However, acne can also persist into or develop during adulthood.

In August, 2021, the Group announced that China NMPA had approved the Phase II clinical trial application of ASC40 for the treatment of patients with moderate to severe acne.

The Phase II trial is a randomized, double-blind, placebo-controlled, multicenter clinical trial to be conducted in China to evaluate the safety and efficacy of ASC40 for the treatment of patients with moderate to severe acne vulgaris. About 180 patients are planned to be enrolled and randomly assigned to one of four cohorts (placebo, 25 mg, 50 mg, 75 mg) at the ratio of 1:1:1:1 in the Phase II trial.

FASN is a key enzyme which regulates de novo lipogenesis (DNL). Human sebum production requires de novo lipogenesis, which is increased in acne and suppressed by the FASN inhibitor ASC40.

Current first-line treatments for acne include topical creams such as topical retinoids and androgen receptor inhibitor, oral isotretinoin and antibiotics. A report recently published by Allied Market Research indicated that the global acne medication market size was US\$11.86 billion in 2019, and is projected to reach US\$13.35 billion by 2027.

#### **FUTURE AND OUTLOOK**

Since 2021, we have focused on NASH, cancer (lipid metabolism and oral checkpoint inhibitors), and viral diseases.

Over the last few years, we have built a global leading NASH pipeline with three single agents and three fixed-dose combination therapies. We have advanced ASC40 into a randomized, double-blind, placebo-controlled 52-week Phase IIb clinical trial of approximately 330 NASH patients with moderate to advanced fibrosis (F2-F3). We are planning to advance ASC41 into a randomized, double-blind, placebo-controlled 52-week Phase IIa/IIb adaptive clinical trial of NASH patients by the end of 2021.

Over the last few years, we have built an oncology pipeline focusing on cancer (lipid metabolism and oral checkpoint inhibitors). In 2021, we have achieved a significant milestone: obtained China NMPA's approval of the Phase III clinical trial application of ASC40 combined with bevacizumab for treatment of patients with rGBM.

We are planning to file an IND of our next generation FASN inhibitor ASC60 for oncology indications by the end of 2021.

In 2021, the Group has achieved another significant milestone: the completion of 149 patient enrollment and the positive interim results of Phase IIb study on CHB patients in China treated with ASC22 (Envafolimab) – a first-in-class, subcutaneously administered PD-L1 antibody, in combination with NAs. We are expecting topline results from this Phase IIb study in the first half of 2022.

In August, 2021, the Group announced the initiation of Phase II trial of ASC42 in China for CHB indication. We are expecting topline results from this Phase II study in the second half of 2022.

In 2021, the Group expanded into a new disease area: acne. We are expecting topline results from the Phase II clinical trial application of ASC40 for the treatment of patients with moderate to severe acne in the second half of 2022.

#### **FINANCIAL REVIEW**

#### Revenue

The Group commercializes three products in China, namely GANOVO® (Danoprevir), ASCLEVIR® (Ravidasvir) and Pegasys®. The revenue generated during the Reporting Period consisted of (i) the promotion service revenue of Pegasys®, (ii) collaboration revenue from our partner, and (iii) sales of products from the all-oral regimen of ASCLEVIR® (Ravidasvir) in combination with GANOVO® (Danoprevir).

The promotion revenue of Pegasys® increased by 12.1% from approximately RMB30.8 million for the six months ended June 30, 2020 to approximately RMB34.5 million for the six months ended June 30, 2021.

The total revenue of the Group increased by 14.8% from approximately RMB31.8 million for the six months ended June 30, 2020 to approximately RMB36.5 million for the six months ended June 30, 2021.

## **Cost of Sales**

The cost of sales of the Group increased by 260.3% from approximately RMB10.9 million for the six months ended June 30, 2020 to approximately RMB39.1 million for the six months ended June 30, 2021.

The increased cost of sales was attributable to the impairment provision of inventories which amounted to RMB23.0 million. The Group considers it as prudent to update sales forecast semi-annually and to take the impairment provision of inventories accordingly.

The cost of sales of the Group consists of direct labor costs, cost of raw materials, overhead, the royalty fee to Roche, the cost of rendering promotion services and the impairment of inventories.

Direct labor costs primary consist of salaries, bonus and social security costs for the employees.

Cost of raw material represented the costs in relation to the purchase of raw materials. We own technologies and intellectual properties to manufacture APIs for Danoprevir and Ravidasvir. We have engaged third party CMOs to manufacture APIs for GANOVO® (Danoprevir) to maintain continuity in our source of APIs in the production of GANOVO® (Danoprevir). We manufacture the APIs and tablet formulation for ASCLEVIR® (Ravidasvir) in-house.

Overhead primarily consists of depreciation charges of the facility and equipment and other manufacturing expenses.

We have agreed to pay Roche and Presidio tiered royalties in the mid-single digits based on net sales of GANOVO® (Danoprevir) and ASCLEVIR® (Ravidasvir) in any and all regimens in Greater China.

The cost of rendering promotion services primarily consists of costs incurred for the promotion.

## **Gross Profit**

The gross profit of the Group decreased by 112.2% from approximately RMB21.0 million for the six months ended June 30, 2020 to approximately RMB(2.6) million for the six months ended June 30, 2021. The decrease in the gross profit was due to RMB23.0 million impairment provision of inventories. If the impairment provision of inventories were excluded, the gross profit would amount to RMB20.5 million for the six months ended 30 June 2021, representing a gross profit margin of 56.0%.

#### **FINANCIAL REVIEW** (Continued)

#### Other Income and Gains

The other income and gains of the Group decreased by 72.5% from approximately RMB58.4 million for the six months ended June 30, 2020 to approximately RMB16.1 million for the six months ended June 30, 2021, primarily because (i) bank interest income decreased by RMB16.5 million from approximately RMB28.1 million for the the six months ended June 30, 2020 to approximately RMB11.6 million for the six months ended June 30, 2021; (ii) government grants decreased by RMB20.6 million from approximately RMB24.3 million for the six months ended June 30, 2020 to approximately RMB3.7 million for the six months ended June 30, 2021.

Government grants mainly represent subsidies received from the local governments for the purpose of compensation for expenses arising from research activities and clinical trials, award for new drug approval and capital expenditure incurred on certain projects.

The following table sets forth the components of our other income and gains for the periods indicated:

Unaudited							
Six months	ended	June	30,				

	202	1	20	20
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Bank interest income Government grants Investment income from financial assets	11,619	72.3	28,119	48.2
	3,697	23.0	24,341	41.7
through profit or loss Foreign exchange gain, net Others	748 - 5	4.7 - -	5,862 37	10.0 0.1
Total	16,069	100.0	58,359	100.0

#### **Selling and Distribution Expenses**

The selling and distribution expenses of the Group decreased by 46.6% from approximately RMB17.8 million for the six months ended June 30, 2020 to approximately RMB9.5 million for the six months ended June 30, 2021, which consist of staff cost for our sales personnel and the expenses for marketing promotion activities.

### **Administrative Expenses**

The administrative expenses of the Group decreased by 2.6% from approximately RMB22.7 million for the six months ended June 30, 2020 to approximately RMB22.1 million for the six months ended June 30, 2021.

Our administrative expenses primarily consist of staff salary and welfare costs for non-research and development personnel, utilities, depreciation and amortization and general office expenses and agency and consulting fees.

### FINANCIAL REVIEW (Continued)

## Administrative Expenses (Continued)

The following table sets forth the components of our administrative expenses for the periods indicated:

## Unaudited Six months ended June 30,

	2021		2020	
	RMB'000	%	RMB'000	%
Staff salary and welfare costs Utilities, depreciation and amortization and	12,181	55.2	12,504	55.2
general office expenses	8,457	38.3	8,244	36.4
Agency and consulting fees	1,292	5.9	1,578	6.9
Others	148	0.6	340	1.5
Total	22,078	100.0	22,666	100.0

## **Research and Development Expenses**

The Group's research and development expenses primarily consist of clinical trial expenses and staff costs.

