Note: This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the original shall prevail.

July 15, 2026

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Representative: Masaki Nonaka, President and CEO
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# Notice Concerning Update to Mid-Term Management Plan

We hereby announce that the Mid-Term Management Plan (for the period from the fiscal year ending June 2026 to the fiscal year ending June 2030), which was announced in August of last year, has been revised and updated to a new Mid-Term Management Plan covering the period from the fiscal year ending June 2027 to the fiscal year ending June 2031.

## 1. Update to the Mid-Term Management Plan

The Company announced its Mid-Term Management Plan in August 2025. In light of changes in the business environment and progress in the execution of its business strategy since then, the Company has formulated a new Mid-Term Management Plan covering the period from the fiscal year ending June 2027 through the fiscal year ending June 2031 (the "New Mid-Term Management Plan" or the "Plan").

## 2. Key Strategic Initiatives and Outline of the New Mid-Term Management Pla

1. Reviewing market assumptions and rebuilding strategy in light of infectious-disease volatility
2. Expanding testing platforms and developing the Data & AI infrastructure
3. Concretizing our entry into chronic-disease areas
4. Presenting our cash allocation

**3. Financial Targets**

| | Latest Earnings Forecast<br>Fiscal Year Ending June 2026 | Target for the Final Year of the<br>New Mid-Term Management Plan |
|---|---|---|
| Net sales | ¥15.0 billion | ¥36.7 billion |
| Gross profit | ¥9.3 billion | ¥18.8 billion |
| Operating income | ¥4.3 billion | ¥11.8 billion |
| Net income | ¥5.6 billion | ¥7.9 billion |

For more information, please refer to the attached document.

# Mid-Term Management Plan
# FY 2027/6 – FY 2031/6

TAUNS Laboratories, Inc.
July 15, 2026

# Background and Outline of the Mid-Term Management Plan Update

- In August 2025, we disclosed our Mid-Term Management Plan (the “Previous Plan”). Reflecting subsequent changes in the business environment and progress in our business strategy, we have formulated a new Mid-Term Management Plan (the “Current Plan”).

### ① Reviewing market assumptions and rebuilding strategy in light of infectious-disease volatility

- The FY 2026/6 forecast was revised down from the ¥20.7 billion net sales disclosed in August 2025 to ¥15.0 billion, mainly due to prolonged destocking in the market and an unexpectedly smaller COVID-19 outbreak.
- Given infectious-disease volatility, this Plan reassesses the infectious-disease POCT market on a more conservative basis.
- **We will strengthen antigen-test competitiveness and expand the lineup—led by share gains from the launch of an improved “ImmunoAce SARS-CoV-2/Flu” (“Combo II”; target Q1 FY 2027/6), a broader combo-test item lineup, and further performance improvements.**
- We will introduce new POCT offerings such as ElectraDx and nodoca to drive steady growth in the infectious-disease POCT business.

### ② Expanding testing platforms and developing the Data & AI infrastructure

- Under the goal of building a mechanism that continuously creates next-generation testing technologies, we will add new testing platforms such as testing services and SaMD alongside our mainstay POCT, and develop the Data & AI infrastructure that supports their R&D.

### ③ Concretizing our entry into chronic-disease areas

- Since the Previous Plan, our relationships with alliance partners have deepened and expanded—beginning with our entry into the SaMD business by making CLAIRVO Technologies, Inc. (“CLAIRVO”) a wholly owned subsidiary. Reflecting this, we set out the alliance strategy and sales plan for entering chronic-disease areas, including heart disease (CLAIRVO et al.), cancer (Craif et al.), dementia (Splink), and diabetes (Provigate).

### ④ Presenting our cash allocation

- Since the Previous Plan, major growth investments—such as the Fujisan Mishima Factory and investments in partners—have largely run their course. Accordingly, we present the direction for using the free cash flow generated during the Plan period (targeting ¥38.5 billion over five years), including shareholder returns.

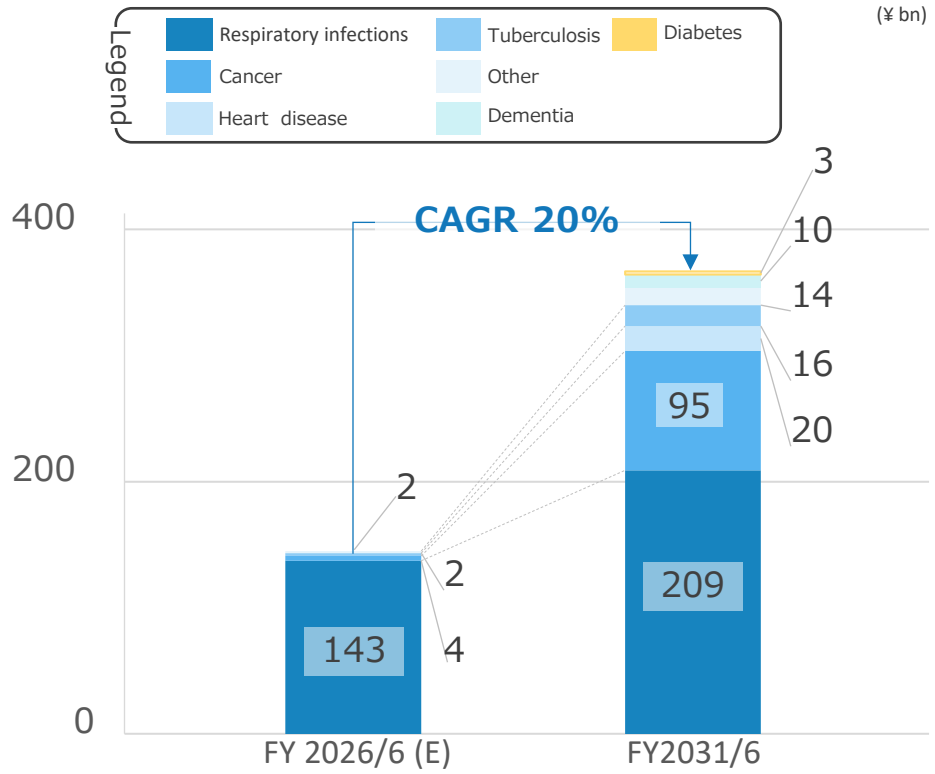
# INDEX

# Overview

# At a glance

- In FY 2031/6, the final year of the Plan, we aim to achieve net sales of ¥36.7 billion and operating income of ¥11.8 billion.
- In addition to sales growth from higher respiratory-infection POCT share, we will grow in chronic-disease areas such as cancer.
- We aim to move to the Prime Market during the Plan period.

## Sales plan by disease (FY 2026/6 → FY 2031/6)



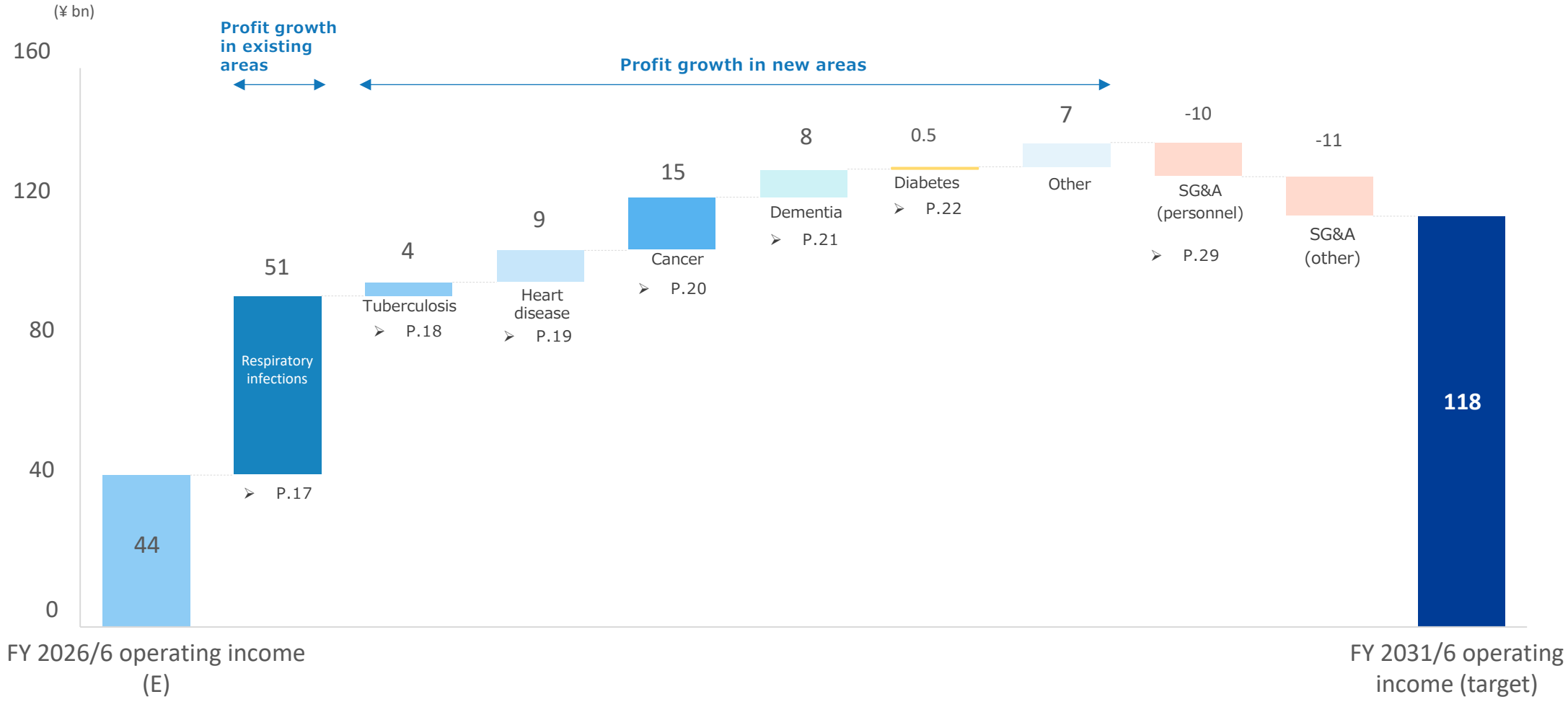

## Key financial items (FY 2026/6 → FY 2031/6)

| | Recent performance FY 2026/6 | | Mid-term plan target FY 2031/6 |
|---|---|---|---|
| Net sales | ¥15.0 bn | → | ¥36.7 bn |
| Gross profit | ¥9.3 bn | → | ¥18.8 bn |
| Operating income | ¥4.3 bn | → | ¥11.8 bn |
| Operating income margin | 29% | → | 32% |
| EBITDA | ¥5.3 bn | → | ¥13.6 bn |
| Net income | ¥5.6 bn[1)] | → | ¥7.9 bn |
| ROE | 31% | → | 32~52%[2)] |

1) FY 2026/6 records subsidies (e.g., the subsidy program to promote domestic investment for supply-chain resilience) in extraordinary income.
2) Shareholder returns (dividends, share buybacks, etc.) are assumed under multiple cases during the Plan period; accordingly, FY 2031/6 ROE is presented as a range.

# Factors for Operating Income Increase/Decrease from FY 2026/6 to FY 2031/6

- Beyond growth in respiratory-infection POCT, we aim to grow profit by launching new areas such as heart disease, cancer, and dementia.
- We will pursue productivity initiatives such as AIX to balance growth with cost efficiency.



