

Denka

Possibility of chemistry

FY2021 Results Presentation Topics Healthcare Business

May 11, 2022

- 1. Corporate History
- 2. Performance Trends
- 3. Priority Measures
 - a) Diagnosis (POCT/non-POCT clinical test reagents)
 - b) Prevention (influenza vaccine)
 - c) Treatment (G47\Delta virus preparation for cancer treatment)
- 4. New Initiatives for the Next Management Plan

1. Corporate History

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Contributing to society as a specialty company dealing in a range of vaccines and test reagents **Established**

Established Niigata Branch, Tokyo Shibaura Electric Co., Ltd Physical and Chemical Research Institute Transitioned to become a subsidiary of Denki Kagaku Kogyo Kabushiki Kaisha (Denka)





Established Physical and Chemical Research Institute Co., Ltd.

> Name changed to Toshiba **Chemical Corporation**

Company name changed to Denka Seiken Co., Ltd.

Launched Life **Innovation Division**

> Business integration

1945

1950 1951

1979 1982

2017

2020

- Vaccine production begins (1945)
- Moved to Toshiba Gosen Plant (1947)
- Influenza vaccine (1952)
- Bacteria test reagents/Shigella (1952)
- Japanese encephalitis vaccine (1954)
- Virus test reagents/Adenovirus (1966)
- Clinical chemistry reagents (1972)
- Influenza HA vaccine (1972)

- Pathogenic escherichia coli immune serum O157 (1985)
- Kagamida Plant begins operations (1994)
- Influenza test reagents (1999)
- Hyaluronic acid preparation (2000)
- Influenza A-B Quick Seiken (2000)
- Small dense LDL-cholesterol measuring reagent sd-LDL (2004)
- QuickNavi™-Flu (2008)

- Acquisition of all shares in Germanybased Icon Genetics (2015)
- Provided Ebola virus rapid diagnostic kits to the Democratic Republic of Congo (2017)
- Acquisition of 33.4% of shares in Taiwan-based PlexBio (2019)
- COVID-19 rapid antigen test kit (2020)
- G47 Δ virus for cancer treatment (2021)









Prevention

- · Influenza HA vaccine
- · Adsorbed tetanus toxoid



 Test reagents (Rapid antigen test kit, immune serum reagents, etc.)

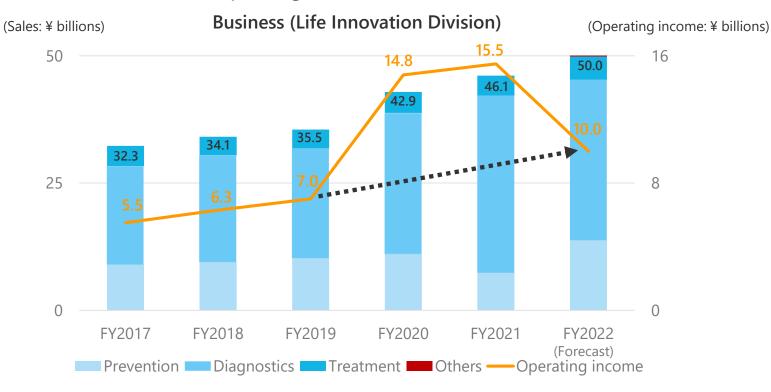


Treatment

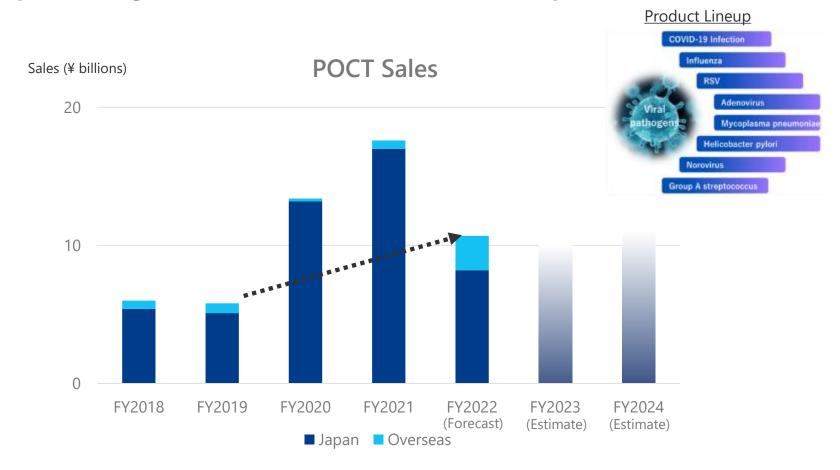
- Macromolecular hyaluronic acid formulation
- G47∆ virus preparation for cancer treatment



