



GNI Group Ltd

Group Introduction

We Bring New Hope to Patients

December 3, 2024

Securities Code: TSE:2160

GNI Group Snapshot

A Tokyo Stock Exchange-listed (TSE 2160) Biopharmaceutical Company since 2007
Innovative Drugs and Medical Devices to Deliver Life-saving Solutions to Patients across the World

<p>2160.T Group Company listed on Tokyo Stock Exchange</p>	<p>GYRE.US Pharma subsidiary Gyre Therapeutics listed on NASDAQ</p>
<p>3 Disease areas focused Fibrosis/Cancers/Orthopedics</p>	<p>3 Major geographical operations China/US/Japan</p>

<p>JPY26.0bn (USD 184.9mn) FY2023 group revenue</p>	<p>+49.3% YoY revenue growth from FY2022</p>
<p>JPY13.1bn (USD 93.2mn) FY2023 group operating profit</p>	<p>+851.3% YoY operating profit growth from FY2022</p>

Steady-expansion business with footholds in China, US, and Japan without additional capital need to fund operations

Global R&D strategy with productivity and efficiency to bring innovative products in inflammatory diseases and cancer to markets

Strategic M&A investments to explore new opportunities in China, US and Japan for long-term stable growth

Three Core Strategic Holdings of GNI Group



Positioned as a Global Biopharmaceutical Company with Three Integrated Businesses across **Pharma**, **Biotech** and **Medtech**

Pharma



Anti-fibrosis and Inflammation Platform

Commercialization / Late-stage

- ✓ Etuary® is the **market leading drug for idiopathic pulmonary fibrosis** (IPF) in China
- ✓ Late-stage proof-of-concept anti-fibrotic agent (F351) to address **huge unmet medical needs in liver fibrosis globally**
- ✓ **Successful commercialization** lays the foundation for future product launches
- ✓ **Listed** on NASDAQ

Biotech



TPD Technology Platform

Innovative Drug Discovery

- ✓ Proprietary **uSMITE™** targeted protein degradation platform featuring novel E3 ligands
- ✓ Inked **strategic collaboration with Astellas** with \$35 million upfront received
- ✓ Well-funded with **\$100 million+** raised since inception from renowned investors, including AZ-CICC Fund
- ✓ Reverse merger with PULM to list on NASDAQ

Medtech



Biomaterials Solutions

Profitable and High Growth Operation

- ✓ **Steady cash flow generation** from orthobiologics business with high entry barrier
- ✓ **Multiple growth levers** through application expansion and bolt-on acquisitions
- ✓ Tapping into **medical aesthetic market** via synergistic operation with **OsDerma Medical**
- ✓ **Acquired** new operation from Elutia

Group Connectivity for Flexibility, Risk Management, Early Commercialization, and Cost Efficiency

Multinational Operation Spearheaded by Seasoned Local Teams



- US R&D center
- MedTech manufacturing site
- MedTech sales and marketing center



- China R&D center
- Pharmaceutical manufacturing site
- Pharmaceutical sales and marketing center



- Global headquarter
- Strategic development center
- Listed on TSE Growth Board (2160)

Research & Development

- **Unique technology platforms** to address huge unmet needs in fibrosis, oncology, orthopedics and medical aesthetics
- **Rapid proof-of-concept** through cost-effective and efficiency pre-clinical studies and early-stage clinical development in China
- **Global clinical development** for global expansion

Regulatory

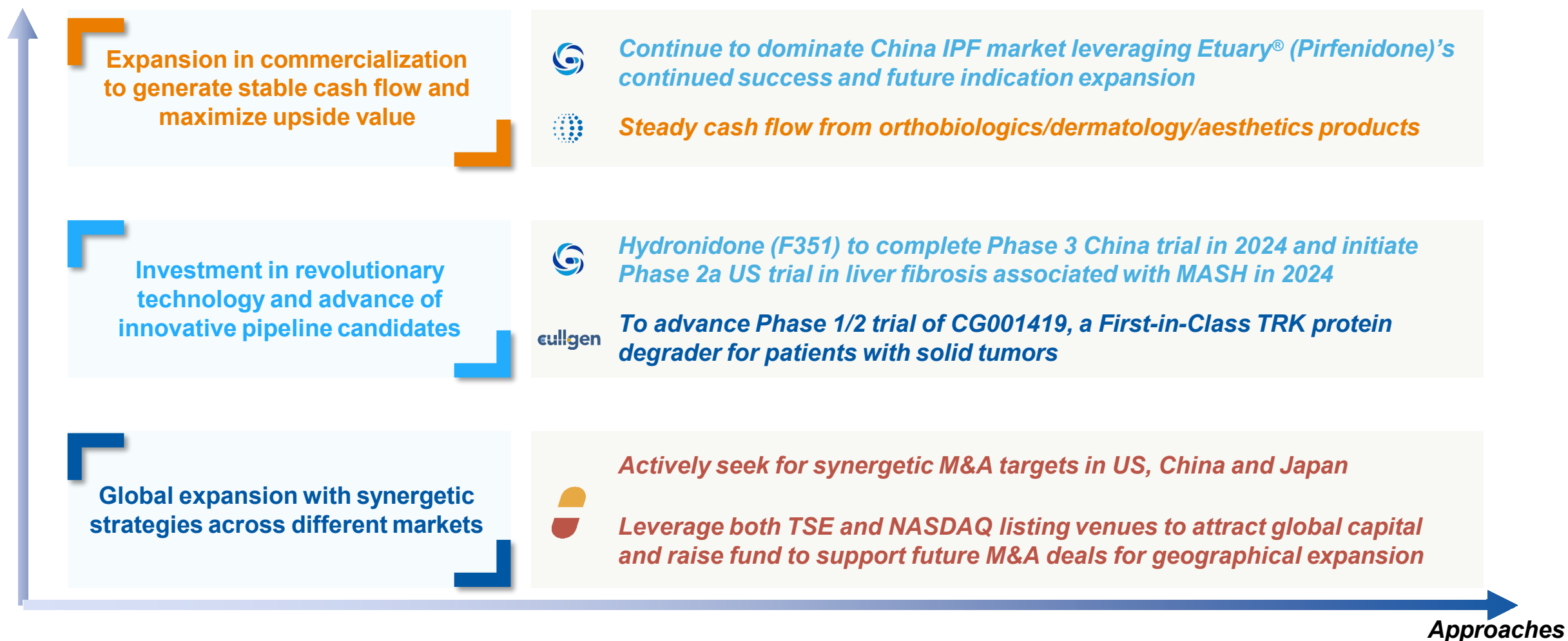
- Hydronidone (F351) received **breakthrough therapy designation** for hepatitis B-associated liver fibrosis in China
- Initiating multiple clinical trials in the US with IND applications to FDA in progress
- Licensed tissue bank accredited by the American Association of Tissue Banks (AATB)