The research and development expenses of the Group increased by 43.1% from approximately RMB51.7 million for the six months ended June 30, 2020 to approximately RMB74.0 million for the six months ended June 30, 2021, mainly due to the increased expenses on the clinical development of NASH and HBV, and cancer drug candidates.

The following table sets forth the components of our research and development expenses for the periods indicated:

## Unaudited Six months ended June 30,

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Clinical trial expenses Staff costs Depreciation and amortization Others Third-party contracting costs	35,004 22,556 10,782 5,684	23,302 16,277 8,983 2,707 466
Total	74,026	51,735

## **FINANCIAL REVIEW** (Continued)

## **Research and Development Expenses** (Continued)

The following table sets forth the components of our research and development expenses by product pipeline for the periods indicated:

	Unaudited Six months ended June 30,	
	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
NASH HBV HCV Oncology Others (Note) ACNE HIV/AIDS	31,598 17,723 8,387 5,669 5,217 2,988 2,444	19,259 10,243 15,593 - 3,133 - 3,507
Total	74,026	51,735

Note:

## **Finance costs**

The Group recorded finance costs to approximately RMB0.04 million for the six months ended June 30, 2021, as a result of the interest on the lease liabilities.

The following table sets forth the components of our finance costs for the periods indicated:

	Six months ended June 30,	
	<b>2021</b> 2020 <i>RMB'000 RMB'000</i>	
Interest on lease liabilities	42	80
Total	42	80

Unaudited

<sup>&</sup>quot;Others" are research and development costs of pre-clinical programs.

### FINANCIAL REVIEW (Continued)

## Other expenses

Other expenses of the Group decreased by 65.6% from approximately RMB30.1 million for the six months ended June 30, 2020 to approximately RMB10.3 million for the six months ended June 30, 2021, mainly due to the decrease of RMB14.7 million in the amount for donation.

The following table sets forth the components of other expenses for the periods indicated:

Unaudited				
Six	months	ended	June	30,

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Foreign exchange loss, net Donation Impairment of inventories Impairment of an intangible asset Others	7,383 2,964 - - 1	17,664 6,631 5,771
Total	10,348	30,067

## **Income tax**

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

The Group calculates the income tax expense by using the tax rate that would be applicable to the expected total annual earnings.

The Group did not incur any income tax expense as the Group did not generate taxable income for the six months ended June 30, 2020 and the six months ended June 30, 2021.

We have tax losses arising in the PRC of RMB762.9 million as at December 31, 2020, which are expected to expire in one to five years for offsetting our future taxable profits.

#### FINANCIAL REVIEW (Continued)

#### **Inventories**

The inventories of the Group consist of raw materials used in the commercial manufacturing, work in progress, finish goods and research materials. The inventories decreased by 36.9% from approximately RMB58.9 million as at December 31, 2020 to approximately RMB37.2 million as at June 30, 2021. The following table sets forth the inventory balances as of the dates indicated:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Raw materials Work in progress Finished goods	24,761 7,812 4,598	32,601 7,871 18,422
Total	37,171	58,894

#### **Trade Receivables**

The Group had approximately RMB26.6 million trade receivables as at December 31, 2020 and approximately RMB47.1 million as at June 30, 2021.

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Trade receivables Less: Impairment of trade receivables	47,070 14	26,629 9
Total	47,056	26,620

The Group's trading terms with its customers are mainly on credit. The credit period is generally from 30 days to 90 days. The Group seeks to maintain strict control over its outstanding receivables and overdue balances are regularly reviewed by senior management. Trade receivables are non-interest-bearing.

An ageing analysis of the trade receivables as at the dates indicated, based on the invoice date, is as follows:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Within 3 months Over 3 months	36,652 10,404	26,620
Total	47,056	26,620

#### FINANCIAL REVIEW (Continued)

## Prepayments, Other Receivables and Other Assets

The following table sets forth the components of prepayments, other receivables and other assets as at the dates indicated:

		ber 31, 2020 udited) <i>MB'000</i>
Value-added tax recoverable Prepayments Prepaid expenses Deposits and other receivables Prepaid income tax Interest receivable	13,056 3,965 3,358 1,943 1,363	19,703 3,437 1,846 2,209 1,363 1,904
Total	23,685	30,462

Our value-added tax recoverable represented value-added taxes paid with respect to our procurement that can be credited against future value-added tax payables. Our value-added tax recoverable decreased from approximately RMB19.7 million as of December 31, 2020 to approximately RMB13.1 million as of June 30, 2021, which was in line with our decreased purchases of service and raw materials.

Our prepayments represented the amounts mainly relating to our expenses on clinical trials. Our prepayments increased by 15.4% from approximately RMB3.4 million as of December 31, 2020 to approximately RMB4.0 million as of June 30, 2021. Prepayments to supplier as at the end of June 30, 2021 are due within one year.

Other receivables and prepaid expenses are miscellaneous expenses including rental and other administrative related expenses.

## Fair Value and Fair Value Hierarchy of Financial Instruments

The financial assets of at fair value through profit or loss of the Group amounted to RMB35.2 million as at June 30, 2021.

We did not have financial instruments other than those with carrying amounts that reasonably approximate to fair value, as at December 31, 2020.

#### **FINANCIAL REVIEW** (Continued)

## **Cash and Cash Equivalents**

The following table sets forth the components of the Group's cash and cash equivalents and time deposits as of the dates indicated:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Cash and bank balances Time deposits	917,045 1,660,803	1,256,267 1,457,744
Total	2,577,848	2,714,011

Cash at banks earns interest at floating rates based on daily bank deposit rates. Time deposits are made for varying periods between one day and 12 months depending on our immediate cash requirements, and earn interest at the respective term time deposit rates. The bank balances and time deposits are deposited with creditworthy banks with no recent history of default.

## **Trade and Other Payables**

Trade and bills payables of the Group primarily consist of payments to raw material suppliers. The following table sets forth the components of trade and bills payables as at the dates indicated:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Trade payables Bills payable	764 596	334 596
Total	1,360	930

The following table sets forth an ageing analysis of trade and bills payables due to third parties as at the dates indicated, which is based on the invoice date:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Within 3 months Over 3 months	414 946	334 596
Total	1,360	930

#### FINANCIAL REVIEW (Continued)

## Trade and Other Payables (Continued)

The following table sets forth the components of other payables and accruals outstanding as at the dates indicated:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Other payables Payroll payable Accrued expenses Taxes other than income tax Refund liabilities	31,757 15,711 13,069 690 85	36,760 19,122 11,960 659 1,473
Total	61,312	69,974

Our other payables and accruals decreased by 12.4% from approximately RMB70.0 million as of December 31, 2020 to approximately RMB61.3 million as of June 30, 2021. Other payables and accruals are non-interest-bearing and are due within one year.

The payroll payable are the annual bonus of 2021 accrued and salary accrued of June 2021, which are due within one year.

The accrued expenses as at June 30, 2021 mainly represented the R&D expenses actually incurred but not yet invoiced, which are non-interest-bearing and due within one year.

## **Deferred Income**

The deferred income of the Group represents government grants which have been awarded, but we have yet to meet the conditions of the grants as of the relevant dates. The following table sets forth the deferred income as of the dates indicated:

	June 30,	December 31,
	2021	2020
	(Unaudited)	(Audited)
	RMB'000	RMB'000
Government grants		
- Current	1,724	1,724
- Non-current	10,345	11,207
Total	12,069	12,931

#### FINANCIAL REVIEW (Continued)

### **Intangible Assets**

The intangible assets of the Group primarily represented (i) a patent that was transferred from Presidio to the Group in relation to the development and license agreement entered between the Group and Presidio in September, 2014, under which we made upfront and milestone payments to Presidio; and (ii) a patent that was transferred from Alphamab to the Group in relation to the exclusive license and development agreement entered between the Group and Alphamab in January, 2019, under which we made upfront payments to Alphamab.