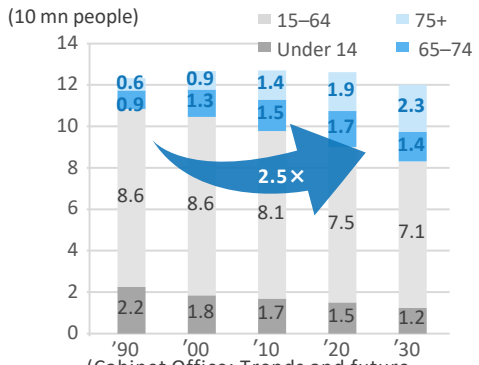
# Vision in Mid-term Management Plan

## Vision for the Mid-Term Management Plan: Solving social issues with diagnostic technology, data, and AI

- While new medical technologies such as cell therapy are being adopted for the growing number of chronic-disease patients driven by aging, medical resources—starting with specialists—are becoming increasingly strained.
- To make effective use of limited medical resources, the role of diagnostic technologies is becoming ever more important.
- By appropriately combining testing platforms such as POCT, testing services, and SaMD, TAUNS aims to help optimize diagnostic workflows across society—including hospitals, clinics, home care, and healthcare services.
- **By combining diagnostic technologies with data and AI, we will build a mechanism that continuously creates next-generation testing technologies to support diagnostic workflows.**

### Accelerating aging

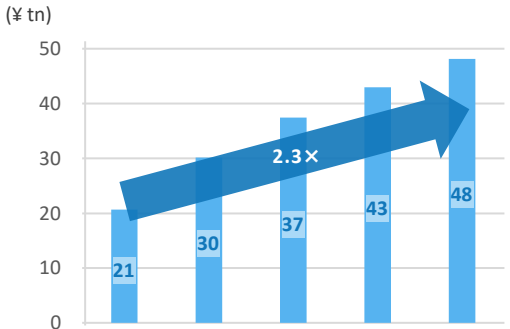
Population aged 65+ has grown about 2.5× over 40 years




(Cabinet Office: Trends and future estimates of aging)

### Rising national healthcare expenditure

About 2.3× over 30 years




(MHLW: National healthcare expenditure by year)

### Advances in medical technology

New medicine emerging from technological innovation

- Genomic medicine
- AI drug discovery
- Cell therapy

### Social implementation of AI

The AI transformation (AIX) is accelerating globally

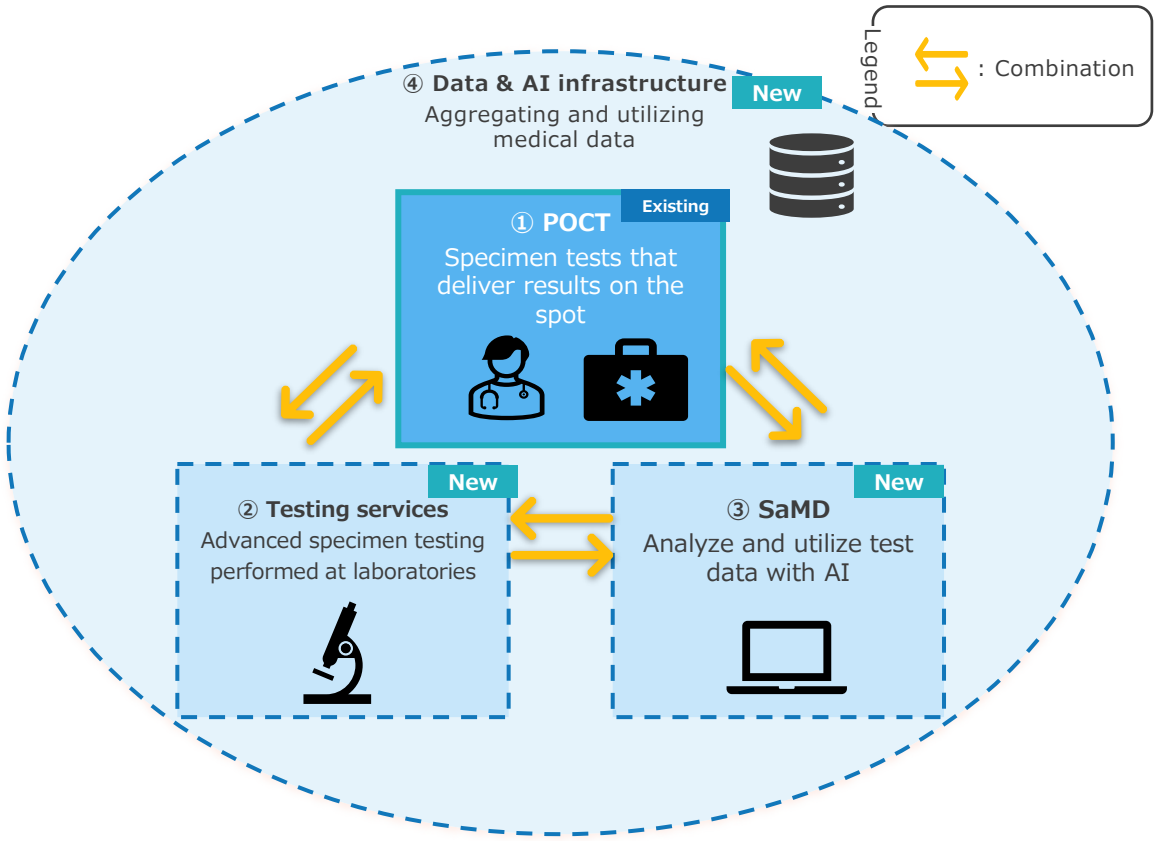
- Establishing mechanisms to aggregate and utilize medical data
- Updating diagnostic workflows through diagnostic technology × AI

# Expanding Testing Platforms and Developing the Data & AI Infrastructure

- In addition to POCT, we introduce new testing platforms such as testing services and SaMD, and develop the Data & AI infrastructure that supports R&D.
- By linking TAUNS's core specimen testing with the Data & AI infrastructure, we aim to expand our business domains and build a sustainable competitive advantage.

**Illustrative image: creating next-generation testing technologies**

Develop and operate next-generation testing technologies by combining testing platforms




| Combination pattern | Direction of next-generation testing tech | |
|---|---|---|
| ① POCT × ③ SaMD | **AI analysis of data obtained from POCT**<br>• nodoca (minimally invasive infectious-disease diagnosis via AI analysis of pharyngeal images)<br>• Dementia POCT (high-accuracy dementia screening combining cognitive-function AI and a blood-marker POCT) | P.17<br>P.21 |
| ② Testing services × ③ SaMD | **AI analysis of data obtained from testing services**<br>• Pancreatic-cancer SaMD (under development by Craif; detects urinary miRNA by NGS and analyzes it with AI to screen for pancreatic cancer) | P.20 |
| Data & AI infrastructure | **Aggregation of usable medical data and an AI operating environment**<br>• Bank biobank samples, medical imaging data, EHR etc. in a readily usable form<br>• Build the operating environment for data use, including computing resources and algorithms | P.15 |

# Key Business Domains

- In the “respiratory infection × screening” business, we aim for steady sales growth by strengthening product and sales capabilities.
- We will enter chronic-disease areas with new testing technologies, building an earnings base resilient to infectious-disease volatility.

Legend
: Existing areas
: New areas of entry (Phase 1)
: New areas of entry (Phase 2)

| | | Before onset | After onset of disease | | Before treatment | After treatment | |
|---|---|---|---|---|---|---|---|
| | | Risk assessment | Screening | Definitive diagnosis | Treatment planning | Monitoring | SOM |
| Infectious disease | Respiratory infections | | Antigen testing nodoca | ElectraDx | | | ¥22.7 bn (Japan) |
| | Tuberculosis | | D-IA | D-IA | | D-IA | ¥9.3 bn (incl. overseas) |
| Chronic disease | Heart disease | | ElectraDx | SaMD (medical imaging) | SaMD (medical imaging) | | ¥3.5 bn (Japan) |
| | Cancer | Testing services (miRNA) | SaMD (miRNA) | SaMD (medical imaging) | Testing services (Th7R) | Testing services (Th7R) | ¥21.0 bn (Japan) |
| | Dementia | | D-IA | | D-IA | | ¥12.6 bn (Japan) |
| | Diabetes | | | | | D-IA | ¥43.0 bn (incl. overseas) |

Note: SaMD = Software as a Medical Device; standalone software used as a medical device for medical purposes.

# Long-Term Timeline

- Grow sales by strengthening antigen tests; launch new products such as testing services and SaMD — Phase 1
- Launch the next-generation POCT digital immunoassay (D-IA); combine with SaMD to solve diagnostic-workflow challenges — Phase 2
- Roll out D-IA globally to achieve further growth — Phase 3 (beyond the Plan period)

| | Strengthen antigen tests and launch new products<br>Phase 1: FY 2027/6–FY 2029/6 | With D-IA and SaMD: solve diagnostic-workflow challenges<br>Phase 2: FY 2030/6–FY 2031/6 | Global rollout of next-generation testing<br>Phase 3: FY 2032/6 onward |
|---|---|---|---|
| **POCT**<br>[Antigen tests, etc.] | • **Launch Combo II**<br>• **Launch Strep A/Adeno combo**<br>• Improve various antigen tests | • Launch ElectraDx nucleic-acid panel (respiratory)<br>• **Launch D-IA (dementia, diabetes, tuberculosis)** | • **Global rollout of the D-IA tuberculosis POCT in cooperation with the WHO**<br>• **Global rollout of D-IA × SaMD (diabetes, dementia)** |
| Testing services<br>[Th7R, etc.] | • **Launch multi-omics testing services**<br>• Launch Th7R (LDT) | • **Convert Th7R to an IVD**<br>• Launch clinical NGS testing | • Expand cancer types covered by Th7R and others<br>• **IVD development using the Data & AI infrastructure** |
| SaMD | • **Launch pancreatic-cancer SaMD**<br>• **Launch coronary-CT SaMD** | • Expand the SaMD lineup<br>• Full-scale adoption of SaMD as insurance coverage and use cases increase | • Provide and support SaMD on our own platform<br>• **Develop SaMD linked with POCT** |
| Data & AI infrastructure | • Expand the medical data bank<br>• Build annotation and data-analysis systems<br>• Secure computing-resource infrastructure | • Analyze target-disease mechanisms<br>• Develop algorithms/AI<br>• Partner with overseas biobanks | • **An ecosystem centered on the Data & AI infrastructure**(joint research and social implementation involving academia, startups, pharmaceutical companies, and local governments) |

# Testing Platform Strategy

# POCT Strategy

- We aim for steady growth of our mainstay antigen tests by strengthening the lineup.
- By introducing ElectraDx, nodoca, and the digital immunoassay (D-IA), we solve challenges in clinical practice.

## Role and challenges of POCT

- POCT delivers results on the spot, supporting appropriate treatment decisions
- Conventional POCT has limits in data accuracy and quality, while outsourcing to laboratories entails long TAT[1)] and cost constraints.
- Insufficient accuracy causing false negatives/positives increases patient burden through retesting.
- During outbreaks, test volumes rise and burden healthcare workers.

## TAUNS's POCT strategy

① Keep simple, rapid **antigen tests** as the core of our POCT strategy, and raise share by strengthening the lineup starting with Combo II.

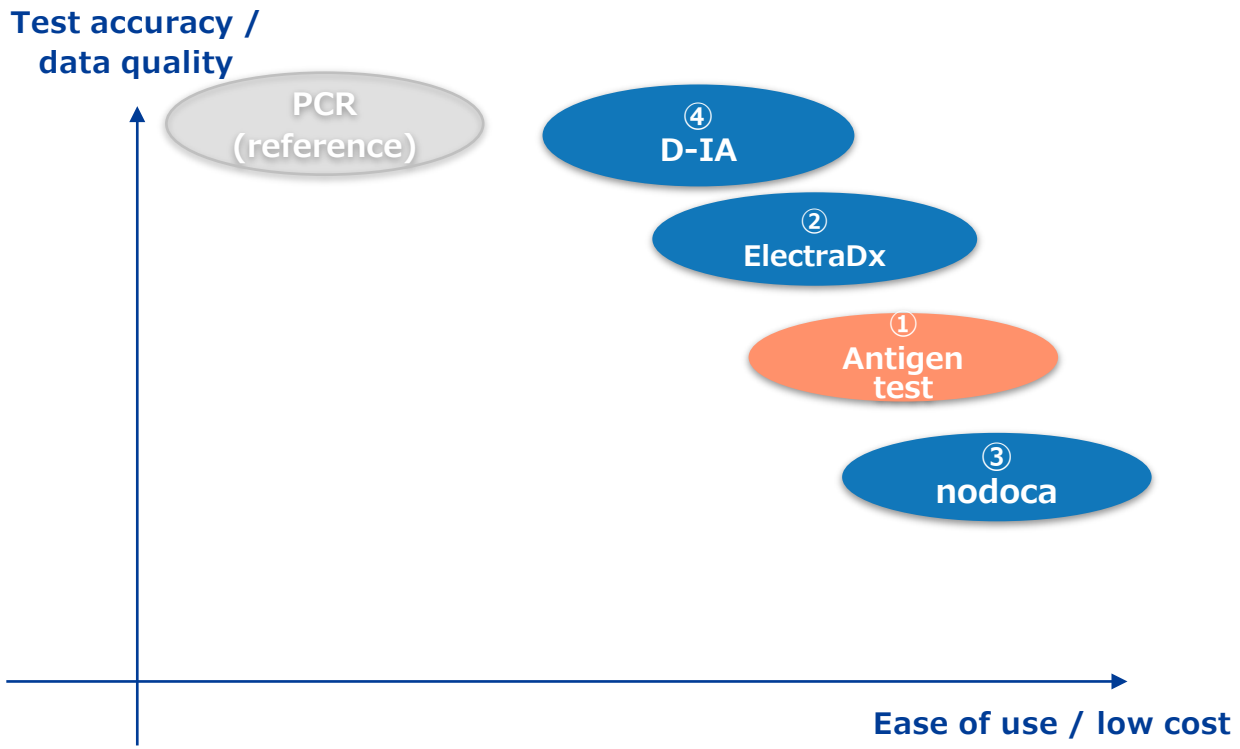
② Introduce **ElectraDx**'s infectious-disease nucleic-acid panel, reducing missed cases and retests through higher accuracy and simultaneous multiplex testing.

