

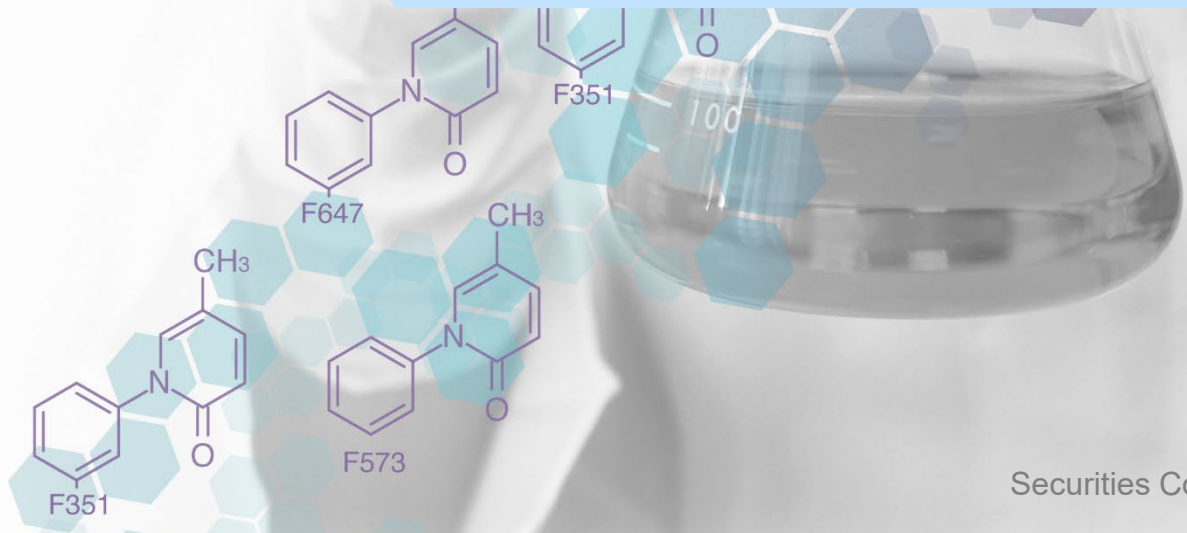


Business Plan and Growth Potential

December 2021

GNI Group Ltd.

Bringing New Hope to Patients in Asia and Worldwide



1. Corporate Profile
2. Business
3. Growth Strategy
4. Companies
5. Market Environment
6. Business Outlook
7. Risk Considerations



1. Corporate Profile



Corporate Profile

Head office address

Nihonbashi-Honcho YS Bldg. 3F 2-2-2
Nihonbashi-Honcho, Chuo-ku,
Tokyo 103-0023, Japan

Establishment

November 2001

Paid-up Capital

10,884 million JPY
(as of the end of September 2021)

Listing

Tokyo Stock Exchange Mothers Market
(August 2007 / Code : 2160)

Business

A global healthcare company that focuses on pharmaceutical drug development and distribution, and biomaterials

Director, Representative Executive Officer, President and CEO

Ying Luo, Ph.D.

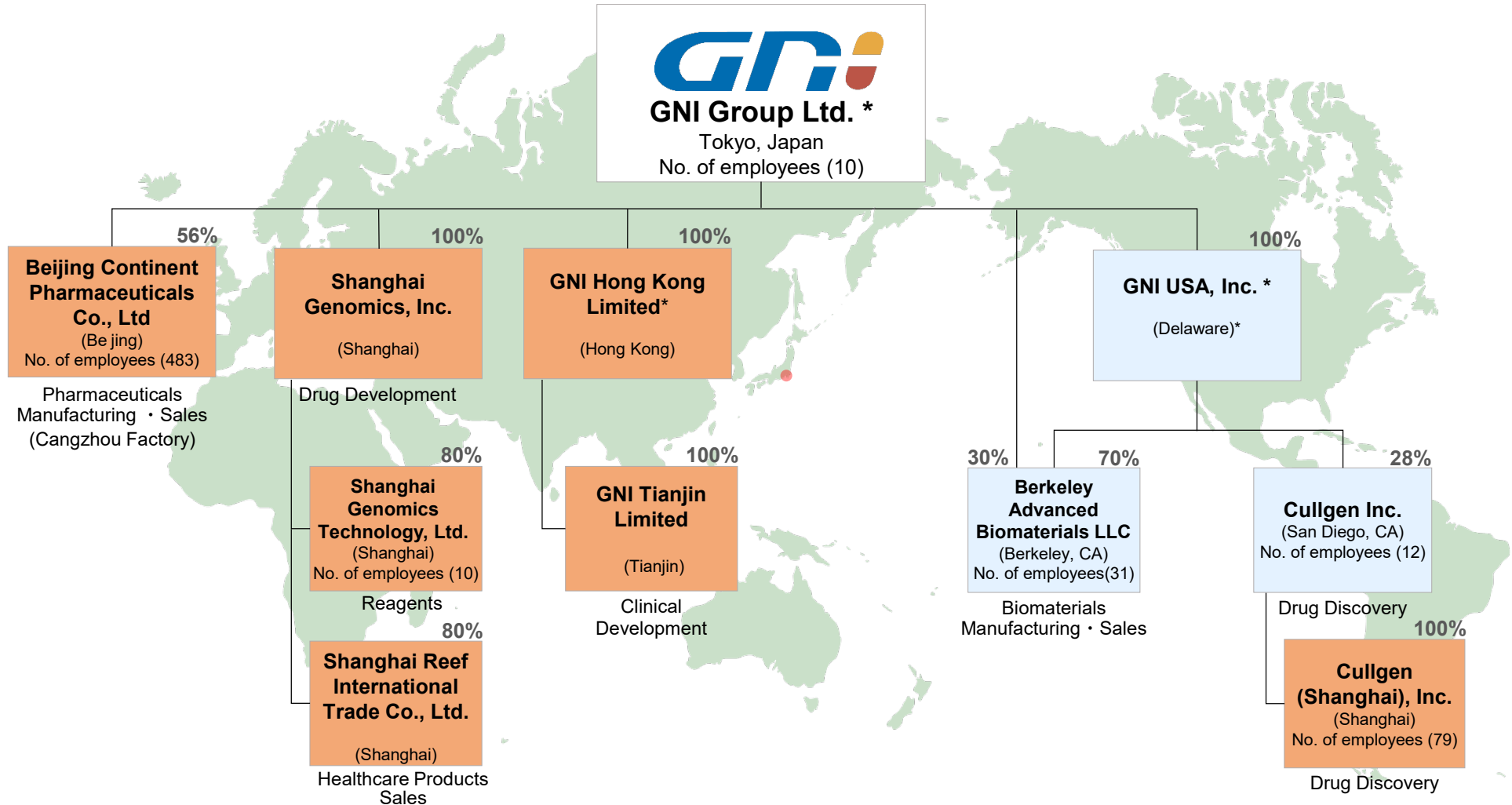
Employees (aggregate)