Commercialization

- **Market access** to fast growing healthcare markets in China, US, Japan and globally
- **Efficient pharmaceutical sales team** built through inaugural commercialization of Etuary®
- **Mature biomaterials distribution network** for robust cash flow generation

Our Continued Internal & External Growth Strategies

Strategies



Incentivized, Independent, Seasoned Management Teams

Group



Ying Luo, Ph.D.
President & CEO



Sekitani Kazuki
COO



Toshiya Kitagawa
CFO

134 employees

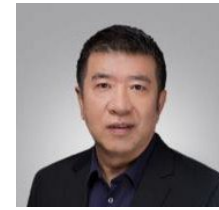
Pharma



Han Ying, Ph.D.
CEO



Weiguo Ye
COO



Songjiang Ma
President



Ruoyu Chen
CFO

540 employees

Biotech



Ying Luo, Ph.D.
Chairman & CEO



Yue Xiong, Ph.D.
Founder & CSO



Thomas Eastling
CFO

130 employees

Medtech



Danielle Kelley.
CEO



Mesfin Mengesha, M.D.
President



David Miao, CPA, MBA
Interim CFO

74 employees

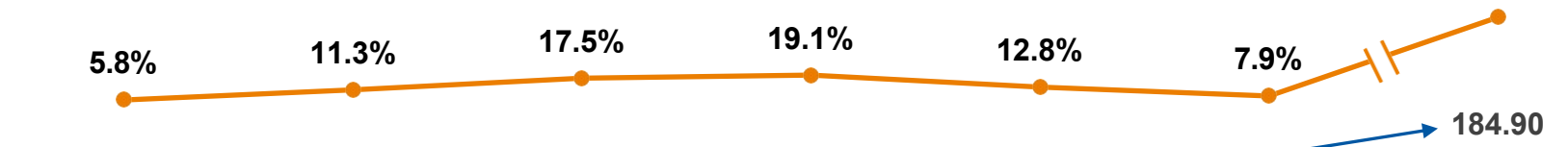
Financial Performance Enables GNI to Support Subsidiaries and Affiliates

Strong Track Record of Revenue Growth

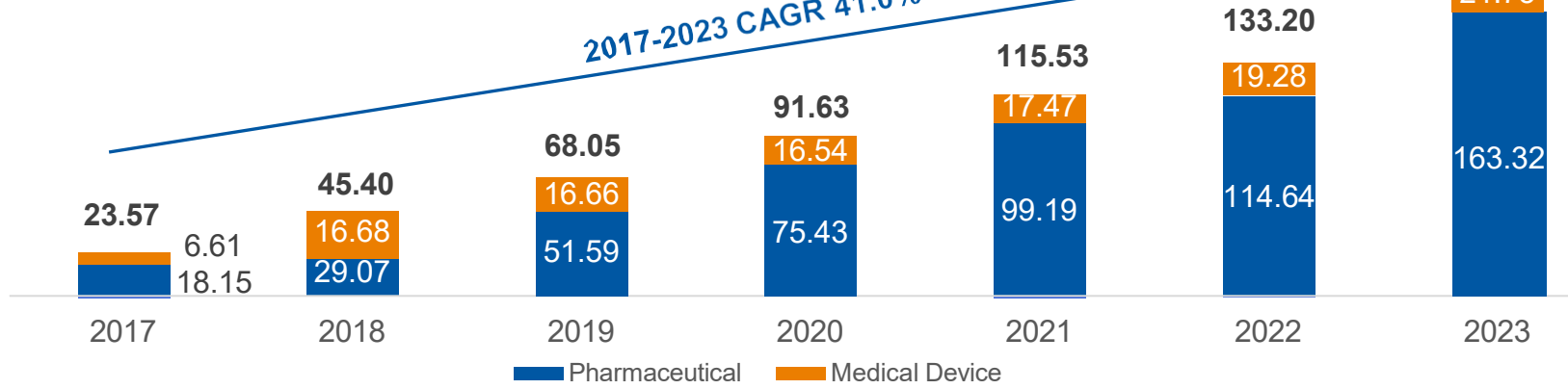
Stable Profitability across Segments

Sustainable Cash Flows with Strong Cash Position

Group Operating Margin (%)

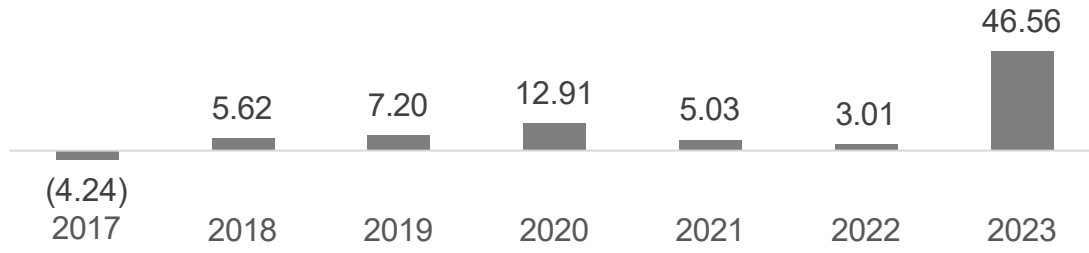


Revenue (Million USD)



