

GNI Group Ltd.

FY2022 Q4 Year to Date Financial Results
Corporate Presentation

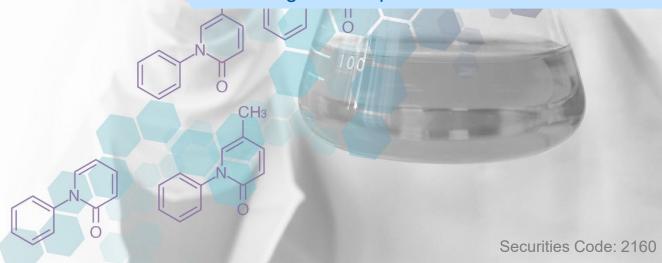
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Joseph Francis Meyer (マイヤー)
Chief Financial Officer

February 17, 2023

СНз

We Bring New Hope to Patients.





Forward-looking Statements

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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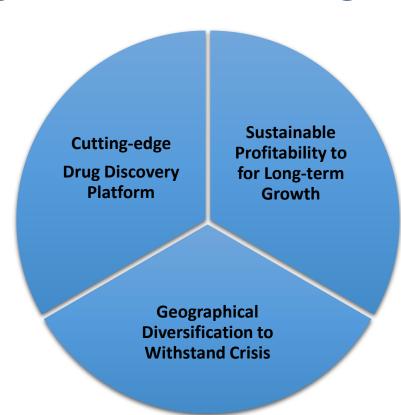
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Competitive Edge: A Profitable Drug Discovery Platform

- ✓ Revolutionary TPD (Targeted Protein Degradation) drug discovery platform
- Steady progress in clinical trials in China (F351, F573, TRK Degrader)
- ✓ Preparing for trials in US
- Combined R&D investments up 26% YoY in yen terms



- Steady income stream from BC and BAB; Revenue up 35% and 31% YoY in yen terms
- ✓ Increasing size of sales and marketing team/network in China
- Profit-driven expansion in both US and China

- ✓ Multiple revenue sources in different country
- ✓ Only the headquarters/administration operation in Japan, and R&D platform in US are not profitable. Other subsidiaries in the Group have operating income.
- ✓ Less impact by economic cycle/geopolitical risk of each country

*CBIO: Catalyst Biosciences, Inc



Cost-Efficient Platform China Presence leverages Group as a whole

US, Japan, China

Basic

Research

- Risk management
- Ideas
- Technology
- Basic research results

China

Clinical Development, Proof-of-Concept, Fast-to-Market, Profit

- Efficiency
- Lab research
- Clinical development
- GMP* manufacturing
- Sales / distribution
- Ample talents

Global

Global Clinical

Development and

Commercialization

- Global talent pool
- Safety and efficacy data
- IPs
- API and raw materials
- Trial drugs
- Financing
- Post-market data

^{*:} Good Manufacturing Practices



Strengthening our Foundation

Corporate Reach and Expansion

• Completed 1st stage of acquisition of Nasdaq-listed CBIO¹⁾ to increase US operation

Business Development and Strategic Positioning

- JV established in China for deployment of BAB's²⁾ biomaterial-based aesthetic solutions: Shanghai Ruixing Medical
- Investment in Micren, first step for medical device segment in Japan; DMAH and ICC regulatory consulting JV

Head office Operations and Governance

- Early 2022 (late 2021): new CFO and new Head of IR;
- Headcount Jan 1, 2022: 12; Headcount Jan 1, 2023: 14
- 2022 in Tokyo HQ: new Head of Business Development, additional financial, tax and corporate finance staff to upgrade and improve systems, JV, M&A and project execution capabilities to seize opportunities

^{1):} Catalyst Biosciences, Inc. (please refer to our <u>disclosure</u> on December 27th, 2022)

^{2):} Berkeley Advanced Biomaterials LLC



Corporate Citizenship



Environment

- BC holds GB/T24001:2016*
 Certificate
- BC keeps spending on environmental protection to contain toxic emissions and waste disposal



Social

- BC's donation of ETUARY to NPO in China up 26.6% YoY
- BAB holds ISO 13485:2016**
 certification for compliance with
 the International standard for
 quality management in medical
 device industry.
- Frequent evaluation at BC's manufacturing facility to ensure a safe work environment.