Sales and Operating Income Trends in the Healthcare



POCT sales almost doubled from pre-COVID levels despite a significant decrease when compared to FY2021



^{*}POCT: Point of Care Testing. Testing performed by a medical professional in the presence of the examinee, providing shorter test times and more familiarity with the test to the examinee, contributing to prompt and accurate medical treatment, nursing care, disease prevention, and health promotion, and thereby improving the quality of medical care, quality of life (QOL), and satisfaction for the examinee.

As a leading manufacturer, proactively adapting to rapid POCT business environment changes driven by COVID-19





Assumptions: POCT Business Environment

COVID-19 becomes endemic

Ease of mutation prevents eradication

Resurgence of influenza

Sharp distinction needed between COVID-19 and influenza in medicating

Entrenchment of testing demand levels for domestic medical institutions

Growing societal needs may lead to a lifted OTC use ban

Overseas markets expand with the spread of self-testing

Polarization into two markets: low-cost and high-end

Market

· Overseas: Accelerating the self-test area Supply for U.S.-based Xtrava Health, etc.

· Domestic: Ensure timely and stable supply and market share (30%) by strengthening cooperation with distributors

Production

- Expansion of manufacturing facilities
- Increase in total production capacity including storage and transportation
- Improvement in productivity through digital technologies and automation
 - ⇒ Proactive investment in the Kagamida Plant

Development

- High sensitivity
- Support for assessment devices (readers/apps)

^{*}OTC: Drugs that can be purchased "over the counter" at pharmacies, drugstores, etc. without a prescription *Self-testing: Testing conducted by a large organization, e.g. corporate, academic, military, rather than a medical institution

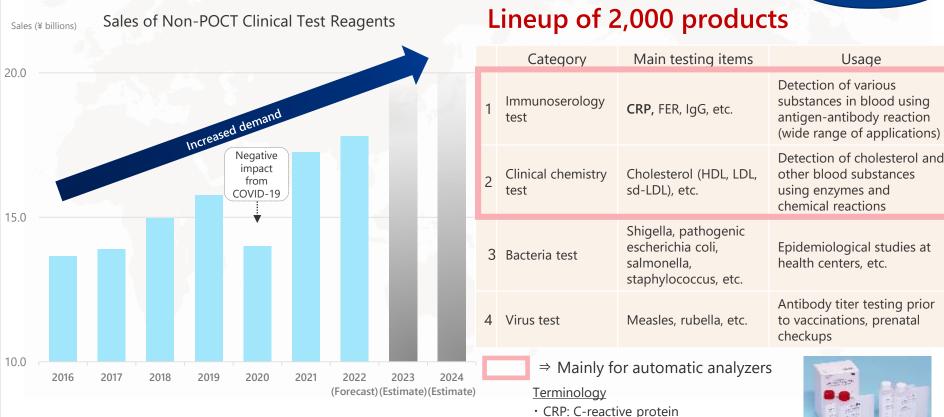
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a) Diagnosis (Non-POCT Clinical Test Reagents)

*Platformers: Companies that sell their own automated analyzers and specialized reagents

Achieving sales of non-POCT clinical test reagents via OEM and bulk supply to major platformers in Europe/North America as well as players in China, meeting growing global demand

> CRP: 30% global market share



· FER: Ferritin, an iron-binding protein

· IaG: Immunoglobulin

a) Diagnosis (All Clinical Test Reagents)

Decided to increase capacity to meet growing worldwide testing demand

POCT

Increasing facility capacity by Approx: 2.5x

Clinical test reagents
(Non-POCT)

Increasing production capacity by Approx: **2x**

Exterior view of the new manufacturing wing of the Gosen Site's Kagamida Plant (illustration)