631 (as of the end of November 2021/
Incl. temporary employees)

Auditor

Grant Thornton Taiyo LLC

Global Business Expansion



* - Holding company
 - China & Hong Kong
 - United States

Note 1 : Only significant investees are shown.
 Note 2 : The number of employees is as of the end of November 2021.
 Note 3 : The number of employees includes temporary employees.

2. Business



GNI Group Vision and Business Overview

Bringing New Hope to Patients in Asia and Worldwide

- ✓ Headquartered in Japan as a global healthcare company and listed on one of the world's major stock exchanges, we operate drug discovery, pharmaceutical development, biomaterial development, clinical studies, manufacturing, and sales in both the US and China.
- ✓ Our fully-integrated drug discovery and pharmaceutical business in China, Beijing Continent Pharmaceutical, focuses on fibrotic disease in lung, liver, and kidney. It also holds a pipeline of products under development for both major and orphan diseases. In the US, Cullgen is engaged in cancer drug discovery utilizing cutting-edge, targeted protein degradation technologies.
- ✓ In the US our biomaterials business Berkeley Advanced Biomaterials develops, manufactures, and markets synthetic / tissue bank biomaterials for orthopedics and cosmetic applications. Its products are considered to be among the premier brands worldwide.
- ✓ Geographically diverse and well-coordinated operations enables us to leverage:
 - Innovations in US
 - Cost efficiencies in China
 - Access to both the largest healthcare market in the world and one of the fastest growing healthcare markets globally
 - Permanent access to the capital on one of the world's leading exchanges