The useful economic lives of these intangible assets are 10 to 17 years, which we consider to be reasonable considering that the duration of the patent right is shorter than the anticipated duration of sales of product. The amortization of intangible assets begins on the transfer date of patent because it is the date from which the intangible assets are available for use by us.

## **Liquidity and Capital Resources**

The primary uses of cash of the Group are to fund research and development, clinical trials, purchase of equipment and raw materials and other recurring expenses. During the Reporting Period, the Group funded its working capital and other capital expenditure requirements through capital injections from Shareholders.

The following table sets forth a condensed summary of the Group's consolidated statements of cash flows for the periods indicated and analysis of balances of cash and cash equivalents for the periods indicated:

	June 30, 2021 (Unaudited) <i>RMB'000</i>	December 31, 2020 (Audited) <i>RMB'000</i>
Net cash used in operating activities  Net cash (used in)/generated from investing activities  Net cash used in financing activities  Net (decrease)/increase in cash and cash equivalents  Cash and cash equivalents at the beginning of the period  Effect of foreign exchange rate changes, net  Cash and cash equivalents at the end of the period/year	(85,824) (338,118) (1,206) (425,148) 2,210,504 (13,333) 1,772,023	(84,911) 132,297 (21,670) 25,716 2,295,044 (110,256) 2,210,504

As at June 30, 2021, cash and cash equivalents were mainly denominated in Renminbi, USD and HK\$.

### **Operating Activities**

Our cash inflows from operating activities mainly consisted of trade receivables from customers, government grants and bank interests. Our cash outflow for operating activities mainly consisted of research and development costs, and administrative expenses.

For the six months ended June 30, 2021, we had net cash flows used in operating activities of approximately RMB85.8 million, primarily as a result of operating loss before changes in working capital of RMB73.3 million. The negative changes in working capital are mainly due to an increase in trade and bills receivables of approximately RMB20.4 million and a decrease in other payables and accruals of approximately RMB8.7 million.

#### FINANCIAL REVIEW (Continued)

## **Operating Activities** (Continued)

For the six months ended June 30, 2020, we had net cash flows used in operating activities of approximately RMB17.9 million, primarily as a result of operating loss before changes in working capital of approximately RMB43.5 million. The negative changes in working capital are mainly due to (i) a decrease of approximately RMB16.9 million in other payables and accruals; (ii) an increase in inventories of approximately RMB2.3 million; and (iii) a decrease in trade and bills receivables of approximately RMB5.8 million.

## **Investing Activities**

Our cash used in investing activities mainly consisted of our cash in time deposits with original maturity of over three months, purchase of property, plant and equipment, purchase of intangible assets, and purchase of financial assets at fair value through profit or loss.

For the six months ended June 30, 2021, our net cash used in investing activities was approximately RMB338.1 million, primarily attributable to: an increase in time deposits with original maturity of over three months of RMB302.3 million.

For the six months ended June 30, 2020, our net cash used in investing activities was approximately RMB362.6 million, primarily attributable to an increase in time deposits with original maturity of over three months of approximately RMB359.1 million.

## **Financing Activities**

Our cash inflow from financing activities primarily related to our corporate financings during the Reporting

For the six months ended June 30, 2021, our net cash flows used in financing activities was RMB1.2 million, primarily attributable to the principal portion of lease payments.

For the six months ended June 30, 2020, our net cash flows used in financing activities was RMB1.0 million, primarily attributable to the principal portion of lease payments.

#### **Capital Expenditures**

The principal capital expenditures of the Group primarily consisted of plant and machinery, expenditures for construction in progress, leasehold improvements and the purchase of office equipment.

For the six months ended June 30, 2021, the Group had RMB1.3 million capital expenditures. For the whole year ended December 31, 2020, the Group's net capital expenditures was RMB4.9 million.

## Significant Investments, Material Acquisitions and Disposals

In 2019, AP11 Limited, a wholly-owned subsidiary of the Company, entered into a capital increase agreement with 3-V Biosciences, Inc. (currently known as Sagimet). On December 21, 2020, AP11 Limited increased investment into Sagimet. As at June 30, 2021, AP11 Limited holds approximately 9.89% of the equity interest in Sagimet. The Group recognizes such investment as an investment in an associate to which the equity method is applied.

#### FINANCIAL REVIEW (Continued)

#### Indebtedness

#### **Borrowings**

As at June 30, 2021, the Group did not have any borrowing, and the undrawn bank facilities was RMB80 million as of the same date.

As at June 30, 2021, the Group did not have any outstanding mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, any guarantees or other material contingent liabilities.

### Contingent Liabilities, Charges of Assets and Guarantees

As at June 30, 2021, the Group were not involved in any material legal, arbitration or administrative proceedings that, if adversely determined, and did not have any contingent liabilities, that, we expected would materially adversely affect our business, financial position or results of operations.

#### **Contractual Commitments**

We lease certain of our properties and warehouse under operating lease arrangements. Leases for properties and warehouse are negotiated for terms ranging mainly from one to five years.

The Group had nil operating lease commitments as at June 30, 2021 and December 31, 2020, respectively.

The Group had RMB2.3 million of capital commitments as at June 30, 2021 and nil capital commitments at December 31, 2020.

#### Gearing Ratio

Gearing ratio is calculated using total liabilities divided total assets and multiplied by 100%. As at June 30, 2021, the gearing ratio of the Group was 2.7% (as at December 31, 2020: 2.8%).

The following table sets forth our key financial ratios as of the dates indicated.

	June 30, 2021 (Unaudited)	December 31, 2020 (Audited)
Current ratio <sup>(1)</sup> Quick ratio <sup>(2)</sup>	40.9 40.3	38.4 37.6

#### Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

#### FINANCIAL REVIEW (Continued)

## Indebtedness (Continued)

## **Gearing Ratio** (Continued)

Our current ratio increased from 38.4 as of December 31, 2020 to 40.9 as of June 30, 2021, and our quick ratio increased from 37.6 as of December 31, 2020 to 40.3 as of June 30, 2021, primarily due to a decrease in current liabilities.

## Foreign Exchange

Foreign currency risk refers to the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between Renminbi and other currencies in which our Group conducts business may affect our financial condition and results of operation.

The Group mainly operates in the PRC and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the USD. Foreign exchange risk arises from recognized assets and liabilities in foreign operations. The conversion of Renminbi into foreign currencies, including the USD, has been based on rates set by the People's Bank of China. The Group seek to limit our exposure to foreign currency risk by closely monitoring and minimizing its net foreign currency position. During the Reporting Period, the Group did not enter into any currency hedging transactions.

## **Employees and Remuneration Policies**

As at June 30, 2021, the Group had a total of 238 employees, 235 of which were located in the PRC, 2 consultants and 1 employee were located abroad, and over 62% of our employees obtained a bachelor's degree or higher. The table below sets forth the Group's employees by function as disclosed:

	Numbers of employees	% of total
Management	5	2.1
Research and development	80	33.6
Commercialization	81	34.0
Manufacturing	26	10.9
Operations	46	19.4
Total	238	100.0

The Group's total staff costs for the six months ended June 30, 2021 was RMB39.8 million, compared to RMB47.8 million for the six months ended June 30, 2020.

The Group recruits employees through recruitment websites, recruiters, internal referral and job fairs. The Group conducts new employee training, as well as professional and compliance training programs for employees of the commercialization team.

