I was appointed CFO in April 2023. Since joining the company, I have been involved in the Group’s overseas development and business expansion through a wide variety of positions in the Human Resources Department, the US assignment, and the Asia, South and Central America businesses. As we continue to advocate and pursue our Purpose of “contributing to the enrichment of quality of life around the world,” we are increasingly feeling the rising expectations from society for our innovations, including our oncology products. Under these circumstances, we must further clarify roles and promote functional collaboration in our operations in order to compete in the dynamic and highly competitive global marketplace, and reform our internal systems to enable swift and precise decision-making and optimal resource allocation at a global level. Accordingly, I would like to demonstrate leadership toward achieving our 2030 Vision of becoming an “innovative global healthcare company contributing to the sustainable development of society.”

Message from the CFO

Executive Officer
Head of Global Corporate Planning and Management, CFO
Koji Ōgawa

Progress and update on the current 5-year business plan (FY2021-FY2025)

The Daichi Sankyo Group is working on its current 5-year business plan (FY2021-FY2025) aimed at achieving its FY2025 target of becoming an innovative global healthcare company with a competitive advantage in oncology and shift to further growth to achieve our 2030 Vision. Specifically, by implementing the four strategic pillars and strengthening the foundation that supports these strategies, we aim to achieve our KPI targets of ¥1.6 trillion in revenue (¥400 billion or more from oncology business), a core operating profit ratio before R&D expenses15 of 40%, RDE of 14% or more, and DOE (dividend on equity ratio)16 of 8% or more in FY2025, which is the final fiscal year of the plan.

It is now available in 35 countries and regions, and revenue in FY2022 has grown to ¥258.4 billion. In addition, the DESTINY-Breast04 (IIB-09) trial for the first-line treatment of HER2-positive breast cancer and other trials for expanding indications is advancing more quickly than initially planned.

The development of the products following Enhertu, Dato-DXd (TROP2-directed ADC) and HER3-DXd (HER3-directed ADC) is also progressing faster than originally planned.

Regarding the second strategic pillar, “profit growth for current business and products,” market penetration further progressed for anticoagulant Lixiana, which saw product value improve with the addition of new dosage and administration, and its revenue grew to ¥24.4 billion in FY2022. In addition, steady growth in revenue from pain treatment Tarlige in Japan and treatment for iron deficiency anemia Injectase® and Venofer® in the US is contributing to strengthen the source of investments for sustainable growth shareholder returns. Moreover, in terms of transforming to a profit structure focused on patented drugs, we launched new drugs such as prophylaxis of migraine attacks Empilat® and anti-cancer agent Ezahar® while making progress in product transfers following the loss of exclusivity in various countries and regions, such as for hypertension treatment Benicar® in the US and antiparkinson agent Efenna® in Europe, thereby strengthening our profitability.

The development of the products following Enhertu, Dato-DXd (TROP2-directed ADC) and HER3-DXd (HER3-directed ADC) is also progressing faster than originally planned.

Furthermore, we are making steady progress in selecting post-Dkx-ADC modalities, including clinical trial initiation for DS-9606, a second-generation ADC. As an important initiative under the fourth strategic pillar, “create shared value with stakeholders,” we have developed the first Japan-produced COVID-19 mRNA vaccine (DS-5670). In August 2023, our origin strain monovalent mRNA vaccine against COVID-19, Daichirona® for Intramuscular Injection, received approval in Japan for prevention of infectious disease caused by SARS-CoV-2 (booster vaccination). We are currently developing the XBB.1-containing monovalent vaccine recommended for use in Japan’s fall/winter 2023 vaccination program, and aim to supply the XBB 1.5-containing monovalent vaccine before the end of 2023 at the earliest. For details on the progress of the current 5-year business plan, please refer to the FY2023 financial results presentation materials.

15 Core operating profit ratio before R&D expenses = (Revenue - R&D expenses) / Revenue × 100
16 DOE = (Dividend on Equity / Total capital) × 100
Expectation on FY2025 KPI achievement (as of April 2023)

In FY2025, we expect revenue of ¥2 trillion, which exceeds the target of ¥1.6 trillion by ¥400 billion more. The main reason for the increase is revenue from oncology business, which we expect will exceed our target by approximately ¥900 billion to ¥1 trillion, mainly driven by higher-than-expected revenue growth for Enhertu.