Growth Trend

Consolidated Revenues

YoY Growth Rate

48%

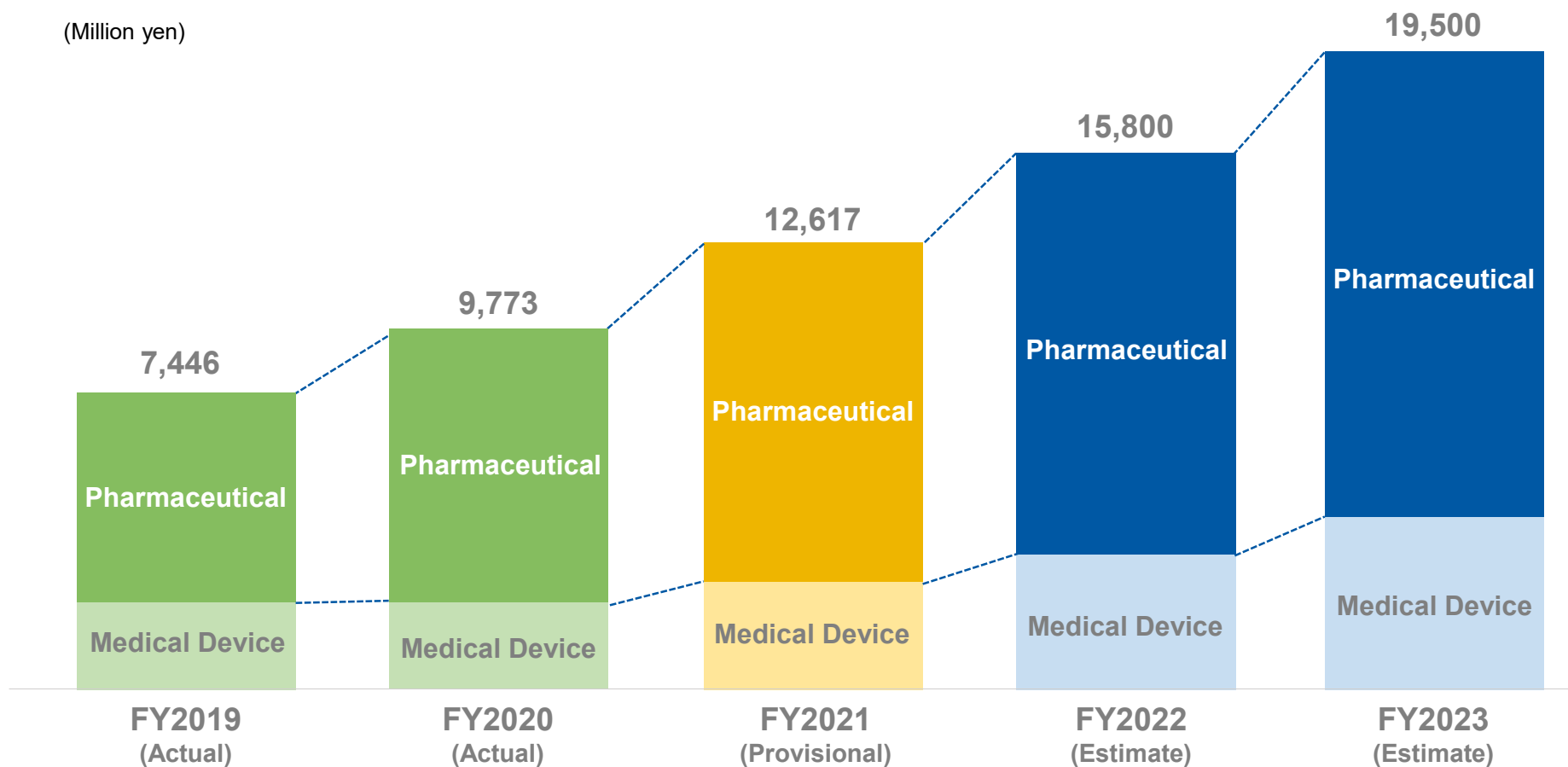
31%

29%

25%

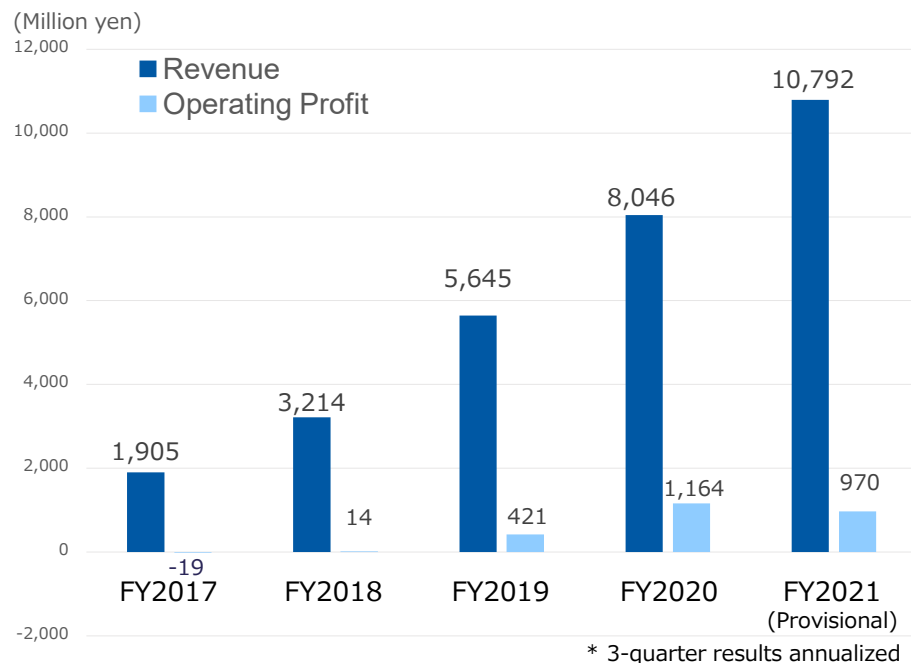
23%

(Million yen)

