

# Healthcare Business

**Tatsuya Yamaguchi**  
Corporate Vice President

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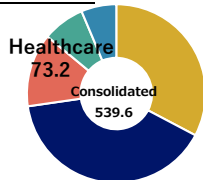
- I'm Yamaguchi, Corporate Vice President and General Manager of Healthcare Business Unit.
- Next, I would like to explain our healthcare business.

## Healthcare: Business Outline

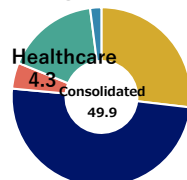
Healthcare Business

FY2022/3 Billions of yen

### Revenue



### Operating profit (\*)



(\*) Operating profit ratio in FY2022/3 is shown before deduction of corporate P/L non-attributable to any reportable segments

### Vision

Support improving quality of life for people through innovation

### Major products & Services

Biological microscopes, Retinal diagnostic imaging system, Contract cell manufacturing(CDMO Business)



Confocal Microscope System [AX/AX R]



Ultra-Widefield retinal diagnostic imaging systems with Integrated UWF-Guided Swept Source OCT [Silverstone]



Contract Cell Manufacturing

### Financial target

	FY2023/3	FY2026/3
Revenue	¥80.0B	¥90.0B
Operating profit	¥6.0B	¥10.0B
OPM	8%	11%

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- The Healthcare BU was established as a business unit in the end of June 2017. Business activities are pursued under the mission to support improving quality of life for people through innovation.
- The business is made up of three segments--Biological microscopes, Retinal diagnostic imaging systems, and Contract cell manufacturing. As shown on the pie chart, the Healthcare Business reported revenue of ¥73.2B and operating profit of ¥4.3B last year.
- In the Biological microscopes business, Nikon is one of four major makers of microscopes and contributes to the advancement of science in a broad range of fields. In particular, in the field of research, our products are used at cutting-edge research institutions and drug discovery companies to elucidate disease and develop new drugs.
- Our Retinal diagnostic imaging systems contribute to the early discovery and early treatment of disease. In particular, our "Optos" brand products deliver high value-added for their ability to diagnose sites peripheral to the retina.
- In Contract Cell Manufacturing, we provide to pharmaceutical companies and bio ventures process development and production services for cells for regenerative medicine and gene therapy.
- Under the Medium-Term Management Plan beginning this fiscal year, these three segments aim to combine for revenue of ¥90B and operating profit of ¥10B by FY2026/3, the final year of the plan. We are targeting both strong topline growth and continued improvement in profitability.

### Vision

Support improving quality of life for people through innovation

### Operational direction

#### Biological microscopes

- Improve profitability via digitalization, stronger application development and lower COGS

#### Retinal diagnostic imaging systems

- Support more sophisticated diagnosis and from-home and remote diagnosis (Add AI diagnosis and OCT features, etc.)

#### Contract Cell Manufacturing

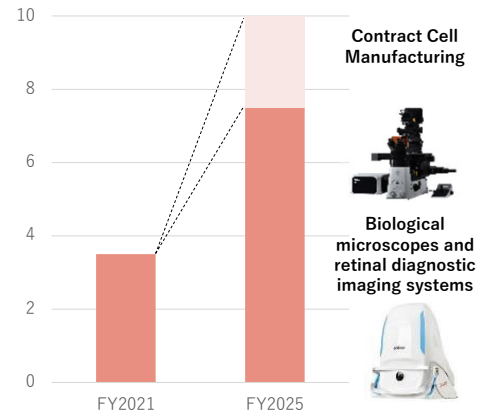
- Leverage Japan's largest production capacity in the field of regenerative medicine
- Advance several projects with major pharmaceutical companies and promising drug discovery ventures and grow operating profit to several billion yen.