Governance

- 7 directors and managers in total enrolled in BDTI's*** director training courses from 2021-2023
- Enhance diversity, equity, and inclusion initiatives
- In HQ, among 14 FTE 7 are women, 4 are foreign citizens

^{*} GB/T24001: Chinese name for ISO 14001 on environmental management system standard

^{**}ISO 13485:2016: International standard for quality management in medical device industry

^{**} Board of Directors Training Institute Director Training | Governance Consulting (bdti.or.jp)



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(Million JPY)

GNI Group: A decade of Growth

Revenue CAGR: 66%

Operating income CAGR: 55%













Q4 Macro Environment and Backdrop

- High inflation pressures and dramatic FX swings
- Operations normalizing with COVID restrictions easing worldwide in Q4
- Supply chain pressures

Open questions for 2022-23:

- Will firehose of capital into early stage investments rebound? (\$680 billion in 2021, down to \$445 billion last year)
- Will down valuations trough? (average value of public listing exits dropped to \$600 million in 2022, a 6-year low and a fraction of 2021's \$2 billion)

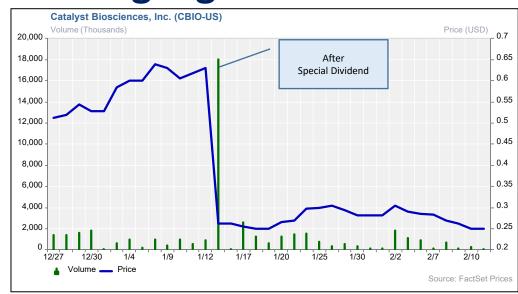






CBIO Transaction Highlights

- Unlock IP value (\$35 million) for the F351
 Program with a view to NASH unmet needs in US
- No dilution to GNI's holding in China business operation with more than 80% holdings in CBIO
- Medium term: establishes platform to secure funding in the US for F351 NASH Phase II trial.
- Create values for BC shareholders, including GNI Group
- Access to deeper liquidity pools, price discovery, specialist bio and institutional investors via Nasdaq





Source: FactSet



Strong Operating Growth, Challenging Environment

Group Consolidated P/L Million JPY								
	FY2020	FY2021	FY2022	20 vs 21	21 vs 22			
Revenue	9,774	12,690	17,419	30%	37%			
cogs	(1,546)	(1,600)	(2,674)	3%	67%			
Gross profit	8,228	11,090	14,745	35%	33%			
SG&A	5,181	7,959	10,966	54%	38%			
R&D	1,243	2,016	2,545	62%	26%			
Operating profit	1,870	1,625	1,378	-13%	-15%			
Finance income	46	130	260	183%	100%			
Finance costs	110	648	870	489%	34%			
Profit before tax	1,806	1,107	768	-39%	-31%			
Profit after tax	1,366	55	(801)	-96%	-1556%			
Owner's profit	1,258	1,066	456	-15%	-57%			
GP %	84%	87%	85%	4%	-3%			
SGA %	53%	63%	63%	18%	0%			
R&D%	13%	16%	15%	25%	-8%			
OP%	19%	13%	8%	-33%	-38%			
PBT%	18%	9%	4%	-53%	-49%			

Full Year data

	FY2020	FY2021	FY2022	20 vs 21	21 vs 22
RMB	15.44	17.02	19.38	10%	14%
USD	106.67	109.84	130.77	3%	19%

Revenue: Up 37% YoY

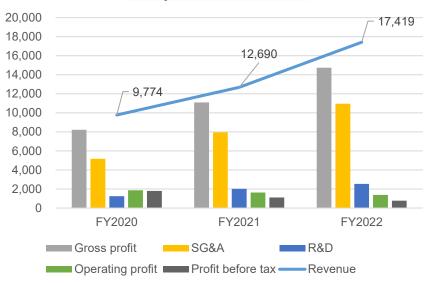
SG&A: BC's one-time IPO expenses JPY 395M

