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Ascletis Pharma Inc.

歌禮製藥有限公司

(incorporated in the Cayman Islands with limited liability)

(Stock Code: 1672)

ANNUAL RESULTS OF ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2021

The Board hereby announces the audited condensed consolidated annual results of the Group for the year ended December 31, 2021, together with the comparative figures for the year ended December 31, 2020 as follows.

FINANCIAL HIGHLIGHTS

	Year ended December 31,		
	2021	2020	Changes
	RMB'000	RMB'000	%
Revenue			
Promotion service revenue	70,918	64,603	9.8
Collaboration revenue	5,925	–	100.0
Sale of products	33	(29,602)	100.1
Total	76,876	35,001	119.6
Gross profit/(loss)	39,173	(23,497)	266.7
Loss before tax	(199,017)	(209,241)	(4.9)
Loss for the year	(199,017)	(209,241)	(4.9)
Loss attributable to the owner of the Group	(199,017)	(209,241)	(4.9)
Net loss margin	(258.9)%	(597.8)%	–
Loss per share			
	RMB	RMB	
– Basic and diluted	(18.13) cents	(20.12) cents	–

CORPORATE PROFILE

Our Vision

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

Overview

The total revenue of the Group increased by 119.6% from approximately RMB35.0 million for the year ended December 31, 2020 to approximately RMB76.9 million for the year ended December 31, 2021.

The Group recorded a turnaround from a gross loss to a gross profit from the year ended December 31, 2020 to the year ended December 31, 2021 and recorded a gross profit approximately RMB39.2 million, representing an increase of approximately 266.7%, as compared with a gross loss of approximately RMB23.5 million for the year ended December 31, 2020.

The research and development expenses of the Group increased by 95.5% from approximately RMB109.1 million for the year ended December 31, 2020 to approximately RMB213.3 million for the year ended December 31, 2021, mainly due to the Group's continuously investment on the research and development of antiviral drug candidates for COVID-19 and chronic hepatitis B (CHB) functional cure.

The loss for the year of the Group decreased by 4.9% from approximately RMB209.2 million for the year ended December 31, 2020 to approximately RMB199.0 million for the year ended December 31, 2021.

As at December 31, 2021, the Group had cash and cash equivalents of approximately RMB2,495.5 million.

During the Reporting Period and up to the date of this announcement, the Group has made the following progress: (i) obtained the market authorization approval from NMPA for ritonavir (100 mg film-coated tablet); (ii) submitted marketing authorization applications for ritonavir (100 mg film-coated tablet) in 12 European countries (Germany, France, Ireland, the United Kingdom, Spain, Portugal, Italy, Belgium, Poland, Sweden, the Netherlands and Denmark); (iii) the all-oral direct anti-hepatitis C virus (HCV) ASCLEVIR®/GANOVO® regimen has been included in the National Reimbursement Drug List ("NRDL"); (iv) advanced (a) one candidate into a Phase III clinical trial (ASC40-rGBM-CN), (b) one candidate into a Phase IIb clinical trial (ASC22-HBV-CN), and (c) four candidates into Phase II clinical trials (ASC42-HBV-CN, ASC40-acne-CN, ASC42-PBC-CN and ASC22-HIV-CN); (v) the Group's partner, Sagimet Biosciences Inc. ("Sagimet Biosciences") (formerly known as 3-V Biosciences, Inc.), has advanced one candidate into a Phase IIb clinical trial (ASC40-NASH-US); and (vi) obtained 10 IND approvals including: (a) four IND approvals from FDA (ASC41-NASH-US, ASC43F-NASH-US, ASC22-HBV-US, ASC61-Oncology-US), and (b) six IND approvals from NMPA (ASC40-rGBM-CN, ASC40-acne-CN, ASC42-PBC-CN, ASC42-NASH-CN, ASC22-HIV-CN, ASC42-HBV-CN).

Viral Disease Pipeline

Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III	NDA	Marketed
Ritonavir (Oral small molecule)	Cytochrome P450	Booster for COVID-19 etc	Global							
Ravidasvir (Oral small molecule)	NS5A	HCV	Greater China							
Danoprevir (Oral small molecule)	NS3/4A	HCV	Greater China							
ASC22 (Subcutaneous mAb)	PD-L1	CHB functional cure	Global ¹							
ASC42 (Oral small molecule)	FXR	CHB functional cure	Global							
ASC22 (Subcutaneous mAb)	PD-L1	HIV functional cure	Global ¹							
ASC10 (Oral small molecule)	RdRp	COVID-19	Global							
ASC11 (Oral small molecule)	3CLpro	COVID-19	Global							

Note:

- ASC22 is licensed from Suzhou Alphamab Co.,Ltd. (“**Suzhou Alphamab**”) for the worldwide exclusive rights.

Abbreviations:

NS5A: Non-structure protein 5A; NS3/4A: Non-structure protein 3/4A; PD-L1: Programmed death ligand 1; FXR: Farnesoid X receptor ;RdRp: RNA-dependent RNA polymerase ; 3CLPro: 3-chymotrypsin like protease; COVID-19: Coronavirus Disease 2019; HCV: Hepatitis C virus; CHB: Chronic hepatitis B; HIV: Human immunodeficiency virus.

NASH/PBC Pipeline¹

Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase IIa	Phase IIb	Phase III
ASC40 (Oral small molecule)	FASN	NASH	Greater China ²						
ASC41 (Oral small molecule)	THRβ	NASH	Global						
ASC42 (Oral small molecule)	FXR	NASH	Global						
ASC43F FDC (Oral small molecule)	THRβ + FXR	NASH	Global						
ASC44F FDC (Oral small molecule)	FASN + FXR	NASH	Global						
ASC45F FDC (Oral small molecule)	FASN + THRβ	NASH	Global						
ASC42 (Oral small molecule)	FXR	PBC	Global						

Notes:

- NASH/PBC pipeline is owned by Gannex Pharma.
- ASC40 is licensed from Sagimet Biosciences for the exclusive rights in the Greater China.

Abbreviations:

FASN: Fatty acid synthase; THRβ: Thyroid hormone receptor beta; FXR: Farnesoid X receptor; NASH: Non-alcoholic steatohepatitis; PBC: Primary biliary cholangitis.

Oncology Pipeline (Lipid Metabolism and Oral Checkpoint Inhibitors)

Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	POC	Pivotal
ASC40 (Oral small molecule) +Bevacizumab	FASN + VEGF	Recurrent glioblastoma	Greater China ¹	Phase III in China approved				
ASC40 (Oral small molecule)	FASN	Drug resistant Breast Cancer	Greater China ¹					
ASC40 (Oral small molecule)	FASN	KRAS mutant NSCLC	Greater China ¹					
ASC61 (Oral small molecule)	PD-L1	Advanced solid tumors	Global					
ASC60 (Oral small molecule)	FASN	Solid tumor 1	Greater China ¹					
ASC60 (Oral small molecule)	FASN	Solid tumor 2	Greater China ¹					
ASC63 (Oral small molecule)	PD-L1	Advanced solid tumors	Global					

Note:

- ASC40 and ASC60 are licensed from Sagimet Biosciences for the exclusive rights in the Greater China.

Abbreviations:

FASN: Fatty acid synthase; VEGF: Vascular endothelial growth factor; PD-L1: Programmed death ligand 1; NSCLC: Non-small cell lung cancer.

Exploratory Indication Pipeline

Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III
ASC40 (Oral small molecule)	FASN	ACNE	Greater China ¹					

Note:

- ASC40 is licensed from Sagimet Biosciences for the exclusive rights in the Greater China.

Abbreviation:

FASN: Fatty acid synthase.

MANAGEMENT DISCUSSION AND ANALYSIS

Business Review

During the Reporting Period and up to the date of this announcement, the Group has made the following progresses with respect to its business.

Viral Diseases

Ritonavir for COVID-19

Recently, the Group has further expanded its ritonavir oral tablet production capacity to approximately 530 million tablets per year, to meet the potential escalation in the domestic and global demands. The Group has taken multiple measures for expansion of the annual ritonavir production capacity, including adding additional key equipment at the manufacturing facilities of Ascleitis Pharmaceuticals Co., Ltd. (“**Ascleitis Pharmaceuticals**”, 歌禮藥業(浙江)有限公司), a wholly-owned subsidiary of the Company.

Ritonavir oral tablet is a pharmacokinetic booster of multiple oral antiviral drugs targeting viral proteases and a component of the approved oral antiviral drug Paxlovid (Nirmatrelvir 300 mg tablet + ritonavir 100 mg tablet co-administration package).

The Group aims to be a global commercial supplier of ritonavir oral tablets. To date, the Group owns the only authorized ritonavir oral tablet in China, which has passed bioequivalence study. The Group’s ritonavir oral tablet was approved in September 2021 by the NMPA (國藥准字 H20213698). Furthermore, the Group has submitted marketing authorization applications for ritonavir (100 mg film-coated tablet) in 12 European countries (Germany, France, Ireland, the United Kingdom, Spain, Portugal, Italy, Belgium, Poland, Sweden, the Netherlands and Denmark) through its agent in Europe.