### Earnings plan

Grow operating profit to ¥10.0B in 2025

### Direction for Healthcare Business

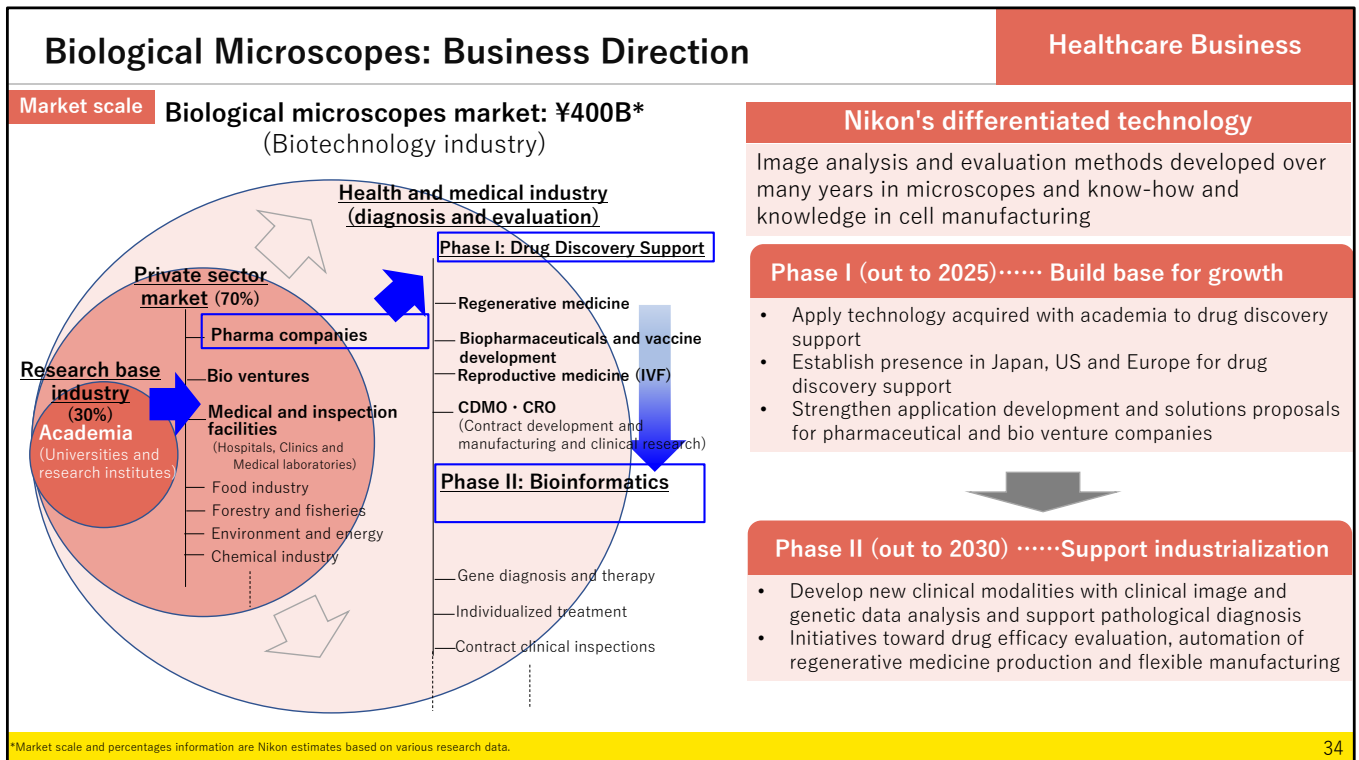
Breakout of operating profit(Billions of yen)




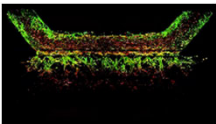
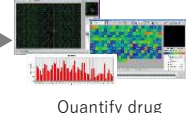

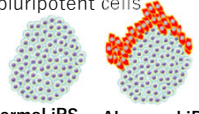
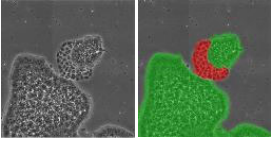
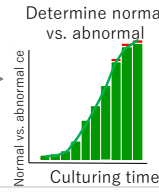