For Enhertu, we expect revenue to grow substantially, driven by higher revenue in the breast cancer market based on the results of the DB-03 and DB-06 trials, an increase in product sales and development milestones from accelerated trials to expand indications, including the DB-09 trial, as well as an increase in sales milestones from higher-than-initially-planned product sales.

We will continue to aim for core operating profit ratio before R&D expenses target of 40%, although we expect the cost of sales and SG&A expenses to rise in line with revenue increase which is higher than initially planned. For SG&A expenses, we expect an increase in profit-share based on a strategic alliance with AstraZeneca driven by growth in Enhertu and Data-DDM product sales, as well as higher expenses from obtaining indications that we had not initially expected to be approved during the current 5-year business plan period. However, we plan to achieve our target by efficiently and effectively managing our expenses and other costs.

Update on 3ADCs launch plan and R&D strategy

Given that the development of the 3ADCs is progressing ahead of plan, we updated our launch plan for the 3ADCs in April 2023, including indications approval that we did not initially expect to achieve during the current 5-year business plan period. In addition, with the growing potential of DS-7300 and DS-6000, which are the potential growth drivers following the 3ADCs, we shifted our R&D strategy from the previous “3 and Alpha” to “5DXd-ADCs and Next Wave” from April 2023 onward. We intend to actively make R&D investments in promising products in our pipeline other than the 3ADCs in order to achieve sustainable growth.

Although we expect R&D expenses to exceed our initial plan owing to the increased costs for related trials, all of them are important trials that are crucial for maximizing 3ADCs, and we will actively make R&D investments with the aim of obtaining approval and launching promotions as soon as possible.

Management focusing on cash allocation and shareholder’s equity cost during the current 5-year business plan period

During the current 5-year business plan period, we plan to allocate cash for investment for growth and shareholder returns in a balanced manner. Specifically, we will allocate a certain amount of cash to investment for growth (R&D expenses and capital expenditures) and shareholder returns, and then flexibly allocate the remaining cash to investments aimed at building pillars for further growth and shareholder returns in a balanced manner, based on the progress of our pipeline.

We expect the source of cash allocation during the current 5-year business plan period, which is the cash in hand at the beginning of the current 5-year business plan period plus the 5-year operating cash flow before R&D expenses, to come to ¥3.1 trillion, approximately ¥300 billion more than initially planned, thanks to steady sales growth of Enhertu and existing products. Of this amount, we plan to allocate approximately ¥1.1 trillion to R&D expenses (an increase of ¥300 billion from the initial plan) as we will prioritize the development of 3DXD-ADCs based on the 3ADCs launch plan and R&D strategy updated in April 2023, while allocating approximately ¥400 billion to capital expenditures (an increase of ¥100 billion from the initial plan), mainly for strengthening our ADC supply capabilities to ensure supply for FY2026 and beyond.

Shareholder return policy

With respect to shareholder returns, we aim to maximize shareholder value by adopting DOE, which is calculated based on shareholders’ equity as a KPI, and by providing stable shareholder returns with a target DOE of 8% or more in FY2025, which is higher than the cost of shareholders’ equity. As we shift from an investment phase to a profit growth phase in the current 5-year business plan, we believe it is essential to consider dividends and acquisition of own shares by looking at both shareholder return and capital efficiency, while taking into account the shareholder’s equity cost. Accordingly, we adopted DOE, an indicator that combines ROE and dividend payout ratio, as a KPI for shareholder return.

We aim to improve capital efficiency by growing the 3ADCs to expand revenues and flexibly executing acquisition of own shares, and continue to target a FY2025 DOE of 14% or more, which is above the shareholder’s equity cost. To ensure financial security, we plan to maintain our equity ratio at approximately 60% during the current 5-year business plan period.

In closing

As of June 30, 2023, our market capitalization is over ¥1 trillion with a P/E ratio of approximately 5 times, and we believe that progress in our oncology business and the value of our pipeline of innovative pharmaceuticals are highly evaluated by investors in the stock market. Going forward, we will continue to work toward maximizing corporate value by engaging in active dialogue with our shareholders, investors, and other stakeholders.

For more information on FY2023 Results and FY2023 Forecast, please refer to FY2023.