\$144.2 million
Cash & Cash Equivalent (1)

Operating Cash Flow (Million USD)



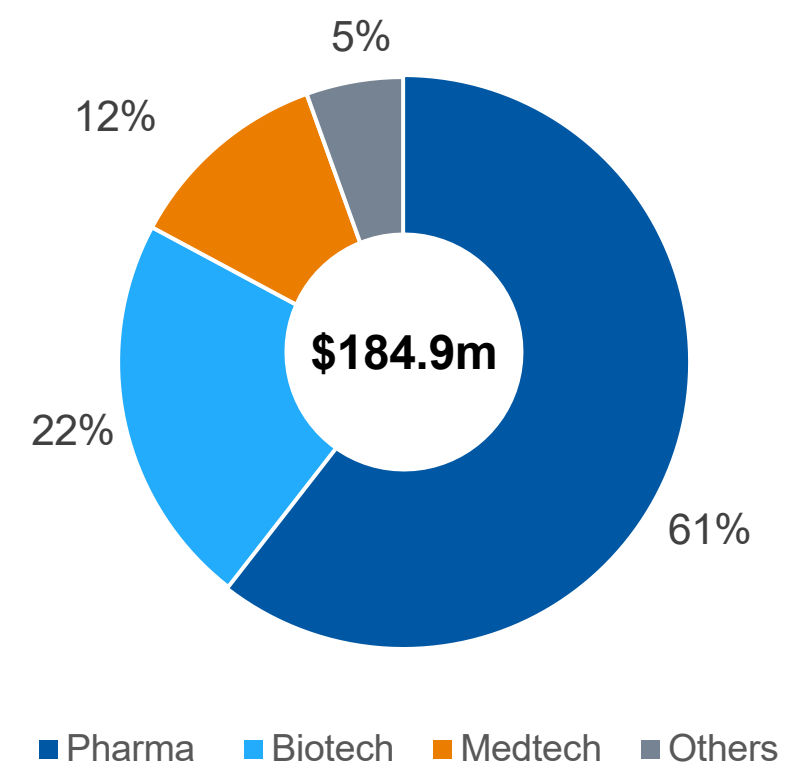
1) JPY/USD = 150. As of December 31, 2023.

Profitability Achieved with Significant Growth across All Segments

Group P&L Summary

(\$m)	2022A	2023A	YoY Change	2022A Margin	2023A Margin
Pharmaceutical	114.64	163.32	40.0%		
Medical Device	19.28	21.75	12.8%		
Revenue	133.20	184.90	38.8%	100.0%	100.0%
COGS	(20.45)	(25.45)	24.5%		
Gross Profit	112.75	159.45	41.4%	84.6%	86.2%
SG&A	(83.85)	(108.71)	29.7%		
R&D	(19.46)	(18.18)	(6.6%)		
Operating Profit	10.54	93.19	784.4%	7.9%	50.4%
Net income	(6.64)	67.56	nm	nm	36.5%

2023 Revenue Breakdown



Pharma



Anti-fibrosis and Inflammation Platform

Biotech



TPD Technology Platform

Medtech



Biomaterials Solutions

Innovative Pipeline as a Leader in Anti-fibrotic Therapies

Candidate	Target	Indication	Development Status					Region
			Pre-clinical	Phase 1	Phase 2	Phase 3	Marketed	
Hydronidone (F351)	TGF-β / Smad	Liver Fibrosis associated MASH						
		Chronic Hepatitis B Liver Fibrosis						
ETUARY® (Pirfenidone)	TGF-β	Idiopathic Pulmonary Fibrosis (IPF)						
		Dermatomyositis Interstitial Lung Disease (DM-ILD)						
		Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						
		Pneumoconiosis						
		Diabetic Kidney Disease (DKD)						
F573	Undisclosed	Acute Liver Failure (ALF) / Acute-on-Chronic Liver Failure (ACLF)						
F528	Undisclosed	Chronic Obstructive Pulmonary Disease (COPD)						
F230	Undisclosed	Pulmonary Arterial Hypertension (PAH)						

ETUARY® – Marketing Leading IPF Therapy in China

ETUARY® (Pirfenidone) Overview

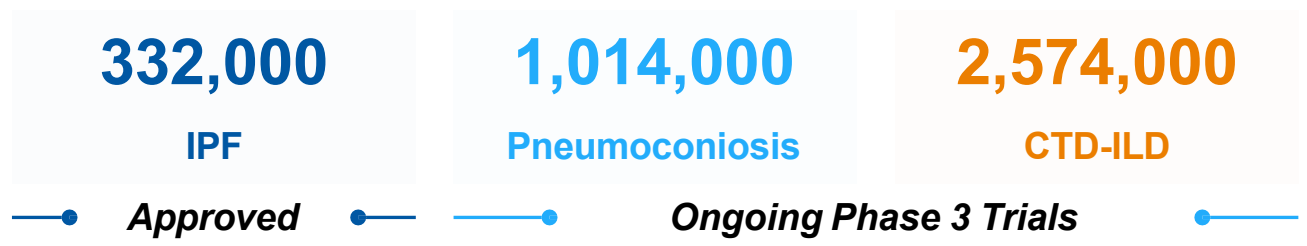


- ✓ **Effective oral treatment for idiopathic pulmonary fibrosis (IPF)**
- ✓ **Early entry into fibrosis therapy market in China since 2014**
- ✓ **Demonstrates anti-fibrotic, anti-inflammatory, and anti-oxidation properties**
- ✓ **Significant market potentials through indication expansion in interstitial lung diseases and diabetic kidney disease, etc.**
- ✓ **Multiple phase 3 trials ongoing in China**