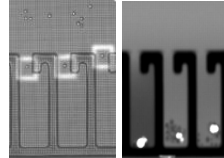


\* OCT stands for Optical Coherence Tomography

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- Next, I will explain the business strategy.
- 2025 will commemorate the 100th anniversary of our first Biological microscope sold in 1925.
- Given the trends toward DX in the market, the massive amounts of images and data obtained from biological microscopes are generating new value in the fields of science, medicine and drug discovery. We strive to maximize customer value and enhance profitability through our solutions.
- The Covid-19 pandemic reminded us of the importance of providing a safe and secure diagnostic infrastructure leveraging Retinal diagnostic imaging systems. We are also working to create diagnostic support frameworks leveraging AI and IT cloud environments with the aim to develop new modalities for retinal diagnosis.
- In Contract Cell Manufacturing, the world's pharmaceutical companies and bio ventures have begun new efforts to address unmet medical needs in oncology and elsewhere. Possibilities are emerging that the field of regenerative medicine may be able to solve challenges presented by rare ailments including intractable diseases with treatments that lack commercial feasibility under cost-benefit analyses, and we aim to contribute to society by contracting regenerative medicine.
- Contract Cell Manufacturing is still in its infancy today. However, Biological microscopes and Retinal diagnostic imaging systems are generating stable revenue. We will actively invest here to develop the business into a presence in terms of revenue by FY2025.



- Beginning with this slide, I will explain each of the three business segments I outlined, starting with Biological microscopes.
- A biological microscope is a medical device that requires filing with each country's certifying organization. The market scale for biological microscopes within the biotechnology field is currently about ¥400B, and we expect the average annual growth rate to exceed 6% through 2025.
- Academia accounts for about 30% of the market, while the private sector, where applications are broad, accounts for the remaining 70%.
- Working together with universities and research institutions in various countries, Nikon has accumulated a great deal of knowledge in five fields of cells, namely, culturing, manipulation, evaluation, analysis and diagnosis.
- Under Phase I looking out to 2025, we aim to deploy the technology, skills, knowledge and experience we have accumulated working with academia into solutions for the fast-growing pharmaceutical and biotechnology fields and build a foundation for growth.
- Under Phase II beginning 2026, we aim to contribute to productivity gains in drug development through drug efficacy evaluation and support for automation of regenerative medicines based on cells. Furthermore, we will strive to support development of new diagnosis and treatment methods by incorporating knowledge from the field of genetics into image-based analysis data.

Biological Microscopes: Concrete Initiatives toward Drug Discovery Support		Healthcare Business	
Drug discovery support: Three market approaches		Solutions	Equipment
<p><b>1</b> Low molecule drugs</p> <p>Use cells to evaluate a drug's efficacy</p>	<p><b>Organ-on-a-chip (OoC)</b> Efficient chemical efficacy evaluation in cells</p>  <p>Analyze and evaluate drug efficacy in 3D</p>  <p>Quantify drug efficacy</p> 	 <p>Confocal microscope</p>	
<p><b>2</b> Regenerative medicines</p> <p>Stable production of cells as a drug product</p>	<p><b>Human iPS cells</b> Drug production using pluripotent cells</p> <p>Normal iPS    Abnormal iPS</p>  <p>Detect normality/abnormality with image analysis</p>  <p>Determine normal vs. abnormal</p>  <p>Culturing time (h)</p>	 <p>Cell Observation Device</p>	
<p><b>3</b> Antibody drugs</p> <p>Select cells with strong antibody production abilities</p>	<p><b>Antibody-producing cells</b> Efficient cell selection</p> <p>Antibody    Cell</p>  <p>Cell manipulation capability evaluation</p>  <p>Production capability evaluation</p> <p>Evaluate cells individually and select and collect target cells</p> 	 <p>Multipurpose cell research and development platform</p>	

\* Global market scale (2020) Nikon estimates: 1. Low molecule drugs 873USDbn (CAGR2.9%), 2+3. Regenerative medicines + Antibody drugs: 389USDbn (CAGR7.7%)

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- Here, I explain three approaches we are taking to drug discovery support.
- In the field of "Low molecule drugs", it is said the probability of investing ¥100B over 10 years and developing a ground-breaking new drug is no better than 0.01%.
- Drug development requires larger investments in later stages and can impact drug discovery companies' earnings. Nikon provides solutions to pharmaceutical companies and bio ventures as methods to efficiently evaluate the efficacy and toxicity of drugs in the initial stages of development leveraging cells that are similar to human histology.
- The field of "Regenerative medicines" requires advanced analysis, evaluation and judgment to select cells that would be therapies. We are working to provide solutions leveraging a variety of analysis and evaluation tools for discerning between normality and abnormality in candidate cell therapies and making predictions based on images and data.
- In the field of "Antibody drugs", we work to support basic research and productivity gains at pharmaceutical companies in the area of cell culturing and selection to enhance the productivity of production capacity of antibodies produced by cells.
- We aim to grow and expand the drug discovery support business through both development of related equipment and delivery of services based on cells.

