

Ascleitis Pharma (1672.HK)

2022 Annual Results & Recent Update

March 20th, 2023





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Appendix--R&D Pipeline

Summary of 2022 Annual Results

Key R&D Pipeline	2022 Major Milestones	Performance in 2022	Anticipated 2023 Major Milestones
ASC40 ACNE	Completed 180 patients enrollment for Phase II clinical trial	√	Announce the Phase II clinical results and initiate Phase III clinical trial
ASC22 CHB	Had Pre-Phase III meeting with the CDE of China NMPA and dosed the first patient in the Phase IIb expansion cohort	√	Announce the topline interim results from Phase IIb expansion cohort
ASC40 NASH	Presented positive interim results from Phase IIb clinical trial of ASC40 in biopsy-confirmed NASH patients with 52 weeks of treatment at The Liver Meeting of AASLD 2022	√	Present Phase IIb topline clinical results from 168 biopsy-confirmed NASH patients after 52 weeks of treatment
ASC41 NASH	Dosed the first patient in Phase II clinical trial for NASH of ASC41 (THR-β)	√	Announce topline interim results of liver fat reduction, LDL-C reduction, liver enzymes and biomarkers of approximately 40 NASH patients after 12-week treatment
ASC40 rGBM	Completed 80% patient enrollment in the Phase III clinical trial	×	Complete the enrollment of ~120 rGBM patients in Phase III clinical of ASC40 (FASN), which is needed for the planned interim analysis with 93 PFS events.

ASC10 RSV

Obtained U.S. FDA approval of conducting Phase IIa clinical trial

√

Phase IIa clinical results of ASC10 for RSV in China or US



Pipeline

Positive progress has been made from six Phase II or III projects in multiple disease such as Acne/HBV/NASH/rGBM/RSV



R&D

R&D expenses increased by 25.2% from 2021 to 2022, which was RMB 0.27 billion; obtained 13 new IND* approvals, 2 pipelines entered Phase II, and filed 23 new patent applications*



BD

Signed commercial supply agreements of ritonavir with multiple companies;
Actively promoted global cooperation across multiple pipelines



Team

Appointed Mr. John P. Gargiulo, the former senior management of Daiichi Sankyo, as Chief Business Officer;
R&D staff increased by 42% year-on-year



Financials

Cash and cash equivalents of RMB 2.47 billion, sufficient to support our R&D activities and operations until 2027



Capital Markets

Included in MSCI China Small Cap Index and Hang Seng Hong Kong-Listed Biotech Index



*As of the date of March 20, 2023

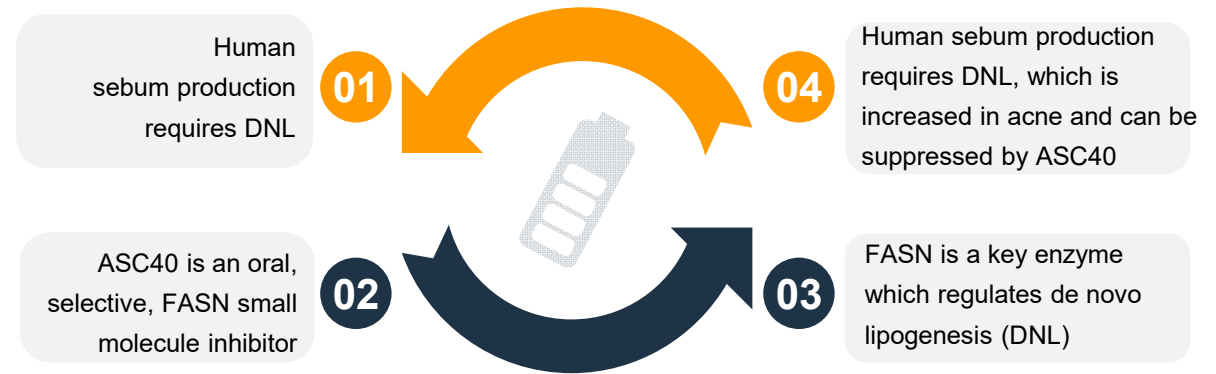
Pipeline Highlights | ASC40 (FASN) for Acne: Phase II Results Expected in Q2, 2023

Acne is a huge market

- Acne is the eighth most prevalent disease in the world and affects more than 640 million people globally
- Among which, 25%-35% are moderate to severe acne

	Adolescent acne, %	Adult acne	
		Persistent acne, %	Late-onset acne, %
Gender distribution			
Male	63.2	47.4	31.6
Female	36.8	52.6	68.4
Severity of acne			
Mild	68.9	64.9	77.2
Moderate	25.6	28.4	21.1
Severe	5.5	6.7	1.8
Premenstrual flare-up (female)	47.5	54.7	38.5