FY2023 Revenue
US\$112.1m

Significant Market Opportunities

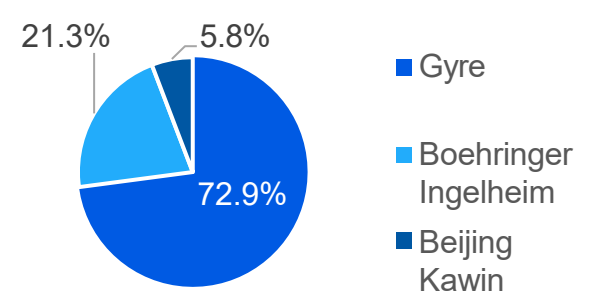
China Prevalence in 2031E
Major Diseases Causing Pulmonary Fibrosis



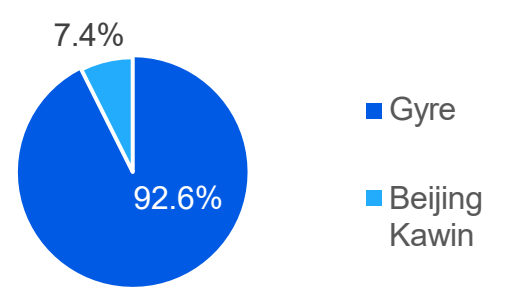
Established and Market Dominant Commercialization

Market Share in China, 2021

Pulmonary Fibrosis Drug Market



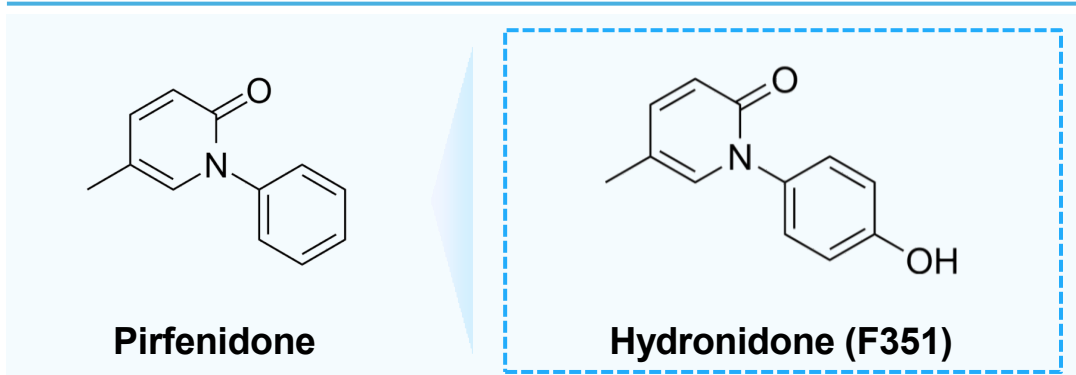
Pirfenidone Market



1) JPY/USD = 150.

Hydronidone (F351) – Lead Candidate Targeting Liver Fibrosis

Hydronidone (F351) Overview



Differentiated Product Profile

- ✓ A structural derivative of marketed antifibrotic drug Pirfenidone
- ✓ Pleiotropic anti-fibrotic TGF-β-targeting mechanism of action, expected to ameliorate liver fibrosis by inhibiting activation of hepatic stellate cells via **Smad7 mediated degradation of TGFβR**
- ✓ Possible to **reduce its potential for idiosyncratic liver toxicity** via phase II metabolism⁽¹⁾
- ✓ Obtained **breakthrough therapy designation status** for chronic HBV-associated liver fibrosis in China

Clinical Development

Phase 1	<ul style="list-style-type: none"> ✓ Well tolerated as single and repeated oral doses with no SAEs ✓ Consistent safety profile to China clinical trials
Phase 2 (Proof-of Concept)	<ul style="list-style-type: none"> ✓ Met primary endpoint of proportion of Ishak of liver fibrosis decreased by ≥ 1 point ✓ Good tolerability with comparable safety data with placebo
Next Milestones	<ul style="list-style-type: none"> ▪ Confirmatory China phase 3 in chronic hepatitis B-associated liver fibrosis completion by 2H 2024 ▪ To initiate U.S. phase 2a in liver fibrosis associated with MASH

Market Opportunities

Global Liver Fibrosis Market

\$15 billion
in 2022⁽²⁾

Global MASH Market

\$108 billion+
in 2030⁽³⁾

No approved therapy globally

(1) Zhou S et al., J Med Chem 2020. (2) Source: Coherent Market Insights. (3) Vantage Market Research.

Huge Market Potential in MASH-associated Liver Fibrosis

Current MASH Competitive Landscape



Drug	F351(Hydronidone)	Resmetirom	Efruxifermin	VK2809	Pegozafermin
Stage	Phase 2	Approved	Phase 3	Phase 2b	Phase 2b
MOA	TGF-β/Smad	THR-β agonist	FGF21 analog	THR-β agonist	FGF21 analog

Gyre's Competitive Advantage

Positive Phase 2 POC data

Substantially de-risked clinical program with upcoming Phase 3 data in chronic HBV-associated liver fibrosis

Unique mechanism capable of directly targeting fibrosis

Well funded by profitable ETUARY®'s global commercialization

Multiple Upcoming Milestones for F351



China



United States

Date	Milestones	Date	Milestones
Completed	Positive Phase 2 results of F351	Completed	Phase 1 trial of F351
Early 2025	Phase 3 topline results	Completed	Gyre publicly listed on the NASDAQ
2025	Commercialize F351 for chronic HBV fibrosis	2025	Initiate Phase 2a in MASH
2025	Initiate Phase 3 trial in MASH		

F351 is Well Positioned with Blockbuster Potential Given its Unique Mechanism, De-risked Profile and Significant Opportunity in MASH