③ Introduce minimally invasive infectious-disease testing with **nodoca** (pharyngeal-image AI).

④ Enable high-accuracy quantitative biomarker testing with **D-IA**, aiming to establish on-the-spot diagnostic workflows without outsourcing.We are developing it for dementia and diabetes, and also use it in tuberculosis monitoring tests

## Illustrative positioning of TAUNS's POCT technologies

### Solving clinical challenges with four types of POCT




1) TAT: Turn Around Time — time from test receipt to reporting

# Testing Services Strategy

- Introduce cutting-edge instruments at the TAUNS laboratory and provide multi-omics[1] testing services.
- Partner with university hospitals, health-screening providers, and local governments to support building and operating medical data banks.

## Background of entry into testing services

- With the spread of next-generation sequencing (NGS) and advances in AI, next-generation testing-service products such as Craif's "miSignal" are emerging.
- Many next-generation testing services products are mainly B2C and have not spread to medical institutions
- Collecting usable medical data is key to developing new testing technologies.

## TAUNS's testing services strategy

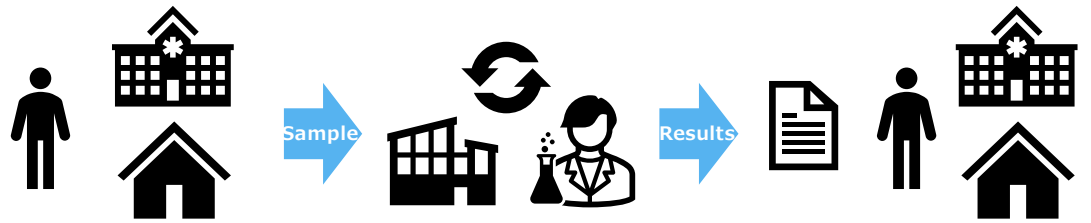
**① Provide testing services**
- A multi-omics[1] testing system
- Promotion to medical institutions
- Regulatory filings

TAUNS

**② Medical data bank**
- Accumulate test data
- Partner with university hospitals and others to support building medical data banks

**③ Develop new testing technologies**
- Leverage the medical data bank
- Market using our own sales capabilities

## What is testing services?

| | Sample collection | Analysis with advanced instruments | Review of results |
|---|---|---|---|
| | Blood/urine/saliva, etc. | Comprehensive/integrated analysis | Detailed test-result reports |
| Illustration |   | | |
| Who | - Individuals<br>- Medical institutions | - Laboratory | - Individuals<br>- Medical institutions |

## Examples of testing services products [2]

| Name | Target disease | Features |
|---|---|---|
| miSignal (Craif) | Cancer (risk assessment) | High-accuracy cancer screening by NGS[3] (urine sample) |
| Th7R | Cancer (treatment planning) | ICI[5] efficacy prediction by FCM[4] (whole-blood sample) |

1) Multi-omics: comprehensive analysis of biological data such as genes, RNA, proteins, and the epigenome
2) See P.41 (Appendix) for details on testing-service products
3) NGS: Next Generation Sequencing — technology that analyzes large volumes of DNA/RNA sequences in parallel
4) FCM: flow cytometry — measuring surface/internal features of cells in a flow channel
5) ICI: immune checkpoint inhibitor — a drug that releases immune brakes to enhance the immune response against cancer cells

# SaMD Strategy

- We obtained exclusive domestic sales rights to Craif's "pancreatic-cancer SaMD" (under development), aiming to spread early pancreatic-cancer testing at clinics and other institutions.
- We launched the Device Solutions Strategy Division to run the SaMD business and drive the fusion of POCT and SaMD.

## Background of entry into SaMD

- The use of medical AI/SaMD is rapidly expanding for early detection, diagnostic support, and workflow efficiency
- Many innovative SaMDs are being developed, but track record, quality assurance, and operational support are essential for confident adoption
- Leveraging the medical-institution relationships and trust built in our POCT business, we lead the validation and adoption of SaMD

## TAUNS's SaMD strategy

### ① Roll out SaMD to medical institutions

- Promote pancreatic-cancer SaMD and coronary-CT SaMD through TAUNS's sales capabilities
- Build a track record with flagship SaMDs to drive adoption of other SaMDs

CLAIRVO TECHNOLOGIES

Core of the SaMD business (subsidiary)

### ② POCT × SaMD

- Build optimal diagnostic workflows combining POCT such as D-IA with SaMD (including combined regulatory filings)

### ③ Imaging core-lab business

- Use SaMD expertise and medical-image datasets to offer medical-image analysis services to pharmaceutical companies

## What is SaMD?

**Software as a medical device that analyzes medical data with AI, etc. to support medical decisions**

| | Data input | AI analysis | Output |
|---|---|---|---|
| Diagnostic imaging AI | • Medical imaging data such as CT, MRI, and pathology images | • Extract image features<br>• Detect/classify candidate lesion regions | • Lesion detection, abnormal-finding extraction, risk stratification, etc. |
| Specimen-test data analysis AI | • Specimen-test data such as POCT and NGS | • Match test-data patterns against a database<br>• Score disease risk, etc. | • Disease-risk assessment, diagnostic-support reports, etc. |

## Examples of SaMD products [1)]

| Name | Target disease | Features |
|---|---|---|
| Pancreatic-cancer SaMD (Craif) | Pancreatic cancer (screening) | Early detection of pancreatic cancer, including stage 1, from a urine sample |
| Coronary-CT SaMD | Heart disease (treatment planning) | Integrated assessment of "morphology × plaque × hemodynamics" via minimally invasive coronary CT, reducing diagnostic use of invasive cardiac catheterization |

1) See P.41 (Appendix) for details on SaMD products

# Developing the Data & AI Infrastructure

- Build an end-to-end system spanning computing resources, data banks, and algorithms/AI, and use it for next-generation IVD/SaMD development.
- Build an ecosystem involving academia, startups, pharmaceutical companies, and local governments as a base that continuously creates new technologies.

Products

infrastructure

| Layers of the Data & AI infrastructure | Purpose of use | Initiatives & partners |
|---|---|---|
| **IVD/SaMD**<br>- POCT, testing services, medical-device software | • Implement new markers as IVDs<br>• Develop new SaMD<br>• Diagnosis via IVD × SaMD<br>• workflow optimization | • New markers from biobank research<br>• used for next-generation IVD development<br>• **Leverage CLAIRVO's[1] SaMD know-how** |
| **Algorithms/AI**<br>- Disease-mechanism analysis via data/models (early diagnosis, severity/treatment-effect/prognosis prediction, etc.) | • Analyze disease mechanisms<br>• Discover/evaluate new markers<br>• Apply to SaMD | • **Disease analysis and algorithm/AI development with EMCH[2] and Callisto[3]** |
| **Wet/dry data bank**<br>- Biobank (stored samples)<br>- Medical images / clinical information / molecular data | • Use for in-house R&D<br>• Provide data to startups<br>• Support external sales of stored samples and data<br>• Imaging core-lab business | • Support biobank construction (partnering with university hospitals, local governments, EMCH, and others)<br>• Collect RWD such as medical images and EHR; develop datasets in partnership with Callisto |
| **Computing resources**<br>- Data centers, analysis environments, secure computing infrastructure | • Use for in-house R&D<br>• Provide computing resources to startups<br>• Monetize via offtake agreements | • Secure efficient, safe computing resources by partnering with data-center operators |

1) CLAIRVO: CLAIRVO Technologies, Inc.
2) EMCH: EMC Healthcare, Inc.
3) Callisto: Callisto, Inc.

# Disease-Specific Strategy

# Respiratory Infectious Disease Strategy

**Target**

**Capture 40%+ domestic market share in major respiratory-infection POCT**

FY 2031/6 target sales (Japan) : ¥20.2 bn
SOM (Japan) : ¥22.7 bn

## Current issues

### Clinical issues

1. Insufficient antigen-test accuracy can miss positive patients or lead to retesting
2. Healthcare workers' workload rises during outbreaks
3. Invasive swab sampling burdens patients

### TAUNS' s issues

1. Delayed Combo II rollout could slow share gains
2. Responding to price competition
3. Need for simple, high-accuracy POCT for the next pandemic

## Business policy

### Initiatives

- **Expand share via the launch of Combo II and the Strep A/Adeno combo**
- Improve price competitiveness through cost reduction
- Improve competitiveness through antigen-test enhancements
- Introduce the ElectraDx nucleic-acid panel
- Introduce nodoca (minimally invasive pharyngeal-image AI test)
- Strengthen the sales structure (see P.26)

### Outlook

- **Q1 FY 2027/6 (target): launch Combo II**
- FY 2027/6: begin handling nodoca
- **FY 2029/6: launch Strep A/Adeno combo**
- FY 2030/6: launch ElectraDx nucleic-acid panel
- Launch improved versions of each antigen test

# Tuberculosis Strategy

**Target**

**Obtain WHO prequalification for the D-IA tuberculosis POCT and expand globally**

FY 2031/6 target sales (incl. overseas) : ¥1.6 bn
SOM (incl. overseas) : ¥9.3 bn

## Current issues

**Clinical issues**

1. Over 10 million people are infected with tuberculosis worldwide each year; multidrug-resistant tuberculosis is also a major challenge
2. Adopting short-course regimens requires quickly assessing treatment effect and resistance, yet monitoring currently relies on culture testing with a 1–6 week TAT
3. Nucleic-acid tests, increasingly used for definitive diagnosis, are ill-suited for monitoring (e.g., they may score dead bacteria as positive)

**TAUNS' s issues**

1. Capilia TB-Neo (confirmatory diagnosis for culture-positive samples) is increasingly being replaced by nucleic-acid tests

## Business policy

**Initiatives**

1. Introduce the D-IA tuberculosis POCT, which detects live-bacteria antigens rapidly (within 1.5 h) at sensitivity close to culture testing, establishing a new monitoring workflow to replace culture testing
2. Cover screening, definitive diagnosis, and monitoring end-to-end
3. Aim to obtain WHO prequalification to rapidly expand the D-IA tuberculosis POCT globally after launch

**Outlook**

- **FY 2031/6:**
  - Launch D-IA tuberculosis POCT
  - Obtain WHO prequalification

# Heart Disease Strategy

**Target**

**Using POCT and SaMD, establish a minimally invasive, efficient heart-disease risk-stratification workflow for the heart-failure pandemic era**

FY 2031/6 target sales (Japan) : ¥1.9 bn
SOM (Japan) : ¥3.5 bn

## Current issues

**Clinical issues**

1. Aging increases heart-disease patients, straining cardiology resources (the “heart-failure pandemic”)
2. Cardiac catheterization is the mainstream for risk stratification but is invasive and time-consuming
3. Coronary-CT image-analysis workflows vary by facility; shortening lead time to diagnosis and building consistent data operations are challenges

## Business policy

**Initiatives**

- **The coronary-CT SaMD supports minimally invasive, rapid risk stratification and treatment planning while accommodating each institution’s data-handling policy (e.g., on-site servers)**
- Progressively expand cardiovascular-CT SaMDs available on a common platform to advance diagnostic workflows across the cardiovascular area, centered on the coronary arteries
- Speed up initial risk assessment of chest-pain patients with ElectraDx (NT-proBNP/troponin)

**Outlook**

- **FY 2027/6:**
  - **Launch coronary-CT SaMD**
  - Establish reference sites
- FY 2028/6: launch ElectraDx NT-proBNP
- FY 2029/6: launch ElectraDx troponin
- Progressively launch cardiovascular-CT SaMDs

# Cancer Strategy

**Target**

**- Establish an early pancreatic-cancer diagnostic workflow**
**- Offer products covering cancer from risk assessment to monitoring**

FY 2031/6 target sales (Japan) : ¥8.6 bn
SOM (Japan) : ¥21.0 bn

## Current issues

**Clinical issues**

1. High-risk groups for pancreatic cancer (e.g., diabetics) are growing, but there is no decisive means of early detection
2. Immune checkpoint inhibitors (ICIs) have a response rate of about 10–30%; identifying responders is a challenge
3. Preoperative ICI testing relies on highly invasive cytology
4. Higher-resolution, higher-volume radiology images increase the burden on reading physicians

## Business policy

**Initiatives**

- **Exclusively sell Craif's pancreatic-cancer SaMD (under development) in Japan, targeting high-risk groups such as diabetic patients and expanding to clinics and other institutions with major drug wholesalers**
- **Launch Th7R (a minimally invasive whole-blood preoperative test assessing ICI response rates) and partner with major laboratories**
- Launch lung- and breast-cancer SaMDs (image-diagnosis support AI) to improve reading accuracy and diagnostic efficiency
- Begin offering miSignal to medical institutions