ASC40's Innovative Mechanism for Acne Treatment



China Phase II Clinical Trial Design for ASC40

Moderate to severe acne patients Total=180	Placebo	Once daily	Follow-up
	25 mg ASC40	Once daily	Follow-up
	50 mg ASC40	Once daily	Follow-up
	75 mg ASC40	Once daily	Follow-up
	D1	W12	W14
Primary Endpoints	<ul style="list-style-type: none"> Percentage change in total lesion count from baseline at week 12 of the treatment Percentage change in inflammatory lesion count from baseline at week 12 of the treatment Percentage of patients with a decrease of ≥ 2 points from baseline in the investigator's overall static score (IGA) and reached 0 or 1 point at week 12 of the treatment 		

Clinical efficacy of ASC40's Phase II in 3 Acne Patients under Blind Condition

	Baseline period		After 12-week treatment		% change from baseline after 12-week treatment	
	inflammatory skin lesions	total skin lesions	inflammatory skin lesions	skin lesions	inflammatory skin lesions	total skin lesions
Subject 1	68	155	4	32	-94.12%	-79.35%
Subject 2	38	136	7	16	-81.58%	-88.24%
Subject 3	36	133	6	13	-83.33%	-90.23%

Potentially a New Choice for Moderate to Severe Acne Patients

All 180 patients enrolled in ASC40 Phase II clinical trial for acne have finished 12-week treatment and 2-week follow-up. The study is still under blind

Good safety and tolerability. Most TRAEs are Grade 1. Potentially better option as existing acne drugs may cause liver injury

Under blind:

- Total/inflammatory skin lesions of 149 subjects who completed 12 weeks of treatment including placebo were superior to those of the FDA approved WINLEVI®
- Inflammatory skin lesions, non inflammatory skin lesions were similar to FDA approved TWYNEO®

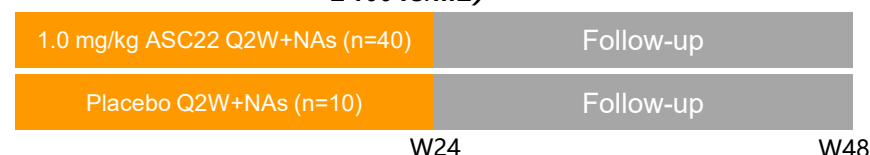
Pipeline Highlights | Interim Data of Phase IIb Expansion Cohort of ASC22 (PD-L1) for CHB Functional Cure to be Released in Q3, 2023

ASC22 (Envafohimab) is the most advanced clinical-stage immunotherapy in the world for CHB functional cure through blocking PD-1/PD-L1 pathway.

- Progress:** As of March 20, 2023, 29 patients with baseline HBsAg ≤ 100 IU/mL have been enrolled in the Phase IIb Expansion Cohort. The enrollment of 50 patients is expected to be completed in early May, 2023.
- Efficacy:** In the Phase IIb study, **43% (3/7)** of patients with baseline HBsAg ≤ 100 IU/mL obtained HBsAg loss and no rebound occurred up to now after the last dosing of ASC22, indicating HBV functional cure.
- Safety:** 1 mg/kg ASC22 Q2W plus NAs group had a rate of any adverse events of 75% which was comparable to that of the placebo Q2W plus NAs group.

- The pathway to the registration of ASC22 has been agreed:** Phase IIb study will enroll more patients to confirm whether the functional cure rate of ASC22 meets the regulatory requirement (about 30%).

Phase IIb Expansion Cohort: To enroll 50 patients with baseline HBsAg ≤ 100 IU/mL)



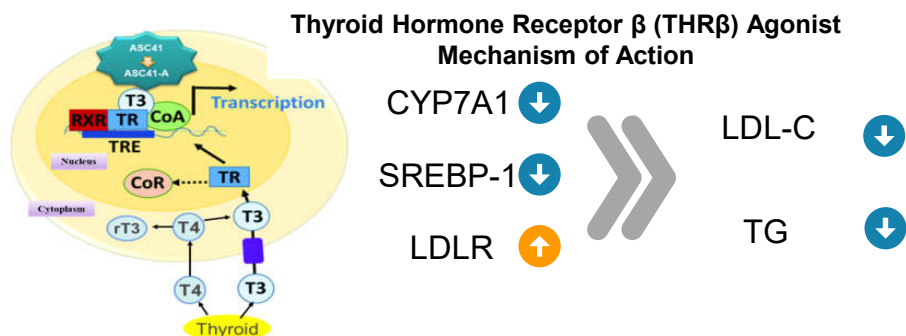
- ASC22 Phase IIa study: “Best of The Liver Meeting’s Summary” (2021 AASLD), ASC22 Phase IIb abstract: Oral Presentation at EASL ILC 2022**