The Group enters into employment contracts with employees to cover matters such as wages, benefits and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally determined by the qualifications, industry experience, position and performance. The Group makes contributions to social insurance and housing provident funds as required by the PRC laws and regulations.

The Group also has adopted a Restricted Stock Unit Scheme, a Restricted Stock Unit Option Incentive Scheme and a Share Option Scheme.

#### **FINANCIAL REVIEW** (Continued)

## **Share Option Scheme**

Pursuant to a share option scheme adopted by the Company on June 6, 2019, the Company may grant options to eligible participants to subscribe for Shares subject to the terms and conditions stipulated therein.

Details of the movement of share options granted under the share option scheme during the Reporting Period are as follows:

		Closing price per share Exercise immediately price before the		Exercise period	Option balance outstanding as of January 1, 2021	Changes during the Reporting Period			Options outstanding as of
Category of participants Date of gr	Date of grant	per share date of grant	Granted			Exercised	Cancelled/ Lapsed	June 30, 2021	
Eligible employees	March 31, 2020	2.90	2.86	March 31, 2021 – March 30, 2030 (Note a)	4,921,050	-	-	(852,982)	4,068,068
	December 31, 2020	2.87	2.88	December 1, 2021 – November 30, 2030 (Note b)	2,000,000	-	-	_	2,000,000
	March 31, 2021	2.882	2.86	March 31, 2022 – March 30, 2031 (Note a)	-	200,000	-	-	200,000
	April 7, 2021	2.89	2.90	April 7, 2022 – April 6, 2031 (Note a)	-	1,000,000	-	-	1,000,000
	June 30, 2021	3.53	3.51	June 30, 2022 – June 29, 2031 (Note a)	-	300,000	-	-	300,000

#### Notes:

- a) All options granted have a vesting period of five years in equal proportions starting from the 1st anniversary and become fully vested on the 5th anniversary of the grant. In this table, "exercise period" begins with the 1st anniversary of the grant date.
- b) Subject to the satisfaction of certain conditions, the first 20% of the total options can be exercised from the date as specified in the relevant grant letter, and each 20% of the total options will become exercisable in each subsequent year.

Save as disclosed above, no options were granted, exercised, cancelled or lapsed under the share option scheme during the Reporting Period.

## FINANCIAL REVIEW (Continued)

## Fair Value of Share Options Granted

The fair value of the options granted during the period was HK\$3,235,000, of which the Group recognised a share option expense of RMB240,000 during the period ended June 30, 2021 (six months ended June 30, 2020: RMB1,114,000).

The fair value of equity-settled share options granted during the period was estimated as at the date of grant using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the inputs to the model used:

	2021
Dividend yield (%)	0
Expected volatility (%)	83.56-85.03
Risk-free interest rate (%)	1.21-1.44
Early exercise multiple	2.20-2.80
Weighted average share price (HK\$ per Share)	2.8-3.53
Forfeiture rate (%)	0

#### COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Company is committed to maintaining high standard of corporate governance to safeguard the interests of the Shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability.

The Company has adopted the code provisions of the CG Code as its own code of corporate governance. The Board is of the view that the Company has complied with all applicable code provisions of the CG Code during the Reporting Period, except for a deviation from the code provision A.2.1 of the CG Code, the roles of chairman and chief executive officer of the Company are not separate and are both performed by Dr. Jinzi Jason WU. The Company is an investment holding company with a professional management team to monitor the operations of the subsidiaries. The Board considers that vesting the roles of chairman and chief executive officer in the same person is more efficient in the direction and management of the Company and does not impair the balance of power and authority of the Board and the management of the business of the Company. The Board will review the corporate governance structure and practices from time to time and shall make necessary arrangements when the Board considers appropriate.

#### COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Written Guidelines on no less exacting terms than the Model Code as its own code of conduct regarding securities transactions by the Directors. Having made specific enquiry of all Directors, all of them have confirmed that they have complied with the Model Code and the Written Guidelines throughout the Reporting Period and to the date of this report. No incident of non-compliance of the Written Guidelines by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

## PURCHASE, SALE OR REDEMPTION OF THE LISTED SECURITIES OF THE COMPANY

During the Reporting Period, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's listed securities.

#### **CHANGES IN DIRECTORS' INFORMATION**

Mr. Jiong Gu has ceased to be an independent non-executive director of Xinming China Holdings Limited (stock code: 2699) since June 2021.

Save as disclosed above, there is no other change in Directors' biographical details which is required to be disclosed pursuant to rule 13.51B(1) of the Listing Rules.

## DIRECTORS' AND CHIEF EXECUTIVE'S INTERESTS AND SHORT POSITIONS IN SHARES, UNDERLYING SHARES AND DEBENTURES OF THE COMPANY OR ITS ASSOCIATED CORPORATIONS

As of the date of this Interim Report, the interests and short positions of the Directors and chief executive of the Company in the Shares, underlying Shares and debentures of the Company or its associated corporations (within the meaning of Part XV of the SFO) as recorded in the register required to be kept pursuant to Section 352 of the SFO; or as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code were as follows:

### (I) Interests in shares or underlying shares of the Company

Name of Director	Capacity/Nature of interest	Number of Shares/underlying Shares	Approximate percentage of shareholder interest
Dr. Wu	Interest in controlled corporation <sup>(2)</sup> Interest held jointly with another person <sup>(3)</sup>	597,221,078 (L) 2,311,000 (L)	54.35% 0.21%
Mrs. Wu	Beneficiary of a trust <sup>(2)</sup> Interest of spouse Interest held jointly with another person <sup>(3)</sup>	44,827,414 (L) 552,393,664 (L) 2,311,000 (L)	4.08% 50.27% 0.21%

#### Notes:

- (1) The letter "L" denotes the person's long position in the Shares.
- (2) 552,393,664 Shares were held by Dr. Wu through JJW12 Limited, a company incorporated in the BVI and wholly owned by Dr. Wu.

As of the date of this report, Lakemont Holding LLC was controlled by Lakemont Remainder Trust as to 56.55% and Dr. Wu as to 43.45%. Mrs. Wu exercises the voting rights of the Shares held through Lakemont Remainder Trust and is a beneficiary of the Lakemont Remainder Trust.

(3) 2,311,000 Shares were held by Dr. Wu and Mrs. Wu in a joint account.

Save as disclosed above, as of the date of this Interim Report, so far as it was known to the Directors or chief executive of the Company, none of the Directors or chief executive of the Company had interests or short positions in the Shares, underlying Shares and debentures of the Company or its associated corporations as recorded in the register required to be kept, pursuant to Section 352 of the SFO; or as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code.

## SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN THE SHARES AND UNDERLYING SHARES OF THE COMPANY

As of the date of this Interim Report, so far as it was known to the Directors or chief executive of the Company, the following persons (other than the Directors and chief executive of the Company) had interests and/or short positions in the Shares or underlying Shares as recorded in the register required to be kept by the Company under section 336 of the SFO.