**Outlook**

- FY 2027/6: begin handling miSignal
  - Launch lung-cancer SaMD
- **FY 2028/6: begin handling pancreatic-cancer SaMD**
  - **Launch Th7R (LDT)**
  - Launch breast-cancer SaMD
- FY 2031/6: convert Th7R to an IVD (for lung cancer)

# Dementia Strategy

**Target**

**Link the D-IA dementia POCT with cognitive-function AI to support screening and triage of dementia/MCI patients**

FY 2031/6 target sales (Japan) : ¥1.0 bn
SOM (Japan) : ¥12.6 bn

## Current issues

**Clinical issues**

1. Disease-modifying therapies (DMTs) such as lecanemab raise the importance of early diagnosis and intervention for dementia/mild cognitive impairment (MCI)
2. Dementia/MCI patients are increasing (an estimated 10M+ in Japan), while there are only about 2,000 dementia specialists—making proper screening and triage in clinics important
3. Existing dementia blood-marker tests (e.g., amyloid-β) are mainly advanced testing services intended for specialists and are little used in clinics

## Business policy

**Initiatives**

- **Enable simple clinic-based measurement of dementia blood markers with the D-IA dementia POCT**
- **Link Splink's cognitive-function AI (CQ Test) with D-IA to enable dementia/MCI screening in clinics**
- Use CQ Test and D-IA to support triage of dementia/MCI patients in clinics (referral to specialists or continued on-site treatment)

**Outlook**

- **FY 2030/6: launch D-IA dementia POCT**
- Establish an optimal dementia diagnostic workflow combining the D-IA dementia POCT and cognitive-function AI; initially target memory clinics

# Diabetes Strategy

**Target**

**Link the D-IA diabetes POCT with a behavior-change app to support behavior change in diabetes patients**

FY 2031/6 target sales (Japan) : ¥0.2 bn
SOM (incl. overseas) : ¥43.0 bn

## Current issues

### Clinical issues

1. Adult diabetes patients and pre-diabetics are estimated at about 1.2 billion[1)] globally and rising
2. Blood-glucose measurement helps management, but existing methods have the following issues
   - HbA1c is measured only at visits every 2–3 months and changes slowly—unsuited to responsively reflect glucose changes in daily life
   - Self-monitoring such as SMBG/CGM is largely reimbursed only for insulin-dependent patients, so the majority of insulin-independent patients do not self-monitor; blood-test invasiveness is also an issue

## Business policy

### Initiatives

- **Through the alliance with Provigate, develop a low-cost, minimally invasive D-IA diabetes POCT using salivary glycated albumin (GA, reflecting ~1 week of average blood glucose) as the indicator**
- Display weekly GA results (≈ the past week's average glucose) in a user app and link with a remote-support service to sustain behavior change for improving/maintaining glucose control
- Visualize GA data in a form easily shared by users, supporters, and healthcare providers

### Outlook

- **FY 2031/6: launch D-IA diabetes POCT**

1) International Diabetes Federation(2024)

# Key Development Pipeline by Disease

| Disease | Products | Product overview | Launch / start-of-handling timing |
|---|---|---|---|
| Respiratory infections | nodoca (Aillis) | Respiratory-infection test via pharyngeal-image AI | FY 2027/6 |
| | Combo II | Simultaneous SARS-CoV-2/influenza test | FY 2027/6 |
| | Strep A/Adeno combo | Simultaneous GABHS/adenovirus test | FY 2029/6 |
| | ElectraDx nucleic-acid panel | High-accuracy respiratory-infection panel test | FY 2030/6 |
| Tuberculosi | D-IA tuberculosis POCT | Tuberculosis screening / definitive-diagnosis / monitoring test | FY 2031/6 |
| Heart disease | ElectraDx NT-proBNP | Heart-disease marker test | FY 2028/6 |
| | ElectraDx troponin | Heart-disease marker test | FY 2030/6 |
| | Coronary-CT SaMD | Heart-disease treatment-planning support via image AI | FY 2027/6 |
| Cancer | Th7R/LDT | Cancer-treatment (ICI) efficacy-prediction test | FY 2028/6 |
| | Th7R/IVD | Cancer-treatment (ICI) efficacy-prediction test | FY 2031/6 |
| | miSignal（Craif） | Urine-based cancer risk-assessment test | FY 2027/6 |
| | Pancreatic-cancer SaMD (under development by Craif) | Urine-based pancreatic-cancer screening test | FY 2028/6 |
| | Lung-cancer SaMD | Lung-cancer definitive-diagnosis support via image AI | FY 2027/6 |
| | Breast-cancer SaMD | Breast-cancer definitive-diagnosis support via image AI | FY 2028/6 |
| Dementia | D-IA dementia POCT | Dementia blood-marker test | FY 2030/6 |
| Diabetes | D-IA diabetes POCT | Diabetes saliva-marker test | FY 2031/6 |

# Key Initiatives to Realize the Vision

# Production and Quality Strategy

**Target**

**① FY 2031/6 production volume: 40%[1)]+ increase vs. FY 2026/6**
**② FY 2031/6 production per capita[2)]: 50%+ increase vs. FY 2026/6**
**③ Strengthen quality management (prevent quality issues that could lead to product recalls)**

## 1. Utilize production capacity

- Operating policy for production sites
  - Fujisan Mishima Factory (new): dedicated to antigen-test mass production
  - Kamishima Factory: launch of D-IA production lines, contract manufacturing, etc.
- Shorten production lead time
  - Respond flexibly to outbreak fluctuations while keeping inventory low

×

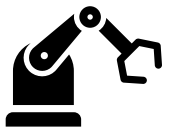
## 2. Improve productivity

- Continuously improve productivity through line efficiency/automation
- Reduce costs by insourcing outsourced processes
- Optimize production planning and streamline indirect work with AI

×

## 3. Strengthen the quality-management system

- Expand in-line inspection
- Reduce inspection man-hours through automation
- Real-time management of inspection data
- AI-based defect-precursor detection and early feedback on quality risks



1) FY 2031/6 production volume ÷ FY 2026/6 production volume
2) Production volume ÷ production-division headcount

# Domestic Sales Strategy

**Target**

**① FY 2031/6 domestic respiratory-infection POCT share: 40%+**
**② FY 2031/6 domestic sales in new areas: ¥13.0 billion+**

## 1. Expand respiratory-infection POCT share

**Internal measures**

- Increase DMRs: from 34 to 50+
- Reorganization/redeployment: streamline indirect work and reorganize to make sales more efficient

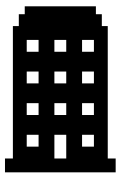
**External measures**

- Wholesaler strategy: efficient supply via strategic inventory allocation and stronger presence within wholesalers
- Alliance strategy: expanded sales of TAUNS products via Shionogi and Roche

×

## 2. Secure sales in new areas

- Promotion of SaMD (CLAIRVO/Craif) to clinics by TAUNS DMRs
- Launch disease-dedicated teams for cancer/dementia/diabetes
- Partner with major drug wholesalers to spread SaMD
- Partner with major laboratories to spread Th7R


# Overseas Business Strategy

**Target**

**① FY 2031/6 overseas sales: ¥2.5 billion+**
**② Build the structure for D-IA's global expansion, including WHO prequalification of the D-IA tuberculosis POCT**

| Market \ Product | Existing | New |
|---|---|---|
| Existing | Market penetration<br>**Grow antigen-test sales, mainly in Asia**<br>➢ Raise adoption at public hospitals by introducing IC readers<br>➢ Expand the product lineup, e.g., Cov-2 kits | New-product launch<br>**New tuberculosis measures via D-IA and SaMD**<br>➢ Strengthen UN cooperation toward WHO prequalification of the D-IA tuberculosis POCT<br>➢ Expand the tuberculosis imaging-diagnosis SaMD into Asia and Africa |
| New | Market development<br>**Develop Latin American/African markets**<br>➢ Recruit new distributors<br>➢ Supply intermediates to local manufacturers (antigen-test kits, lipase reagents, etc.) | New areas<br>**Global expansion of D-IA × chronic diseases**<br>➢ Prepare overseas regulatory filings for the D-IA dementia and diabetes POCTs<br>➢ Prepare for North American entry |

# AIX (AI Transformation) Strategy

- Reallocate human resources to new businesses and high-value work through AI-driven productivity gains
- Clarify the purpose of AI use, design KPIs, and build evaluation systems

## Step 1

**Start AIX with tasks that AI can make efficient immediately**

**R&D**
- Gather papers/patents/competitive intel
- Search past documents and study data

**Alliances / investment**
- List alliance candidates
- Organize synergy hypotheses

**Corporate management**
- Market research/competitive analysis
- Draft business plans

## Step 2

**Focus on areas hard to embed AI in but with high efficiency ROI**

**Production / SCM / factories**
- Draft production plans
- Detect stockout/overstock risks

**Sales / medical affairs / CS**
- Prepare pre-visit briefs
- Create meeting summaries

**Regulatory / QA / safety**
- Search past documents
- Search similar deviations/complaints

## Step 3

**AIX in areas requiring extensive prior organization of work and data**

**SaMD / medical data**
- Organize specimen/test/image data
- Build disease-specific datasets

**Clinical samples / testing services**
- Search available samples
- Flag abnormal test results

**What we need to make it happen**

**Prepare the usage environment**
- Provide AI-ready tools, data, and rules

**Talent development**
- Develop people who can use AI in each department

**Reliable on-the-ground implementation**
- Embed in real operations, not just planning

**Security / personal-data management**
- Build a secure AI environment protecting confidential, personal, and medical data

Note: AIX Steps 1–3 are current proposals; scope and sequence will be refined

# Human Capital Strategy

- By ① redeploying the human resources freed up by AIX to new businesses, we advance into new businesses while controlling headcount growth
- and by ② investing in individuals and ③ energizing the organization, we strengthen the foundation that supports growth

## (Previous page) Work efficiency / freeing up human resources via AIX

**Streamline routine/indirect work to free up resources for priority areas**

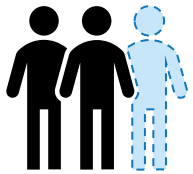
- Streamline information gathering, document creation, and routine work
- Reduce hours spent on meetings, coordination, and information sharing
- Standardize processes and knowledge

## Effective use of human resources

### ① Redeploy talent to new businesses

**Redeploy talent to new businesses and high-value work**

- Redeploy talent to new businesses

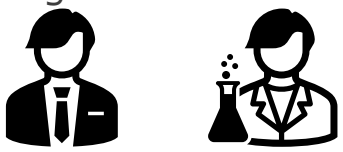


Focus on high-value work

### ② Invest in individuals

**Investment in individuals, including AI adoption and reskilling**

- Raise AI skills company-wide
- Reskilling for new businesses



### ③ Energize the organization

**Energize the organization through management reform**

- Development/evaluation suited to new businesses
- Dialogue-oriented management
- Introduce diverse ways of working

# Business Alliance Strategy

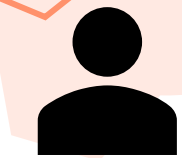
- TAUNS forms strategic alliances with startups and large enterprises to capture startups' innovation and growth
- As a hub between the two, TAUNS commits to commercializing advanced technologies and accelerates implementation and adoption at medical institutions

## Startups' pain points

**Insufficient credibility / track record**
- "Hard to get medical institutions and partners to decide to adopt"

**Sales structure still developing**
- "Channels to medical institutions and adoption-support mechanisms are still being built"

**Limited healthcare-industry knowledge**
- "Gaps in industry-specific regulatory, clinical, and distribution knowledge"



Startup CEO

## TAUNS

**Investment track record**
- A strong in-house investment team that has invested in 11 companies over the past three years
- CEO Nonaka has invested in over 50 startups and provides strong leadership in investment decisions

**Deep industry knowledge and client base**
- 30+ years in the IVD business
- A track record of supplying tens of thousands of medical institutions

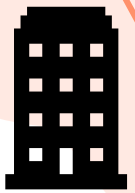
**Diverse talent & partners**
- Specialists across fields
- Strong relationships with KOLs

## Large enterprises' pain points

**Difficulty appraising new technologies**
- "Hard to spot promising tech early; feel we miss opportunities"

**Limited investment/alliance experience**
- "Hard to learn by trying many investment/partnership deals"

**Slow decision-making: "Structurally, decisions and collaboration tend to take time"**



Drug wholesalers
Laboratories
Pharmaceutical companies

# Investment Strategy

- Production capacity is secured with the Fujisan Mishima Factory in operation; going forward we will improve productivity and launch D-IA mass-production lines
- As strategic investment, we will make the equity investments needed to enter new areas and pursue company-wide productivity gains via AIX

| Illustration | | Main investments | Investment amount | Expected effects |
|---|---|---|---|---|
| **Production**  | | ● Production-equipment renewal investment<br>● Productivity-improvement investment<br>● Set up D-IA mass-production capacity | ¥2.9 bn | • Stable supply and higher per-capita productivity<br>• D-IA supply |
| **Development**  | | ● Strengthen the R&D structure<br>● D-IA mass-production development investment<br>● Introduce advanced instruments at the laboratory | ¥0.5 bn | • Stronger antigen-test competitiveness<br>• D-IA implementation<br>• Rollout of multi-omics testing services |
| **Strategic investment** | AI  | ● Redefine and implement all work processes assuming AI use<br>● Set KPIs/KGIs and run a monitor-and-improve loop to accelerate adoption | ¥0.7 bn | • Accelerate new areas and global expansion while managing headcount growth<br>• Development of next-generation IVD/SaMD using data and AI |
| | Equity investment  | ● Invest in Craif, Splink, Provigate, and Callisto (FY 2027/6)<br>● Investment to strengthen new areas<br>● Investment to expand overseas channels<br>● Consider M&A as needed | Up to ¥6.0 bn | • Growth in new areas<br>• Stronger global expansion |