ASC22 (PD-L1) VS Other Treatments for CHB Functional Cure

Drug Candidate	Treatment	Enrollment	HBsAg Loss at the End of Treatment	Functional Cure Rate after Follow-up
ASC22	PD-L1 antibody	1.0 mg/kg: N=60, (Baseline HBsAg ≤ 100 IU/mL: N=7)	Baseline HBsAg ≤ 100 IU/mL: 42.9% (3/7)	Baseline HBsAg ≤ 100 IU/mL: 42.9%
GSK836	ASO	300 mg: N=68	26% (18/68)	9%
BR11-835+BR11-179 ± Interferon	siRNA + vaccine siRNA + vaccine+ interferon	N=20 N=20	5% 0%	Unknown, follow-up is ongoing.

1.Wang GQ, et al, APASL 2023 abstract FP05-26;
 2.Yuen MF, et al. N Engl J Med. 2022.;
 3.Yuen MF, et al. APASL 2023 abstract FP13-68

Pipeline Highlights | ASC41 (THR-β) Phase II Topline Interim Results from ~40 NASH Patients after 12-Week Treatment Expected in Q3, 2023



ASC41 Phase II Design		
Biopsy-confirmed NASH patients with moderate to advanced fibrosis (F1-F3), N=180	Placebo, QD	Follow up
	2 mg ASC41, QD	Follow up
	4 mg ASC41, QD	Follow up
Primary Endpoint	NAFLD activity score (NAS) improvement ≥2 points (improvement in inflammation or ballooning) and no worsening of fibrosis	

Timeline: D1, Biopsy; Week 52, Biopsy; Week 54

ASC41-Phase II Clinical Trial is Progressing Quickly

ASC41 VS VK2809

	ASC41 ^[1]	VK2809 ^[2]
Oral formulation	Tablet, room temp storage, commercially ready	Capsule, refrigerated
Dosing frequency	Once a day	Once every two days
Drug-Drug Interaction	Weak	Strong
Human dose needed for > 30% TG reduction	1 mg	2.5 mg

ASC41 Owns Various Patents^[3]

Category	Application Date	Publication Number	Patents Applied	Patents Authorized	Pending
Formulation Patent (Tablet)	2020/3/27	US20210308155A1 (U.S.) CN115427022A (China) WO2021190624A1 (PCT)	U.S., China and Globally	\	U.S., China and Globally
Formulation Patent (Capsule)	2020/2/20	US11583502B2 (U.S.) CN113274368A (China)	U.S. and China	U.S.	China
Crystal Patent	2020/9/30	CN114315902A (China) WO2022067602A1 (Globally)	China and Globally	\	China and Globally
Synthesis Patent	2020/2/18	US11292805B2 (U.S.) US20220332738A1 (U.S.) CN113336792A (China)	U.S. and China	U.S.	China
Composition Patent	2021/7/6	WO2023280152A1 (PCT)	Globally	\	\

1. EASL 2021 Abstract No. PO-1851

2. EASL 2020 Abstract No. AS073.

3. Patents and patent applications information released as of March 20, 2023

Pipeline Highlights | ASC41 vs Resmetirom on Reduction of LDL-C

Study Design of Ascletis' ASC41 Phase II VS Madrigal's Resmetirom Phase III

	ASC41 Phase II	Resmetirom Phase III
Target	THRβ	THRβ
Dosage	Placebo, ASC41 2 mg, ASC41 4 mg, once daily	Placebo, Resmetirom 80 mg, Resmetirom 100 mg, once daily
Liver-biopsy confirmed?	Yes	Yes
Treatments	52 weeks	52 weeks
Enrollments	180 patients	around 1000 patients
Ratio	1:1:1	1:1:1
Inclusion	NASH on liver biopsy: NASH F1 (up to 15%), F2, or F3, NAS≥4	NASH on liver biopsy: NAS≥4 with fibrosis stage 1A (up to 3%) 1B, total F1 up to 15%; F3, at least 50%, the rest F2
Histology efficacy endpoints	Resolution of NASH at Week 52 with at least 2 point reduction in NAS (improvement in inflammation or ballooning) with no worsening of fibrosis; OR reduction in fibrosis stage by 1-point with no worsening of NAS	Resolution of NASH at Week 52 with at least 2 point reduction in NAS with no worsening of fibrosis; OR reduction in fibrosis stage by 1-point with no worsening of NAS
Key secondary endpoint	LDL-C lowering at Week 12, Week 24, and Week 52	LDL-C lowering at Week 24

Comparison of Key Secondary Endpoint LDL-C Reduction (Not Head to Head)