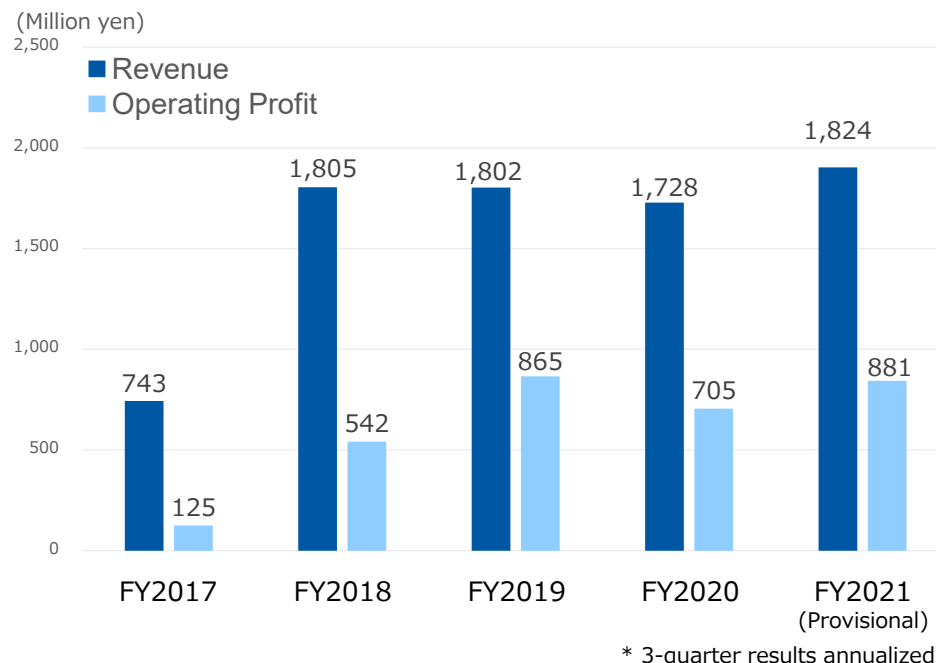


Revenue and Operating Profit by Segment

Pharmaceutical Business Revenue and Operating Profit

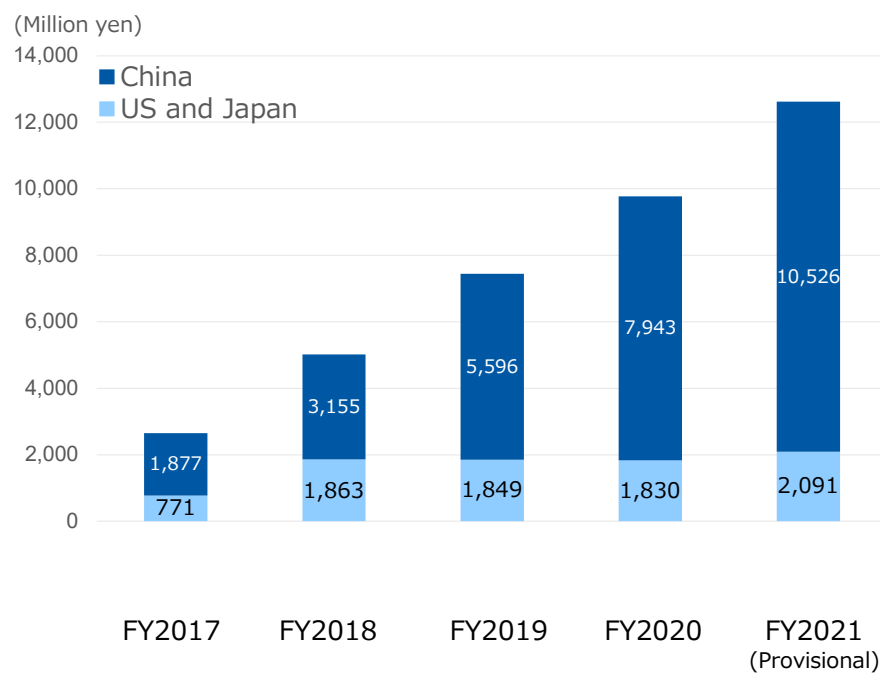


Biomaterials business Revenue and Operating Profit



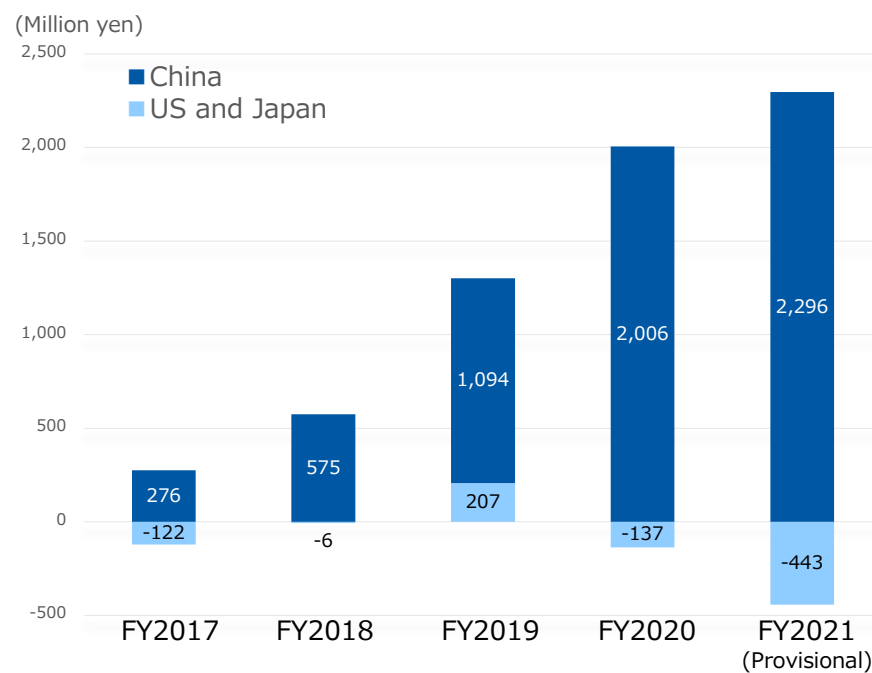
Revenue and Operating Profit by Geographical Regions

Revenue by Region



* 3-quarter results annualized

Operating Profit by Region



* 3-quarter results annualized

Assumptions Behind Our Projections

Pharmaceutical Business

- Lung fibrosis drug market in China continues to grow in spite of the disruptions caused by COVID pandemic.
- Beijing Continent Pharmaceuticals' Etuary® continues to hold a commanding market share in the face of tough competition.
- Drugs development pipeline in both the US and China is robust.

Biomaterials Business

- Berkeley Advanced Biomaterials came through COVID well and growth has resumed while maintaining strong margins.
- Expanding into cosmetic applications in Asia



Competitions and Our Strengths

Pharmaceutical Business

Beijing Continent Pharmaceuticals Co., Ltd

Competitions

Boehringer Ingelheim

Our Strengths

- First launch of idiopathic pulmonary fibrosis drug in China
- Access to local talents and hospital networks
- Strong and orphan-drug specialized sales force within China
- Drug pipeline for various forms of fibrosis
- Regulatory relationships and experience



Cullgen Inc.

Competitions

Arvinas, Nurix, Kymera Therapeutics, C4 Therapeutics, Monte Rosa Therapeutics

Our Strengths

- Top-tier scientists
- Cost-effective development and testing operations in the US and China
- Innovative and differentiated platform
- Many new drugs in the pipeline
- Regulatory relationships and experience



Biomaterials Business

Berkeley Advanced Biomaterials LLC

Competitions

Ventris Medical, Biologica Technologies, Biogenix, Access2Bone, PUR Biologics

Our Strengths

- Long and stable operating history
- High-quality and premier-brand products
- Well-established market share in orthobiologics
- Strong and stable margins



3. Growth Strategy



GNI Group's Growth Strategy

Medium Term Strategy

In the medium term, our goal is to continue operating a profitable, global healthcare company with strong product pipelines, continuous R&D, and multiple revenue bases in various parts of the pharmaceutical value chain.