The Group continues the engagement with both domestic and major multi-national pharmaceutical companies for the commercial supplies of ritonavir within China and globally.

ASCLEVIR®/GANOVO® Regimen for Hepatitis C

In December 2021, the Group announced that its all-oral direct anti-HCV ASCLEVIR® (Ravidasvir)/GANOVO® (Danoprevir) regimen has been included in the NRDL.

The results from the Phase II/III clinical trials in China with the all-oral direct anti-HCV ASCLEVIR®/GANOVO® regimen showed a 99% cure rate in genotype 1 non-cirrhosis HCV patients. ASCLEVIR® is a pan-genotypic NS5A inhibitor with high genetic barrier to resistance, with a cure rate of 100% in patients with baseline NS5A resistance. Both ASCLEVIR® and GANOVO® have been included in The Guideline of Prevention and Treatment for Chronic Hepatitis C (2019 version) (《丙型肝炎防治指南(2019版)》) and Management Process of Hospital Screening for Hepatitis C in China (Trial) in 2021 (《中國丙型病毒性肝炎院內篩查管理流程(試行)》). Ascleitis was the leader for the anti-HCV Program of National Science and Technology Major Project for “Innovative Drug Development” Programs, and both ASCLEVIR® and GANOVO® are the important achievements of this Project during the 13th Five-year Plan Period.

ASC22 for CHB Functional Cure

In November 2021, the Group announced that the interim results of 44 CHB patients from a Phase IIb trial of ASC22 (Envafolelimab), a subcutaneously administered PD-L1 antibody (ClinicalTrials.gov Identifier: NCT04465890), demonstrated sustained HBsAg loss in CHB patients with baseline HBsAg \leq 500 IU/mL. Interim results, which were accepted for oral presentation in Late Breaking Session at The Liver Meeting® 2021 by the American Association for the Study of Liver Diseases (AASLD) showed that in patients with the baseline hepatitis B surface antigen (HBsAg) level \leq 500 IU/mL, approximately 19% (3/16) of patients in the treatment group obtained HBsAg loss versus no subject achieved HBsAg loss in the placebo group and no rebound after the last dosing of ASC22, indicating CHB functional cure.

The Phase IIb study is a randomized, single-blind, placebo-controlled, multi-center clinical trial in China which evaluates the efficacy and safety of treating CHB patients for 24-week treatment (with 24 week follow-up) of 1 mg/kg or 2.5 mg/kg ASC22 or matching placebo given once every two weeks (Q2W) in combination with NAs. A total of 149 CHB patients were enrolled in the trial.

ASC22 is the most advanced clinical stage immunotherapy in the world for CHB functional cure, i.e. HBsAg loss, through blocking PD-1/PD-L1 pathway.

The Group announced it had obtained a global and exclusive license on 8 November, 2021 from Suzhou Alphamab to develop and commercialize ASC22 for all viral diseases including Hepatitis B. The Group books sales globally for ASC22 of all viral diseases.

Recently, the Group announced the IND application approval by FDA and initiation of global development of ASC22 (Envafolelimab), a first-in-class, subcutaneously administered PD-L1 antibody for functional cure of CHB.

The recent research paper, titled “Prevalence of Chronic Hepatitis B Virus Infection in the United States” published in June 2020, showed an overall estimated prevalence for chronic HBV infection in the U.S. of 1.59 million patients (range 1.25-2.49 million). Both the World Health Organization (WHO) and U.S. Department of Health and Human Services (DHHS) have articulated formal hepatitis elimination plans.

Anticipated 2022 Milestone: Initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial of ASC22 + NAs in CHB patients.

ASC42 for CHB Functional Cure

Recently, the Group announced the dosing of the first patient in the Phase II clinical trial of ASC42 for CHB indication. The Phase II clinical trial is a multi-center, randomized, single-blind, placebo-controlled study in China to evaluate safety and efficacy of ASC42 tablets in combination with Entecavir and pegylated interferon- α -2a (PEG-IFN- α -2a) in subjects with CHB. About 45 CHB patients will be enrolled and receive ASC42 tablets (10 mg or 15 mg) or matching placebo orally once daily in combination with Entecavir (0.5 mg, orally once daily) and PEG-IFN- α -2a (180 μ g, subcutaneous injection once a week) for 12 weeks, and serum hepatitis B surface antigen (HBsAg) and HBV pregenomic RNA (pgRNA) change from baseline will be measured during 12-week intervention period and 24-week follow-up period.

ASC42 is an in-house developed, selective, potent (FXR agonist with best-in-class potential. The U.S. Phase I trial of ASC42 indicated that there was no pruritus observed and LDC-C values remained within normal range during 14-day treatment of the once-daily human therapeutic dose of 15 mg while FXR target engagement biomarker Fibroblast Growth Factor 19 (FGF19) increased 1,780% and 7 α -hydroxy-4-cholesten-3-one (C4) decreased 91% on Day 14.

As an FXR agonist, ASC42 has unique mechanism of action against HBV: ASC42 inhibits the transcription of HBV covalently closed circular DNA (cccDNA) into HBV RNA, which in turn inhibits the translation of HBV RNA into HBsAg. ASC42 may also reduce HBV cccDNA stability. Both *in vitro* primary human hepatocyte (PHH) cells and *in vivo* AAV/HBV mouse studies demonstrated that ASC42 significantly inhibited serum HBsAg and pgRNA, indicating that ASC42 has therapeutic potential to functionally cure CHB.

Anticipated 2022 Milestone: Data from the multi-center, randomized, single-blind, placebo-controlled Phase II clinical trial of ASC42 + Entecavir + PEG-IFN- α -2a in CHB patients.

Pegasys®

As a marketed drug of clinically curing CHB, Pegasys®'s promotion service revenue increased 9.8% from approximately RMB64.6 million for year ended December 31, 2020 to approximately RM70.9 million for year ended December 31, 2021.

Oral Direct-Acting Antivirals (ASC10 and ASC11) Against SARS-CoV-2

ASC10 for COVID-19

Recently, the Group announced the positive *in vivo* and *in vitro* data of oral double prodrug ASC10 and its antiviral nucleoside analog ASC10-A against multiple SARS-CoV-2 virus variants including Omicron variant.

ASC10-A is a potent inhibitor of RdRp of SARS-CoV-2 virus. ASC10-A demonstrated an excellent *in vitro* antiviral activity against multiple SARS-CoV-2 virus variants including Omicron variant. Compared to wildtype or early variants of SARS-CoV-2 virus, ASC10-A remained the same inhibitory activity *in vitro* against Omicron variant despite that Omicron variant carried many mutations including a mutation in RdRp. ASC10-A showed potent cellular antiviral activity against Omicron variant (EC₅₀ = 0.3 μ M), Delta variant (EC₅₀ = 0.5 μ M) and wildtype virus (EC₅₀ = 0.7 μ M). Furthermore, the drug exposure of ASC10-A required for efficacy against Omicron is likely achievable in clinical trials of patients based on bioavailability studies in monkeys. New experimental data also suggested that there were no drug-drug interactions between ASC10 and other common medicines.

ASC10, discovered and developed in-house to treat COVID-19, is the orally bioavailable double prodrug of the antiviral nucleoside analog ASC10-A. After taken orally, double prodrug ASC10 is adsorbed mainly at gut into blood circulation. ASC10 is then rapidly cleaved in blood into the antiviral nucleotide analog ASC10-A.

By applying a double prodrug strategy, ASC10's permeability in Caco-2 cells was 3.2-fold of Molnupiravir. As a result of increased permeability, ASC10's oral bioavailability in monkeys was 2.9-fold of Molnupiravir. Based on drug exposure relationship between monkeys and humans, double prodrug ASC10 is predicted to have higher drug exposure in patients, that may result in better efficacy against COVID-19 in clinical trials compared to Molnupiravir.

Based on the positive data, the submission of INDs for clinical trials in China, the U.S. and other countries may be sooner than that expected by the Company earlier.

To date, Ascletis has filed multiple patent applications for ASC10 and its use globally. The Group plans to submit INDs for clinical trials in China, U.S. etc. in the first half of 2022.

By taking multiple measures, the manufacturing costs of ASC10 reduced significantly, which is critical to accessibility and affordability of COVID-19 drugs.

Anticipated 2022 Milestone: Initiate ASC10 clinical trials for the treatment of COVID-19.

ASC11 for COVID-19

ASC11 is an oral direct-acting antiviral drug candidate, targeting 3CLpro, to treat SARS-CoV-2 infection. ASC11 is an in-house discovered drug candidate with the global intellectual property and commercial rights. Compared to 3CLpro-targeted Nirmatrelvir which was approved by the FDA, ASC11 has a new and differentiated chemical structure. The Company has filed the compound and use patent applications. The Company plans to submit INDs for clinical trials in China, U.S. etc. in the second half of 2022.

Anticipated 2022 Milestone: Initiate ASC11 clinical trials for the treatment of COVID-19.

