



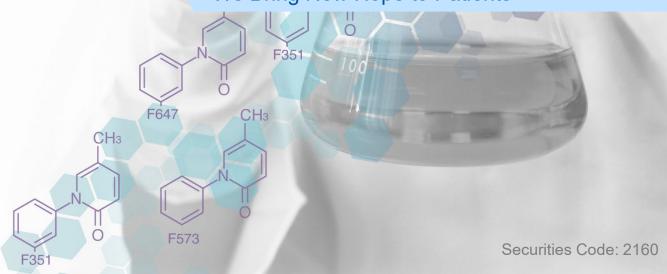
# Q2 FY2021 Financial Results Corporate Presentation August 18, 2021

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We Bring New Hope to Patients





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# FY2021 – Q2 Highlights

# ✓ Revenue increased 47.6% year on year, achieved an increase in all profits

- Revenue trend of Etuary® is steady
- Acceleration of revenue and profitability recovery in our Medical Device Segment (Biomaterials)
- Through the acquisition of Reveal by AI diagnostics company CellCarta GNI Group exchanged its ownership stake in Reveal for a stake in CellCarta which resulted in a valuation gain of 374 million yen as Other Income in Q2
- Profit attributable to GNI increased mainly due to following:
  - 1) Following a successful USD50 million capital raise in Q1 GNI's ownership in Cullgen declined; its share of Cullgen's operating costs also declined
  - 2) GNI's PNL absorbs the full impact of BABL's earnings from Q2 as it became a 100% owned subsidiary in the prior quarter

#### ✓ Investment in Healthcare Business

- Reinvestment for future collaboration with CellCarta

Reveal: Reveal Biosciences Cullgen: Cullgen Inc.

BABL: Berkeley Advanced Biomaterials LLC



# FY2021-Q2 Consolidated Financial Results Comparison (YoY)

Statements of Income	FY2020 JanJune	FY2021 JanJune	Change
Revenue	4,380	6,465	47.6%
Gross profit	3,639	5,679	56.0%
Selling, general and administrative expenses	△2,212	△3,677	66.2%
Research and development expenses	△582	△864	48.5%
Operating profit	861	1,455	68.9%
Finance income	24	32	33.8%
Finance costs	△68	△290	325.3%
Quarterly profit before tax	817	1,197	46.4%
Income tax expense	△291	△452	55.6%
Quarterly profit	526	744	41.4%
Quarterly profit attributable to owners of the parent	244	941	285.0%

Statements of Financial Position	As of Dec. 31, 2020	As of June 30, 2021	Change
Cash and cash equivalents	10,322	13,821	33.9%

#### \* Differences due to rounding

#### **Revenue & Gross Profit**

Due to continuous strong sales of Etuary® in China in which recorded concentrated sales in the Q1 and remarkable recovery in the Medical Device Segment

#### **SG&A** expenses

Increase in costs due to expansion of Cullgen's business, in addition to BC's sales-related costs of Etuary® and IPO-related costs

#### **R&D** expenses

Mainly an increase of BC's R&D expenses and Cullgen's preparation expenses of IND filings

#### **Operating profit**

In addition to continuous expansion of the Pharmaceutical business and the rollover of Reveal's shareholding into CellCatra, resulting in a valuation gain

#### **Quarterly profit**

Due to an increase in Operating profit

#### Quarterly profit attributable to owners of the parent

Increase in profit due to an increase in shareholding ratio in BABL and reduction in cost burden due to a decrease in shareholding ratio in Cullgen

Cullgen: Cullgen Inc. BC: Beijing Continent Pharmaceutical Co.

Reveal: Reveal Biosciences BABL: Berkeley Advanced Biomaterials LLC



## Forecasts for FY2021

#### Revised Forecasts of Consolidated Financial Results for FY2021

	Revenue	Operating Profit	Profit before tax	Profit for the year	Profit attributable to owners of the parent	Basic earnings per share
	Million yen	Million yen	Million yen	Million yen	Million yen	Yen
Previous forecast (A)	11,803	1,220	1,180	470	778	17.91
Revised forecast (B)	12,753	1,828	1,245	410	1,235	26.04
Change amount (B-A)	950	607	64	△60	457	
Rate of change (%)	8.1	49.8	5.5	△12.8	58.8	
(Reference) FY2020 results	9,773	1,869	1,805	1,365	1,258	28.96

- Revised the Consolidated Earnings Forecasts for FY2021 in consideration of the results of the  $1^{\rm st}$  half
- In the 2<sup>nd</sup> half, as originally planned, R&D expenses are expected to be higher due to the progress of drug discovery's R&D and clinical trials
- Expect to record Interest expense in Cullgen's financial activities in the 2<sup>nd</sup> half

Cullgen: Cullgen Inc.