### Interests in shares or underlying shares of the Company

Name of Shareholder	Capacity/Nature of Interest	Number of Shares <sup>(1)</sup>	Approximate percentage of shareholding interest
JJW11 Limited <sup>(2)</sup> CBC Investment Twelve Limited <sup>(3)</sup> CBC Investment Fifteen Limited <sup>(4)</sup>	Beneficial owner	63,761,928 (L)	5.80%
	Beneficial owner	50,729,518 (L)	4.62%
	Beneficial owner	25,570,542 (L)	2.33%

#### Notes:

- (1) The letter "L" denotes the person's long position in the Shares.
- (2) As of the date of this Interim Report, the only one issued share of JJW11 Limited was held by Dr. Wu on behalf of the participants under the RSU Scheme adopted by JJW11 Limited. Dr. Wu has irrevocably appointed Ms. Heying YANG (楊荷英) (being a supervisor of Ascletis BioScience Co., Ltd. and the sole director of JJW11 Limited) as proxy to exercise all voting rights on such shares in her absolute discretion. Dr. Wu does not enjoy and disclaim any beneficial interest in JJW11 Limited.
- (3) Each of CBC Investment Ascletis Limited (as the sole shareholder of CBC Investment Twelve Limited ("CBC 12")), CBC Investment Eleven Limited ("CBC 11", holding approximately 95.24% equity interest in CBC Investment Ascletis Limited), C-Bridge Healthcare Fund II. L.P. (as the sole shareholder of CBC 11), C-Bridge Healthcare Fund GP II. L.P.), C-Bridge Capital GP, Ltd., (as general partner of C-Bridge Healthcare Fund GP II. L.P.), TF Capital II, Ltd. (holding approximately 38.34% equity interest in C-Bridge Capital GP, Ltd.), Kang Hua Investment Company Limited and Nova Aqua Limited (holding approximately 52.17% and 47.83% respectively equity interest in TF Capital II, Ltd.), Dan YANG (as the sole shareholder of Kang Hua Investment Company Limited) and Wei FU (as the beneficial owner of Nova Aqua Limited) is deemed to be interested in the Shares held by CBC 12 under the SFO.
- (4) Each of CBC Investment Seven Limited ("**CBC 7**", as the sole shareholder of CBC Investment Fifteen Limited ("**CBC 15**")), C-Bridge Healthcare Fund, L.P. (holding approximately 75.47% equity interest in CBC 7), C-Bridge Healthcare Fund GP, L.P. (as general partner of C-Bridge Healthcare Fund L.P.), C-Bridge Capital GP, Ltd., (as general partner of C-Bridge Healthcare Fund GP, L.P.), TF Capital II, Ltd. (holding approximately 38.34% equity interest in C-Bridge Capital GP, Ltd.), Kang Hua Investment Company Limited and Nova Aqua Limited (holding approximately 52.17% and 47.83% respectively equity interest in TF Capital II, Ltd.), Dan YANG (as the sole shareholder of Kang Hua Investment Company Limited) and Wei FU (as the beneficial owner of Nova Aqua Limited) is deemed to be interested in the Shares held by CBC 15 under the SFO.

Save as disclosed above, as of the date of this Interim Report, the Directors and the chief executives of the Company were not aware of any other person (other than the Directors or chief executives of the Company) who had an interest or short position in the shares or underlying shares of the Company as recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO.

#### **USE OF PROCEEDS FROM LISTING**

In connection with the Company's initial public offering, 224,137,000 ordinary shares of US\$0.0001 each were issued at a price of HK\$14.00 per share for a total cash consideration, before expenses, of approximately HK\$3,137,918,000 (equivalent to RMB2,730,284,000).

The intended use of the net proceeds was set out in the announcement of the Company dated November 18, 2020, which was modified from the original plan for use of proceeds as set out in the prospectus of the Company dated July 20, 2018 pursuant to the relevant resolutions of the Board. The table below sets out the planned applications of the net proceeds and actual usage up to June 30, 2021:

Use of proceeds	The unutilized net proceeds after the re-allocation as at June 30, 2020 (HK\$ million)	Percentage of total net proceeds after the re-allocation (%)	Actual usage from June 30, 2020 to June 30, 2021 (HK\$ million) updated	Unutilized net proceeds as at June 30, 2021 (HK\$ million) updated	Expected timeframe for use of proceeds
For the Core Products					
For continued research and development of the Core Product pipeline in Viral hepatitis, NASH, HIV/AIDS.	1,218.3	53.4	121.6	1,096.7	The remaining amount is expected to be utilized in around two years from June 30, 2021.
For the other assets and other purposes					
For upfront and milestone payments of in-licensing new drug candidates.	438.3	19.2	35.2	403.1	The remaining amount is expected to be utilized in around two years from June 30, 2021.
For supporting the research and development of new pipeline drug candidates.	264.5	11.6	21.9	242.6	The remaining amount is expected to be utilized in around two years from June 30, 2021.
For continued enhancement of current commercialization capability of marketed core products and future products.	248.3	10.9	19.1	229.2	The remaining amount is expected to be utilized in around two years from June 30, 2021.
For the working capital and other general corporate purposes	112.9	4.9	57.1	55.8	The remaining amount is expected to be utilized in around two years from June 30, 2021.
Total	2,282.3	100.0	254.9	2,027.4	

#### **REVIEW OF INTERIM REPORT**

The independent auditors of the Company, namely, Ernst & Young, have carried out a review of the interim financial information in accordance with the 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.

The Audit Committee comprises three independent non-executive Directors, namely, Mr. Jiong GU, Dr. Yizhen WEI, and Ms. Lin HUA. The chairman of the Audit Committee is Mr. Jiong GU. The Audit Committee has jointly reviewed with the management the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the unaudited interim results for the six months ended June 30, 2021) of the Group. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

#### INTERIM DIVIDEND

The Board does not recommend any payment of an interim dividend for the six months ended June 30, 2021.

#### **APPRECIATION**

The Board would like to express its sincere gratitude to the shareholders, management team, employees, business partners and customers of the Group for their support and contribution to the Group.

For and on behalf of the Board Ascletis Pharma Inc. 歌禮製藥有限公司 Jinzi Jason WU Chairman

Hangzhou, the People's Republic of China, August 26, 2021

## **Independent Review Report**



Ernst & Young 27/F, One Taikoo Place 979 King's Road Quarry Bay, Hong Kong 安永會計師事務所 香港鰂魚涌英皇道979號 太古坊一座27樓 Tel 電話: +852 2846 9888 Fax 傳真: +852 2868 4432

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To the board of directors of Ascletis Pharma Inc. (Incorporated in the Cayman Islands with limited liability)

#### **INTRODUCTION**

We have reviewed the interim financial information set out on pages 36 to 52, which comprises the condensed consolidated statement of financial position of Ascletis Pharma Inc. (the "Company") and its subsidiaries (the "Group") as at 30 June 2021 and the related condensed consolidated statements of profit or loss, comprehensive income, changes in equity and cash flows for the six-month period then ended, and explanatory notes. The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited require the preparation of a report on interim financial information to be in compliance with the relevant provisions thereof and Hong Kong Accounting Standard 34 *Interim Financial Reporting* ("HKAS 34") issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"). The directors of the Company are responsible for the preparation and presentation of this interim financial information in accordance with HKAS 34. Our responsibility is to express a conclusion on this interim financial information based on our review. Our report is made solely to you, as a body, in accordance with our agreed terms of engagement, and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

#### **SCOPE OF REVIEW**

We conducted our review 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 HKICPA. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the interim financial information is not prepared, in all material respects, in accordance with HKAS 34.