Long Term Strategy

In the long term, our goal is to become a fully-integrated multinational healthcare company.



Growth Strategy for Each Business

Pharmaceutical Business

Beijing Continent Pharmaceutical Co., Ltd (China)

- Further strengthen Etuary® sales for idiopathic pulmonary fibrosis
- Expand Etuary® to other organ fibrotic indications
- Develop new drugs such as F351 as the next generation of anti-fibrosis therapeutics
- Push at least two more products into late clinical stage development
- Maintain the annual growth rate of above 20%

Cullgen Inc. (US)

- A leader in protein degradation through discovery of novel E3 ligases
- Develop novel therapies for cancers
- Build excellent R&D team
- Focus on global markets

Biomaterials Business








Berkeley Advanced Biomaterials LLC (US)

- Maintain high quality reputation in the field
- Expand tissue bank operation
- Increase direct sales worldwide, especially in China
- Seek new commercial application of products in cosmetic surgery/operation

Shanghai Reef International Trade, Shanghai Genomics Technology, Shanghai Hanyu Biotechnology, CellCarta, Recro

- Generate synergy among existing businesses
- Opportunistic and selective investments to create economic value
- Seek significant financial returns

Drug Development Pipeline

Product - Indication	Origin	Phase I	Phase II	Phase III	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, US)					
- Liver Fibrosis (China)	Proprietary				Start of Phase III was approved by NMPA Waiting for Phase III trial launch
- Liver Fibrosis (US)	Proprietary				Consultations with Key Opinion Leaders (KOLs) and advisors, scheduled to file with the FDA by the end of Q1 FY2022
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

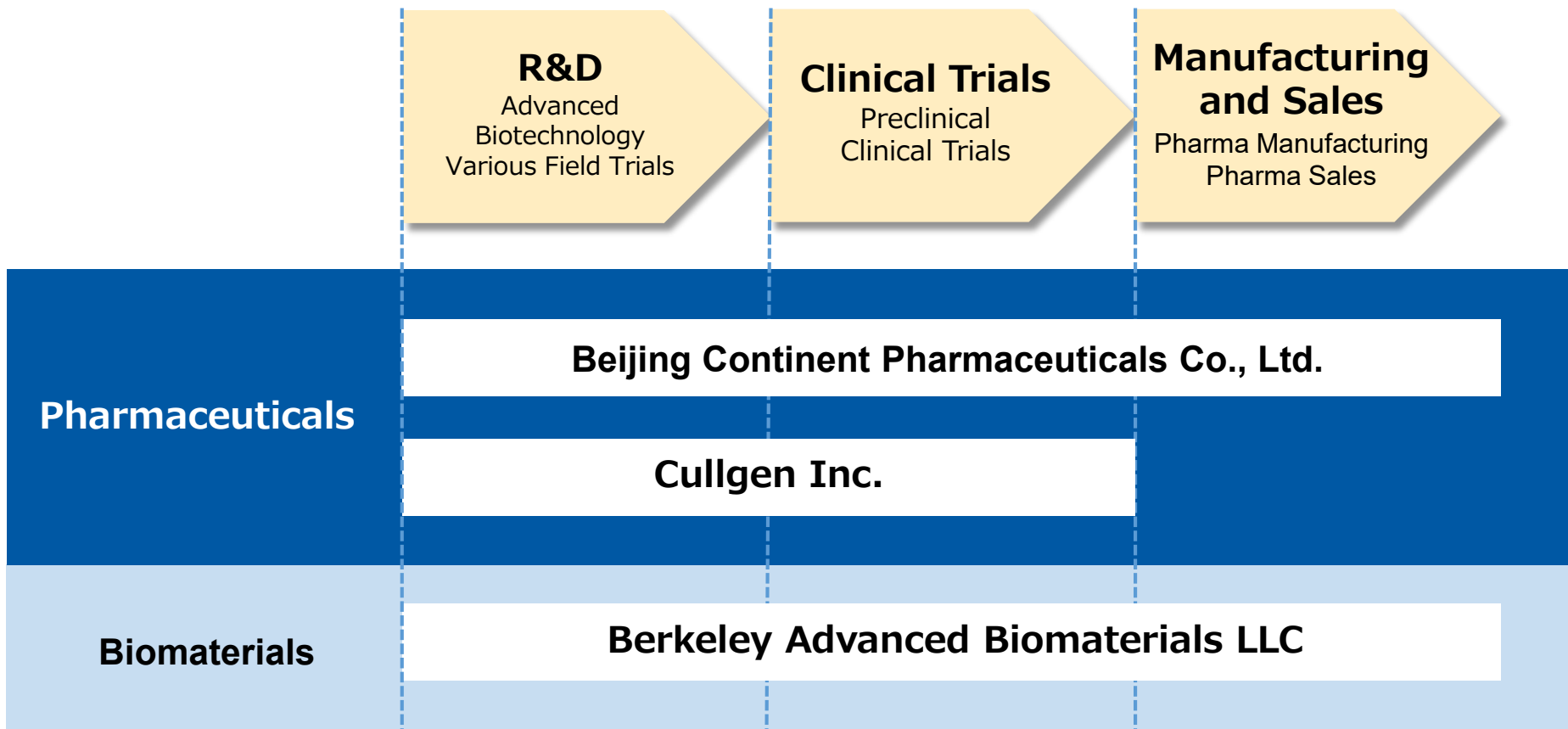
*Other than the above, new drugs for cancer, Chronic Obstructive Pulmonary Disease (COPD), and pulmonary hypertension are under development.