## Biological Microscopes: Network Supporting Technology Development for Drug Discovery Support

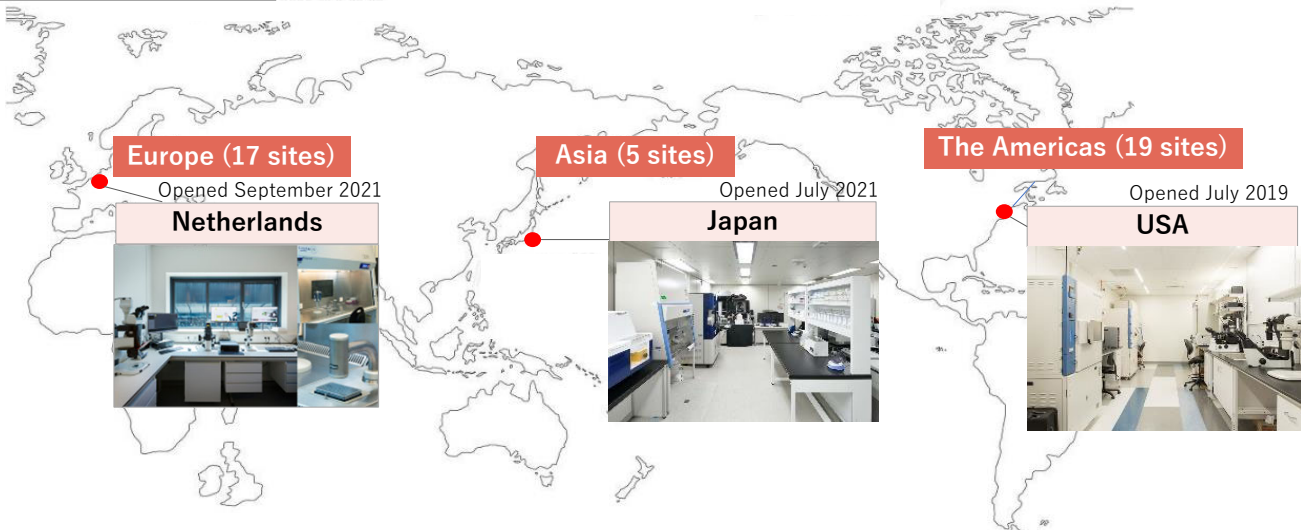
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### R&D sites

Active in joint research, collaboration and research support in the world's leading facilities

### Nikon BioImaging Lab

Drug discovery R&D support facility



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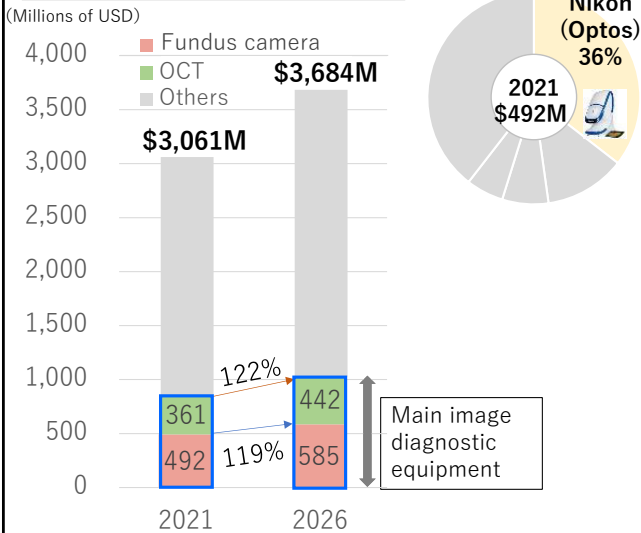
- Our source of innovation in such initiatives aimed at drug discovery support has been the cooperative relationships and networks we have built over many years working with research institutions inside and outside Japan.
- In July 2019, we opened the Nikon BioImaging Lab in Boston, Massachusetts (US) to support drug discovery and development.
- The Boston area is a hub for innovation, much like Silicon Valley. There, globally known pharmaceutical companies, drug discovery startups, and other IT companies have built out a drug discovery ecosystem.
- Amid that, we have begun support activities aimed at efficient drug development leveraging live cell imaging and image analysis technologies.
- Also, in July 2021, we opened a facility aimed at drug discovery research and support leveraging cutting-edge equipment within the Shonan Health Innovation Park (Shonan I-Park), where pharmaceutical companies and bio ventures have gathered.
- Moreover, in September 2021, we opened a site inside the Leiden Bio Science Park, which is an authority in drug discovery activities and located in the outskirts of Amsterdam (Netherlands), and have begun activities supporting bio ventures.
- In addition to our presence in Japan, the Americas and Europe, moving forward we will accelerate similar activities at our regional headquarters in China and Singapore.