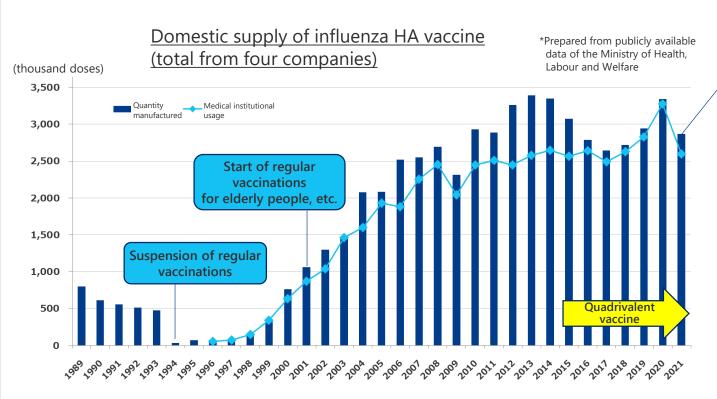


Business, production, logistics process reform and automation through area expansion and digitalization

Strengthening cost competitiveness

Completion: Second half of 2024 / Investment: Approx. ¥11 billion

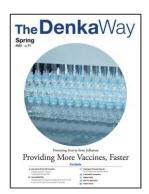




Supply volume significantly decreased due to degraded productivity among manufacturing strains and difficulties in procuring materials from COVID-19.

Stable demand even amid the COVID-19 pandemic

Four companies (including Denka) support social systems by manufacturing domestic influenza vaccines



Protecting Society from Influenza

Providing More Vaccines, Faster

b) Prevention (Influenza Vaccine)

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Significant increase in facility capacity enables faster and more stable supply FY2022 manufacturing target: 10 million vaccines (for approximately 20 million people)

Advantage

Flexibly adapting to productivity fluctuations and contributing to stable supply

⇒ Fulfillment of social responsibility

Advantage

Increasing supply early in the vaccination season

⇒ Elimination of lost vaccination opportunities

Advantage

Installing state-of-the-art automation equipment

⇒ Productivity Improvement

- Launched March 2022
- Investment: Approx. ¥16 billion

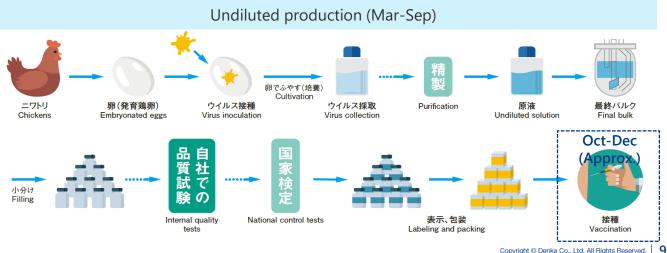
Influenza Vaccine Manufacturing Timeline

Selection of manufacturing strains (Jan-Mar)

World Health Organization (WHO) expert meeting to determine recommended strains to be used in vaccines each year

The Ministry of Health, Labour and Welfare and the National Institute of Infectious Diseases select strains for production based on epidemic status, productivity of candidate production strains, and other factors

Productivity evaluation of candidate strains by four Japanese manufacturers



c) Treatment (G47 \Delta Virus Preparation for Cancer Treatment)



June 2021

Daiichi Sankyo Company, Limited receives approval to manufacture and market a regenerative medicine product for the treatment of malignant glioma in Japan under conditional and time-limited approval

October 2021

Shipments begin from Denka to Daiichi Sankyo

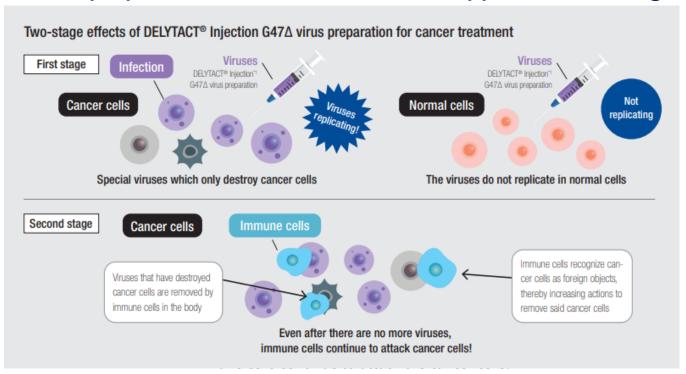
November 2021

Daiichi Sankyo begins sales of a treatment for malignant glioma under the product name "DELYTACT® Injection"