Valuation loss: Cell Carta JPY321M; Societal JPY 33M

Financial income: Forex gain due to depreciation of JPY

Financial costs: Non-cash accruals of Cullgen's interest expenses JPY 837M

Group Consolidated P/L





In-depth Analysis: Adjusted View of PnL for One-off and Non-cash Items

- ☐ The Group's financial results from profitable operations of BC and BAB are offset by spendings in Cullgen R&D and headquarter administrative operations including income tax expenses.
- ☐ Adjusting the PnL for deconsolidation of Cullgen benefits our PnL; likewise adjusting for non-cash charges and one-time costs

(Million JPY)	Actual 2021	Actual 2022	Pro Forma 2022 Scenario 1	Pro Forma 2022 Scenario 2
			<u>Cullgen</u> <u>Deconsolidated</u>	Non-Cash Interest and BC IPO expenses Adjusted
Operating profit	1,625	1,378	3,119	1,773
Profit before tax	1,107	768	3,342	2,021
Profit for the year	55	(801)	1,773	353



Capital Allocation

	Group Co	nsolidated	Million JPY		
	FY2020	FY2021	FY2022	20 vs 21	21 vs 22
Current assets	13,025	18,187	17,147	40%	-6%
Non-current assets	10,195	12,110	16,760	19%	38%
Total assets	23,219	30,297	33,907	30%	12%
Current liabilities	6,603	2,543	3,503	-61%	38%
Non-current liabilities	3,847	8,488	10,524	121%	24%
Total liabilities	10,450	11,031	14,028	6%	27%
Capital Stock etc	11,859	17,108	17,126	44%	0%
Retained earnings	(608)	308	764	-151%	148%
Other components of equity	(251)	1,444	3,149	-675%	118%
Attributable to owners of the parent	11,000	18,860	21,038	71%	12%
Non-controlling interests	1,769	406	(1,159)	-77%	-385%
Total equity	12,769	19,266	19,879	51%	3%

FY21 vs. FY22 Total assets +3,610

- •+1,007 PPE: Acquisition of property, plant, and equipment in China
- •+1,027 Goodwill: Mainly FX impact plus acquisition of Micren (60%)
- •+ 622 Investments-Equity Method: Acquisition of CBIO (17%)
- •+1,318 Other financial assets: Long-term deposits in China

Total liabilities +2,997

- •+2,167 Other financial liabilities: Mainly interest expenses accrual of Cullgen
- •+ 578 Trade and other receivables: Business growth in China
- •+ 637 Current tax payable: Business growth in China and acquisition of CBIO
- •- 500 Borrowings

Total equity +613

- •+2,178 Attributable to owners of the parent: mainly FX impact and Retained earnings
- •-1,565 Non-controlling interests: due to loss increased in Cullgen



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Powered by Growth in China Despite COVID Outbreak

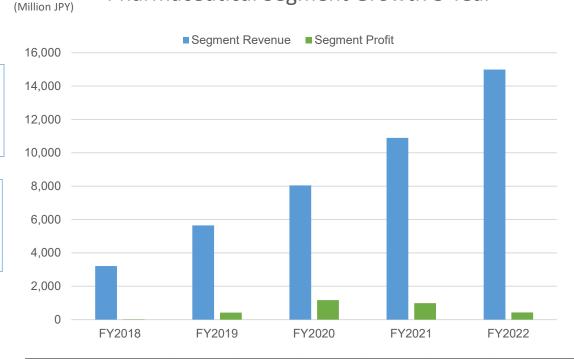


Revenue grew 38% YoY. Segment profit is down due to increased R&D on TPD platform.



Despite a slowdown in participant enrollment during NOV, DEC '22, the Stage III clinical trials for F351 are continuing to advance in China.