Dosage	2 mg	5 mg	5 mg	10 mg	20 mg	50 mg	80 mg	100 mg
Drug Candidates	ASC41*	ASC41*	Resmetirom**	ASC41***	Resmetirom**	Resmetirom**	Resmetirom**	Resmetirom**
% Change from baseline after 14-day (mean)	-32.8%	-40.8%	3.2%	-44.8%	8.8%	-11.3%	-25.4%	-20.9%

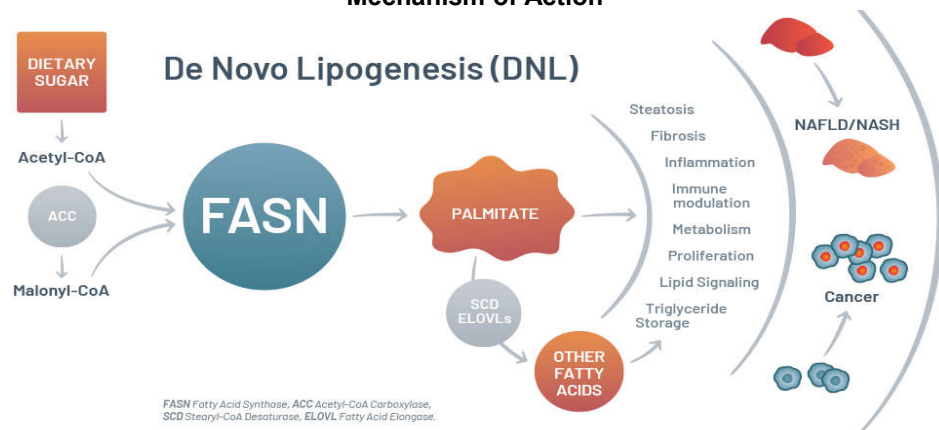
* Data derived from ASC41 Phase I study

** Data derived from Taub et al. Atherosclerosis 230 (2013) 373-380

*** Data derived from ASC41 Phase Ib study

Pipeline Highlights | ASC40 (FASN) Phase IIb Results from Biopsy-Confirmed NASH Patients Expected in Q4, 2023

Fatty Acid Synthase Inhibitor (FASN) Mechanism of Action

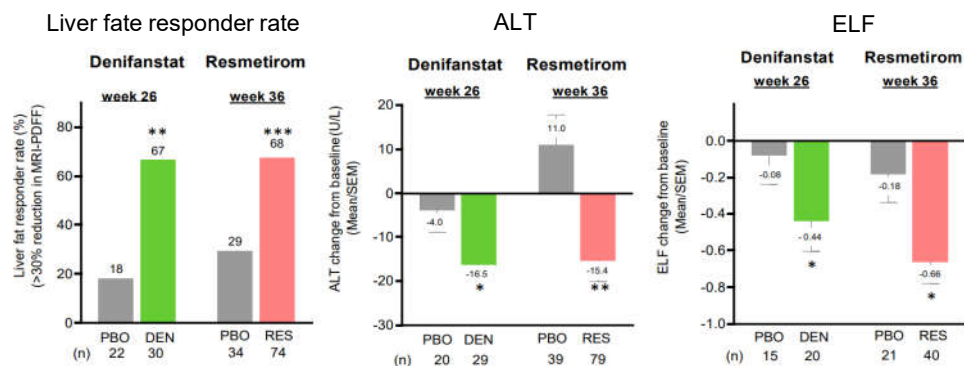


Interim Data from Phase IIb Clinical Trial¹: 67% of Patients Reduced Liver Fat by More Than 30%

ASC40 50 mg (n=30)	ASC40 50 mg (n=30)	Placebo (n=22)	P-value VS placebo
Relative reduction in liver fat	- 34.1%	- 1.5%	$p < 0.002$
≥30% reduction of liver fat (responder rate)	67%	18%	$p < 0.002$
ALT (U/L)	- 16.5	- 4.0	$p < 0.05$
Enhanced liver fibrosis (ELF) score*	- 0.41	- 0.01	$p < 0.05$
LDL cholesterol (mg/dL)	-12.4	0.0	$p < 0.05$

* based upon available data (Denifanstat n=20, placebo=15)