Pharma



Anti-fibrosis and Inflammation Platform

Biotech



TPD Technology Platform

Medtech



Biomaterials Solutions

Cullgen – Differentiated Targeted Protein Degradation Platform

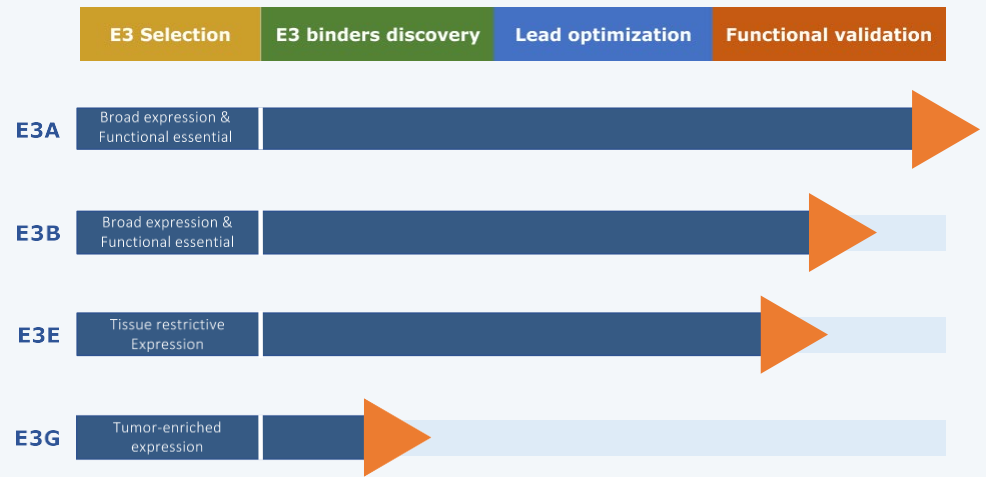


uSMITE™



ubiquitin-mediated, Small Molecule-Induced Target Elimination

Industry Leading Novel E3 Ligands and Next Generation Degraders



Cullgen Progress on Novel E3 Ligands:

- ✓ Demonstrated **functional degradation of six different proteins** using degraders that recruit the broadly expressed and functionally essential E3A ligase
- ✓ Several E3A ligands have been optimized and successfully used for the development of potent (IC50 and DC50 < 10 nM) heterobifunctional degraders
- ✓ Most advanced program using E3A ligands is now at the lead optimization stage

Novel E3 ligands could provide significant benefits

- ✓ Recruit functionally essential E3 ligases for cancers
- ✓ Expand E3 ligand toolbox to target proteome
- ✓ Achieve desired tissue delivery

Strategic Validation

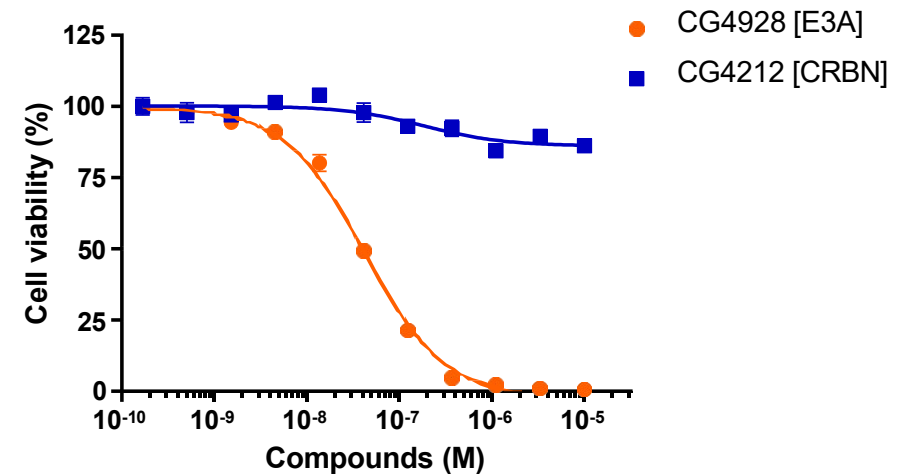
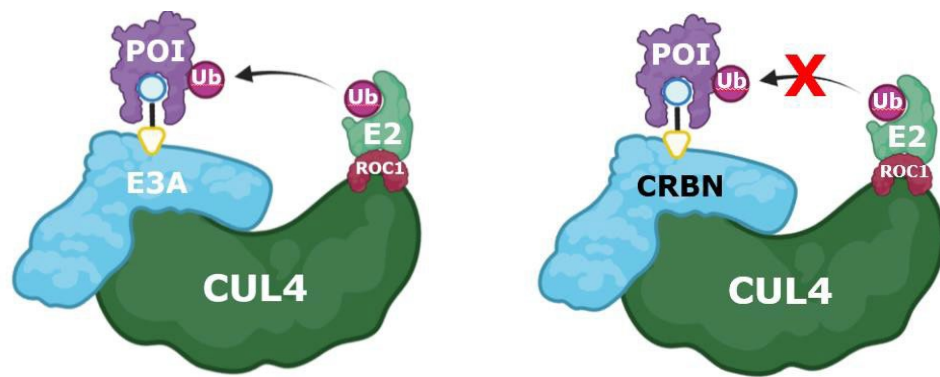


Collaboration, Option and License Agreement

\$35 million	\$1.9 billion
Upfront Payment	Total Deal Size

Includes **option for Cullgen to jointly share in profits / losses from lead candidate** product sales in the US; Cullgen eligible to receive royalties on other products & geographies

Potent Degradation and Cell Growth Inhibition by Cullgen's E3A-Recruiting, but not CRBN-Recruiting Degraders