Pharmaceutical Segment Growth 5 Year



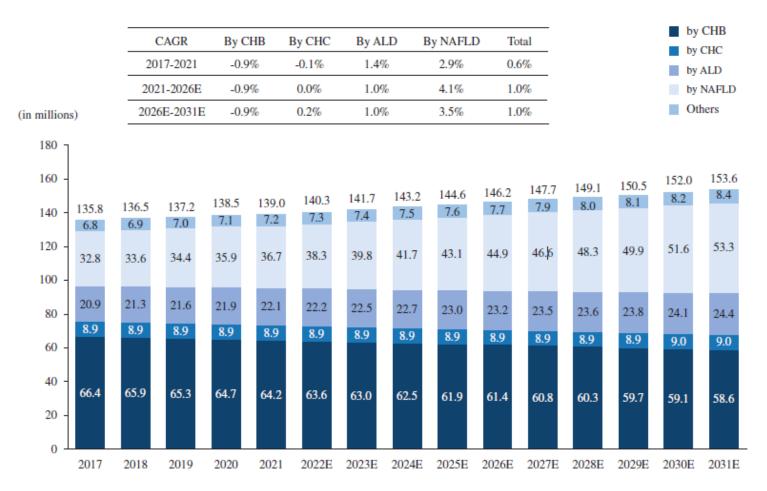
Pharmaceutical	FY2018	FY2019	FY2020	FY2021	FY2022	CAGR
Segment Revenue	3,214	5,645	8,046	10,895	14,991	47%
Segment Operating Profit	15	422	1,202	983	431	132%

Note: Includes Beijing Continent, Cullgen, Shanghai Genomics, and Reef.



Next Breakthrough is Liver Fibrosis Therapy

Prevalence of Liver Fibrosis in China

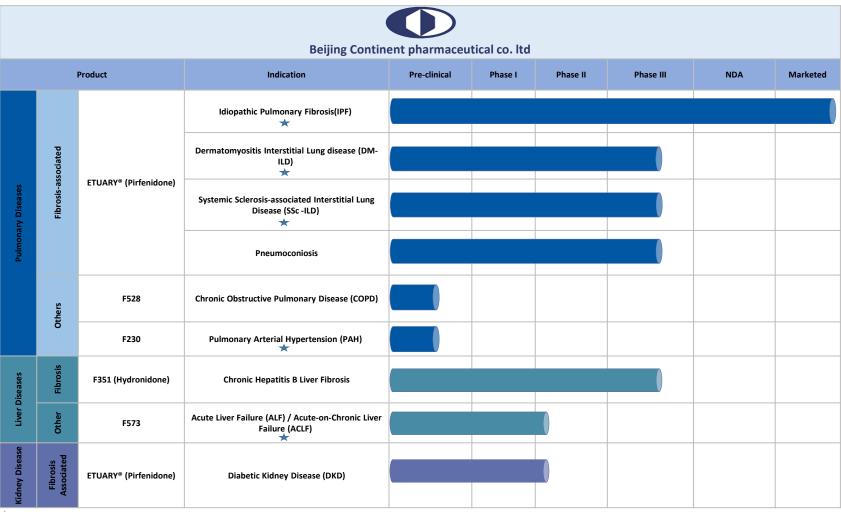


Source: Fu-Sheng Wang, et al. The global burden of liver disease: the major impact of China. Hepatology. December 2014; Lin MH, et al. Liver Fibrosis in the Natural Course of Chronic Hepatitis B Viral Infection: A Systematic Review with Meta-Analysis. Dig Dis Sci. May 2021. Literature Review; Expert Interview; Frost & Sullivan Analysis



R&D: BC's Drug Pipeline in China

Modest slowdown of F351 trial enrollees Q4'22 due to COVID-19 impact in China



^{*}Rare Disease



Beijing Continent Financials

(Legal entity, local currency)

	000s RMB				
	FY2020	FY2021	FY2022	20 vs 21	21 vs 22
Revenue	447,002	571,038	688,630	28%	21%
cogs	26,627	25,629	29,299	-4%	14%
Gross profit	420,375	545,409	659,331	30%	21%
SG&A	228,460	314,799	413,936	38%	31%
R&D	37,212	46,188	53,768	24%	16%
Profit before tax	156,656	188,704	194,193	20%	3%
Profit after tax	127,927	149,387	151,594	17%	1%
Headcount	419	481	523	15%	9%





Spotlight is on Targeted Protein Degrader (TPD)