## Retinal Diagnostic Imaging Systems: Business Direction

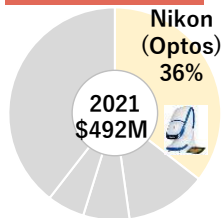
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### Market scale

Ophthalmic diagnostic equipment market scale\* CAGR :3.8%

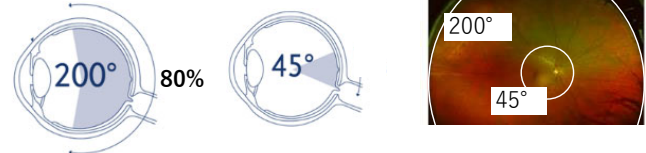


### Market share (by value)



### Optos' differentiated technology

Nikon(Optos) General fundus cameras



Capture images of about 80% of the fundus of the eye with ultra wide field, no dilation, at ultra high-speed (0.4s)

#### Phase I (out to 2025): Develop the market and new technologies

- Grow volume share (currently 10%) by developing Europe and Asia markets
- Expand into ophthalmologist market (Currently, Optometrist > Ophthalmologist)
- Develop new devices (equipment and software) and acquire diagnostic support technology

#### Phase II (out to 2030): Develop diagnostic support systems

- More sophisticated diagnosis (combined diagnosis) and at-home assisted diagnosis
- Physician's fixed diagnostic support system. Disease prevention and prognosis management

\*Market values from MarketScope2021 (research data)

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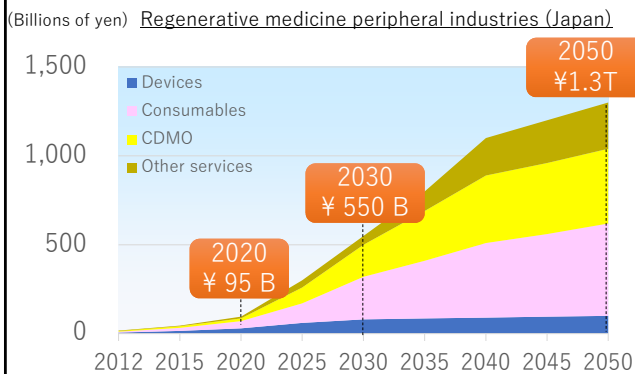
- Next, I will explain the second business segment, Retinal diagnostic imaging systems.
- The graph on the left shows the overall market size of ophthalmic diagnostic equipment. Long-term growth projections are around a little less than 4% per year, but the Covid-19 pandemic over the past two years has resulted in actual current growth exceeding that.
- Working together with Optos (UK), which we acquired in 2015, we have worked on two diagnostic equipment units, a retinal camera that diagnoses the retina surface and an OCT that diagnoses deep into the fundus of the eye.
- The pie chart in the middle indicates share by value for retinal cameras. Our diagnostic equipment can diagnose about 80% of the fundus of the eye at high-speed in a non-invasive fashion. With an aging society and increased incidence of ophthalmological ailments in the young, diagnostic equipment capable of shooting wide angles are more profitable than entry level models and represent a promising market over the mid- to long-term.
- Under Phase I looking out to 2025, we aim to expand our share by volumes in Europe, Japan, China and the rest of Asia. We are also working to develop new diagnostic equipment fusing technologies from Optos and Nikon.
- Under Phase II beginning in 2026, tools that support accurate and rapid diagnosis will be increasingly important to counter a continuing rise in the number of patients.
- Furthermore, as diagnosis and treatment shift from the hospital to the home or off-site facilities, the medical support system will change dramatically. We will strive to develop new diagnosis modalities in line with changes in the market and advances in medicine.