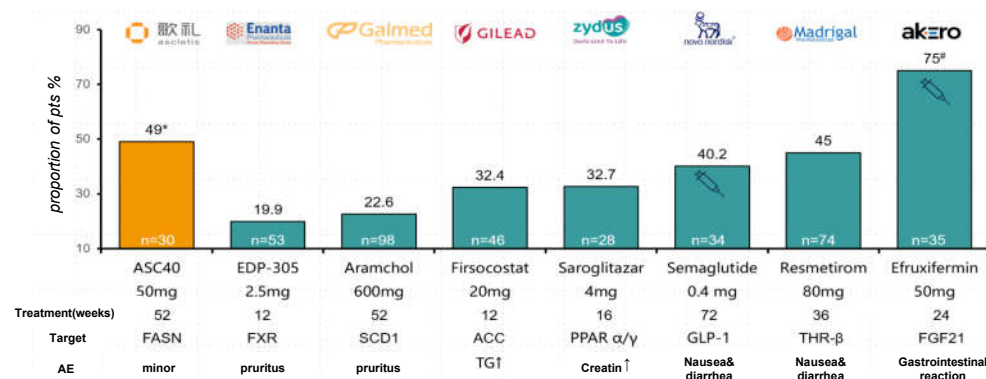
ASC40 26-week Treatment VS Resmetirom 36-week Treatment Significant Improvements Across Key Disease Markers are Comparable



Baseline MRI-PDFF were similar across cohorts with mean of 19-20%.
Baseline ALT were similar across cohorts with mean 30-69 U/L.
Data sources: Denifanstat w26 from FASN/NASH-2 Interim Analysis, Two-sided
CMH test for responder rate, and two-sided ANCOVA for ALT, Resmetirom w36
LSM from PH2, Harrison et al., 2019, Lancet 394:2023-2024.

ASC40-IIb Results in Comparison with Other NASH Candidates

≥30% reduction of liver fat (responder rate, placebo adjusted)



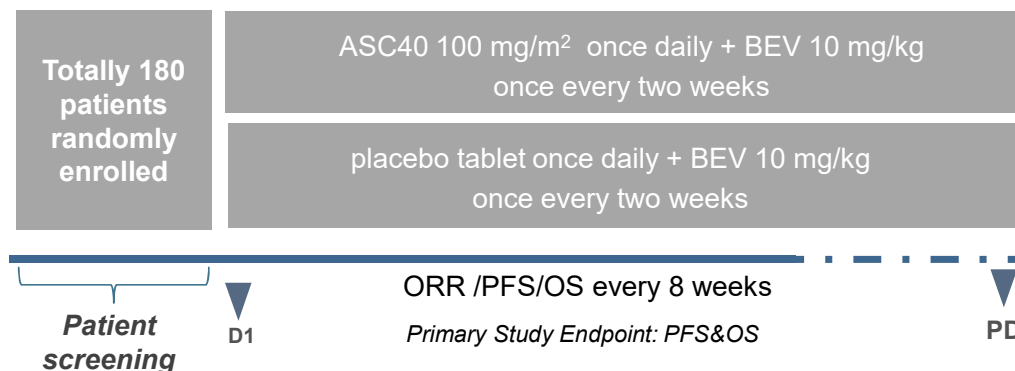
Reference: 1. <https://saqimet.com/saqimet-biosciences-announces-positive-interim-phase-2b-clinical-trial-data-with-denifanstat-tvb-2640-a-first-in-class-fatty-acid-synthase-inhibitor-in-moderate-to-severe-non-alcoholic-steatohepa/>

Pipeline Highlights | ASC40 (FASN) for rGBM: Phase III Clinical Trial Expected to Enroll 120 Patients in Q3, 2023

ASC40-rGBM Outline

- **Highly unmet clinical need:** 90% of patients with rGBM will relapse after basic therapy, the 5-year survival rate is only 5.8%, effective treatment methods are extremely limited
- **Innovative mechanism:** tumor cells are more dependent on de novo synthesis of fatty acids, ASC40 is a FIC targeted FASN inhibitor to explore metabolic mechanisms for the treatment of rGBM
- **Support from top medical centers:** Beijing Tiantan Hospital as the main research unit, 28 well-known hospitals across the country participated in clinical research
- **Phase III clinical progress:** 77 patients have been enrolled as of March 20, 2023, and 120 patients are expected to be enrolled in Q3, 2023, which will meet the cases required for pre-planned midterm analysis (93 PFS events)

The Phase III Clinical Trial of ASC40 for Treatment of rGBM



ASC40 (TVB-2640) + BEV Phase II clinical data indicate: PFS6 was 47%

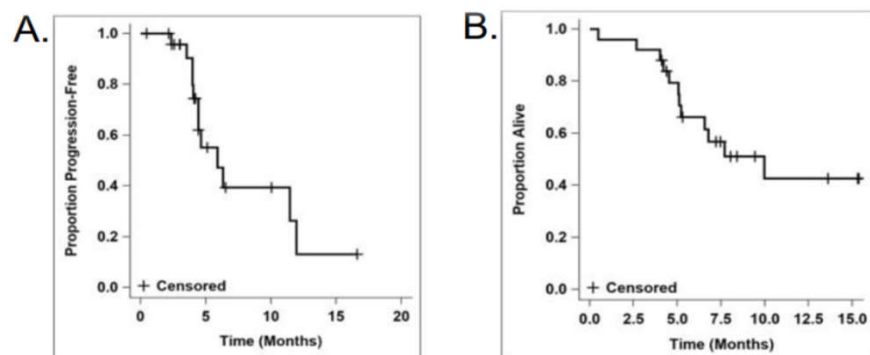


Figure 1. Kaplan-Meier plot of progression (A) and survival (B)