Date	Japan's Media	Title / One-line Summary
Feb 14	Nikkei Biotechnology & Business	Kyushu Univ. confirmed VGLL3's efficacy as a target for fibrosis treatment drug, proceeding to explore applications to Targeted Protein Degradation
Feb 10	Nikkei Biotechnology & Business	ADDP (Axcelead Drug Discovery Partners), who specializes in drug discovery support business, to start the support services for Targeted Protein Degradation and Nucleic Acid drug discovery
Jan 31	Nikkei Newspaper	Targeted Protein Degradation drug: new path to cancer treatment, the first clinical trial by a Japanese company
Jan 23	Nikkei Biotechnology & Business	Why Astellas could create a new KRAS G12D Targeted Protein Degradation drug in a short period of time?
Jan 18	AnswersNews	Astellas "Targeted Protein Degradation Drug" development progress – to "continuously create new drugs" by establishing a technology platform
Jan 13	Nikkei Newspaper	Targeted Protein Degradation drug snipes a whole pathogen: Astellas to run a clinical trial in the U.S.
Jan 2	Nikkei Newspaper	Overcoming cancers by innovative technology: spotlight on mRNA and Targeted Protein Degradation



Targeted Protein Degrader (TPD) in focus

Demand for new treatments for various diseases

Overcoming limitations of conventional drug discovery and development

Advancements in technology

Investment by key players in the pharmaceutical industry

Rising collaborations and partnerships

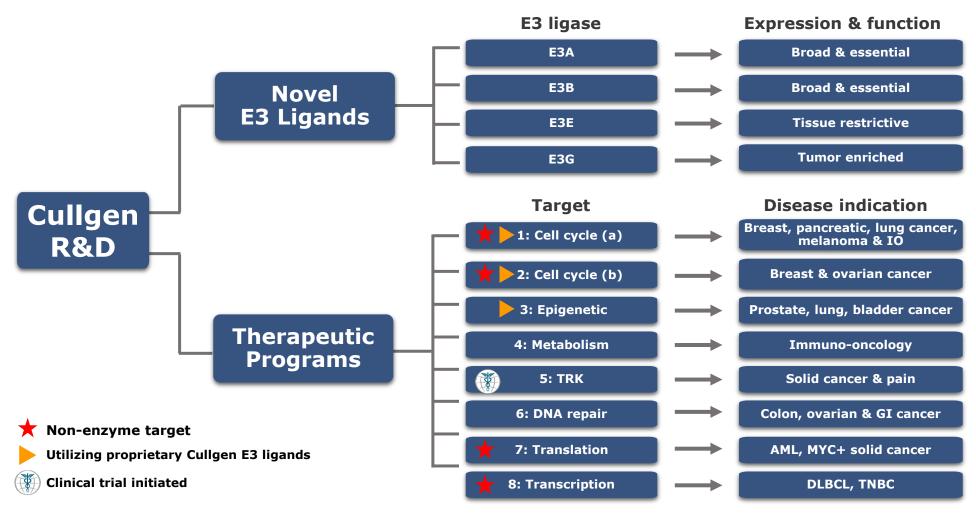
Projected growing market size reaching billions in the next few years.





R&D: Cullgen's Drug Pipeline

Several promising new drug candidates for TPD are in progress.





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Steady Growth and Cash Generation



Steadily growing and generating cash



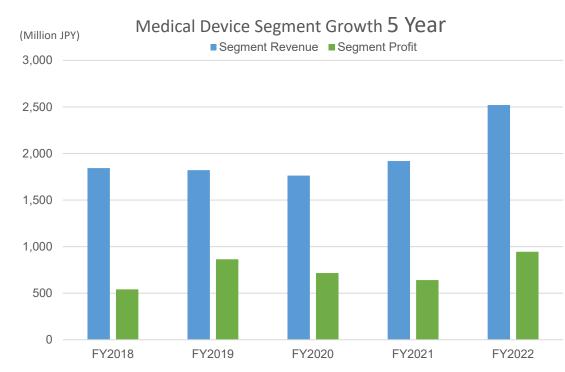
New product (bone fiber) under FDA registration



Expanding applications to aesthetics in China through Ruixing



Collaborate and leverage new Micren's DMAH business in Japan



Medical Devices	FY2018	FY2019	FY2020	FY2021	FY2022	CAGR
Segment Revenue	1,844	1,823	1,764	1,919	2,521	8%
Segment Operating Profit	542	865	705	642	946	15%

Note: Includes Berkeley Advanced Biomaterials.