Ernst & Young
Certified Public Accountants
Hong Kong
26 August 2021

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

For the six months ended 30 June 2021

	Notes	2021 (Unaudited) <i>RMB'000</i>	2020 (Unaudited) <i>RMB'000</i>
REVENUE Cost of sales including royalties	4	36,549 (39,109) (19)	31,834 (10,854) (41)
Gross (loss)/profit		(2,560)	20,980
Other income and gains Selling and distribution expenses Research and development costs Administrative expenses Other expenses Finance costs Share of loss of an associate		16,069 (9,487) (74,026) (22,078) (10,348) (42) (8,356)	58,359 (17,773) (51,735) (22,666) (30,067) (80) (8,483)
LOSS BEFORE TAX	5	(110,828)	(51,465)
Income tax	6		
LOSS FOR THE PERIOD		(110,828)	(51,465)
Attributable to: Owners of the parent		(110,828)	(51,465)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted	8	RMB (10.09) cents	RMB (4.94) cents

## Interim Condensed Consolidated Statement of Comprehensive Income For the six months ended 30 June 2021

	2021 (Unaudited) <i>RMB'000</i>	2020 (Unaudited) <i>RMB'000</i>
LOSS FOR THE PERIOD	(110,828)	(51,465)
OTHER COMPREHENSIVE (LOSS)/INCOME		
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:  Exchange differences on translation of foreign operations	(653)	3,381
Other comprehensive (loss)/income that will not be reclassified to profit or loss in subsequent periods:  Exchange differences on translation of the Company's financial statements into presentation currency	(13,387)	28,225
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE PERIOD, NET OF TAX	(14,040)	31,606
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	(124,868)	(19,859)
Attributable to: Owners of the parent	(124,868)	(19,859)

## Interim Condensed Consolidated Statement of **Financial Position**

30 June 2021

	Notes	30 June 2021 (Unaudited) <i>RMB'000</i>	31 December 2020 (Audited) <i>RMB'000</i>
NON-CURRENT ASSETS Property, plant and equipment Right-of-use assets Intangible assets Investment in an associate Long-term deferred expenditure	9	77,242 4,387 83,640 51,969 696	82,556 2,023 90,702 60,915 889
Total non-current assets		217,934	237,085
CURRENT ASSETS Inventories Trade receivables Financial assets at fair value through profit or loss Prepayments, other receivables and other assets Cash and cash equivalents	10	37,171 47,056 35,200 23,685 2,577,848	58,894 26,620 - 30,462 2,714,011
Total current assets		2,720,960	2,829,987
CURRENT LIABILITIES Trade and bills payables Other payables and accruals Lease liabilities Deferred income	11	1,360 61,312 2,121 1,724	930 69,974 1,144 1,724
Total current liabilities		66,517	73,772
NET CURRENT ASSETS		2,654,443	2,756,215
TOTAL ASSETS LESS CURRENT LIABILITIES		2,872,377	2,993,300
NON-CURRENT LIABILITIES Lease liabilities Deferred income		1,749 10,345	443 11,207
Total non-current liabilities		12,094	11,650
Net assets		2,860,283	2,981,650
EQUITY Equity attributable to owners of the parent Share capital Reserves		749 2,859,534	750 2,980,900
Total equity		2,860,283	2,981,650

## Interim Condensed Consolidated Statement of Changes in Equity For the six months ended 30 June 2021

	Attributable to owners of the parent						
	Share capital <i>RMB'000</i>	Treasury shares* <i>RMB'000</i>	Share premium account* <i>RMB'000</i>	Capital reserve* <i>RMB'000</i>	Exchange fluctuation reserve* <i>RMB'000</i>	Accumulated losses* <i>RMB'000</i>	Total equity <i>RMB'000</i>
At 1 January 2021 (audited) Loss for the period Other comprehensive loss for the period:	750 -	(4,522) -	2,898,056 -	657,540 -	(54,346) -	(515,828) (110,828)	2,981,650 (110,828)
Exchange differences					(14,040)		(14,040)
Total comprehensive loss for the period Shares cancelled Equity-settled share award	- (1)	- 4,522	- (4,473)	-	(14,040) (48)	(110,828) -	(124,868) -
and option arrangements				3,501			3,501
At 30 June 2021 (unaudited)	749	_	2,893,583	661,041	(68,434)	(626,656)	2,860,283

These reserve accounts comprise the consolidated reserves of RMB2,859,534,000 in the interim condensed consolidated statement of financial position as at 30 June 2021.

	Attributable to owners of the parent					
	Share capital <i>RMB'000</i>	Share premium account <i>RMB'000</i>	Capital reserve <i>RMB'000</i>	Exchange fluctuation reserve RMB'000	Accumulated losses RMB'000	Total equity <i>RMB'000</i>
At 1 January 2020 (audited) Loss for the period Other comprehensive income for the period:	754 -	2,913,131	652,928 -	63,991 -	(306,587) (51,465)	3,324,217 (51,465)
Exchange differences				31,606		31,606
Total comprehensive loss for the period Equity-settled share award and	-	-	-	31,606	(51,465)	(19,859)
option arrangements			2,504			2,504
At 30 June 2020 (unaudited)	754	2,913,131	655,432	95,597	(358,052)	3,306,862

## Interim Condensed Consolidated Statement of **Cash Flows**

For the six months ended 30 June 2021

	Notes	2021 (Unaudited) <i>RMB'000</i>	2020 (Unaudited) <i>RMB'000</i>
CASH FLOWS FROM OPERATING ACTIVITIES  Loss before tax  Adjustments for: Finance costs Share of loss of an associate Bank interest income Investment income from financial assets at fair value through profit or loss Depreciation of items of property, plant and equipment Depreciation of right-of-use assets Lease payment concession from lessors Amortisation of intangible assets Amortisation of long-term deferred expenditure Impairment of inventories Impairment of an intangible asset	55 5 555	(110,828)  42 8,356 (11,619)  (748) 6,388 1,083 - 7,219 223 23,036 5	(51,465)  80 8,483 (28,119)  - 6,302 1,118 (197) 5,103 244 6,639 - 5,771
Increase in inventories Increase in long-term deferred expenditure (Increase)/decrease in trade receivables Decrease in prepayments, other receivables and other assets Increase/(decrease) in trade and bills payables Decrease in other payables and accruals Decrease in deferred income  Cash used in operations Interest received  Net cash flows used in operating activities	5	3,501 (73,342) (1,313) (30) (20,441) 4,873 430 (8,662) (862) (99,347) 13,523 (85,824)	2,504 (43,537) (2,333) (43) 5,768 4,364 (1,622) (16,911) (862) (55,176) 37,240 (17,936)

#### **Interim Condensed Consolidated Statement of Cash Flows**

For the six months ended 30 June 2021

	2021	2020
	(Unaudited)	(Unaudited)
	RMB'000	RMB'000
Net cash flows used in operating activities	(85,824)	(17,936)
The cash house assa in operating assimiles		(17,000)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of items of property, plant equipment	(1,074)	(3,488)
Purchase of intangible assets	(274)	(5, 155)
Proceeds from disposal of items of	` '	
property, plant and equipment	_	6
Purchases of financial assets at fair value through profit or loss	(82,400)	_
Proceeds from disposal of financial assets at fair value through		
profit or loss	47,200	_
Investment income from financial assets at fair value through		
profit or loss	748	_
Increase in time deposits with original maturity of over three months	(302,318)	(359,129)
Net cash flows used in investing activities	(338,118)	(362,611)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal portion of lease payments	(1,164)	(933)
Interest paid for lease liabilities	(42)	(80)
Net cash flows used in financing activities	(1,206)	(1,013)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(425,148)	(381,560)
Cash and cash equivalents at 1 January	2,210,504	2,295,044
Effect of foreign exchange rate changes, net	(13,333)	30,178
Lifect of foreign exchange rate changes, her	(13,333)	30,178
CASH AND CASH EQUIVALENTS AT 30 JUNE	1,772,023	1,943,662
CASH AND CASH EQUIVALENTS AT 30 JUNE	1,772,023	1,945,002
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS		
Cash and cash equivalents as stated in the interim condensed	0.577.040	0.000.011
consolidated statement of financial position  Non-pledged time deposits with original maturity of over	2,577,848	2,996,911
three months when acquired	(805,825)	(1,053,249)
tinee months when acquired	(003,023)	(1,033,249)
Cook and each equivalents as stated in the interim condensed		
Cash and cash equivalents as stated in the interim condensed consolidated statement of cash flows	1 772 022	1 0/2 662
Consolidated Statement of Cash Hows	1,772,023	1,943,662

30 June 2021

#### 1. CORPORATE INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on 25 February 2014. The registered office address of the Company is located at 190 Elgin Avenue, George Town, Grand Cayman KY1-9008, Cayman Islands. The principal place of business in Hong Kong of the Company is located at 40th Floor, Dah Sing Financial Centre, No. 248 Queen's Road East, Wanchai, Hong Kong.