# Sustainability Initiatives

## Strengthening organization for promoting sustainability

### Establishment of Sustainability Committee

- Establish a system for sharing and improving materiality across departments

### Redefining and expanding materiality

- Incorporate “promotion of personalized medicine and predictive medicine” into materiality
- Advance research base and establish a sustainable data utilization system
- Promote an ecosystem that continuously advances medical technologies and products

## Strategy and tactics development and execution

### Designing KGI/KPIs aligned with materiality

- Establish a tracking system that aligns materiality and KPIs in each business area and reflects them in evaluations of departments

### Responsibility for sustainable and stable supply

- More efficient supply system and BCP with new factory

### Expansion of HR development and training programs

- Support the growth of “T-shaped human resources” who can respond to multiple areas, rather than “human resources specialized in a single area” in order to steadily execute strategies in a changing business environment

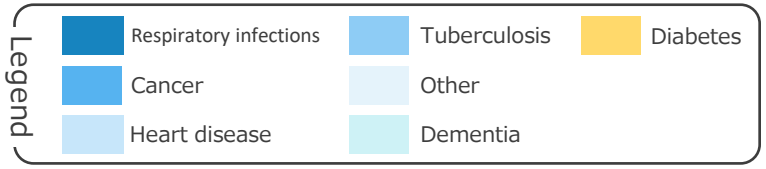
## Enhancing sustainability through stakeholder feedback

- Medical-related companies, academic institutions, and capital alliance partners with whom we conduct joint research
- Institutional and individual investors
- Customers, suppliers
- External directors and auditors
- Outside experts with specialized knowledge

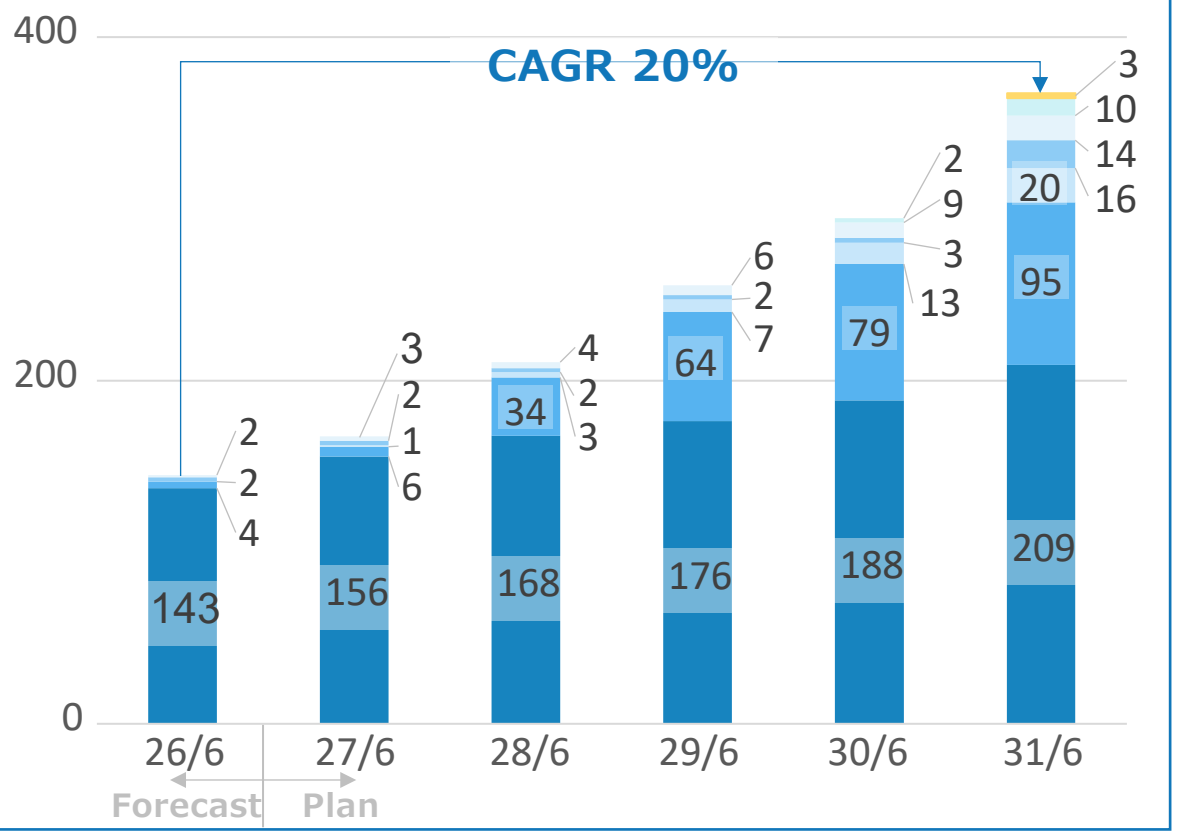
# Financial Plan

# Sales plan by disease

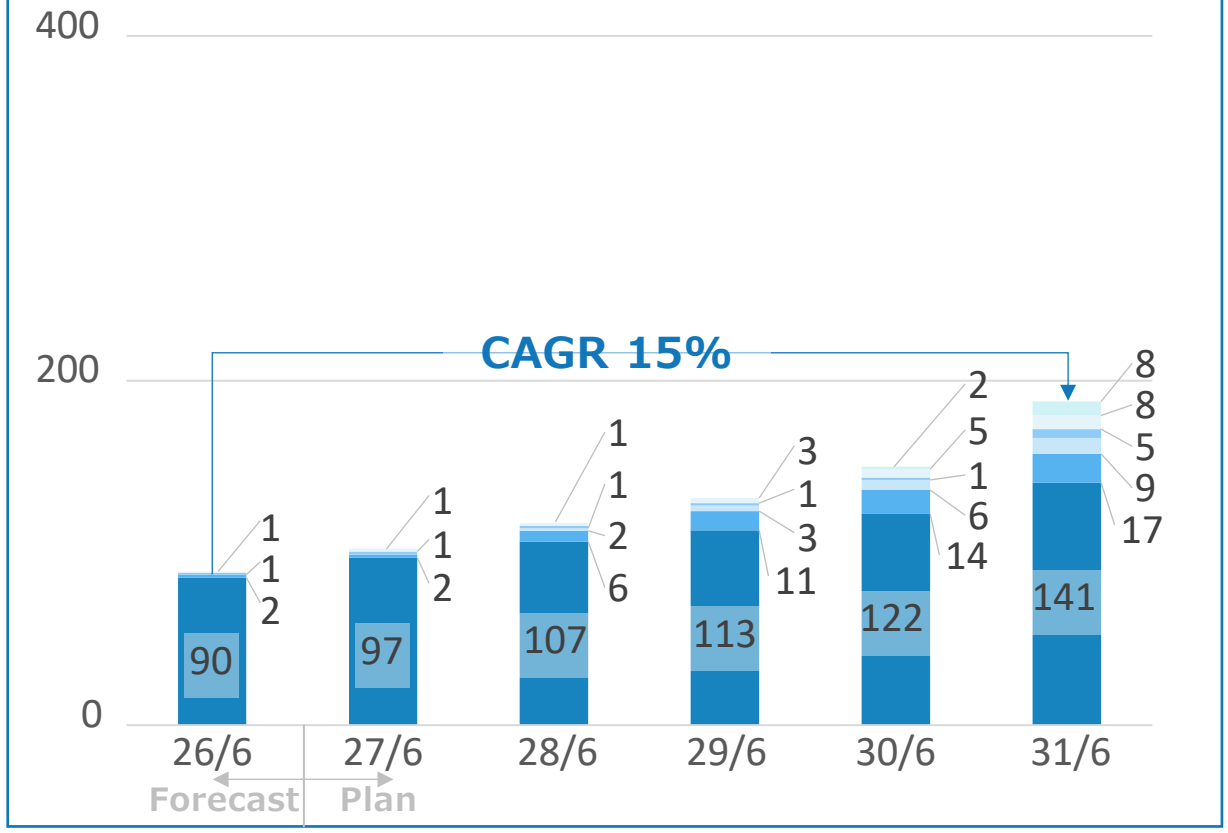
- In respiratory infections, we aim for steady growth via higher share by strengthening the product lineup (including the Combo II launch) and the sales structure
- Make products for chronic diseases such as cancer and heart disease a new earnings pillar




## Net sales

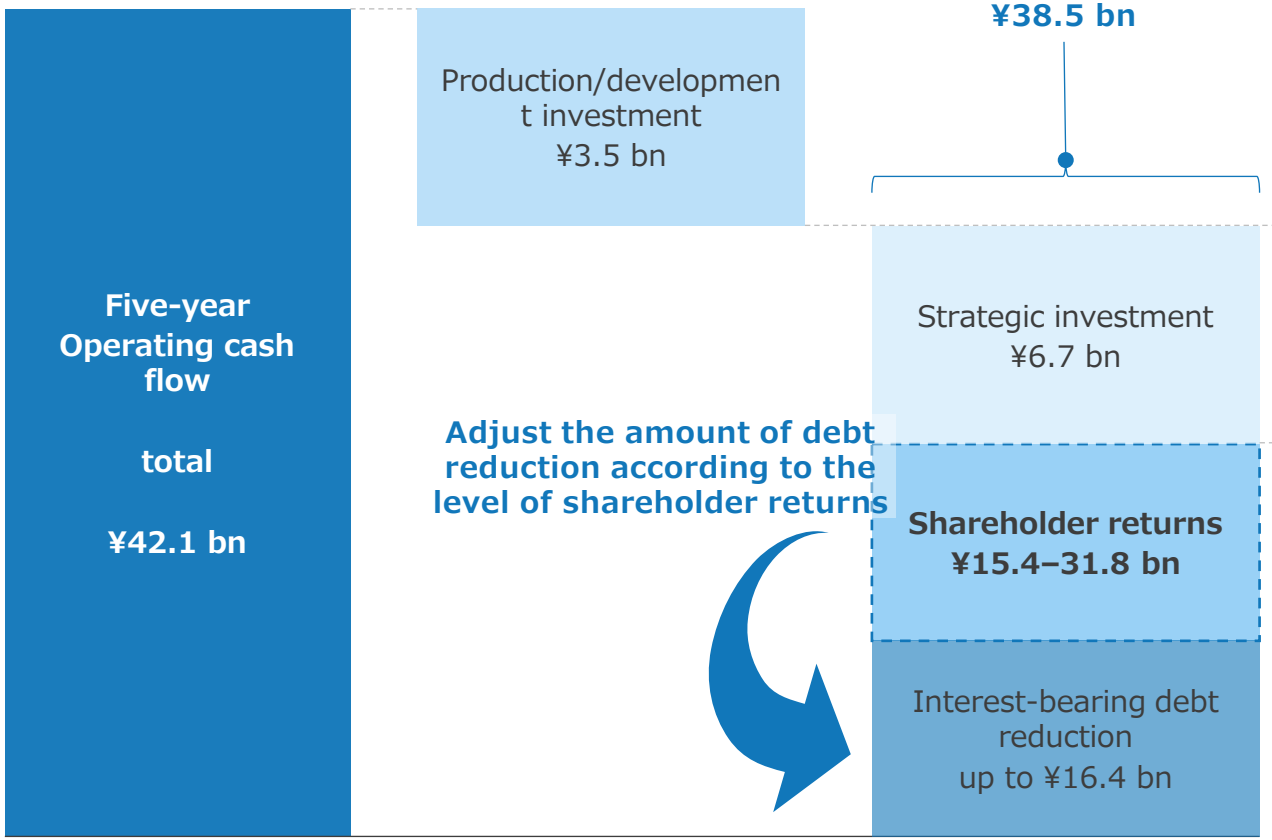



## Gross profit



# Cash Allocation

- Allocate the free cash flow generated over the five-year Plan period (targeting ¥38.5 billion) to strategic investment, shareholder returns, and interest-bearing debt reduction
- Policy of actively returning capital to shareholders (progressive dividends and share buybacks) while maintaining financial stability




Specific measures

- Production-equipment renewal investment
- Productivity-improvement investment
- Set up D-IA mass-production capacity
- Strengthen the R&D structure
- D-IA mass-production development investment
- Introduce advanced instruments at the laboratory

- Invest in Craif, Splink, Provigate, and Callisto
- Investment to strengthen new business areas
- Investment to expand overseas channels
- Consider M&A as needed
- Advance AIX

- In addition to progressive-dividend returns, consider share buybacks
- Actively return capital while maintaining financial stability (shareholder returns + debt reduction: ¥31.8 bn in total)

# Shareholder Return Information

- We will introduce a progressive dividend starting at 29 yen during the mid-term management plan period from FY 2027/6 to FY 2031/6.
- We will conduct share buybacks as necessary, considering the business environment and stock market trends.