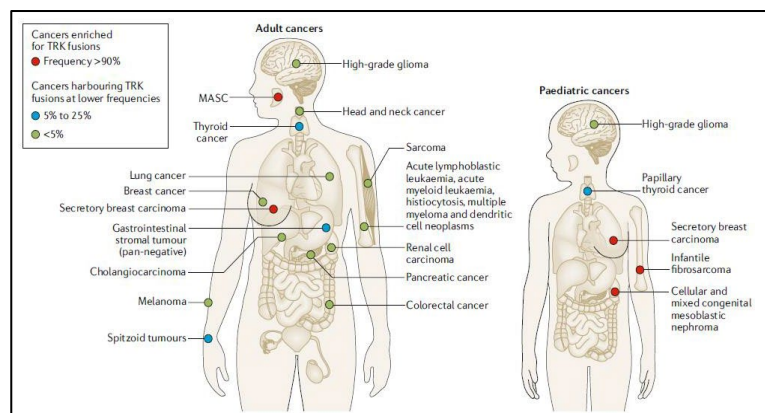
Compound (μM, 16 h)	DMS	CG4928 [E3A]						CG4212 [CRBN]						DMS
		0.02	0.06	0.2	0.6	1.7	5	0.02	0.06	0.2	0.6	1.7	5	
Lane	1	2	3	4	5	6	7	14	15	16	17	18	19	20
Cell Cycle Target 1	[Western blot bands showing degradation of Target 1 with increasing E3A concentration]													
Cell Cycle Target 2	[Western blot bands showing degradation of Target 2 with increasing E3A concentration]													
Tubulin	[Western blot bands showing consistent Tubulin levels across all lanes]													

Targeted Protein Degradation (Protac) Programs on Oncology

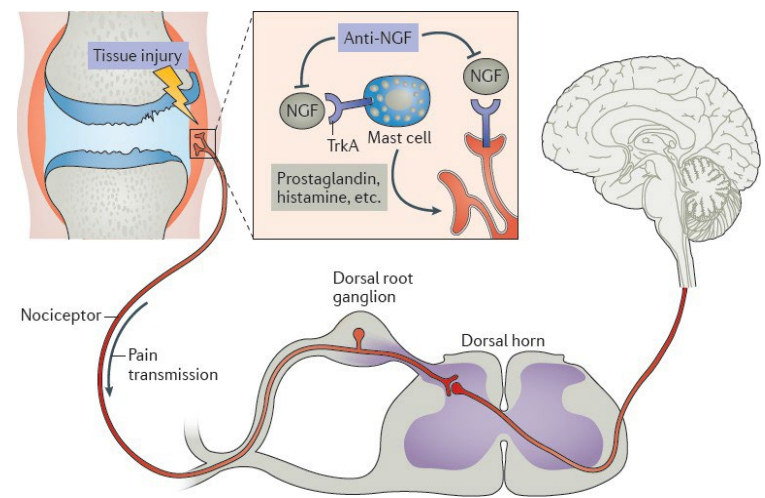
Program / Target	Indication(s)	Development Status					Partner	
		Target Selection	Hit Discovery	Lead Optimization	PCC Selection	IND-enabling		Clinical
Cyclin D	Breast cancer and multiple solid tumors	█	█	█▶	★▶			
CDK2	Breast and ovarian cancers	█	█▶	▶▶★				
p300	Prostate, lung & bladder cancers	█	█	█▶▶				
CG001419 (TRK)	Acute and chronic pain	█	█	█	█	█		
CG001419 (TRK)	Solid tumors with NTRK gene alterations	█	█	█	█	█	█▶	
Metabolic protein	Immuno-oncology of multiple solid tumors	█	█▶					
WRN	Colon, ovarian and GI cancers	█	█	█▶				
GSPT1	Leukemia and MYC+ cancers	█	█	█	█	█▶	★	
Kinase	Autoimmune diseases	█	█	█▶	★▶			

★ Non-enzyme target ▶ Utilizing proprietary Cullgen E3 ligands

CG001419 – First Clinical Program for Cancers and Pain



Cocco, Scaltriti & Drilon (2017) *Nat Rev Clin Oncol*, PMID: 30333516



Target Product Profile in Solid Tumors

Target indication	Tumors with NTRK gene alterations
Market size	<ul style="list-style-type: none"> Fusion: 1,500 to 5,000/year in US Mutation, amplification and overexpression, ~14% of all tumors
Current SOC & options	<ul style="list-style-type: none"> TRK inhibitors after r/r from SOC per tumor type Entrectinib & Larotrectinib
Unmet clinical needs	<ul style="list-style-type: none"> 50% relapse in 12 months Development of kinase inhibitor resistant mutations No approved therapy for NTRK amplification, mRNA overexpression
Clinical position	<ul style="list-style-type: none"> r/r NTRK gene fusion tumors r/r TRK kinase inhibitor resistance Solid tumors with TRK amplification/overexpression

Target Product Profile in Acute Perioperative Pain

Market Size	<ul style="list-style-type: none"> 180,280 abdominoplasties in 2019 (56% increase from 2000) 2.7 million cosmetic surgeries in 2019 (22% increase from 2000) 1 million total joint replacements/year, up to 4 million in 2030 150,000 bunionectomies performed each year
Current SOC (US)	Opioids, NSAIDs, COX-2 inhibitors, Regional anesthesia/nerve block
Unmet medical needs	<ul style="list-style-type: none"> Opioids: respiratory depression, tolerance, dependence potential, constipation NSAIDs: GI, Renal, and CV side effects, discouraged/contraindicated in older adult Regional anesthesia: not available at all centers
Clinical position	First line therapy

Pharma



Anti-fibrosis and Inflammation Platform

Biotech



TPD Technology Platform

Medtech



Biomaterials Solutions

Medtech Segment Overview

Segmental Strategy in Orthobiologics, Dermatology and Aesthetics

Long Product Life Cycle

Long-term and sticky customer base

Positive Cash Flow

JPY2.5bn revenue and 946m operating profit in 2022

New Opportunities

Organic growth and expansion via acquisition

Global Strategy in US, China and Japan



United States



Berkeley Advanced Biomaterials
Berkeley, CA

Orthopedics products
manufacture/sales

Acquisition of Elutia (NASDAQ:ELUT)'s orthobiologics business for up to \$35m



Elutia Announces Sale of Orthobiologics Business Unit for Cash Proceeds of Up to \$35 Million



China



Osderma/ Ruixing Medical
Shanghai

Aesthetics products
manufacture/sales



JIUCE Medical
Shanghai

Distribution of BAB products in China



Japan



Micren
Tokyo

Medical devices
consulting/registration

Acquisition of Elutia's Orthobiologics Business Unit



Elutia Announces Sale of Orthobiologics Business Unit for Cash Proceeds of Up to \$35 Million

September 18, 2023 16:08 ET | Source: Elutia Inc. [Follow](#)

– Transaction Reflects Increasing Strategic Focus on Proprietary Drug-Eluting Biomatrix Platform –

SILVER SPRING, Md., Sept. 18, 2023 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia"), a company pioneering drug-eluting biomatrix products, today announced the divestiture of the Company's Orthobiologics business unit to Berkeley Biologics LLC, a wholly owned subsidiary of GNI Group Ltd. Elutia will receive cash proceeds of up to \$35 million, comprised of an upfront payment at closing of \$15 million plus potential earnout payments of up to \$20 million over a five-year period. The transaction is expected to close in the fourth quarter of 2023.