The Company is an investment holding company. The Company's subsidiaries are principally engaged in the research and development, production, marketing and sale of pharmaceutical products.

The shares of the Company were listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "Stock Exchange") on 1 August 2018.

#### 2. BASIS OF PREPARATION AND CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

#### 2.1 BASIC OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2021 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 annual consolidated financial statements for the year ended 31 December 2020.

#### 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 31 December 2020, 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 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16 Amendment to HKFRS 16 Interest Rate Benchmark Reform - Phase 2

Covid-19-Related Rent Concessions beyond 30 June 2021 (early adopted)

30 June 2021

### 2. BASIS OF PREPARATION AND CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES (Continued)

#### 2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES (Continued)

The nature and impact of the revised HKFRSs are described below:

(a) Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS 4 and HKFRS 16 address issues not dealt with in the previous amendments which affect financial reporting when an existing interest rate benchmark is replaced with an alternative risk-free rate ("RFR"). The phase 2 amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount of financial assets and liabilities when accounting for changes in the basis for determining the contractual cash flows of financial assets and liabilities, if the change is a direct consequence of the interest rate benchmark reform and the new basis for determining the contractual cash flows is economically equivalent to the previous basis immediately preceding the change. In addition, the amendments permit changes required by the interest rate benchmark reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued. Any gains or losses that could arise on transition are dealt with through the normal requirements of HKFRS 9 to measure and recognise hedge ineffectiveness. The amendments also provide a temporary relief to entities from having to meet the separately identifiable requirement when an RFR is designated as a risk component. The relief allows an entity, upon designation of the hedge, to assume that the separately identifiable requirement is met, provided the entity reasonably expects the RFR risk component to become separately identifiable within the next 24 months. Furthermore, the amendments require an entity to disclose additional information to enable users of financial statements to understand the effect of interest rate benchmark reform on an entity's financial instruments and risk management strategy.

The application of the amendments did not have any impact on the financial position and performance of the Group.

(b) Amendment to HKFRS 16 issued in April 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the covid-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods beginning on or after 1 April 2021 with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

The Group has early adopted the amendment on 1 January 2021 and the amendment did not have any impact on the financial position and performance of the Group as the Group did not have any Covid-19-related rent concessions for the period ended 30 June 2021.

30 June 2021

#### 3. OPERATING SEGMENT INFORMATION

Management monitors the operating results of the Group's operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment.

#### **Geographical information**

#### (a) Revenue from external customers

	For the six months ended 30 June		
	2021 (Unaudited) <i>RMB'000</i>	2020 (Unaudited) <i>RMB'000</i>	
Mainland China Other country	34,842 1,707	31,834	
Total	36,549	31,834	

The revenue information above is based on the locations of the customers.

#### (b) Non-current assets

	30 June 2021 (Unaudited) <i>RMB'000</i>	31 December 2020 (Audited) <i>RMB'000</i>
Mainland China British Virgin Islands Cayman Islands	155,198 51,969 10,767	164,360 60,915 11,810
Total	217,934	237,085

The non-current asset information above is based on the locations of the assets.

30 June 2021

#### 4. REVENUE

An analysis of revenue is as follows:

	For the six months ended 30 June		
	2021 <i>RMB'000</i> (Unaudited)	2020 <i>RMB'000</i> (Unaudited)	
Revenue from contracts with customers	36,549	31,834	

#### Disaggregated revenue information for revenue from contracts with customers

	For the six months ended 30 June		
	2021 <i>RMB'000</i> (Unaudited)	2020 <i>RMB'000</i> (Unaudited)	
Types of goods or services Promotion service revenue Collaboration revenue Sale of products  Total revenue from contracts with customers	34,488 1,707 354 36,549	30,772 - 1,062 31,834	
Geographical markets Mainland China Other country	34,842 1,707	31,834	
Total revenue from contracts with customers  Timing of revenue recognition	36,549	31,834	
Goods/services transferred at a point in time  - Promotion service revenue  - Collaboration revenue  - Sale of products	34,488 1,707 354	30,772 - 1,062	
Total revenue from contracts with customers	36,549	31,834	

30 June 2021

#### 5. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

For the six month	is ended 30 June
2021	2020
D14D1000	D44D/000

	(Unaudited)	(Unaudited)
Cost of inventories sold Cost of services provided Depreciation of items of property, plant and equipment Depreciation of right-of-use assets Amortisation of intangible assets Impairment of inventories Impairment of an intangible asset Impairment of trade receivables Auditor's remuneration Research and development costs Exchange differences, net Equity-settled share award and option expense	23,232 15,877 6,388 1,083 7,219 23,036 - 5 740 74,026 7,383 3,501	46 10,808 6,302 1,118 5,103 6,639 5,771 - 740 51,735 (5,862) 2,504

#### 6. INCOME TAX

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

The Group calculates the income tax expense for the period using the tax rate that would be applicable to the expected total annual earnings. The Group did not incur any income tax expenses as the Group did not generate taxable income for the periods ended 30 June 2021 and 2020.

#### 7. DIVIDENDS

The board does not recommend the payment of any dividend in respect of the six months ended 30 June 2021 (six months ended 30 June 2020: Nil).

#### 8. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss attributable to ordinary equity holders of the parent for the period, and the weighted average number of ordinary shares of 1,098,782,000 (six months ended 30 June 2020: 1,041,390,980) in issue during the period, as adjusted to reflect the rights issue during the period.

No adjustment has been made to the basic loss per share amounts presented for the periods ended 30 June 2021 and 2020 in respect of a dilution as the impact of the share awards and options had an anti-dilutive effect on the basic loss per share amounts presented.

30 June 2021

#### 8. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (Continued)

The calculation of basic loss per share is based on:

	For the six months ended 30 June		
	2021 <i>RMB'000</i> (Unaudited)	2020 <i>RMB'000</i> (Unaudited)	
Loss Loss attributable to ordinary equity holders of the parent	(110,828)	(51,465)	
	For the six month	is ended 30 June	
	2021 (Unaudited)	2020 (Unaudited)	
Shares Weighted average number of shares in issue during the period	1,098,782,000	1,041,390,980	

#### 9. PROPERTY, PLANT AND EQUIPMENT

During the six months ended 30 June 2021, the Group acquired assets at a cost of RMB1,074,000 (six months ended 30 June 2020: RMB3,488,000).

No assets were disposed of by the Group during the six months ended 30 June 2021 (six months ended 30 June 2020: RMB6,000), and thus there was no gain or loss on disposal (six months ended 30 June 2020: Nil).

#### 10. TRADE RECEIVABLES

	30 June 2021 <i>RMB'000</i> (Unaudited)	31 December 2020 <i>RMB'000</i> (Audited)
Trade receivables Impairment	47,070 (14)	26,629 (9)
	47,056	26,620

30 June 2021

#### 10. TRADE RECEIVABLES (Continued)

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	30 June 2021 <i>RMB'000</i> (Unaudited)	31 December 2020 <i>RMB'000</i> (Audited)
Within 3 months Over 3 months	36,652 10,404	26,620
	47,056	26,620

#### 11. TRADE AND BILLS PAYABLES

An ageing analysis of the trade and bills payables as at the end of the reporting period, based on the invoice date, is as follows:

	30 June 2021 <i>RMB'000</i> (Unaudited)	31 December 2020 <i>RMB'000</i> (Audited)
Within 3 months Over 3 months	414 946	334 596
	1,360	930

#### 12. COMMITMENTS

The Group had the following capital commitments at the end of the reporting period:

	30 June 2021 <i>RMB'000</i> (Unaudited)	31 December 2020 <i>RMB'000</i> (Audited)
Contracted, but not provided for: Plant and machinery	2,287	

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#### 13. RELATED PARTY TRANSACTIONS

(a) The Group had the following transaction with a related party during the period:

# | For the six months ended 30 June | 2021 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 | 2020 |

#### Note:

- (i) The revenue from an associate is based on the price mutually agreed between the parties.
- (b) Outstanding balance with a related party:

The Group had an outstanding balance due from its associate of RMB66,000 (31 December 2020: Nil) as at the end of the reporting period. This balance is unsecured, interest-free and is repayable within 30 days.