## **Development: Pipeline Update**

Product - Indication	Origin	Phase I	Phase II	Phase III	Latest Status
Etuary® (China)					
- Connective Tissue Disease Associated Interstitial Lung Disease (CTD-ILD)	Proprietary				Dual Phase III clinical trials ongoing. Proceeding smoothly
- Radiation Pneumonitis (RP)	Proprietary				Expanded RP clinical trial is ongoing
- Diabetic Nephropathy (DN)	Proprietary				Phase I clinical trial is underway on schedule
- Pneumoconiosis (PD)	Proprietary				Preparations for Phase III are underway
F351 (China, U.S.)					
- Liver Fibrosis (China)	Proprietary				July 29, 2021, start of Phase III was approved by NMPA
- Liver Fibrosis (U.S.)	Proprietary				Consultations with Key Opinion Leaders(KOLs) and advisors in order to decide the possible indications. Scheduled to file with the FDA in the latter half of 2021
F573 (China)					
- Acute/Acute-on-chronic Liver Failure	License-in				Phase I clinical Trial protocols were approved by Union Hospital. Protocol has been revised and resubmitted to the HGRAC pending approval

■ Other than the above, preparation for new products in Cancer, Chronic Obstructive Pulmonary Disease(COPD), and pulmonary hypertension underway

NMPA: National Medical Products Administration (Formerly known as China Food and Drug Administration)

FDA: Food and Drug Administration HGRAC: Human Genetic Resource Administration of China



# **Topics**

#### ✓ Received approval for F351 Phase III clinical trial in China and preparing for the start

- Without an effective and approved therapy for liver fibrosis anywhere in the world, the development of F351 is a significant milestone for a disease which affects millions of people
- As F351 was designated as a "Breakthrough Drug" by NMPA in March 2021 based on the positive results of its Phase II clinical trials, priority processing is expected
- Scheduled enrollment of 248 HBV associated liver fibrosis patients from approximately 40 clinical centers during an expected 3-year Phase III trial period
- The Phase III clinical trial is scheduled to start in Q3 FY2021.
- To facilitate administration of this trial, BC has engaged Beijing Stem Technology Co., Ltd, an experienced CRO in liver diseases in China.
- The primary endpoint will be the lowering of Ishak score of liver fibrosis by 1 grade
- In addition to clinical trials in China, also planning clinical trials in other countries

BC : Beijing Continent Pharmaceutical Co., Ltd

NMPA: National Medical Products Administration (Formerly known as China Food and Drug Administration)

CRO: Contract Research Organization



# Investing in Both Healthcare and Related Businesses Profitable New Business

#### 1. Reveal

- CellCarta, a global precision medical services company, acquired GNI Group's ownership of Reveal (6% in 2019 for 111 million yen)
- As part of this transaction, GNI Group exchanged its shareholding for a stake in CellCarta in order to continue strategic collaboration; return on investment of 374 million yen or 363.9%

#### 2. IRISYS

- The acquisition of IRISYS by Recro, a NASDAQ listed CMO company was announced on 13 August 2021 (GNI Group originally owned 35% and overtime reduced its ownership to 15%) for a gain of 190 million yen.
- Taking into account valuation changes ROI generated was 111% past ownership
- Since our initial investment in 2015, GNI Group and IRISYS cooperated on a number of fronts including IRISYS' provision of FDA registration consulting services for F351 and contract manufacture services.



### **Future Direction**

- 1. Target profitable growth while continuously investing into drug discovery globally
- 2. Realize the value of core assets of GNI Group Beijing Continent Pharmaceutical Co., Cullgen Inc., Berkeley Advanced Biomaterials LLC, and Shanghai Genomics, Inc. for GNI Group shareholders -through collaboration and/or subsidiary listings opportunistically
- 3. Identify additional Healthcare businesses for synergy and potential investment
- 4. Ongoing efforts to strengthen GNI Group corporate governance
- 5. With a view to expanding business in Japan, GNI Group will monitor the progress of TSE's new listing platforms and explore the value of listing on the new Prime Market in due course

CMO: Contract Manufacturing Organization FDA: Food and Drug Administration



# **Contact Information**

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