This transaction represents a pivotal milestone in Elutia's progress toward pioneering the drug-eluting biomatrix. The Company continues to make progress towards gaining U.S. Food and Drug Administration clearance for CanCaroo® RM, the Company's lead drug-eluting product. CanCaroo RM features an advanced biomatrix and the drugs rifampin and minocycline (RM) for extended antibiotic protection for cardiac pacemakers and defibrillators, a \$28 billion market. Elutia is targeting the first half of 2024 for the launch of CanCaroo RM. The Company's pipeline also includes an RM version of its SimpliDerm® biomatrix for use in breast reconstruction procedures.

\$15m
Upfront payment

Up to \$20m
Earnout payment over a 5-year period

Comprehensive Orthobiologics Products Portfolio

Viable Bone Matrix

Viable Bone Allograft

- Second generation
- Launched in 2019



Human Tissue Allograft consisting of terminally sterilized Bone Matrix

- Third generation
- Launched in 2020

Cellular Allograft Bone Matrices

- Fourth generation
- Launched in 2023

Other Bone Matrix

- First generation
- Launched in 2017

Contract Manufacturing

- Demineralized bone matrix (DBM)
- Cortical & cancellous products
- Sports medicine tendons
- Precision milled grafts



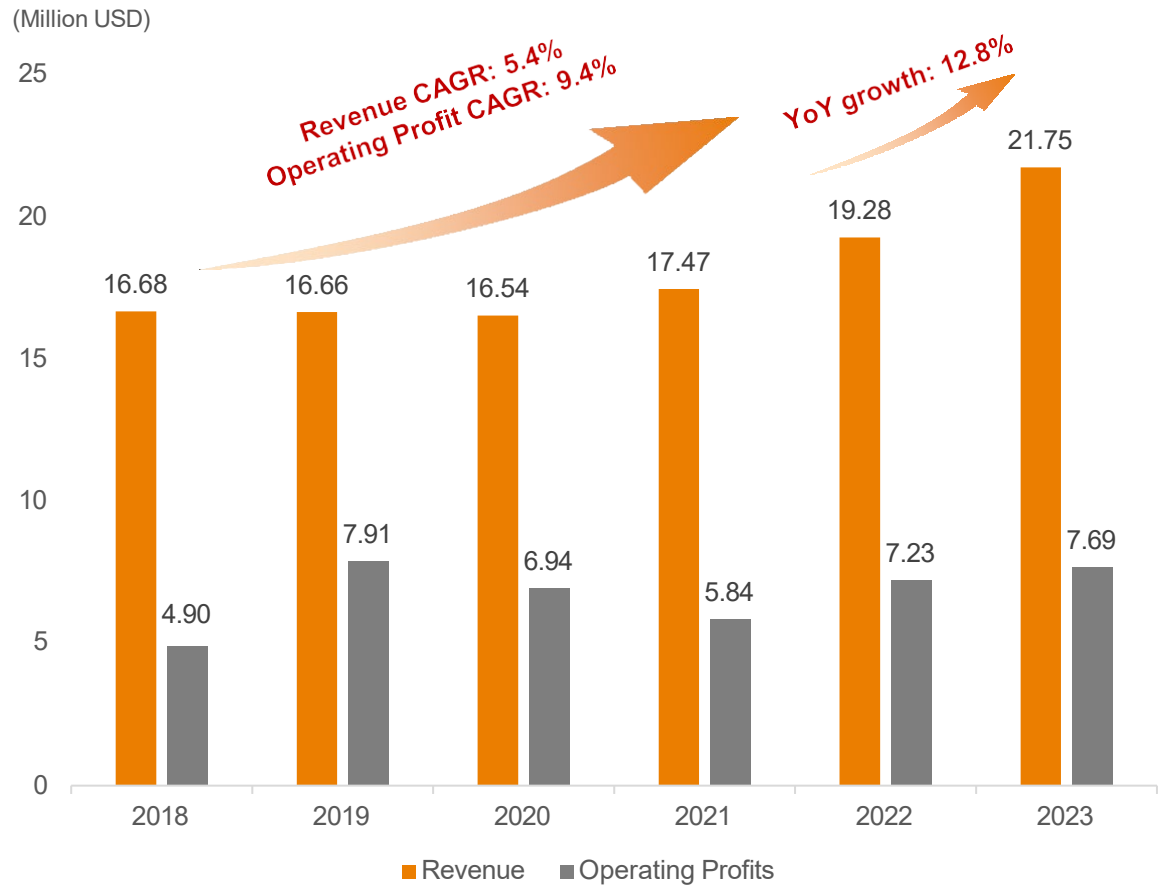
- Lyophilized dermis
- Hydrated dermis



- Amnion membrane
- Amnion chorion membrane

Robust Growth of Our Medtech Sector

Strong Resurgence after COVID Pandemic



Note: Includes Berkeley Advanced Biomaterials; excludes inter-company revenue and profits

Steady Cash Flow Business with Significant Growth Potential



Direct sales/distribution network in China for BAB products by Shanghai JIUCE



New product (bone fiber) under FDA registration



Expansion in applications to **aesthetics market** in China through Osderma/Ruixing Medical