Source:

Press Release on July 22, 2021

William Kelly et.al. TVB-2640 with Bevacizumab in Relapsed High-grade Astrocytoma. ESMO 2020

10

- Of the 25 patients enrolled, all treated with ASC40 (TVB-2640) (100 mg/m² PO QD) plus BEV (10 mg/kg IV D1, 15) until disease progression or toxicity was intolerable
- Representing a statistically significant improvement in PFS over the historical Bevacizumab monotherapy PFS of 16% (BELOB Trial) ($P=0.01$)
- ASC40 (TVB-2640) in combination with BEV was safe and well tolerated for the treatment of rGBM patients

Results Presented at the 2020 Annual Meeting of the ESMO

Objective Response	(ORR) 65%
Complete Response	(CR) 20%
Partial Response	(PR) 45%



Pipeline Highlights | FDA Approved to Conduct Phase IIa Clinical Trial for ASC10 to Treat RSV Infection

RSV poses a persistent threat to infants and the elderly population



RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs) in children younger than 1 year of age in the U.S.^[2]



causes approximately 58,000 hospitalizations among children under five annually^[3]

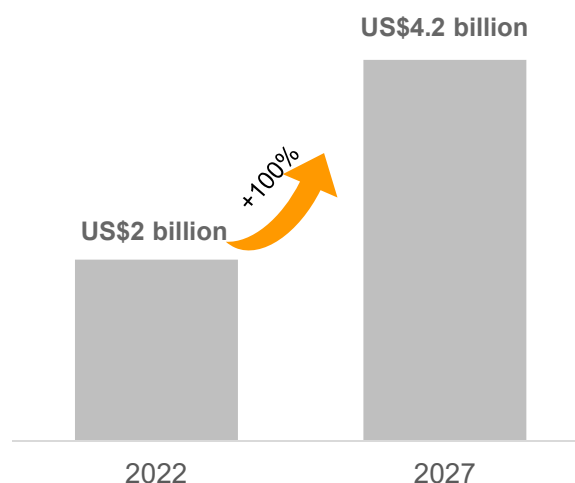


cause about 14,000 annual deaths in U.S. adults over age 65



Globally, RSV affects an estimated 64 million people and causes 160,000 deaths each year^[3]

The global market of RSV therapies is expected to grow rapidly^[4]



ASC10 has shown significant anti-RSV activity in animal and cell experiments



Preclinical research^[1] shows ASC10-A (NHC) has a potent inhibitory effect on RSV



ASC10-A (NHC) is a potent inhibitor with EC₅₀ of 0.51 to 0.6 uM against two RSV clinical isolates using *in vitro* infection assay in HEp-2 cells^[1]



Based on ASC10 Phase I data and anti-RSV preclinical data, the FDA approved the Phase IIa clinical trial

References:

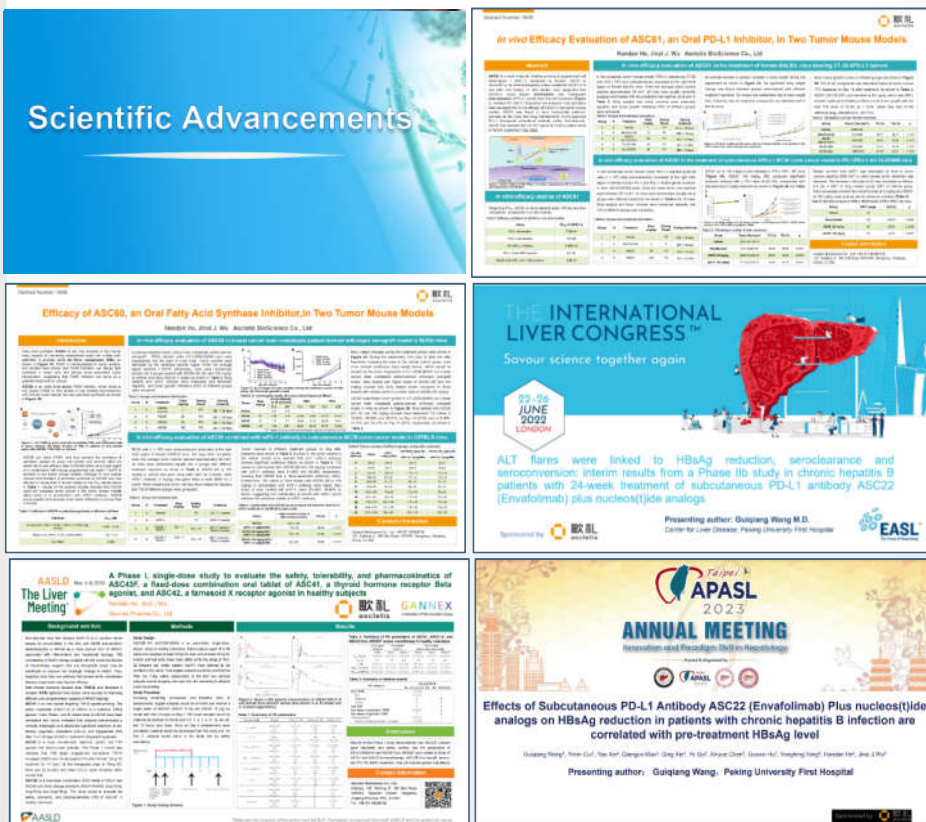
[1] Jeong-Joong Yoon, Mart Toots, Sujin Lee, et al. Orally Efficacious Broad-Spectrum Ribonucleoside Analog Inhibitor of Influenza and Respiratory Syncytial Viruses. *Antimicrob Agents Chemother*. 2018;62(8):e00766-18.

[2] <https://www.cdc.gov/rsv/index.html>

[3] <https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv>

[4] <https://www.astuteanalytica.com/industry-report/respiratory-syncytial-virus-market>

Scientific Advancements



AACR
 American Association
 for Cancer Research

The 2022 Annual Meeting of the AACR

- Poster Presentation of ASC61
- Poster Presentation of ASC60

EASL
 European Association
 for the Study of the Liver

The International Liver Congress™ 2022 of the EASL

- Oral Presentation of ASC22

AASLD
 AMERICAN ASSOCIATION FOR
 THE STUDY OF LIVER DISEASES

The Liver Meeting® 2022 of the AASLD

- Poster Presentation of ASC43F

APASL
 Asian Pacific Association
 for the Study of the Liver

The 2023 Annual Meeting of the APASL

- Oral Presentation of ASC22

High Efficiency of R&D

- R&D expense in 2022 was ~270 RMB mm, 13 new IND approvals*, 6 projects at Phase II or Phase III
- High output in comparison with other biotechs listed in HKEX

6 Projects at Phase II or Phase III

2 Projects starting Phase II clinical trials

5 IND approvals from China NMPA

8 IND approvals from U.S. FDA

New patent applications* **23**

Total patent applications **82**

China patent applications **38**

International patent applications **44**

*As of March 30, 2023

Business Development | Ritonavir Supply Agreements with Multiple Partners

Ritonavir



Ritonavir tablet is a pharmacokinetic booster of multiple oral antiviral protease inhibitors



Currently the only approved ritonavir oral tablets in China which has passed BE study. Well-positioned in the market



Capacity expansion completed, flexible to market demand



Ascletis has entered into supply agreements of ritonavir with multiple partners



Successfully passed the quality audit by various partners and regulatory agencies



Demonstrated strong business development ability

Financials

2022 Full Year Highlights



Cash on hand: **2.5** bn RMB



R&D expense: approx. **270** mm RMB
YoY increase **25.2%**



Net loss: **310** mm RMB



Sufficient cash to support R&D activities
and operations in next **5** years

Sales Updates of Ritonavir*



Ascletis has entered into supply agreements of ritonavir with multiple partners



As of March 20, 2023, the receipt in advance for ritonavir tablets reached ~55 RMB million (tax inclusive) based on irrevocable orders



Ritonavir sales will generate revenue, which will further improve the cashflow

Given the continuous uncertainty of COVID-19 pandemic in 2023, the Company remains cautious on revenue generated from sale of ritonavir tablets for the full year of 2023

*As of March 20, 2023



Anticipated Key Milestones in 2023

Viral Diseases

- **2023 Q3:** Topline interim results from Phase IIb expansion cohort of ASC22 (PD-L1) for functional cure of CHB in patients with the baseline HBsAg \leq 100 IU/mL
- **2023 Q4:** Completion of Phase IIa clinical trial of ASC10 (RdRp) for RSV in the U.S. or China

Oncology

- **2023 Q3:** Complete the enrollment of ~120 rGBM patients in Phase III clinical of ASC40 (FASN), which is needed for the planned interim analysis with 93 PFS events.