**Progressive dividend**

- Under the Previous Plan, a progressive dividend starting at 28 yen per share was introduced from FY 2026/6 to FY 2030/6.
- In light of our mid- to long-term growth prospects, we will raise the starting point of the progressive dividend to 29 yen per share for FY 2027/6 to FY 2031/6.
- Even with this dividend policy, we believe we will be able to secure the investment resources necessary to execute our strategy going forward (see P.35).

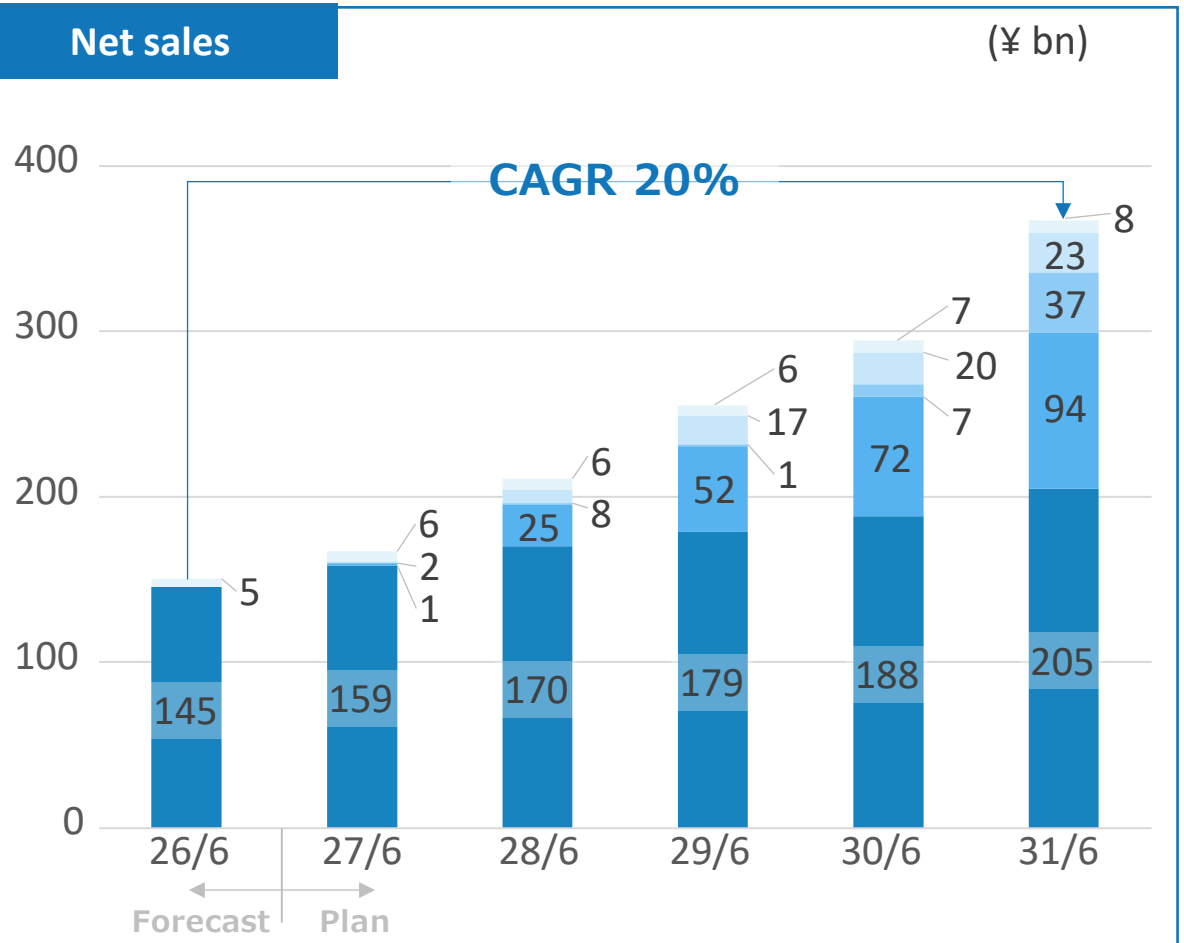
| Fiscal year | Interim dividend | Year-end dividend | Annual dividend | Remarks |
|---|---|---|---|---|
| FY 2024/6 | 6.00 | 21.75 | 27.75 | Special dividend of 11.10 yen per share to commemorate listing on the Tokyo Stock Exchange Standard Market |
| FY 2025/6 | 6.00 | 22.00 | 28.00 | Special anniversary dividend of 10.00 yen per share will be paid at the end of the FY to celebrate the 10th anniversary of the Company's establishment |
| FY 2026/6 (Forecast) | 14.00 | 14.00 | 28.00 | A progressive dividend will be introduced, starting at 28.00 yen per share |
| FY 2027/6 onward | - | - | 29.00 or more | From FY 2027/6 to FY 2031/6, the starting point of the progressive dividend will be raised to 29.00 yen per share |

# Appendix

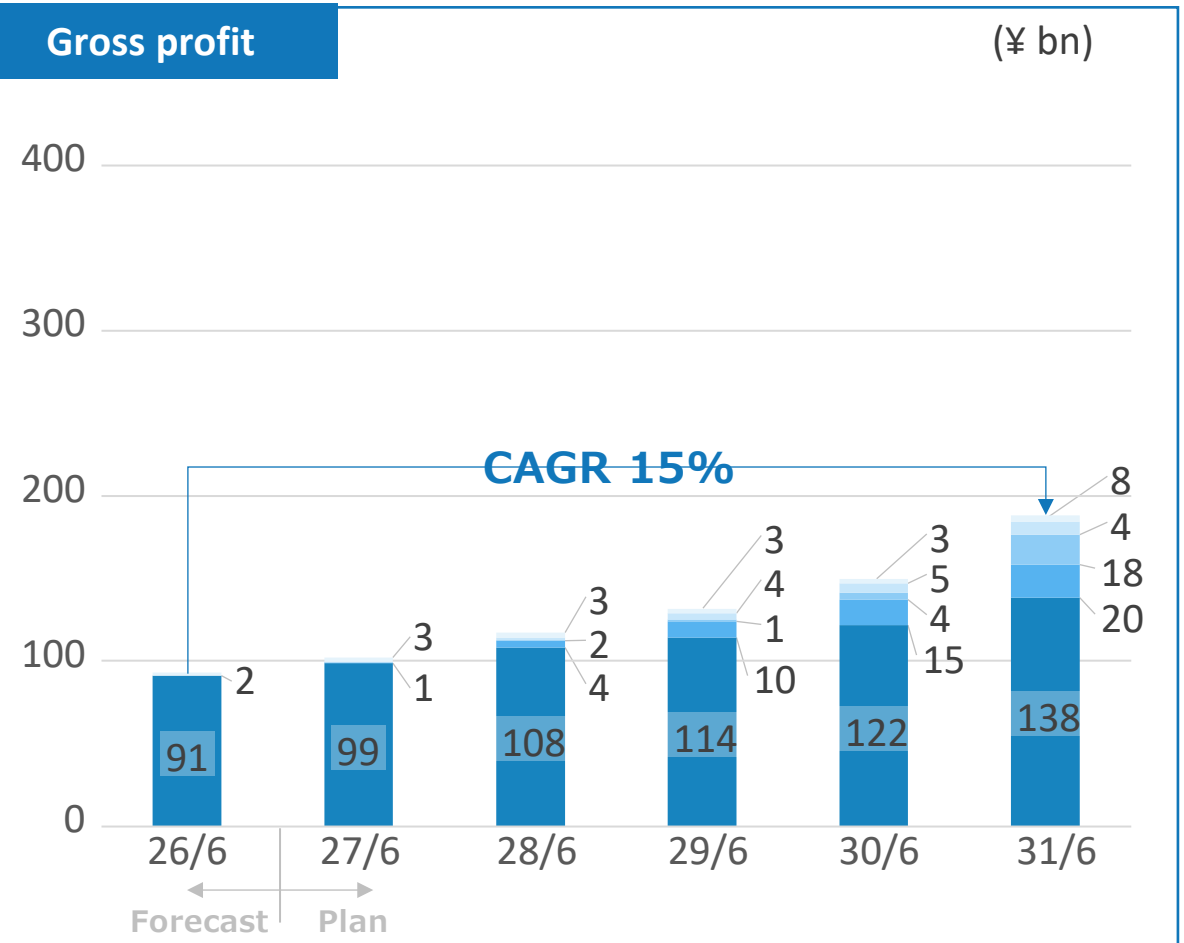
# Appendix: Sales plan by testing technology

- Strengthen the antigen-test lineup and aim for steady growth via higher share
- Make new POCT[1)], SaMD, and testing services new earnings pillars


## Net sales




## Gross profit




1) New POCT: D-IA, ElectraDx, nodoca

# Appendix: Prime Market Listing Criteria and TAUNS's Status

| | | Prime Market listing criteria 1) | TAUNS's status | Compliance status |
|---|---|---|---|---|
| Liquidity | Number of shareholders | 800 or more | 39,059<br>End of June 2026 | Met |
| | Number of tradable shares | 20,000 units or more | Approx. 360,013 units<br>End of June 2026 | Met |
| | Tradable share market capitalization | ¥10.0 bn or more | Approx. ¥16.9 bn<br>Closing price on June 30, 2026 | Met |
| | Trading value | Average trading value of ¥20 mn or more | Approx. ¥150 mn<br>May 2026 average | Met |
| | Tradable share ratio | 35% or more | Approx. 33.7%<br>End of June 2026 | Not met |
| Governance | Earnings base | Total profit of ¥2.5 bn or more over two years (non-consolidated ordinary income) | Total ordinary income: approx. ¥13.4 bn<br>FY 2025/6 +<br>FY 2026/6 (E) | Met |
| Operating results<br>Financial position | Financial condition | Net assets of ¥5.0 bn or more | ¥16.3 bn<br>End of March 2026 | Met |

1) Japan Exchange Group: Prime Market listing criteria

# Appendix: Key Products (1/2)

| Testing technology | Product name | Target disease | Purpose of test | Product overview | Partner | Planned launch |
|---|---|---|---|---|---|---|
| Antigen testing | Combo II | Influenza / SARS-CoV-2 | Screening | Improved version of the existing combo kit | | Target: Q1 FY 2027/6 |
| | ImmunoAce Flu | Influenza | Screening | Kit for simple, rapid influenza testing | | Launched |
| | ImmunoAce SARS-CoV-2 III | SARS-CoV-2 | Screening | Kit for simple, rapid SARS-CoV-2 testing | | Launched |
| | ImmunoAce Adeno | Adenovirus | Screening | Kit for simple, rapid adenovirus testing | | Launched |
| | ImmunoAce Strep A II | GABHS | Screening | Kit for simple, rapid GABHS testing | | Launched |
| | Strep A/Adeno combo | GABHS / adenovirus | Screening | Kit that simultaneously tests for adenovirus and GABHS, which present similar clinical symptoms | | FY 2029/6 |
| | RSV/Adeno combo | RS virus / adenovirus | Screening | Kit that simultaneously tests for RS virus and adenovirus | | FY 2030/6 |
| | RSV/hMPV combo | RS virus / human metapneumovirus | Screening | Kit that simultaneously tests for RS virus and human metapneumovirus | | FY 2030/6 |
| D-IA | Tuberculosis POCT | Tuberculosis | Screening, definitive diagnosis, monitoring | Detects proteins from live Mycobacterium tuberculosis complex within 1.5 hours at accuracy close to culture testing; covers tuberculosis screening, definitive diagnosis, and monitoring end-to-end | | FY 2031/6 |
| | Dementia POCT | Dementia | Screening, treatment planning | Measures blood dementia markers with high accuracy; supports screening of dementia/MCI patients and decisions on referral to specialists | Splink | FY 2030/6 |
| | Diabetes POCT | Diabetes | Monitoring | Measures salivary GA weekly; used as an indicator to support behavior change in diabetes patients and pre-diabetics | Provigate | FY 2031/6 |
| ElectraDx | Nucleic-acid panel | Respiratory infections | Definitive diagnosis | High-accuracy nucleic-acid POCT that simultaneously tests for multiple respiratory infections | ElectraDx | FY 2030/6 |
| nodoca | Flu | Influenza | Screening | Analyzes minimally invasive pharyngeal images with AI to test for influenza | Aillis | Launched |