NASH/PBC

ASC40 for NASH

In August 2021, the Group announced that its partner Sagimet Biosciences 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 non-alcoholic fatty liver disease (NAFLD) activity score (NAS) that results from reduction of necro-inflammation (inflammation or ballooning); or
2. improvement in fibrosis.

The 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 FDA for accelerated approval following Phase III studies. The study will also measure liver fat, assessed by magnetic resonance imaging-proton density fat fraction (MRI-PDFF), and other serum biomarkers of inflammation, fibrosis, and liver injury in a portion of patients at 26 weeks of treatment in an interim analysis.

In March 2021, Gannex Pharma, a wholly-owned subsidiary of the Company, and Sagimet Biosciences jointly announced positive topline results from the China cohort of a Phase II randomized, placebo-controlled clinical trial of oral, once-daily FASN inhibitor ASC40, known as TVB-2640 outside of China. The preliminary data showed that ASC40 meaningfully reduced liver fat, the primary efficacy endpoint of this trial, with a 50% responder rate (patients achieving $\geq 30\%$ liver fat reduction). Participants also showed robust improvement in ALT, a liver enzyme associated with inflammation. These data from the China cohort are consistent with those of the U.S. cohort.

Anticipated 2022 Milestone: Interim results from the multi-center, randomized, double-blind, placebo-controlled Phase IIb clinical trial of ASC40 in NASH patients with biopsy.

ASC43F for NASH

Recently, the Group announced the completion of the U.S. Phase I trial of ASC43F, an in-house developed, first-in-class dual targeting fixed-dose combination (FDC) tablet for NASH.

ASC43F is a once-a-day (QD), single tablet, FDC of 5 mg ASC41, a thyroid hormone receptor beta (THR β) agonist, and 15 mg ASC42, a FXR agonist. The U.S. Phase I trial (ClinicalTrials.gov Identifier: NCT05118516) was an open-label, single-dose study evaluating the safety, tolerability and pharmacokinetics of ASC43F in healthy subjects. The results showed that ASC43F was safe and well tolerated, without clinically significant adverse effects. The pharmacokinetic parameters of ASC41 and ASC42 from ASC43F are similar to those of ASC41 and ASC42 as monotherapy.

Previous Phase I studies in the U.S. and China have shown ASC41 at 5 mg to be safe and well tolerated in both healthy volunteers, overweight and obese subjects and patients with NAFLD. In these studies, ASC41 significantly reduced low density lipoprotein cholesterol (LDL-C), triglyceride (TG), and total cholesterol (TC) in overweight and obese subjects with elevated LDL-C, a population that is characteristics of NASH.

Previous Phase I clinical data indicated that ASC42 was safe and well tolerated, with no pruritus and with LDC-C values remaining within normal range during 14-day treatment with once-daily therapeutic dose of 15 mg. FXR target engagement biomarkers Fibroblast Growth Factor 19 (FGF19) increased 1,780% and 7 α -hydroxy-4-cholesten-3-one (C4) decreased 91% on Day 14 of treatment with 15 mg, once-daily dose.

With three single agents against three distinct but complementary targets, the Group has taken 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 THR β	ASC42 FXR	ASC43F THR β + FXR	ASC44F FASN + FXR	ASC45F FASN+ THR β
Liver fat reduction	★★★	★★★	★★	★★★	★★★	★★★
Anti-inflammation	★★	★★	★★	★★	★★	★★
Anti-fibrosis	★★	★★	★★★	★★★	★★★	★★
Lowering LDL-C and TG		★★★		★★★		★★★

ASC42 for PBC

In November 2021, the Group announced that the protocols of Phase II and III clinical trials of ASC42 to treat patients with PBC has been approved by NMPA. PBC is a new chronic hepatobiliary disease indication approved for clinical trials of ASC42. The other two chronic hepatobiliary disease indications approved by NMPA and/or FDA are CHB and NASH.

With the approval of ASC42 PBC Phase II and III protocols by the NMPA, Gannex Pharma is expected to complete the Phase II trial in 100 patients who have an inadequate response to or are unable to tolerate Ursodeoxycholic acid (UDCA). The Phase II study consists of three active treatment arms and one placebo control arm at the ratio of 1:1:1:1 and is expected to complete in the second half of 2022. Gannex Pharma will initiate the Phase III trial after the communications with NMPA in terms of drug registration related matters such as Chemistry, Manufacturing and Control (CMC) and toxicology studies.

ASC42 is an in-house developed, novel non-steroidal, selective, potent FXR agonist with best-in-class potential and global intellectual property. The data from the U.S. Phase I trial of ASC42 indicated there was no pruritus observed during 14-day treatment of the once-daily human therapeutic dose of 15 mg and FXR target engagement biomarker FGF19 increased 1,780% on Day 14 of treatment with 15 mg dose. Furthermore, mean LDL-C values remained within the normal range during 14-day, once daily treatment with 15 mg.

UDCA is the only drug which is approved in China for PBC and approximately 40% PBC patients have an inadequate response to or are unable to tolerate UDCA. Obeticholic Acid (OCA), which is not approved in China, is the only approved medicine in the U.S. for PBC patients who have an inadequate response to or are unable to tolerate UDCA. However, there are significantly increased pruritus rates and LDL-C levels in patients with OCA treatment. Lack of pruritus and LDL-C level increase at the therapeutic dose makes ASC42 a potential best-in-class PBC drug. Gannex Pharma intends to start a Phase III trial in the U.S. and European Union after the completion of the Phase II study in China.

Anticipated 2022 Milestone: Data from the multi-center, randomized, double-blind, placebo-controlled Phase II clinical trial of ASC42 in PBC patients.

Oncology Pipeline (Lipid Metabolism and Oral Checkpoint Inhibitors)

ASC40 for recurrent glioblastoma (rGBM)

Recently, the Group announced the dosing of the first patient in the Phase III registration clinical trial of ASC40 combined with bevacizumab for treatment of rGBM. ASC40 is an oral, selective inhibitor of FASN, a key enzyme which regulates de novo lipogenesis (DNL). ASC40 inhibits energy supply and disturbs membrane phospholipid composition of tumor cells by blocking DNL.

The Phase III registration study (ClinicalTrials.gov Identifier: NCT05118776) 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 once daily + Bevacizumab) and Cohort 2 (matching placebo tablet once daily + Bevacizumab). Approximately 80% of such 180 patients with rGBM in the Phase III clinical trial are expected to be randomized and enrolled by the end of December 2022.

The Phase II study, completed in the U.S., in patients with rGBM has shown that the objective response rate (ORR) for ASC40 plus Bevacizumab treatment was 65% including a complete response (CR) of 20% and a partial response (PR) of 45%.

Based on published data, in China, glioblastoma (GBM) represents 57% 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 U.S., GBM represents 56.6% of gliomas and has an incidence rate of approximately 3.21 per 100,000 population per year.

Anticipated 2022 Milestone: 80% patients enrolled in the multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial of ASC40 + Bevacizumab in patients with rGBM.

ASC61, an oral PD-L1 small molecule inhibitor for cancer

Recently, the Group announced the approval of the IND application by the FDA for in-house developed oral PD-L1 small molecule inhibitor, ASC61, for the treatment of advanced solid tumors.

The ASC61 Phase I trial in the U.S. is a dose escalation study in patients with advanced solid tumors. The objectives of such study are to find a recommended Phase II dose (RP2D) and obtain preliminary efficacy in patients with advanced solid tumors. The first U.S. patient is expected to be dosed in the first half of 2022.

ASC61 is an oral potent and highly selective PD-L1 small molecule inhibitor and blocks PD-1/PD-L1 interaction through inducing PD-L1 dimerization and internalization. As a single agent, ASC61 demonstrated significant antitumor efficacy in multiple animal models such as the humanized mouse model. Preclinical studies showed that ASC61 has good safety and pharmacokinetic profiles in animal models.

ASC61 oral tablets, which will be used in the clinical trial, were developed with the in-house proprietary technology.

Compared to injectable PD-1/PD-L1 antibodies, ASC61, as an oral PD-L1 inhibitor, has the following benefits: (i) ease of dosing and no need for hospital visits for injections; (ii) all-oral combinations with other oral anti-tumor drugs; and (iii) rapid titration of doses for better management of immune-related adverse events (irAEs).

Exploratory Indications

ASC40 for moderate to severe acne

Recently, the Group announced the dosing of the first patient in the Phase II clinical trial of ASC40 for moderate to severe acne. ASC40 is an oral, selective inhibitor of FASN, a key enzyme which regulates DNL. Human sebum production requires DNL, which is increased in acne and suppressed by the FASN inhibitor ASC40.

The Phase II trial is a randomized, double-blind, placebo-controlled, multicenter clinical trial in China to evaluate the safety and efficacy of ASC40 for the treatment of patients with moderate to severe acne. About 180 patients will be randomized into three active treatment arms or one placebo control arm at the ratio of 1:1:1:1 and receive ASC40 (25 mg, 50 mg or 75 mg) or matching placebo orally once a day for 12 weeks. The primary outcomes include percentage change of total lesion count at week 12 compared to baseline and ratio of subjects, whose Investigator's Global Assessment (IGA) grades are decreased by ≥ 2 grades at week 12 compared to baseline.