Berkeley Advanced Biomaterials Product Portfolio

H-Genin

100% DBM Products – Putty, Sponges Allograft

Machined Grafts, Chips/Crushed Advanced Mineralized Graft (AMG)

> Processed Cortical Fiber Strips & Putty

Bi-Ostetic

HA/TCP HA/TCP+Bovine Collagen Bi-Ostetic BioActive Glass

> TCP+Bovine Collagen+45s5 Bioglass

Cem-Ostetic

Calcium-based osteoconductive products





















DBM: Demineralized Bone Matrix

HA: Hydroxyaptite

TCP: Tricalcium phosphate





DMAH (Designated Marketing Authorization Holder) Services

Support overseas clients through the life cycle of medical devices

Pre approval

- Regulatory consulting services – help determine the appropriate regulatory pathway
- Support for manufacturing and marketing approval applications, etc.
- Support for insurance application
- Setup before shipping

Judgement of shipment

 Judge whether shipment is OK or not

Post marketing

- Post marketing safety management
- Assist with regulatory amendment procedures
- Assist in adverse event and recall reporting in Japan as needed



Biomaterials market opportunity

Increasing demand for medical devices such as implants, wound dressings, and surgical sutures

Advancements in technology and materials science leading to development of improved biomaterials

Rising demand for regenerative medicine and tissue engineering products

Investment by key players in medical device and pharmaceutical industries

Growing collaborations and partnerships between biomaterials companies, academic institutions, and research organizations

Projected growth to reach several billion dollars in the next few years.



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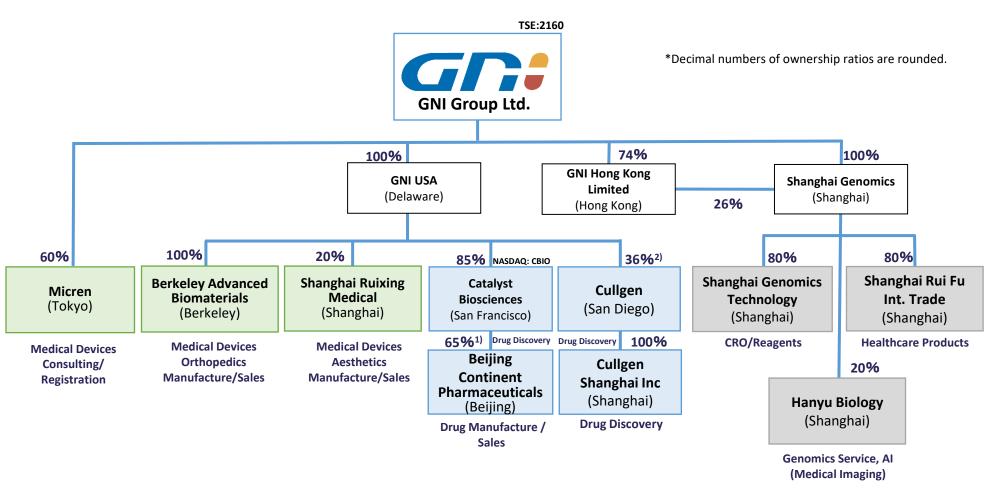
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5. Appendix

GNI Group Organization after CBIO Reverse Merger

Percentage of holdings in profitable/nearly break-even subsidiaries are higher



^{1):}Through other pass-through entities currently 100% owned by GNI Group as well as non-GNI Group entities

^{2):} Fully diluted basis including the warrants held by GNI USA



5. Appendix

Human Capital

Name/Year	2020	2021	2022
Beijing Continent	419	481	523
Berkeley Advanced Biomaterials	29	30	31
Cullgen San Diego	4	8	11
Cullgen Shanghai	57	78	90
Other	30	31	46
Total	539	628	701



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