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

4. Companies



Our Therapeutic Products Value Chain - Overview



Key Attributes of Beijing Continent Pharmaceuticals Co., Ltd

- ✓ Spanning the entire pharmaceutical industry value chain from new drug discovery to compound search, clinical trials, manufacturing, and sales.
- ✓ Established API / formulation production capabilities through the production and commercial launch of Etuary[®] (艾思瑞[®]), a treatment for idiopathic pulmonary fibrosis, which boasts a commanding market share in Chinese market. Also promotes clinical trials to expand Etuary[®]'s indications.
- ✓ Built a leadership position in fibrotic diseases in Chinese market through a nationwide sales/distribution network in China.
- ✓ Investing excess earnings in new drug development and other biotech companies with unique strengths in the pharmaceutical business.
- ✓ Developing F351 for liver fibrosis and Etuary[®] for renal fibrosis to lead global organ fibrosis therapies.
- ✓ Continuing therapeutic pipeline expansion through prudent selection of drug candidates involved in organ inflammation and failure.



Key Attributes of Cullgen Inc.

- ✓ Combining cutting-edge research with China's speed and cost-effectiveness to revolutionize drug discovery through our proprietary drug discovery technology platform uSMITE™ (ubiquitin-mediated, small molecule-induced target elimination).
- ✓ Top-tier research scientists in the fields of cancer biology, and ubiquitin-proteasome system in both the US and China.
- ✓ Building a pipeline of new drugs cost-effectively in laboratory facilities in the US and China.
- ✓ Strong financial support and partnership from global venture capital and specialized private equity investors.



Key Attributes of Berkeley Advanced Biomaterials LLC

- ✓ Manufacture and sell a variety of self-transplanting, synthetic and tissue bank biomaterial products for bones and soft tissue (such as alternative bones, artificial bones, plates, etc.).
- ✓ Proprietary development and manufacturing expertise.
- ✓ Skilled management team with proven track records.
- ✓ Market penetration through direct sales and OEM for multinational companies.
- ✓ Streamlined and efficient organizational structure.
- ✓ Potential to expand business into non-US markets.



Balanced Profit and R&D Investment Structure

1. GNI Group has achieved a balance of developing important new products while maintaining profitability - rare among global biotech ventures.
2. All major group subsidiaries, (Beijing Continent Pharmaceuticals, Berkeley Advanced Biomaterials, Shanghai Genomics Technology, and Shanghai Reef International Trade) are either increasing or maintaining profitability.
3. Although Cullgen will continue to invest more into next generation of drug discovery technology, its financing is supported by global venture capital and private equity firms with GNI leading the efforts.
4. Our group structure enables each subsidiary to pursue the most suitable corporate development plan flexibly under the leadership of its own management team.
5. Subject to robust governance, subsidiary companies are free to consider listings as a means to further strengthen financing for expansion in their individual sectors.

5. Market Environment



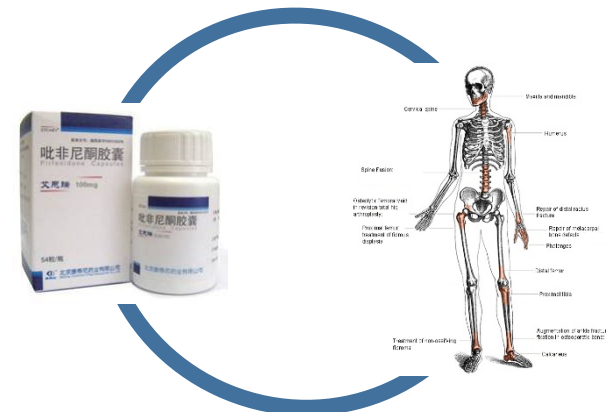
Addressable Markets

Pharmaceutical Business

- Beijing Continent Pharmaceuticals focuses on the market of fibrosis in lung, liver, and kidney diseases. This is a RMB 25 billion market with 76 million patients in China with very limited therapeutic options. (Source: Frost & Sullivan)
- Global liver fibrosis market alone is USD 13 billion in 2021 and is forecasted to grow to USD 22 billion by 2026. (Source: Market Data Forecast)
- The total cancer market size globally, to which Cullgen's underlying technology and drug development platform can be applied, is expected to reach USD 394 billion by 2027. (Source: Fortune Business Insights)