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.

Current first-line treatments for acne include topical creams such as topical retinoids and androgen receptor inhibitor, oral isotretinoin, and antibiotics. A report 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.

Anticipated 2022 Milestone: Data from the multi-center, randomized, double-blind, placebo-controlled Phase II clinical trial of ASC42 in patients with moderate to severe acne.

CAPABILITY OF COMMERCIALIZATION

The Group has demonstrated potent capability and established a solid commercial presence in China in the area of hepatitis. As of December 31, 2021, the Group's commercialization team has covered approximately 636 hospitals and pharmacies strategically located in regions where Hepatitis C and B are prevalent in China. Our commercial team has identified and educated approximately 3,969 specialists and KOLs in the hepatitis field. We have entered into 30 distribution agreements with different distributors that cover approximately 345 direct-to-patient (DTP) pharmacies, hospital-linked pharmacies and other pharmacies through our distributors, either directly or through their sub-distributors.

THE GROUP'S FACILITIES

The Group has manufacturing facilities located in Shaoxing, Zhejiang Province with a total gross floor area of 17,000 square meters. Recently, the Group announced that it has further expanded its ritonavir oral tablet production capacity to approximately 530 million tablets per year, to meet the potential escalation in the domestic and global demands. The Group has taken multiple measures for expansion of the annual ritonavir production capacity, including adding additional key equipment. For our manufacturing facility, the Group has obtained the commercial drug production licenses of Ritonavir, ASCLEVIR® and GANOVO®. Our manufacturing facility is equipped with state-of-the-art production equipment with cutting-edge technology capabilities such as hot-melt extrusion and high-speed press to ensure the high quality of our products.

As of December 31, 2021, we had 10 wholly-owned subsidiaries. Our business was mainly conducted through three operating subsidiaries in China, namely Ascletis BioScience Co., Ltd. (歌禮生物科技(杭州)有限公司), Ascletis Pharmaceuticals and Gannex Pharma.

IMPACT OF COVID-19 PANDEMIC

During the Reporting Period, COVID-19 pandemic had limited impacts on the Group's business, such as research and development and sales activities. The Group took various measures to minimize negative impacts of COVID-19 pandemic on our operations and business activities. As a result, the Pegasys® promotion still increased 9.8% from approximately RMB64.6 million for the year ended December 31, 2020 to approximately RMB70.9 million for the year ended December 31, 2021.

FUTURE AND OUTLOOK

In 2022, the Group will focus on three therapeutic areas: viral diseases, NASH/PBC and oncology as well as continue to explore new indications.

The following are strategies and outlook in 2022:

1. Maximize revenues from Ritonavir, ASCLEVIR® and GANOVO®;
2. Strengthen competitiveness in the therapeutic area of viral diseases by focusing on clinical development of ASC22 (CHB functional cure) and two novel COVID-19 oral drug candidates, ASC10 and ASC11;
3. Accelerate Phase II and III clinical trials of ASC40 (rGBM), ASC42 (PBC) and ASC40 (acne);
4. Seek domestic and global license-out and license-in opportunities; and
5. Further improve production efficiency and reduce manufacturing costs.

FINANCIAL REVIEW

Revenue

The Group have commercialized three products as at December 31, 2021, namely GANOVO® (Danoprevir), ASCLEVIR® (Ravidasvir) and Pegasys®. The revenue generated during the Reporting Period consisted of (i) the promotion services 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 total revenue of the Group increased by 119.6% from approximately RMB35.0 million for the year ended December 31, 2020 to approximately RMB76.9 million for the year ended December 31, 2021.

In particular, the promotion service revenue of Pegasys® increased by 9.8% from approximately RMB64.6 million for the year ended December 31, 2020 to approximately RMB70.9 million for the year ended December 31, 2021. The collaboration revenue amounted to RMB5.9 million for the year ended December 31, 2021, as compared with nil from the collaboration partner for the year ended December 31, 2020.

Gross Profit

The Group recorded a turnaround from a gross loss for the year ended December 31, 2020 to a gross profit for the year ended December 31, 2021. It increased from a gross loss of approximately RMB23.5 million for the year ended December 31, 2020 to a gross profit of approximately RMB39.2 million for the year ended December 31, 2021, representing a gross profit margin of 51.0%.

The increased gross profit was primarily attributable to (i) the stable increase in promotion service revenue of Pegasys® (a marketed drug for CHB); (ii) the on-going cost-effective strategy on the promotion service of Pegasys®; and (iii) the increased revenue from the collaboration partner.

Cost of Sales

The cost of sales of the Group decreased by 35.5% from approximately RMB58.5 million for the year ended December 31, 2020 to approximately RMB37.7 million for the year ended December 31, 2021.

The decreased cost of sales was mainly attributable to the improved inventory management.

The cost of sales of the Group consisted of direct labor costs, cost of raw materials, overheads, royalty fees, costs of rendering promotion services and the write-down of inventories to net realizable value.

Direct labor costs primarily consisted of salaries, bonus and social security costs for our employees.

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

Overheads primarily consisted of depreciation expenses on our facilities and equipment and other manufacturing expenses.

We entitled 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 the Greater China.

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

Other Income and Gains

Other income and gains of the Group decreased by 26.7% from approximately RMB89.9 million for the year ended December 31, 2020 to approximately RMB65.9 million for the year ended December 31, 2021, primarily due to (i) government grants decreased by RMB8.0 million from approximately RMB48.9 million for the year ended December 31, 2020 to approximately RMB40.9 million for the year ended December 31, 2021; and (ii) bank interest income decreased by RMB18.1 million from approximately RMB40.6 million for the year ended December 31, 2020 to approximately RMB22.5 million for the year ended December 31, 2021.

The government grants mainly represented the subsidies we received from the local governments for compensating our expenses from research activities and clinical trials, awarding our new drug development and capital expenditure incurred on certain projects.

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

	Year ended December 31,			
	2021		2020	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Government grants	40,883	62.0	48,861	54.4
Bank interest income	22,506	34.2	40,626	45.2
Investment income from financial assets at fair value through profit or loss	2,484	3.8	290	0.3
Others	18	0.0	79	0.1
Total	65,891	100	89,856	100

Selling and Distribution Expenses

The selling and distribution expenses of the Group decreased by 23.7% from approximately RMB27.4 million for the year ended December 31, 2020 to approximately RMB20.9 million for the year ended December 31, 2021, which mainly consisted of staff cost for our sales personnel and the expenses for marketing promotion activities.

Administrative Expenses

The administrative expenses of the Group decreased by 28.4% from approximately RMB41.8 million for the year ended December 31, 2020 to approximately RMB29.9 million for the year ended December 31, 2021.

Our administrative expenses primarily consisted of (i) staff salary and welfare costs for non-research and development personnel; (ii) utilities, depreciated and amortization; and (iii) general office expenses and agency and consulting fees.

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

	Year ended December 31,			
	2021		2020	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Staff salary and welfare	13,456	44.9	21,408	51.2
Utilities, rent and general office expenses	12,048	40.2	15,217	36.4
Agency and consulting fee	3,948	13.2	4,315	10.3
Others	495	1.7	905	2.1
Total	29,947	100	41,845	100

Research and Development Expenses

Our Group's research and development expenses primarily consisted of preclinical and clinical expenses, staff costs and depreciation and amortization costs.

The research and development expenses of the Group for developing our drug candidates increased by 95.5% from approximately RMB109.1 million for the year ended December 31, 2020 to approximately RMB213.3 million for the year ended December 31, 2021. This was primarily because of the Group's continuous investment on the research and development of antiviral drug candidates for COVID-19 and CHB functional cure.

The following table sets forth the components of our research and development costs for the years indicated:

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Preclinical and clinical expenses	106,219	49,960
Staff costs	68,557	33,829
Depreciation and amortization	25,650	18,067
Others	12,894	6,707
Third-party contracting costs	—	536
Total	213,320	109,099

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

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
NASH/PBC	80,212	42,642
Viral diseases	67,261	58,597
Oncology	50,109	—
Others ^(Note)	9,062	7,860
Exploratory indications	6,676	—
Total	213,320	109,099

Note: "Others" includes research and development costs of pre-clinical programs.

Finance Costs

The Group recorded finance costs of approximately RMB0.1 million for the year ended December 31, 2021. The slightly decreased finance costs was primarily attributable to the interest on lease liabilities.

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

	Year ended December 31,			
	2021		2020	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Interest on the lease liabilities	125	100	135	100
Total	125	100	135	100

Other Expenses

Other expenses of the Group decreased by 73.7% from approximately RMB83.4 million for the year ended December 31, 2020 to approximately RMB21.9 million for the year ended December 31, 2021, mainly due to the decreased donation and foreign exchange loss.