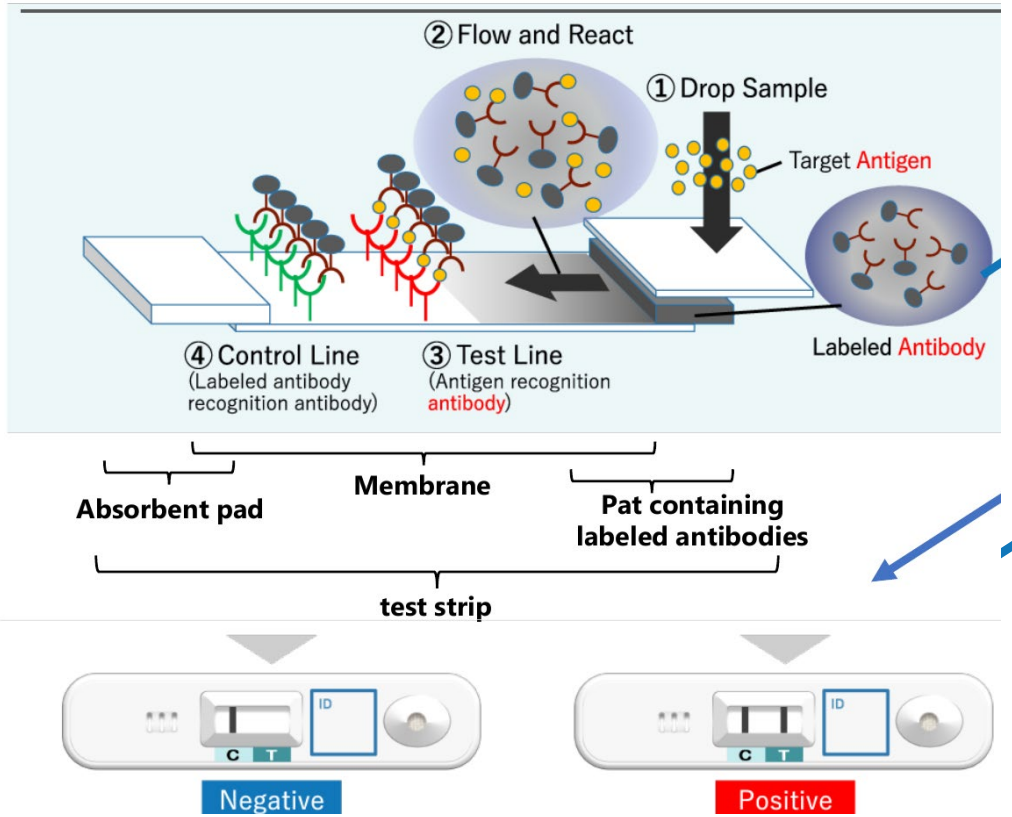
# Appendix: Key Products (2/2)

| Testing technology | Product name | Target disease | Purpose of test | Product overview | Partner | Planned launch |
|---|---|---|---|---|---|---|
| Testing services / NGS | miSignal | Cancer | Risk assessment | A Craif service that analyzes urinary miRNA by NGS (next-generation sequencing) to assess the risk of 10 cancer types | Craif | Launched |
| Testing services / FCM | Th7R | Lung cancer | Treatment planning | Analyzes a patient's immune status by FCM (flow cytometry) using a whole-blood sample to predict the efficacy of immune checkpoint inhibitors in advance | | FY 2028/6 |
| SaMD/ NGS | Pancreatic-cancer SaMD | Pancreatic cancer | Screening | A SaMD under development by Craif that analyzes urinary miRNA by NGS to screen for pancreatic cancer | Craif | FY 2028/6 |
| SaMD / imaging | Coronary-CT SaMD | Heart disease | Treatment planning | A SaMD that estimates blood flow in heart-disease patients via AI analysis of minimally invasive coronary CT images, replacing highly invasive cardiac catheterization | CLAIRVO | FY 2027/6 |
| | Vascular-CT SaMD | Heart disease | Definitive diagnosis | A SaMD that rapidly analyzes and visualizes vessel morphology from CT images—from the head and neck to the aorta and lower limbs. Using AI, it delivers faster, more accurate analysis than general-purpose software, reducing the burden on analysts and shortening the time to report results to patients | CLAIRVO | FY 2027/6 |
| | Breast-cancer SaMD | Breast cancer | Definitive diagnosis | A SaMD that analyzes mammography images to detect masses and calcifications suspected of breast cancer. It can accurately detect lesions even in the opaque shadows of dense breasts, which are difficult even for experienced readers—reducing the risk of missed findings and contributing to early detection | CLAIRVO | FY 2028/6 |
| | Lung-cancer SaMD | Lung cancer | Definitive diagnosis | A SaMD that automatically detects nodules suspected oflung cancer from chest CT images. By quickly and appropriately extracting suspicious regions, it greatly improves reading efficiency as CT volumes rise year by year, improving workflow efficiency and helping prevent missed findings | CLAIRVO | FY 2027/6 |

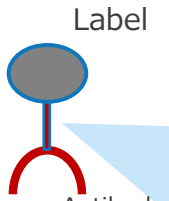
# Appendix: Principle of Antigen Test Kits and Strengths of Our Technology

- High technological capabilities, including a track record in the development of numerous in-house antibodies (including patents) and proprietary platinum-gold colloid technology
- Utilizing our technological capabilities, we have developed high-quality products with both specificity and sensitivity. In addition, we supply products that are of high value to both the medical community and patients, such as those that enable the broad sharing of specimens among multiple infectious diseases.

## Principle of Antigen Test Kits




## Our core technologies and product value-added




Highly visible black lines

### Our Core Technologies

**Proprietary platinum-gold colloid technology to achieve highly visible black lines on black signage**

Acquired technology to improve sensitivity while suppressing nonspecific reactions through many years of accumulated know-how

**Possesses advanced antibody development technology and a wealth of experience and know-how**

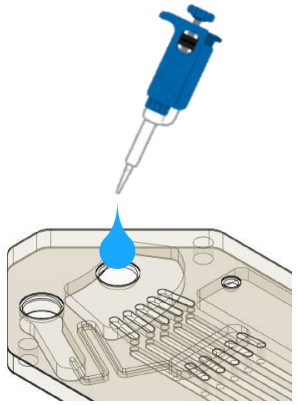
The creation of high-performance antibodies contributes significantly to the sensitivity and specificity of the kit

**Specificity × Sensitivity**

# Appendix: Digital Immunoassay (D-IA)

- TAUNS's next-generation POCT technology, enabling accurate and rapid quantitative detection of biomarkers
- Microfluidic channels are used to produce antigen-antibody reactions in a small volume (space) to significantly improve reaction efficiency. Centrifugal force generated by the rotation of the measurement chip delivers both speed and high accuracy.
- Detects scattered light originating from gold colloids, enabling ultra-sensitive and quantitative determination by digital detection at the particle level.
- Supports multiplex testing of up to 20 items


**D-IA Dedicated Measuring Device**



**Multiplex test compatible measurement chip**

# Appendix：ElectraDx

- Technology that brings laboratory-level measurement to POCT and home settings via a proprietary electrochemical test strip and a connected compact device
- Integrates microfluidics, temperature control, and measurement control within the strip, detecting protein and nucleic-acid reactions as electrochemical signals
- Applicable to rapid testing for respiratory infections, sexually transmitted infections, chronic diseases such as heart failure, diabetes, and inflammation markers

**Ease of use**

Easy to use

Simple, convenient, rapid test results (<10 minutes)

**Broad test menu**

Broad Test Menu

Diverse platform offers various community and home tests for key health needs.

**Cloud data connectivity**

Connected

Integrated healthcare data enhances medical decision-making.


**Laboratory-level accuracy**

Lab-Quality Performance

Next-Gen electrochemical tech ensures precise lab performance

**Low cost**

Ultra Low Cost

Affordable: <$100 device, ultra low-cost strips.

**High-performance strip**

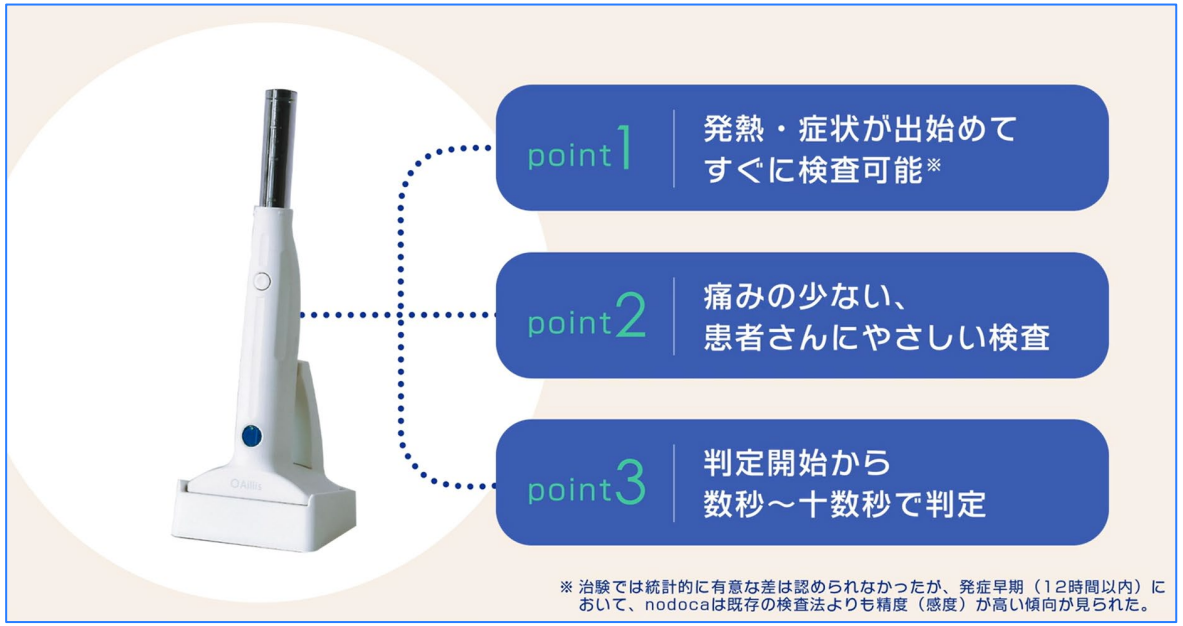
Intelligent Strip

Intelligent test strip with on-strip electronic assay controls.

* This product is under development and is subject to regulatory approval.

# Appendix: nodoca (Aillis)

- A software medical device that captures pharyngeal images with a dedicated camera (endoscopic telescope: nodoca) and uses AI to analyze them together with clinical information such as interview data and body temperature, supporting the diagnosis of influenza and other conditions
- A minimally invasive test with low patient burden, taking only seconds to tens of seconds
- By expanding training data, the technology has the potential to display results for many diseases simultaneously from a single image capture


Source: Aillis website (https://nodoca.aillis.jp/#)

# Appendix: What Is SaMD?

- SaMD (Software as a Medical Device) is “software that functions as a medical device.” In Japan it is regulated as a “program medical device” under the Pharmaceuticals and Medical Devices Act
- It is software that improves workflow efficiency at medical institutions and supports physicians in diagnosis, treatment planning, and patient management; products with high clinical significance are eligible for insurance listing

| Type | Overview | Main input data | Main output | Product examples |
|---|---|---|---|---|
| ① Diagnostic imaging support AI | Uses AI to analyze medical images and support reading, diagnosis, and treatment decisions | CT, MRI, X-ray, endoscopy, pathology images, etc. | Lesion detection, abnormal-finding extraction, severity assessment, risk stratification | Products handled by CLAIRVO (e.g., heart-disease SaMD) |
| ② Apps / DTx | Uses smartphones and similar devices to support cognitive assessment, behavior change, symptom management, and treatment adherence | Patient inputs, PHR, lifestyle, cognitive-function data, etc. | Cognitive assessment, behavior-change support, symptom monitoring, disease management | Cognitive-function AI (e.g., CQ Test) |
| ③ Analytical algorithms | Analyzes test data from POCT, testing services, and others to support diagnosis and patient stratification | POCT, NGS, miRNA, immune profiles, etc. | Disease risk, diagnostic-support reports, treatment-response prediction | Pancreatic-cancer SaMD |