NASH

- **2023 Q3:** Topline interim results from Phase II clinical trial of ASC41 (THR- β) of liver fat reduction, LDL-C reduction, liver enzymes and biomarkers of approximately 40 NASH patients after 12-week treatment
- **2023 Q4:** Phase IIb topline clinical results from 168 biopsy-confirmed NASH patients of Phase II clinical trial of ASC40 (FASN) after 52 weeks of treatment

Acne

- **2023 Q2:** Topline Phase II clinical results of ASC40 (FASN) for treatment of acne
- **2023 Q4:** Initiation of Phase III clinical trial of ASC40 (FASN) for treatment of acne

Global Collaboration

Oral Drugs for COVID-19

- ✓ ASC10 (RdRp)
- ✓ ASC11 (3CL)

CHB Functional Cure

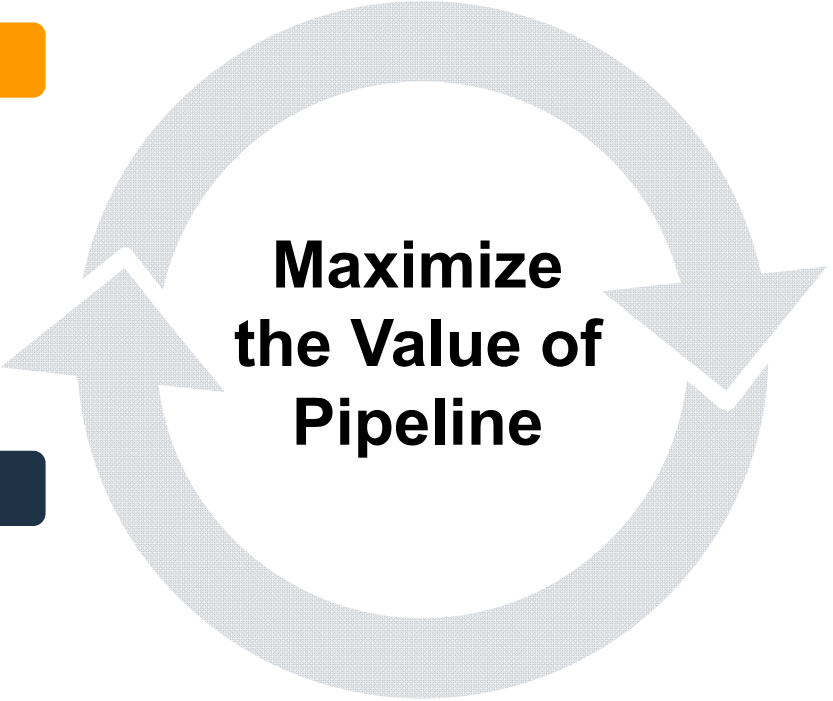
- ✓ ASC22 (PD-L1)

NASH

- ✓ ASC41 (THR- β)

Moderate to Severe Acne

- ✓ ASC40 (FASN)



**Maximize
the Value of
Pipeline**



Appendix—R&D Pipeline

Viral Diseases

	Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III
Viral diseases	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					
	ASC22 (Subcutaneous mAb) +Chidamide	PD-L1	HIV functional cure	Global ¹					
	ASC10 (Oral small molecule)	RdRp	COVID-19	Global					
	ASC10 (Oral small molecule)	Viral polymerase	Monkeypox	Global					
	ASC10 (Oral small molecule)	Viral polymerase	Respiratory syncytial virus	Global					
	ASC11 (Oral small molecule)	3CLpro	COVID-19	Global					

Notes:

1. ASC22 is licensed from Suzhou Alphamab Co.,Ltd. for global exclusive rights.

NASH/PBC

	Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III
NASH & PBC	ASC40 (Oral small molecule)	FASN	NASH	Greater China ¹	U.S. FDA Fast Track				
	ASC41 (Oral small molecule)	THRβ	NASH	Global					
	ASC42 (Oral small molecule)	FXR	NASH	Global	U.S. FDA Fast Track				
	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:

1. NASH/PBC pipeline is owned by Gannex Pharma Co., Ltd., a wholly-owned subsidiary of Ascleitis Pharma Inc.(1672.HK).
2. ASC40 is licensed from Sagimet Biosciences Inc. for the exclusive rights in the Greater China.

Oncology

	Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	POC	Pivotal
Oncology	ASC40 (Oral small molecule) +Bevacizumab	FASN + VEGF	rGBM	Greater China ¹					
	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	Advanced solid tumors	Greater China ¹					
	ASC60 (Oral small molecule)	FASN	Solid tumor 2	Greater China ¹					
	ASC63 (Oral small molecule)	PD-L1	Advanced solid tumors	Global					

Notes:

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

Exploratory Indications

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

Notes:

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