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

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Foreign exchange loss, net	16,439	30,425
Donation	5,480	31,789
Others	23	20
Write-down of inventories to net realisable value	–	15,315
Impairment of an intangible asset	–	5,771
Loss on disposal of items of property, plant and equipment	–	92
Total	21,942	83,412

Income Tax

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

The Group calculates the income tax expense by using the tax rate that would be applicable to the expected total annual earnings. For the years ended December 31, 2020 and 2021, the Group did not incur any income tax expense as we did not generate any taxable income.

The Group had tax losses arising in the PRC of approximately RMB762.9 million and approximately RMB930.3 million for the year ended December 31, 2020 and 2021, respectively, which are expected to expire in one to ten years for offsetting our future taxable profits.

Inventories

The inventories of the Group consisted of raw materials used in the commercial manufacturing and research and development, work in progress and finished goods. Our inventories remained relatively stable at approximately RMB56.2 million in 2021, as compared to approximately RMB58.9 million in 2020.

The following table sets forth the inventory balances as of the dates indicated:

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	44,348	32,601
Work in progress	3,345	7,871
Finished goods	8,540	18,422
Total	<u>56,233</u>	<u>58,894</u>

Trade Receivables

The Group had approximately RMB26.6 million trade receivables as at December 31, 2020 and RMB53.6 million as at December 31, 2021. The following table sets forth the trade receivables balances as of the dates indicated:

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables	53,622	26,629
Less: Impairment of trade receivables	16	9
Total	<u>53,606</u>	<u>26,620</u>

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 aging analysis of the trade receivables as at the dates indicated, based on the invoice date and net of loss allowance, is as follows:

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	38,676	26,620
3 to 6 months	14,930	—
	<u>53,606</u>	<u>26,620</u>

Prepayments, Other Receivables and Other Assets

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

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Value-added tax recoverable	13,785	19,703
Deposits and other receivables	2,593	2,209
Prepayments	2,340	3,437
Prepaid expenses	2,298	1,846
Interest receivable	–	1,904
Prepaid income tax	–	1,363
Total	<u>21,016</u>	<u>30,462</u>

Our value-added tax recoverable represented the 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 by 30.0% from approximately RMB19.7 million as at December 31, 2020 to approximately RMB13.8 million as at December 31, 2021, which was mainly due to the incremental tax rebate received in 2021.

Our prepayments mainly included our purchase of services. Our prepayments decreased by 31.9% from RMB3.4 million as at December 31, 2020 to RMB2.3 million as at December 31, 2021. Prepayments to suppliers as at December 31, 2021 are due within one year. None of the above assets is past due or impaired.

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

Fair Value and Fair Value Hierarchy of Financial Instruments

The financial assets at fair value through profit or loss of the Group amounted to RMB5.2 million as at December 31, 2021.

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

Cash and Cash Equivalents

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

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Cash and bank balances	1,727,411	1,256,267
Time deposits	768,085	1,457,744
Total	<u>2,495,496</u>	<u>2,714,011</u>

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

Trade and Bills Payables

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

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	1,054	334
Bills payable	–	596
Total	<u>1,054</u>	<u>930</u>

An aging analysis of the trade and bills payables as at the end of the Reporting Period, based on the invoice date, is as follows:

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	648	930
3 to 6 months	406	–
	<u>1,054</u>	<u>930</u>

Other Payables and Accruals

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

	December 31, 2021	December 31, 2020
	<u>RMB'000</u>	<u>RMB'000</u>
Other payables	34,344	36,760
Accrued expenses	25,240	11,960
Payroll payable	23,095	19,122
Taxes other than income tax	3,959	659
Refund liabilities	123	1,473
Total	<u>86,761</u>	<u>69,974</u>

Our other payables remained relatively stable and decreased slightly from RMB36.8 million as at December 31, 2020 to RMB34.3 million as at December 31, 2021.

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

The accrued expenses as at December 31, 2021 mainly represented the accrued research and development 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 represented 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:

	December 31, 2021	December 31, 2020
	<u>RMB'000</u>	<u>RMB'000</u>
Government grants		
– Current	1,588	1,724
– Non-current	8,734	11,207
Total	<u>10,322</u>	<u>12,931</u>

Liquidity and Capital Resources

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

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

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Net cash used in operating activities	(146,930)	(84,911)
Net cash (used in)/ from investing activities	(274,492)	132,297
Net cash used in financing activities	(31,098)	(21,670)
Net (decrease)/increase in cash and cash equivalents	(452,520)	25,716
Cash and cash equivalents at the beginning of year	2,210,504	2,295,044
Effect of foreign exchange rate changes, net	(30,573)	(110,256)
Cash and cash equivalents at the end of year	<u>1,727,411</u>	<u>2,210,504</u>

As at December 31, 2021, our cash and cash equivalents were mainly denominated in Renminbi, USD and HKD.

Operating Activities

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

For the year ended December 31, 2021, we had net cash flows used in operating activities of approximately RMB146.9 million, primarily as a result of operating loss before changes in working capital of approximately RMB161.2 million. The negative changes in working capital are mainly due to (i) bank interest received of approximately RMB24.4 million; (ii) an increase in trade receivables of approximately RMB27.0 million in relation to our product sales; and (iii) an increase in trade and bills payables and other payables and accruals of approximately RMB16.9 million.

Investing Activities

Our cash used in investing activities mainly consisted of 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 year ended December 31, 2021, our net cash used in investing activities was approximately RMB274.5 million, primarily attributable to an increase in time deposits with original maturity of over three months of approximately RMB264.6 million.

Financing Activities

Our cash used in financing activities primarily related to our corporate financings during the Reporting Period.

For the year ended December 31, 2021, our net cash flows used in financing activities was approximately RMB31.1 million, primarily attributable to repurchase of shares in an aggregate consideration of approximately RMB28.7 million.

Capital Expenditures

The principal capital expenditures of the Group primarily consisted of plant and machinery, the purchase of office equipment and expenditures for construction in progress. The following table sets forth our net capital expenditures as at the dates indicated:

	December 31, 2021	December 31, 2020
	<i>RMB'000</i>	<i>RMB'000</i>
Plant and machinery	2,764	852
Office equipment	1,758	720
Construction in progress	34	3,350
Total	<u>4,556</u>	<u>4,922</u>

Significant Investments, Material Acquisitions and Disposals

In 2019, AP11 Limited, a wholly-owned subsidiary of the Company, entered into a capital increase agreement with Sagimet Biosciences. On December 21, 2020, AP11 Limited increased investment into Sagimet Biosciences. As at December 31, 2021, AP11 Limited held approximately 9.84% of the equity interest in Sagimet Biosciences. The Group recognizes such investment as an investment in an associate to which the equity method is applied.

Indebtedness

Borrowings

As at December 31, 2021, the Group did not have any indebtedness. The undrawn bank facilities was RMB200.0 million as at the same date.

As at December 31, 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 December 31, 2021, the Group was not involved in any material legal, arbitration or administrative proceedings, or any contingent liabilities or charges of assets and guarantees, that, if adversely determined, 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 three years.

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

The Group had RMB2.1 million of capital commitment as at December 31, 2021 and nil capital commitment at December 31, 2020.

Key Financial Ratios

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

	December 31, 2021	December 31, 2020
Current ratio ⁽¹⁾	28.9	38.4
Quick ratio ⁽²⁾	28.3	37.6
Gearing ratio ⁽³⁾	3.6%	2.8%

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.
- (3) Gearing ratio represents total liabilities divided by total assets as of the same date and multiplying by 100%.

Our current ratio decreased from 38.4 as at December 31, 2020 to 28.9 as at December 31, 2021, and our quick ratio decreased from 37.6 as at December 31, 2020 to 28.3 as at December 31, 2021, primarily due to a decrease in current asset. Our gearing ratio increased from 2.8% as at December 31, 2020 to 3.6% as at December 31, 2021.

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 the 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 from foreign currencies, including the USD, has been based on rates set by the People's Bank of China. The Group seeks 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 December 31, 2021, the Group had a total of 266 employees, 257 of which were located in the PRC. Over 64% of our employees obtained a bachelor's degree or higher. The table below sets forth our Group's employees by function as disclosed:

	As at December 31, 2021	
	Numbers of employees	% of total
Management	6	2
Research and development	117	44
Commercialization	70	26
Manufacturing	25	10
Operations	48	18
Total	266	100

Our Group's total staff costs for the year ended December 31, 2021 was approximately RMB110.6 million, compared to approximately RMB94.1 million for the year ended December 31, 2020.