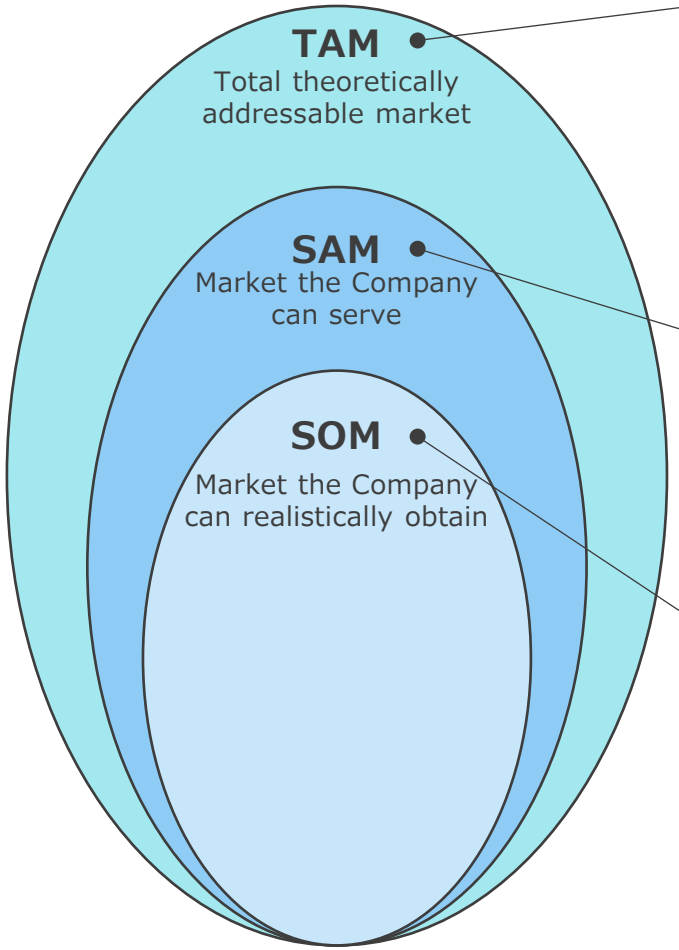
# Appendix: Heart-Disease SaMD Product Suite (CLAIRVO)

Plan to roll out in Japan the heart-disease SaMD suite developed by overseas Company S. Source: CLAIRVO Technologies, Inc. website

| Chest-pain patient Risk stratification | Stenosis/plaque assessment | Hemodynamic assessment | Treatment-decision support |
|---|---|---|---|
| Early rule-out of low-risk patients | Improved reading/diagnostic workflow | Fewer invasive tests | Optimized healthcare costs and reduced patient burden |

- CLAIRVO rolls out in Japan a suite of heart-disease SaMD products from overseas Company S that use AI image analysis; CLAIRVO holds exclusive domestic distribution rights for these products
- The suite runs on a common user interface, integrating assessment of “morphology/stenosis,” “plaque characteristics,” and “hemodynamics” from coronary CT images to support physicians’ treatment decisions
- We will expand coverage to peripheral vascular areas such as the head and neck, aorta, and lower limbs. During the Plan period we aim to launch seven products in total, building evidence and pursuing insurance listing through collaboration with academic societies and KOLs

# Appendix: Our Approach to TAM/SAM/SOM

| Illustration | Example: respiratory-infection antigen tests | Example: dementia POCT |
|---|---|---|
|  | **Annual number of febrile patients in Japan** | **Number of elderly people in Japan** |
| | **Estimated number of respiratory-infection tests performed in Japan, based on market data such as IQVIA** | **TAM × cognitive-test uptake rate × dementia blood-marker uptake rate** |
| | **SAM × target share** | **SAM × target share** |

# Appendix: Glossary (1/5)

| Category | Term | Description |
|---|---|---|
| Disease | Adeno | Adenovirus — a virus causing pharyngitis, conjunctivitis, gastroenteritis, etc. |
| | CoV-2 | SARS-CoV-2 — one of the viruses causing respiratory infections |
| | Flu | Influenza virus — one of the viruses causing respiratory infections |
| | hMPV | Human metapneumovirus — a virus causing respiratory infections, common in children and the elderly |
| | RSV | RS virus — a virus causing respiratory infections that can become severe in infants and the elderly |
| | Strep A | Group A beta-hemolytic streptococcus — a bacterium causing pharyngitis and other conditions |
| | TB | Mycobacterium tuberculosis complex — bacteria causing pulmonary tuberculosis |
| | Heart failure | A condition in which the heart's pumping function declines and cannot supply enough blood to the body |
| | Ischemic heart disease | A group of heart diseases in which coronary stenosis or occlusion reduces blood flow to the myocardium |
| | Diabetes | A disease characterized by chronically elevated blood glucose |
| | Pancreatic cancer | Cancer arising in the pancreas |
| | Lung cancer | Cancer arising in the lungs |
| | Breast cancer | Cancer arising in the breast |
| Product | CoV-2/Flu combo | An antigen test kit that simultaneously detects SARS-CoV-2 and influenza virus |
| | Strep A/Adeno combo | An antigen test kit that simultaneously detects group A beta-hemolytic streptococcus and adenovirus |
| | RSV/Adeno combo | An antigen test kit that simultaneously detects RS virus and adenovirus |
| | RSV/hMPV combo | An antigen test kit that simultaneously detects RS virus and human metapneumovirus |

# Appendix: Glossary (2/5)

| Category | Term | Description |
|---|---|---|
| Product | miSignal | A service that uses AI to analyze urinary miRNA and assess the risk of 10 cancer types; a Craif product |
| | Pancreatic-cancer SaMD | A software medical device that uses AI to analyze urinary miRNA to support early detection of pancreatic cancer; under development by Craif |
| | Coronary-CT SaMD | A software medical device that uses AI to analyze coronary CT images and support assessment of stenosis and hemodynamics |
| | Cardiovascular-CT SaMD | A software medical device that analyzes vascular CT images of the head and neck, aorta, and lower limbs to support assessment of vessel morphology |
| | Breast-cancer SaMD | A software medical device that analyzes mammography images to support detection of masses and calcifications suspected of breast cancer |
| | Lung-cancer SaMD | A software medical device that analyzes chest CT images to support detection of nodules suspected of lung cancer |
| Testing terms | nodoca | A respiratory-infection test in which AI analyzes pharyngeal images captured by a dedicated camera together with interview information; technology from Aillis |
| | ElectraDx | A POCT technology that performs nucleic-acid tests and antigen/biomarker tests, covering respiratory infections, heart disease, and others |
| | D-IA | Digital immunoassay — TAUNS's next-generation POCT technology for high-accuracy quantitative detection of antigens and biomarkers |
| | FCM | Flow cytometry — a technology that measures surface and internal features of cells by passing blood cells through a flow channel |
| | Antigen testing | A technology for rapid antigen detection using immunochromatography |
| | SaMD | Software as a Medical Device — software that analyzes medical data with AI and supports medical decisions |
| | Testing services | A service in which specimen testing and related work is performed at a laboratory under contract from medical institutions |
| | CGM | Continuous Glucose Monitoring — a device that continuously measures glucose fluctuations with a sensor |
| | SMBG | Self-Monitoring of Blood Glucose — a method in which patients draw blood from a fingertip and measure glucose with a self-monitoring device |
| | IVD | In Vitro Diagnostics — products that test for diseases and infections using specimens collected from the body |
| | NGS | Next Generation Sequencing — a technology that rapidly analyzes DNA/RNA sequences in a specimen |
| | PCR | A test that amplifies specific DNA or RNA sequences to determine whether a target is present |
| | POCT | Point of Care Testing — testing performed at the point of care or near the patient to obtain rapid results |
| | Nucleic-acid test | A test that detects DNA or RNA, including PCR and NGS |
| | Multiplex test | A test that simultaneously detects multiple pathogens or genes in a single run; a panel test |
| | LDT | Laboratory Developed Test — a test independently developed and performed by a laboratory |
| | Amyloid PET | An imaging test that evaluates amyloid-β accumulation in the brain |
| | Image AI | A technology that uses AI to analyze medical images for lesion detection and diagnostic support |

# Appendix: Glossary (3/5)

| Category | Term | Description |
|---|---|---|
| Medical terms | Screening | An initial test for people suspected of having a disease |
| | Biobank | A system that stores specimens such as blood along with linked medical data for use in R&D |
| | Minimally invasive | Tests or treatments that minimize pain and physical burden |
| | miRNA | MicroRNA — short RNA that regulates gene expression, among other functions |
| | TAT | Turn Around Time — the time from test receipt to result reporting |
| | ICI | Immune checkpoint inhibitor — a drug that releases immune brakes to enhance the immune response against cancer cells (e.g., Opdivo) |
| | DMT | Disease Modifying Therapy — a treatment that acts on the mechanism of disease progression (e.g., lecanemab) |
| | Amyloid-β | A protein associated with Alzheimer's disease |
| | High-risk group | A patient group with a relatively high likelihood of developing a specific disease |
| | Risk stratification | An approach that classifies patients by risk level to determine testing and treatment plans |
| | Lecanemab | A disease-modifying therapy for Alzheimer's disease targeting amyloid-β |
| | Swab | A cotton-tipped device used to collect specimens from the nasal cavity, pharynx, and similar sites |
| | Dementia marker | Biomarkers such as amyloid-β and phosphorylated tau associated with Alzheimer's-type dementia |
| | Companion diagnostics | A test essential for selecting patients so that a specific drug can be used safely and effectively |
| | Th7R | A biomarker test related to predicting the efficacy of immune checkpoint inhibitors, using a minimally invasive whole-blood sample |

# Appendix: Glossary (4/5)

| Category | Term | Description |
|---|---|---|
| Medical terms | Insurance listing | Recognition of a medical technology or device as covered by public health insurance |
| | HbA1c | Hemoglobin A1c — glycated hemoglobin; an indicator reflecting average glucose over the past 1–2 months |
| | Glycated albumin | GA — glycated serum albumin; an indicator reflecting average glucose over roughly the past week |
| | BNP | A biomarker used to diagnose or rule out heart failure |
| | NT-proBNP | A biomarker used to assess heart-failure severity and risk |
| | Troponin | A myocardium-derived protein marker used to assess myocardial injury and infarction |
| | Coronary CT | A CT imaging test that assesses coronary stenosis, plaque, and related findings |
| | Plaque | Lesions such as lipid deposits that accumulate in vessels; used in cardiovascular risk assessment |
| | Stenosis | Narrowing of a vessel or lumen; important in assessing coronary artery disease |
| | Hemodynamics | The state of blood flow, pressure, and related factors |
| Data & AI | EHR | Electronic Health Record — a system for medical institutions to record and share patient clinical information electronically |
| | PHR | Personal Health Record — a system for individuals to manage and use their own health and medical data |
| | RWD | Real World Data — real-world clinical data obtained from routine care, claims, registries, wearables, and similar sources |
| | Wet data | Medical data derived from physical samples such as blood, urine, saliva, and tissue |
| | Dry data | Medical data handled as digital information, such as medical images, EHR, PHR, and RWD |
| | Computing resources | Servers, GPUs, cloud, and analysis environments required for AI and genomic analysis |
| | Algorithm | Computational procedures and models that analyze data for classification, prediction, and diagnostic support |
| | Imaging core lab | Work that aggregates, standardizes, and analyzes medical imaging data in clinical trials and research |
| | AIX | AI Transformation — transforming operations, organization, and talent on the premise of AI use |

# Appendix: Glossary (5/5)

| Category | Term | Description |
|---|---|---|
| Business | R&D | Research & Development — research and development activities |
| | TAM | Total Addressable Market — the total market theoretically addressable by the Company |
| | SAM | Serviceable Available Market — the portion of the market the Company can serve |
| | SOM | Serviceable Obtainable Market — the market the Company can realistically obtain |
| | KOL | Key Opinion Leader — influential specialists and researchers |
| | WHO PQ | WHO Prequalification — the WHO's prequalification scheme, which assesses the quality, safety, and performance of IVDs and is referenced in international procurement |
| | Offtake agreement | A contract to purchase future products or services under set conditions |
| | Co-promotion | Multiple companies jointly conducting sales-promotion activities for a product |
| | Co-marketing | Multiple companies jointly selling the same product |
| | DMR | Diagnostic Medical Representative — a sales representative who provides information on diagnostics and testing-related products to medical institutions |
| Company names | EMCH | EMC Healthcare, Inc. https://www.emcjpn.com/ |
| | Craif | Craif Inc. https://craif.com/ |
| | CLAIRVO | CLAIRVO Technologies, Inc. https://www.clairvotech.com/ |
| | Splink | Splink, Inc. https://www.splinkns.com/ |
| | Provigate | Provigate, Inc. https://provigate.com/ |
| | Callisto | Callisto, Inc. https://callisto-ai.com/ |
| | Aillis | Aillis, Inc. https://aillis.jp/ |
| | ElectraDx | ElectraDX, Inc.。https://electradx.com/ |
| | Shionogi | Shionogi & Co., Ltd. https://www.shionogi.com/jp/ja/company/outline.html |
| | Roche | Roche Diagnostics K.K. https://www.roche-diagnostics.jp/ |