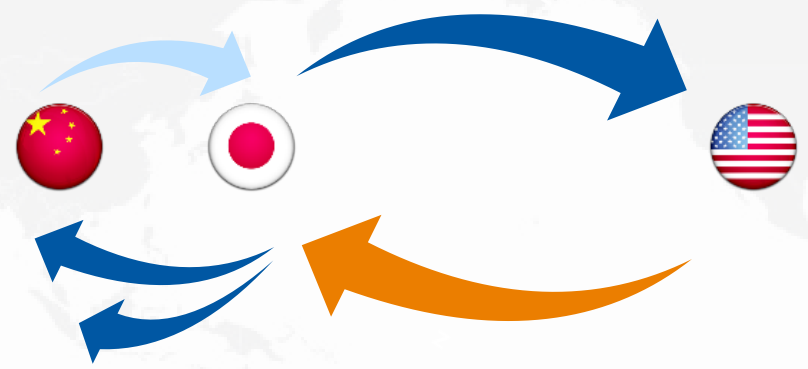
Collaborate and leverage Micren's **Designated Marketing Authorization Holder (DMAH)** business in Japan

We Are the Optimal Solution under the Geopolitical Tension

GNI is Uniquely Positioned to Leverage the Robust Japanese Economy as the Bridge to Create Strategic Value between the Increasingly De-coupled US and China

China

- Established sales and marketing team with successful commercialization track record
- POC trial in China to save time and costs
- Pharmaceutical manufacturing site for global supply



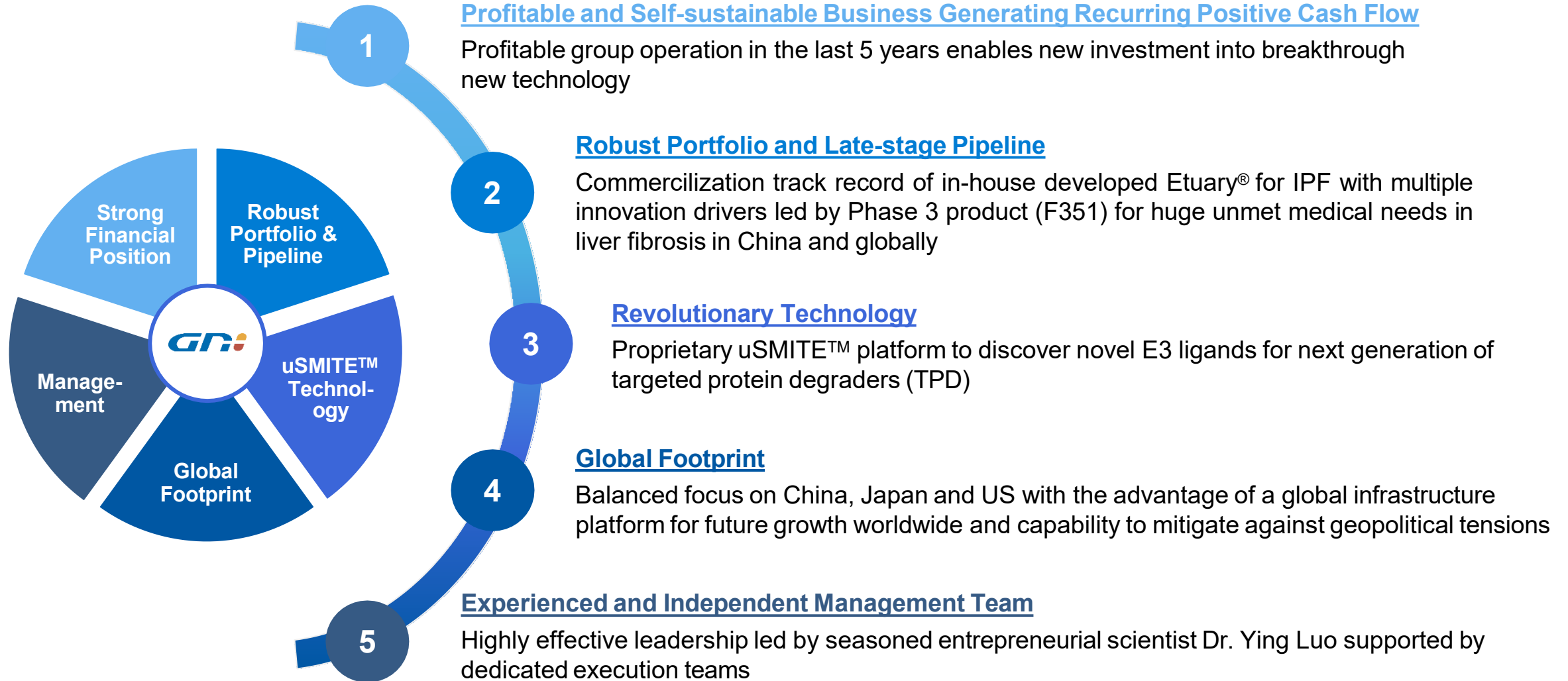
US

- Listing venue of Gyre Therapeutics
- Pivotal trial to support US FDA approval
- MedTech hub for biomaterials sales, R&D and manufacturing
- R&D center for next-generation technology development

Japan

- Headquarter and GNI Group's listing venue
- Bridge to connect China and US under geopolitical tension
- Operational and strategic center for key decisions

GNI Group Investment Highlights



This presentation contains statements concerning the current plans, expectations and strategies of GNI Group Ltd. (GNI Group). Any statements contained herein that pertain to future operating performance and that are not historic facts are forward-looking statements. Forward-looking statements may include, but are not limited to, words such as “believe,” “plan,” “strategy,” “expect,” “forecast,” “possibility” and similar words that describe future operating activities, business performance, events or conditions. Forward-looking statements, whether spoken or written, are based on judgments made by the management of GNI Group, based on information that is currently available to it. As such, these forward-looking statements are subject to various risks and uncertainties, and actual business results may vary substantially from the forecasts expressed or implied in forward-looking statements. Consequently, investors are cautioned not to place undue reliance on forward-looking statements.

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Forward-looking Statements

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