We 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 for our employees 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.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

Year ended 31 December 2021

		2021	2020
	<i>Notes</i>	<i>RMB'000</i>	<i>RMB'000</i>
REVENUE	4	76,876	35,001
Cost of sales		(37,703)	(58,498)
<i>including royalties</i>		8	1,322
Gross profit/(loss)		39,173	(23,497)
Other income and gains	4	65,891	89,856
Selling and distribution expenses		(20,872)	(27,356)
Research and development costs		(213,320)	(109,099)
Administrative expenses		(29,947)	(41,845)
Other expenses		(21,942)	(83,412)
Finance costs		(125)	(135)
Share of loss of an associate		(17,875)	(13,753)
LOSS BEFORE TAX	5	(199,017)	(209,241)
Income tax	6	—	—
LOSS FOR THE YEAR		<u>(199,017)</u>	<u>(209,241)</u>
Attributable to:			
Owners of the parent		<u>(199,017)</u>	<u>(209,241)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted	8	<u>(18.13) RMB cents</u>	<u>(20.12) RMB cents</u>

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CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2021

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
LOSS FOR THE YEAR	<u>(199,017)</u>	<u>(209,241)</u>
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	(1,572)	45,677
Other comprehensive loss 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	<u>(30,430)</u>	<u>(164,014)</u>
OTHER COMPREHENSIVE LOSS FOR THE YEAR, NET OF TAX	<u>(32,002)</u>	<u>(118,337)</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	<u>(231,019)</u>	<u>(327,578)</u>
Attributable to:		
Owners of the parent	<u>(231,019)</u>	<u>(327,578)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2021

	<i>Notes</i>	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		74,237	82,556
Advance payments for property, plant and equipment		412	—
Right-of-use assets		3,272	2,023
Other intangible assets		78,213	90,702
Investment in an associate		41,858	60,915
Long-term deferred expenditure		416	889
		<hr/>	<hr/>
Total non-current assets		198,408	237,085
CURRENT ASSETS			
Inventories	<i>9</i>	56,233	58,894
Trade receivables	<i>10</i>	53,606	26,620
Financial assets at fair value through profit or loss		5,200	—
Prepayments, other receivables and other assets	<i>11</i>	21,016	30,462
Cash and cash equivalents		2,495,496	2,714,011
		<hr/>	<hr/>
Total current assets		2,631,551	2,829,987
CURRENT LIABILITIES			
Trade and bills payables	<i>12</i>	1,054	930
Other payables and accruals		86,761	69,974
Lease liabilities		1,568	1,144
Deferred income	<i>13</i>	1,588	1,724
		<hr/>	<hr/>
Total current liabilities		90,971	73,772

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	<i>Note</i>	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
NET CURRENT ASSETS		<u>2,540,580</u>	<u>2,756,215</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>2,738,988</u>	<u>2,993,300</u>
NON-CURRENT LIABILITIES			
Lease liabilities		1,182	443
Deferred income	<i>13</i>	<u>8,734</u>	<u>11,207</u>
Total non-current liabilities		<u>9,916</u>	<u>11,650</u>
Net assets		<u>2,729,072</u>	<u>2,981,650</u>
EQUITY			
Equity attributable to owners of the parent			
Share capital		746	750
Reserves		<u>2,728,326</u>	<u>2,980,900</u>
Total equity		<u>2,729,072</u>	<u>2,981,650</u>

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

Year ended 31 December 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 2020	754	–	2,913,131	652,928	63,991	(306,587)	3,324,217
Loss for the year	–	–	–	–	–	(209,241)	(209,241)
Other comprehensive loss for the year:							
Exchange differences	–	–	–	–	(118,337)	–	(118,337)
Total comprehensive loss for the year	–	–	–	–	(118,337)	(209,241)	(327,578)
Shares repurchased	–	(19,601)	–	–	–	–	(19,601)
Shares cancelled	(4)	15,079	(15,075)	–	–	–	–
Equity-settled share award and option arrangements	–	–	–	4,612	–	–	4,612
At 31 December 2020	<u>750</u>	<u>(4,522)</u>	<u>2,898,056</u>	<u>657,540</u>	<u>(54,346)</u>	<u>(515,828)</u>	<u>2,981,650</u>

continued/

	Attributable to owners of the parent						Total equity RMB'000
	Share capital RMB'000	Treasury shares* RMB'000	Share premium account* RMB'000	Capital reserve* RMB'000	Exchange fluctuation reserve* RMB'000	Accumulated losses* RMB'000	
At 1 January 2021	750	(4,522)	2,898,056	657,540	(54,346)	(515,828)	2,981,650
Loss for the year	-	-	-	-	-	(199,017)	(199,017)
Other comprehensive loss for the year:							
Exchange differences	-	-	-	-	(32,002)	-	(32,002)
Total comprehensive loss for the year	-	-	-	-	(32,002)	(199,017)	(231,019)
Shares repurchased	-	(28,689)	-	-	-	-	(28,689)
Shares cancelled	(4)	14,502	(14,498)	-	-	-	-
Equity-settled share award and option arrangements	-	-	-	7,130	-	-	7,130
At 31 December 2021	<u>746</u>	<u>(18,709)</u>	<u>2,883,558</u>	<u>664,670</u>	<u>(86,348)</u>	<u>(714,845)</u>	<u>2,729,072</u>

* These reserve accounts comprise the consolidated reserves of RMB2,728,326,000 (2020: RMB2,980,900,000) in the consolidated statement of financial position.

CONSOLIDATED STATEMENT OF CASH FLOWS

Year ended 31 December 2021

	<i>Notes</i>	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
CASH FLOWS FROM			
OPERATING ACTIVITIES			
Loss before tax		(199,017)	(209,241)
Adjustments for:			
Finance costs		125	135
Share of loss of an associate		17,875	13,753
Bank interest income	4	(22,506)	(40,626)
Investment income from financial assets			
at fair value through profit or loss	4	(2,484)	(290)
Loss on disposal of items of property, plant and equipment	5	–	92
Depreciation of property, plant and equipment	5	12,875	12,611
Depreciation of right-of-use assets	5	2,198	2,210
Covid-19-related rent concessions from lessors	5	–	(292)
Amortisation of intangible assets	5	14,472	12,342
Amortisation of long-term deferred expenditure		431	447
Write-down of inventories to net realisable value	5	7,729	45,518
Impairment of an intangible asset	5	–	5,771
Impairment of trade receivables	5	7	(79)
Equity-settled share award and option expense	5	7,130	4,612
		(161,165)	(153,037)
Increase in inventories		(5,068)	(18,373)
Increase in long-term deferred expenditure		(262)	–
(Increase)/decrease in trade receivables		(26,993)	42,984
Decrease in prepayments, other receivables and other assets		7,846	416
Increase/(decrease) in trade payables		124	(5,713)
Increase/(decrease) in other payables and accruals		16,787	(7,085)
Decrease in deferred income		(2,609)	(1,724)
Cash used in operations		(171,340)	(142,532)
Interest received		24,410	57,621
Net cash flows used in operating activities		(146,930)	(84,911)

continued/...

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Net cash flows used in operating activities	<u>(146,930)</u>	<u>(84,911)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of items of property, plant and equipment and construction in progress	(4,968)	(4,922)
Proceeds from disposal of items of property, plant and equipment	–	6
Purchases of intangible assets	(2,230)	(34,038)
Purchase of a shareholding in an associate	–	(19,652)
Purchases of financial assets at fair value through profit or loss	(337,400)	(75,418)
Proceeds from sales of financial assets at fair value through profit or loss	332,200	75,418
Investment income from financial assets at fair value through profit or loss	2,484	290
(Increase)/decrease in time deposits with original maturity of over three months	<u>(264,578)</u>	<u>190,613</u>
Net cash flows (used in)/from investing activities	<u>(274,492)</u>	<u>132,297</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal portion of lease payments	(2,284)	(1,934)
Shares repurchased	(28,689)	(19,601)
Interest paid for lease liabilities	<u>(125)</u>	<u>(135)</u>
Net cash flows used in financing activities	<u>(31,098)</u>	<u>(21,670)</u>

continued/...

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
NET (DECREASE)/INCREASE IN		
CASH AND CASH EQUIVALENTS	(452,520)	25,716
Cash and cash equivalents at beginning of year	2,210,504	2,295,044
Effect of foreign exchange rate changes, net	(30,573)	(110,256)
	<u> </u>	<u> </u>
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u>1,727,411</u>	<u>2,210,504</u>
ANALYSIS OF BALANCES OF		
CASH AND CASH EQUIVALENTS		
Cash and cash equivalents as stated in the consolidated		
statement of financial position	2,495,496	2,714,011
Non-pledged time deposits with original maturity of		
over three months when acquired	(768,085)	(503,507)
	<u> </u>	<u> </u>
Cash and cash equivalents as stated		
in the consolidated statement of cash flows	<u>1,727,411</u>	<u>2,210,504</u>

NOTES TO FINANCIAL STATEMENTS

Year ended 31 December 2021

1. CORPORATE AND GROUP 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.

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with Hong Kong Financial Reporting Standards ("HKFRSs") (which include all Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards ("HKASs") and Interpretations) issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"), accounting principles generally accepted in Hong Kong and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for financial assets at fair value through profit or loss, which have been measured at fair value. These financial statements are presented in RMB and all values are rounded to the nearest thousand except when otherwise indicated.

2.2 ISSUED BUT NOT YET EFFECTIVE HONG KONG FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised HKFRSs, that have been issued but are not yet effective, in these financial statements.