Biomaterials Business

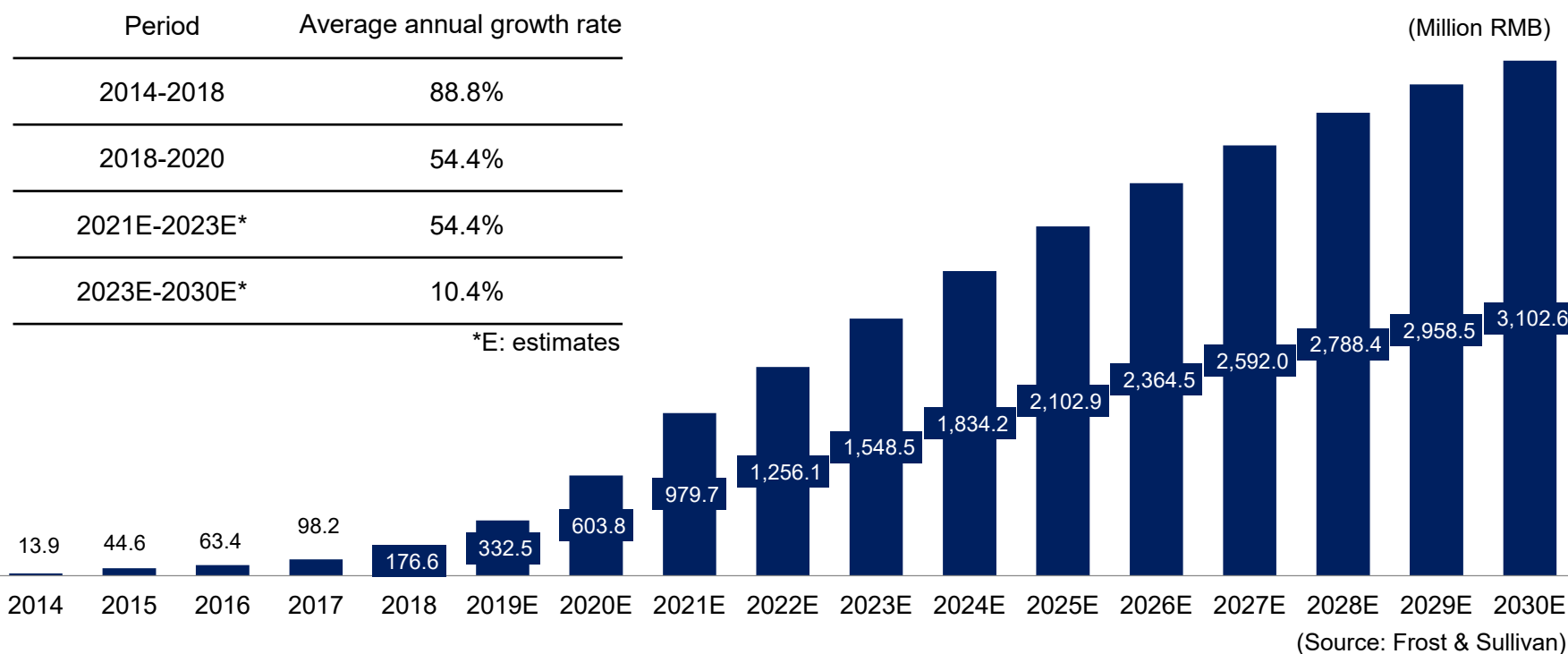
- The size of the biomaterials market worldwide in which Berkeley Advanced Biomaterials operates is USD 1.7 billion. (Source: iData Research)



Etuary[®]'s Market

Chinese Market for Idiopathic Pulmonary Fibrosis (IPF)

- ✓ The market for idiopathic pulmonary fibrosis drugs is expected to continue growing to RMB 1.5 billion by 2023, representing an average annual growth rate of 54.4%.
- ✓ Beijing Continent Pharmaceuticals' Etuary[®] (Pirfenidone) was the early mover, has gained trust of the medical establishment, and leads the market.

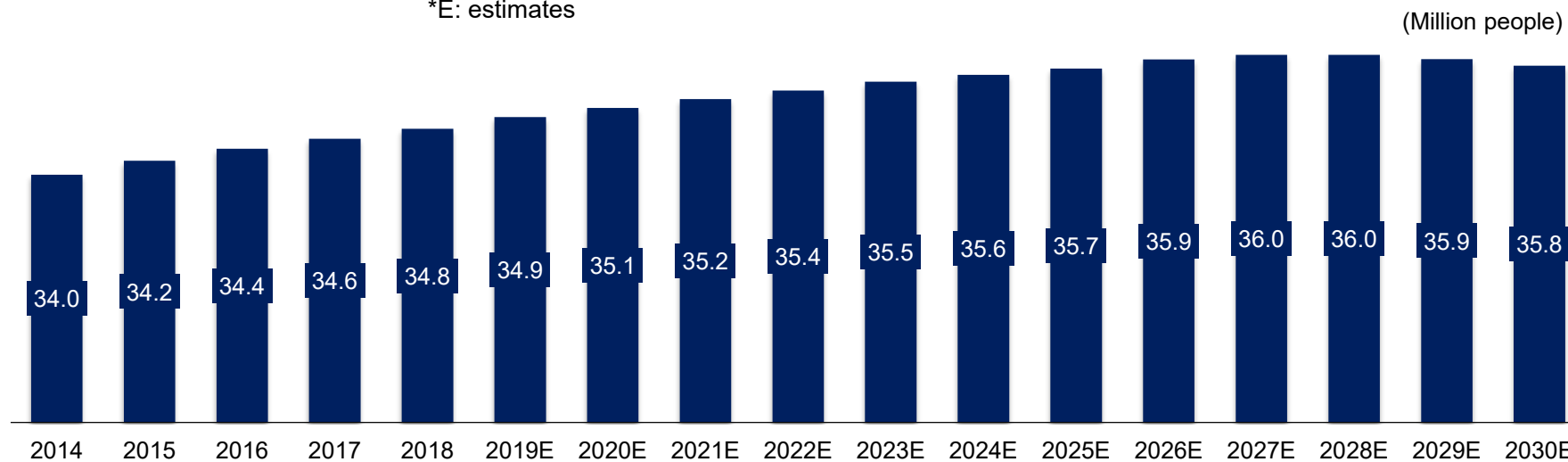


F351's Potential Market Number of Hepatic Fibrosis Patients in China

The number of chronic HCV patients that is the target of Beijing Continent Pharmaceuticals' F351 reached 34 million in 2014 and is expected to grow 36 million or more by 2027.