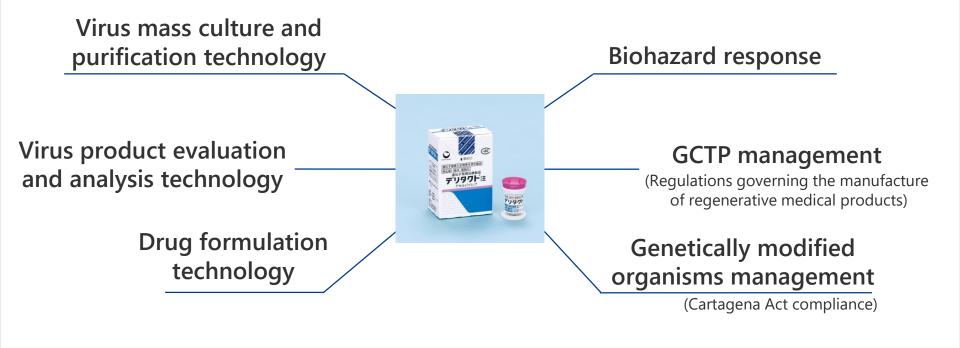
(Drug price: Approx: ¥1.43 million/1mL per vial)

→ Daiichi Sankyo-driven studies are underway for expanding its range of indications

World's first virus preparation for cancer treatment approved for malignant glioma



Developing commercial production technology by integrating fundamental technologies cultivated in the vaccine and test reagent business



Aiming to develop a stable supply system and expand into the Contract **Development and Manufacturing Organization (CDMO) business** for viral preparations, etc.

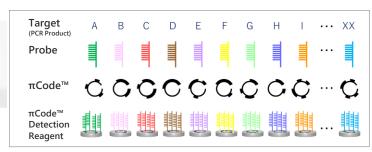
4. Outlook for the Next Management Plan (IntelliPlex Business Development)

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IntelliPlex[™] System Features (PlexBio Taiwan)

- Multiple, simultaneous measurements
- High sensitivity
- Compatible with both antigen/antibody (immunoassay) and genetic testing





Add to one well as detection reagent



Number of sepsis cases worldwide: 20-30 million/year

Strengthen collaboration to develop systems (reagents and instruments) for identifying pathogenic microorganisms and conducting genetic testing for drug-resistant bacteria in sepsis ~ Acquired 33.4% stake in PlexBio Co., Ltd. (2019) ~

Reagents

- Contribute solutions to the global challenge of combating drug-resistant bacteria
 - -Develop a proprietary **sepsis** diagnostic reagent
- **Diagnostic Instruments**
- Improve convenience in clinical settings
 - -Produce fully automated equipment via joint development

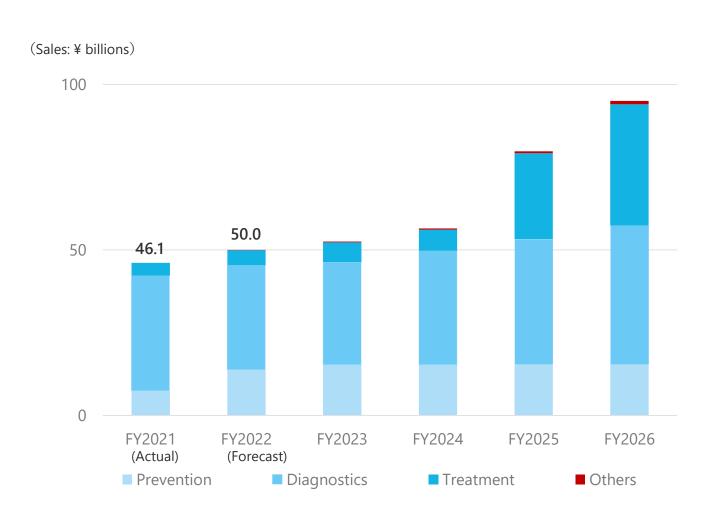
File for regulatory approval in Japan by the end of fiscal 2022





Fully Automated Device (Conceptual Image)

Significant growth in the "Treatment" field



Respecting the Dignity of Life and Protecting People's Health

Possibility of chemistry



Corporate Communications Dept, Denka Co., Ltd.



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