Amendments to HKFRS 3	<i>Reference to the Conceptual Framework¹</i>
Amendments to HKFRS 10 and HKAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture³</i>
HKFRS 17	<i>Insurance Contracts²</i>
Amendments to HKFRS 17	<i>Insurance Contracts^{2,5}</i>
Amendments to HKFRS 17	<i>Initial Application of HKFRS 17 and HKFRS 9 – Comparative Information²</i>
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-current^{2,4}</i>
Amendments to HKAS 1 and HKFRS Practice Statement 2	<i>Disclosure of Accounting Policies²</i>
Amendments to HKAS 8	<i>Definition of Accounting Estimates²</i>
Amendments to HKAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction²</i>
Amendments to HKAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use¹</i>
Amendments to HKAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract¹</i>
Annual Improvements to HKFRSs 2018-2020	Amendments to HKFRS 1, HKFRS 9, Illustrative Examples accompanying HKFRS 16, and HKAS 41 ¹

¹ Effective for annual periods beginning on or after 1 January 2022

² Effective for annual periods beginning on or after 1 January 2023

³ No mandatory effective date yet determined but available for adoption

⁴ As a consequence of the amendments to HKAS 1, Hong Kong Interpretation 5 *Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause* was revised in October 2020 to align the corresponding wording with no change in conclusion

⁵ As a consequence of the amendments to HKFRS 17 issued in October 2020, HKFRS 4 was amended to extend the temporary exemption that permits insurers to apply HKAS 39 rather than HKFRS 9 for annual periods beginning before 1 January 2023

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

	2021 RMB'000	2020 RMB'000
Mainland China	70,951	35,001
Other country	5,925	—
Total	<u>76,876</u>	<u>35,001</u>

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

(b) Non-current assets

	2021 RMB'000	2020 RMB'000
Mainland China	146,770	164,360
British Virgin Islands	41,858	60,915
Cayman Islands	9,714	11,810
United States	66	—
Total	<u>198,408</u>	<u>237,085</u>

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

Information about a major customer

Revenue of RMB70,918,000 (2020: RMB64,603,000) was derived from the rendering of promotion services to a single customer during the year.

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2021 RMB'000	2020 RMB'000
Revenue from contracts with customers	<u>76,876</u>	<u>35,001</u>

Revenue from contracts with customers

(i) Disaggregation of revenue information

	2021 RMB'000	2020 RMB'000
Types of goods or services		
– Sale of products	33	(29,602)
– Promotion service revenue	70,918	64,603
– Collaboration revenue	5,925	–
Total revenue from contracts with customers	<u>76,876</u>	<u>35,001</u>

	2021 RMB'000	2020 RMB'000
Timing of revenue recognition		
At a point in time		
– Sale of products	33	(29,602)
– Promotion service revenue	70,918	64,603
– Collaboration revenue	5,925	–
Total revenue from contracts with customers	<u>76,876</u>	<u>35,001</u>

	2021 RMB'000	2020 RMB'000
Geographical markets		
Mainland China		
– Sale of products	33	(29,602)
– Promotion service revenue	70,918	64,603
Other country		
– Collaboration revenue	5,925	–
Total revenue from contracts with customers	<u>76,876</u>	<u>35,001</u>

The following table shows the amount of revenue recognised during the reporting period that was included in the contract liabilities at the beginning of the reporting period and recognised from performance obligations satisfied in previous periods:

	2021 RMB'000	2020 RMB'000
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Sale of products	<u>–</u>	<u>–</u>

(ii) Performance obligations

Information about the Group's performance obligations is summarised below:

Sale of products

The performance obligation is satisfied upon acceptance of the products and payment is generally due within 30 to 90 days from acceptance.

Promotion services

The performance obligation is satisfied at a point in time when the customer's sales occur and payment is generally due within 60 days from the date of billing.

Collaboration revenue

The performance obligation is satisfied at a point in time as output generated from the development activities is accepted by the collaboration partner, and payment is generally due within 30 days from the date of billing.

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
<u>Other income and gains</u>		
Government grants*	40,883	48,861
Bank interest income	22,506	40,626
Investment income from financial assets at fair value through profit or loss	2,484	290
Others	18	79
	<u>65,891</u>	<u>89,856</u>

* The government grants mainly represent subsidies received from the local governments for the purpose of compensation for expenses arising from research activities and clinical trials, awards for new drug development and capital expenditure incurred on certain projects.

5. LOSS BEFORE TAX

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

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Cost of inventories sold	7,931	27,734
Cost of services provided	29,772	30,764
Depreciation of property, plant and equipment	12,875	12,611
Depreciation of right-of-use assets	2,198	2,210
Amortisation of intangible assets*	14,472	12,342
Write-down of inventories to net realisable value**	7,729	45,518
Lease payments not included in the measurement of lease liabilities	64	19
Auditor's remuneration	2,290	2,190
Research and development costs	213,320	109,099
Government grants	(40,883)	(48,861)
Covid-19-related rent concessions from lessors	–	(292)
Donation	5,480	31,789
Foreign exchange differences, net	16,439	30,425
Impairment of an intangible asset	–	5,771
Impairment of trade receivables, net	7	(79)
Loss on disposal of items of property, plant and equipment	–	92
Employee benefit expenses (excluding directors' and chief executive's remuneration):		
Wages and salaries	63,973	62,835
Pension scheme contributions	14,388	9,077
Staff welfare expenses	2,644	3,876
Equity-settled share award and option expense	7,130	4,612
	<u>88,135</u>	<u>80,400</u>

- * The amortisation of intangible assets is included in “Administrative expenses” and “Research and development costs” in the consolidated statement of profit or loss.
- ** The write-down of inventories to net realisable value of RMB7,729,000 for the year ended 31 December 2021 (2020: RMB45,518,000) is included in “Cost of sales” and “Other expenses” in the consolidated statement of profit or loss.

6. INCOME TAX

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

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

British Virgin Islands

Under the current laws of the British Virgin Islands (“BVI”), PowerTree is not subject to tax on income or capital gains. In addition, upon payments of dividends by PowerTree to its shareholder, no BVI withholding tax is imposed.

Hong Kong

Under the current laws of the Hong Kong, the subsidiary in Hong Kong is subject to profits tax at a rate of 16.5% (2020: 16.5%) on the estimated assessable profits arising in Hong Kong. During the year, no provision for profits tax has been made as the subsidiary did not generate any assessable profits in Hong Kong.

United States

Under the current laws of the United States, the subsidiary in the United States is subject to tax at a maximum of 21% (2020: 21%) federal corporate income tax rate and 2.5% (2020: 2.5%) North Carolina state tax rate. During the year, no provision for income tax has been made as the subsidiary did not generate any assessable income in United States.

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% (2020: 25%) on the taxable income. Preferential tax treatment is available to Ascleitis Pharmaceuticals since it was recognised as a High and New Technology Enterprise, and it was entitled to a preferential tax rate of 15% (2020: 15%) during the year. Gannex Pharma, Ascleitis Biopharma and Ascleitis XinNuo are qualified as Small and Micro Enterprises and were subject to a preferential tax rate of 2.5% (2020: 5%) during the year.

The income tax of the Group for the year is analysed as follows:

	2021 RMB'000	2020 RMB'000
Current tax:		
Charge for the year	—	—
Deferred tax	—	—
	—	—
Total tax for the year	—	—

A reconciliation of the tax applicable to loss before tax at the statutory rate in Mainland China to the tax at the effective tax rate is as follows:

	2021 RMB'000	2020 <i>RMB'000</i>
Loss before tax	(199,017)	(209,241)
At the PRC's statutory income tax rate of 25%	(49,754)	(52,310)
Effect of tax rate differences in other countries	5,771	371
Preferential income tax rates enacted by local authority	18,660	21,257
Effect of tax concessions and allowances	(23,979)	(10,625)
Tax losses not recognised	45,151	39,161
Expenses not deductible for tax	4,151	2,146
Tax at the Group's effective rate	—	—

7. DIVIDENDS

The board does not recommend the payment of any dividend in respect for the year ended 31 December 2021 (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 for the year attributable to ordinary equity holders of the parent of RMB199,017,000 (2020: RMB209,241,000), and the weighted average number of ordinary shares of 1,097,608,054 (2020: 1,040,055,731) in issue during the year. The number of shares for the current year has been arrived at 1,094,448,000 after eliminating the shares repurchased.

No adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2020 and 2021 in respect of a dilution as the impact of the share award had an anti-dilutive effect on the basic loss per share amount presented.

9. INVENTORIES

	2021 RMB'000	2020 <i>RMB'000</i>
Raw materials	44,348	32,601
Work in progress	3,345	7,871
Finished goods	8,540	18,422
	56,233	58,894

10. TRADE RECEIVABLES

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Trade receivables	<u>53,622</u>	<u>26,629</u>
Impairment	<u>(16)</u>	<u>(9)</u>
	<u>53,606</u>	<u>26,620</u>

The Group's trading terms with its customers are mainly on credit. The credit period is generally 30 days to 90 days. The Group seeks to maintain strict control over its outstanding receivables and overdue balances are reviewed regularly by senior management. In view of the before mentioned and the fact that the Group's trade receivables relate to large number of diversified customers, there is no significant concentration of credit risk. Trade receivables are non-interest-bearing.