Period	Average annual growth rate
2014-2018	0.5%
2018-2023E*	0.4%
2023E-2030E*	0.1%

*E: estimates



(Source: Frost & Sullivan)

6. Business Outlook



Outlook for FY2021

(Million yen)	FY2020 (Actual)	FY2021 (Provisional)	YoY Percentage change
Revenue	9,773	12,617	29.1%
Gross profit	8,227	10,985	33.5%
Selling, general and administrative expenses	5,180	7,494	44.7%
Research and development expenses	1,243	1,980	59.3%
Operating profit	1,869	1,852	△0.9%
Finance income	46	89	94.3%
Finance costs	109	624	469.7%
Profit before tax	1,805	1,316	△27.1%
Income tax expense	440	804	82.9%
Profit after tax	1,365	511	△62.5%
Profit attributable to owners of the parent	1,258	1,260	0.2%

Assumptions:

- ✓ Revenue
 - Beijing Continent and Berkeley Advanced Biomaterials continue to follow the strong sales trend.
- ✓ Selling, General & Admin Expenses
 - Beijing Continent successfully expands their sales force, and Cullgen successfully on-boards additional research scientists as planned.
- ✓ R&D Expenses
 - Increase in Beijing Continent's R&D and Cullgen's IND filing preparations.
- ✓ Finance Costs
 - Non-cash accrual of dividends are treated as interest expense as per IFRS.

Capital for Growth:

We have a strong financial position: JPY 13.7 billion as of Nov 2021. We also issued additional equity warrants in Feb 2021, total of which amounted to about 9% of our existing equities. We are planning to invest these funds into R&D and other strategic opportunities.

Financial Results

(Million yen)

	Revenue	Operating profit (loss)	Profit (loss) before tax	Profit (loss) after tax	Profit (loss) attributable to owners of the parent
FY2021 (Provisional)	12,617	1,852	1,316	511	1,260
FY2020 (Actual)	9,773	1,869	1,805	1,365	1,258
FY2019 (Actual)	7,446	1,302	1,197	629	181
FY2018 (Actual)	5,018	568	364	192	△200
FY2017 (Actual)	2,648	154	137	28	△175
FY2016 (Actual)	1,306	△276	△385	△465	△513

7. Risk Considerations



Risk Considerations (1/2)

Item	Risk	Countermeasure
Development of pharmaceuticals	<ul style="list-style-type: none"> ■ There is no guarantee that new compounds will receive approval. ■ Changes in the content of required clinical trial data during the clinical development period and may vary depending on the country in which the application is filed <ul style="list-style-type: none"> ◎ Risk level : medium ◎ Time line : medium to long term ◎ Impact : large 	<ul style="list-style-type: none"> ■ Monitoring of relevant agencies and early detection of regulatory changes ■ Examine in advance how to respond to regulatory changes
Business expansion on a global level	<ul style="list-style-type: none"> ■ Possibility that global supply chain disruption constrains business activities in the pharmaceutical manufacturing, distribution, sales, medical practices, and biomaterials industries <ul style="list-style-type: none"> ◎ Risk level : medium ◎ Time line : medium to long term ◎ Impact : large 	<ul style="list-style-type: none"> ■ In parallel to collaborating across multiple regions, establish business operations in such a way that each region can run their businesses independently
Competition	<ul style="list-style-type: none"> ■ Lower revenues, sluggish selling prices and declining market share as a result of subordination to competitors, which may affect operating results and profit margins <ul style="list-style-type: none"> ◎ Risk level : medium ◎ Time line : medium to long term ◎ Impact : medium 	<ul style="list-style-type: none"> ■ Improvement of existing products and development of novel and price competitive products

Risk Considerations (2/2)

Item	Risk	Countermeasure
Regulatory environment	<ul style="list-style-type: none"> ■ Pharmaceutical R&D activities are subject to various regulations imposed by the regulatory authorities in each country in which they are conducted ◎ Risk level : low ◎ Time line : unknown ◎ Impact : large 	<ul style="list-style-type: none"> ■ Monitoring of relevant agencies and early detection of regulatory changes ■ Examine in advance how to respond to regulatory changes
Natural disasters, terrorism, wars, etc.	<ul style="list-style-type: none"> ■ The possibility that the progress of operations associated with system failures, etc. may become difficult due to natural disasters, terrorism, war, etc. ◎ Risk level : low ◎ Time line : unknown ◎ Impact : large 	<ul style="list-style-type: none"> ■ Outsourcing a backup system to an external vendor to determine how to respond to system failures
Impact of COVID-19 infectious diseases	<ul style="list-style-type: none"> ■ Prolonged outbreak of COVID-19 infectious diseases may affect sales revenue due to the progress of clinical trials and the status of hospitals ◎ Risk level : medium ◎ Time line : short to medium term ◎ Impact : large 	<ul style="list-style-type: none"> ■ Take steps to minimize the impact of the spread of COVID-19 infectious diseases by changing business forms and methods

Handling of this Document

- Statements contained herein with respect to our current plans, estimates and strategies that are not historical facts are forward-looking statements.
- Forward-looking statements are based on our management's beliefs in light of information currently available to it. Actual results may differ materially from these forward-looking statements due to a variety of risks and uncertainties. Therefore, please do not rely on these forward-looking statements to make investment decisions.
- Important factors that could affect actual results include economic conditions surrounding the Group's business areas, market trends, and global conditions.
- The next disclosure of "Business Plan and Growth Potential" is scheduled for March 2022. However, if there is a material change in our management policy, we may disclose it separately.

Contact Information

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