(c) Compensation of key management personnel of the Group:

	For the six months ended 30 June		
	<b>2021</b> 202		
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Short term employee benefits	12,031	9,424	
Pension scheme contributions	<sup>154</sup>	84	
Equity-settled share award and option expense	1,940	1,117	
Total compensation paid to key management			
personnel	14,125	10,625	

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#### 14. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of the reporting period are as follows:

#### 30 June 2021 (Unaudited)

#### Financial assets

	Financial assets at fair value through profit or loss RMB'000	Financial assets at amortised cost <i>RMB'000</i>	Total <i>RMB'000</i>
Trade receivables Financial assets included in prepayments,	-	47,056	47,056
other receivables and other assets Financial assets at fair value through	-	7,108	7,108
profit or loss	35,200	_	35,200
Cash and cash equivalents	<u> </u>	2,577,848	2,577,848
	35,200	2,632,012	2,667,212

#### **Financial liabilities**

	Financial liabilities at amortised cost <i>RMB'000</i>	Total <i>RMB'000</i>
Trade and bills payables Lease liabilities	1,360 3,870	1,360 3,870
Financial liabilities included in other payables and accruals	44,826	44,826
	50,056	50,056

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#### 14. FINANCIAL INSTRUMENTS BY CATEGORY (Continued)

The carrying amounts of each of the categories of financial instruments as at the end of the reporting period are as follows: (continued)

#### 31 December 2020 (Audited)

#### Financial assets

	Financial assets at amortised cost <i>RMB'000</i>	Total <i>RMB'000</i>
Trade and bills receivables Financial assets included in prepayments, other	26,620	26,620
receivables and other assets Cash and cash equivalents	4,113 2,714,011	4,113 2,714,011
	2,744,744	2,744,744
Financial liabilities		
	Financial liabilities at amortised cost <i>RMB'000</i>	Total <i>RMB'000</i>
Trade and bills payables Lease liabilities Financial liabilities included in other payables and accruals	930 1,587 48,720	930 1,587 48,720
	51,237	51,237

#### 15. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

The carrying amounts and fair values of the Group's financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

	Carrying amounts and fair values		
	30 June 31 December 2021 202 RMB'000 RMB'000 (Unaudited) (Unaudited)		
<b>Financial assets</b> Financial assets at fair value through profit or loss	35,200		

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#### 15. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (Continued)

The Group's finance department headed by the finance director is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the finance director. At each reporting date, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the finance director. The valuation process and results are discussed with the directors once a year for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The fair values of lease liabilities have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities. The changes in fair value as a result of the Group's own non-performance risk for lease liabilities as at the end of the reporting period were assessed to be insignificant.

The Group invests in unlisted investments, which represent certain financial products issued by commercial banks in Mainland China. The Group has estimated the fair value of these structured products linked to exchange rates by using a Monte Carlo Simulation technique based on the underlying USD/EUR FX rate which is assumed to follow log-normal dynamics. The model incorporates various market unobservable inputs.

#### Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group's financial instruments:

#### Assets measured at fair value:

As at 30 June 2021 (unaudited)

	Fair valu Quoted prices in active markets (Level 1) RMB'000	in active observable unobservable markets inputs inputs (Level 1) (Level 2) (Level 3)		
Financial assets at fair value through profit or loss		35,200		35,200

The Group did not have any financial assets measured at fair value as at 31 December 2020, and did not have any financial liabilities measured at fair value as at 30 June 2021 and 31 December 2020.

During the period, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities (six months ended 30 June 2020; Nil).

#### **DEFINITIONS**

"Ascletis", "Company", "the Company" or "We"

Ascletis Pharma Inc. (歌禮製藥有限公司) (an exempted company incorporated in the Cayman Islands with limited liability on

February 25, 2014

"Audit Committee" the audit committee of the Board

"API(s)" Active Pharmaceutical Ingredient, the component of a drug

product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any

function of the body

"Board" or "Board of Directors" the board of directors of the Company

"CG Code" the Corporate Governance Code as set out in Appendix 14 to the

Listing Rules

"Chairman" the Chairman of the Board

"China", "Mainland China" or the People's Republic of China, excluding, for the purpose of "the PRC"

this report, Hong Kong, Macau Special Administrative Region

and Taiwan

"CMO" Contract Manufacturing Organization, a company that serves

other companies in the pharmaceutical industry on a contract basis to provide comprehensive drug manufacturing services

"COVID-19" an infectious disease caused by the most recently discovered

coronavirus (severe acute respiratory syndrome coronavirus 2),

first reported in December 2019

"Director(s)" the director(s) of the Company

"FASN" Fatty acid synthase

"FXR" farnesoid X receptor

"Group" or "the Group" the Company and its subsidiaries

"Greater China" Mainland China, Hong Kong, Macau and Taiwan

"HK\$" Hong Kong dollars, the lawful currency of Hong Kong

"HKFRS" the Hong Kong Financial Reporting Standards

"Hong Kong" the Hong Kong Special Administrative Region of the PRC

"IND" investigational new drug, an experimental drug for which a

> pharmaceutical company obtains permission to ship across jurisdictions (usually to clinical investigators) before a marketing

application for the drug has been approved

"Listing Rules" the Rules Governing the Listing of Securities on the Stock

Exchange, as amended or supplemented from time to time

#### **DEFINITIONS**

"Main Board" the Main Board of the Stock Exchange

"Model Code" the Model Code for Securities Transactions by Directors of Listed

Issuers contained in Appendix 10 to the Listing Rules

"NDA" new drug application, an application through which the drug

sponsor formally proposes that the relevant regulatory authority

approve a new drug for sales and marketing

"China NMPA" China National Medical Products Administration

"NRDL" the National Reimbursement Drug List

"R&D" research and development

"Reporting Period" the six-month period from January 1, 2021 to June 30, 2021

"Renminbi" or "RMB" Renminbi Yuan, the lawful currency of China

"Roche" F. Hoffmann-La Roche AG, a Swiss multi-national healthcare

company

"Shareholder(s)" holder(s) of Shares

"Share(s)" ordinary shares in the share capital of our Company of

US\$0.0001 each

"Stock Exchange" The Stock Exchange of Hong Kong Limited

"THRβ" thyroid hormone receptor beta

"U.S. dollar(s)", "USD" or "US\$" United States dollars, the lawful currency of the United States of

America

"Written Guidelines" the Guidelines for Securities Transactions by Directors adopted

by the Company

In this interim report, the terms "associate", "connected person", "controlling shareholder" and "subsidiary" shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

By order of the Board Ascletis Pharma Inc. 歌禮製藥有限公司 Jinzi Jason WU Chairman

Hangzhou, the People's Republic of China, August 26, 2021

As at the date of this report, the Board of Directors of the Company comprises Dr. Jinzi Jason WU and Mrs. Judy Hejingdao WU, as executive Directors; and Dr. Yizhen WEI, Mr. Jiong GU and Ms. Lin HUA, as independent non-executive Directors.