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:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Within 3 months	38,676	26,620
3 to 6 months	<u>14,930</u>	<u>—</u>
	<u>53,606</u>	<u>26,620</u>

The movement in the loss allowance for impairment of trade receivables is as follows:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
At beginning of year	9	88
Impairment losses, net	<u>7</u>	<u>(79)</u>
At end of year	<u>16</u>	<u>9</u>

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions.

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

As at 31 December 2021

		Past due			
	Current	Less than 3 months	3 to 6 months	over 6 months	Total
Expected credit loss rate	0.03%	—	—	—	0.03%
Gross carrying amount (<i>RMB'000</i>)	53,606	—	—	—	53,606
Expected credit losses (<i>RMB'000</i>)	16	—	—	—	16

As at 31 December 2020

	Current	Past due			Total
		Less than 3 months	3 to 6 months	over 6 months	
Expected credit loss rate	0.03%	–	–	–	0.03%
Gross carrying amount (RMB'000)	26,629	–	–	–	26,629
Expected credit losses (RMB'000)	9	–	–	–	9

11. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	2021 RMB'000	2020 RMB'000
Value-added tax recoverable	13,785	19,703
Deposits and other receivables	2,593	2,209
Prepayments	2,340	3,437
Prepaid expenses	2,298	1,846
Interest receivable	–	1,904
Prepaid income tax	–	1,363
	21,016	30,462

Other receivables mainly represent rental and other deposits. An impairment analysis is performed at each reporting date by applying an expected credit loss rate approach with reference to the historical loss record of the Group. The loss rate is adjusted to reflect the current conditions and forecasts of future economic conditions. As at 31 December 2021 and 2020, the expected credit loss rate was close to zero.

The financial assets included in the above balances are non-interest-bearing, unsecured and repayable on demand and relate to receivables for which there was no recent history of default and past due amounts. As at 31 December 2021 and 2020, the loss allowance was assessed to be minimal.

12. TRADE AND BILLS PAYABLES

	2021 RMB'000	2020 RMB'000
Trade payables	1,054	334
Bills payable	–	596
	1,054	930

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:

	2021 RMB'000	2020 RMB'000
Within 3 months	648	930
3 to 6 months	406	–
	1,054	930

The trade payables are non-interest-bearing and are normally settled within three months.

The maturity of the bills payable is within six months.

13. DEFERRED INCOME

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Government grants		
Current	1,588	1,724
Non-current	8,734	11,207
	<u>10,322</u>	<u>12,931</u>

The movements in government grants during the year are as follows:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
At beginning of year	12,931	14,655
Amount released	(2,609)	(1,724)
At end of year	<u>10,322</u>	<u>12,931</u>
Current	1,588	1,724
Non-current	8,734	11,207
	<u>10,322</u>	<u>12,931</u>

The grants are related to the subsidies received from the government for the purpose of compensation for expenses arising from research activities and clinical trials, awards for its new drug development and capital expenditure incurred on certain projects.

14. DEFERRED TAX

The movements in deferred tax liabilities and assets during the year are as follows:

2021

Deferred tax liabilities

	Right-of-use assets <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2021	396	396
Deferred tax credited to profit or loss during the year	(170)	(170)
Gross deferred tax liabilities at 31 December 2021	<u>226</u>	<u>226</u>

Deferred tax assets

	Lease liabilities <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2021	396	396
Deferred tax charged to profit or loss during the year	(170)	(170)
Gross deferred tax assets at 31 December 2021	<u>226</u>	<u>226</u>

2020

Deferred tax liabilities

	Right-of-use assets <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2020	785	785
Deferred tax credited to profit or loss during the year	(389)	(389)
Gross deferred tax liabilities at 31 December 2020	<u>396</u>	<u>396</u>

Deferred tax assets

	Lease liabilities <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2020	785	785
Deferred tax charged to profit or loss during the year	(389)	(389)
Gross deferred tax assets at 31 December 2020	<u>396</u>	<u>396</u>

For presentation purposes, certain deferred tax assets and liabilities have been offset in the statement of financial position. The following is an analysis of the deferred tax balances of the Group for financial reporting purposes:

	2021 <i>RMB'000</i>	2020 <i>RMB'000</i>
Net deferred tax recognised in consolidated statement of financial position	<u>-</u>	<u>-</u>

The Group has tax losses arising in Mainland China of RMB930,267,000 (2020: RMB762,867,000) that will expire in one to ten years for offsetting against future taxable profits.

Deferred tax assets have not been recognised in respect of these losses as they have arisen in subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

OTHER INFORMATION

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 (which has been re-numbered as code provision C.2.1 of the CG Code since 1 January 2022), 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 announcement. 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

The Company repurchased a total of 12,048,000 Shares on the Stock Exchange during the year ended December 31, 2021 pursuant to the repurchase mandate approved by the Shareholders at the annual general meeting held on June 29, 2021. Such repurchased shares have already been cancelled and the total number of Shares in issue has been reduced accordingly as at the date of this announcement.

Save for the above, neither the Company nor any of its subsidiaries purchased, sold or redeemed interest in any of the Company's listed Shares for the year ended December 31, 2021.

REVIEW OF ANNUAL RESULTS

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 reviewed the annual results of the Group for the year ended December 31, 2021 and has recommended for the Board's approval thereof.

The Audit Committee has reviewed together with the management the accounting principles and policies adopted by the Group and the consolidated financial statements for the year ended December 31, 2021. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

ANNUAL DIVIDEND

The Board does not recommend any payment of an annual dividend for the year ended December 31, 2021.

ANNUAL GENERAL MEETING AND CLOSURE OF REGISTER OF MEMBERS

The Company will announce the date of the AGM and the period of closure of register of members in due course.

PUBLICATION OF ANNUAL RESULTS AND ANNUAL REPORT

This announcement is published on the website of the Stock Exchange (www.hkexnews.hk) and the Company's website (www.ascletis.com). The annual report for the year ended December 31, 2021 containing all the information in accordance with the requirements under the Listing Rules will be despatched to the Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

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.

DEFINITION

“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
“AGM”	annual general meeting of the Company
“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”	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 PRC”	the People’s Republic of China, excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan
“Controlling Shareholders”	has the meaning ascribed thereto under the Listing Rules and unless the context requires otherwise, refers to Dr. Wu, Mrs. Judy Hejingdao Wu, JJW12 Limited, Lakemont Holding LLC and the Lakemont Remainder Trust, as a group, or any member of them
“COVID-19”	An infectious disease caused by a newly discovered coronavirus (severe acute respiratory syndrome coronavirus)
“Director(s)”	the director(s) of the Company
“Dr. Wu”	Dr. Jinzi Jason WU (吳勁梓), our Founder and the spouse of Mrs. Judy Hejingdao Wu, chairman of the Board, chief executive officer, an executive Director of the Company, one of our Controlling Shareholders
“FASN”	fatty acid synthase
“FDA”	U.S. Food and Drug Administration
“FXR”	Farnesoid X receptor
“Gannex Pharma”	Gannex Pharma Co., Ltd. (甘萊製藥有限公司), a limited liability company incorporated under the laws of the PRC on September 3, 2019, a wholly-owned subsidiary of the Company
“Group”, “our Group” or “the Group”	the Company and its subsidiaries
“Greater China”	Mainland China, Hong Kong, Macau and Taiwan
“HCV”	hepatitis C virus

“HK\$” or “HKD”	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
“IFRS”	International Financial Reporting Standards
“IND(s)”	investigational new drug(s), (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
“KOL(s)”	Key opinion leader(s)
“Listing”	the listing of the Shares on the Main Board of the Stock Exchange on August 1, 2018
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time
“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
“NASH”	non-alcoholic steatohepatitis
“NDA”	new drug application
“NMPA”	China National Medical Products Administration (中國國家藥品監督管理局)
“NS3/4A”	a protease that plays an essential role in translation and polyprotein processing during the HCV viral replication process
“NS5A”	non-structural protein 5A, a zinc-binding and proline-rich hydrophilic phosphoprotein that plays a key role in HCV RNA replication
“PBC”	primary biliary cholangitis
“PD-L1”	programmed death ligand1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T-cell that causes the T-cell to turn off its ability to kill the cancer cell
“Omicron variant”	variant of lineage B.1.1.529 of SARS-Co-2, the virus that causes COVID-19
“RdRp”	RNA-dependent RNA polymerase
“Reporting Period”	the one-year period from January 1, 2021 to December 31, 2021
“Renminbi” or “RMB”	Renminbi Yuan, the lawful currency of the PRC

“Roche”	F. Hoffmann-La Roche AG, a Swiss multi-national healthcare company
“SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended or supplemented from time to time
“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
“U.S.”	United States of America, its territories, its possessions and all areas subject to its jurisdiction
“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 announcement, 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
Asclepis Pharma Inc.
 歌禮製藥有限公司
Jinzi Jason WU
Chairman

Hangzhou, the People’s Republic of China, March 21, 2022

As at the date of this announcement, the Board 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.