## Contract Cell Manufacturing: Business Direction

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### Market scale\*



### Nikon initiatives and strengths

- Business alliance with Lonza, the world's largest contract cell maker
- Japan's largest GCTP/GMP\* compliant production facility (7,500m<sup>2</sup>)
- Provide full range of contract services, from process development to commercial production
- Track record of many clinical studies and commercial projects in Japan

### Phase I (out to 2025): Build infrastructure for regenerative medicine industry

- Expand existing projects (expand clinical trials and commercial manufacturing)
- Capture promising pipeline and build up track record and know-how
- Strategic investment aimed at facility expansion and stable operations



### Phase II (out to 2030): Grow regenerative medicine into a standard treatment

- Support mass production: mass manufacturing at third parties
- Support flexible production: In-house simultaneous manufacture of multiple batches

\* Nikon forecasts based on March 2020 Ministry of Economy, Trade and Industry Evaluation Study Group for Industrialization of Regenerative Medicine and Gene Therapy

(\*)GCTP: Good Gene, Cellular, and Tissue-based Products Manufacturing Practice

(\*)GMP: Good Manufacturing Practice

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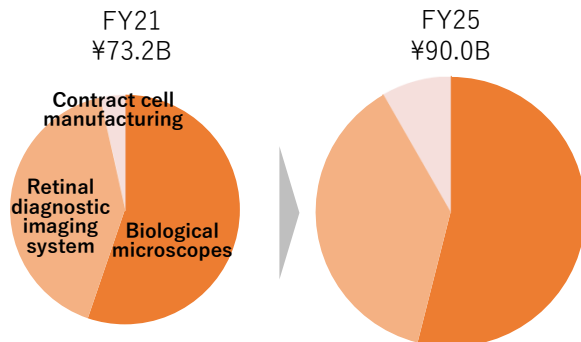
- The third business segment is Contract Cell Manufacturing.
- The graph on the left shows market scale forecasts for Japan in industries adjacent to regenerative medicine. The period from 2020 to 2025 represent the industry's infancy. Beginning in 2026, the new industry ramps up rapidly.
- Our subsidiary Nikon Cell Innovation Co., Ltd. has a business alliance with Lonza, the world's largest contract cell maker, and provides pharmaceutical companies and bio ventures with world-class contract services.
- Currently, about 10 pipelines have been progressing, and we have already been approved for a number of regenerative-medicine products in Japan. We are involved in the production of clinical drugs, as well.
- Under Phase I looking out to 2025, we will strengthen alliances with leading pharmaceutical companies and promising ventures and expand projects.
- At the same time, we will build out a base for business growth over the mid- to long-term by getting involved in process development from early on in promising drug candidates.
- Under Phase II beginning in 2026, we will advance support of mass production and flexible manufacturing, based on the production know-how we have developed during Phase I and a promising pipeline.
- The development of ground-breaking novel drugs for rare ailments is a challenge for society and one of the important solutions that can be provided by regenerative medicine.
- We will work to develop production technology to make flexible manufacturing commercially feasible.



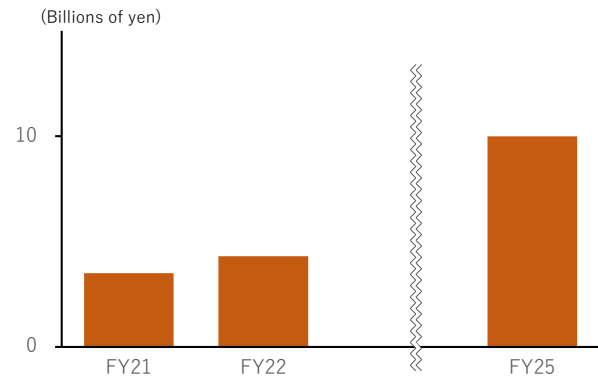
## Healthcare: Earnings Plan

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### Revenue



### Operating profit



Grow operating profit to ¥10.0B in 2025

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- The three business segments of Biological microscopes, Retinal diagnostic imaging systems and Contract Cell Manufacturing that I have described leverage the technology we have accumulated to target markets that promise tremendous growth in the future.
- In particular, Nikon will invest actively in Drug discovery support and Contract Cell Manufacturing so as to become a pioneer in these new industries.
- We aim to achieve revenue of ¥90B and operating profit of ¥10B by FY2025 through stable growth in existing businesses and business growth in new areas.