

# Review of FY2021

Looking back on my first year as CFO, FY2021, the first year of our current 5-year business plan (FY2021-FY2025) was a very important year for us as we steadily worked to achieve our annual performance targets and began reforming our management system in order to shift to a business model with a focus on our FY2025 targets and 2030 Vision. In the first year of the current 5-year business plan, the revenue of existing mainstay products such as anticoagulant Lixiana®, pain treatment Tarlige®, and iron deficiency anemia treatment Injectafer increased steadily, and the launched market of Enhertu® expanded to 25 countries and regions as part of our efforts to "maximize 3ADCs," which is one of the pillars of the strategy for the current 5-year business plan. As a result, revenue rose substantially year-on-year, and core operating profit, which indicates ordinary profitability, and operating profit both grew at double-digit rates. In addition, positive results from two clinical trials of Enhertu, DESTINY-Breast03 and DESTINY-Breast04, which are the drivers for achieving our current 5-year business plan targets, have given us confidence in our future growth.

As for FY2022, we have formulated a plan to absorb the performance impact of measures to curb drug costs in Japan and overseas, while securing R&D investment to accelerate the R&D of 3ADCs including *Enhertu*, and to steadily advance toward achieving our current 5-year business plan targets. In addition, we have begun to enhance our budget management in order to further improve the consistency between our current 5-year business plan and the single-year targets and business plans formulated in light of the latest changes in the business environment. By accurately grasping the latest changes in the business environment and linking positive changes to business opportunities in a timely manner, as well as by incorporating measures to reduce the impact of any negative changes, we will maximize business performance by ensuring flexible resource allocation through annual updates to the 3-year forecast.

As *Enhertu*'s development progresses and sales expand, we are transforming our business model from one anchored in the cardiovascular field to one that delivers oncology drugs to patients on a global scale. The oncology field is a therapeutic area where the global standard of care continues to change rapidly, and operations need to continue to evolve in a dynamic manner. To this end, we must speed up and improve sound decision-making at the global level. We are holding Executive Management Committee meetings more frequently than in the past in order to facilitate discussions by global leaders and to ensure the appropriate delegation of authority. In particular, in the Portfolio Prioritization of clinical development projects, we review the frequency and timing of meetings and make agile decisions so that supply plans and investment plans for the next fiscal year can be formulated based on the results of the rapid and integrated prioritization process, which combines science and business perspectives.

Furthermore, as part of our efforts to strengthen the management foundation that supports the four strategic pillars of the current 5-year business plan, we have launched "Project 4D (Daiichi-Sankyo Data Driven Decision making)," which aims to achieve data-driven management for flexible decision-making based on prompt and accurate recognition of current issues. We are making steady progress in standardizing and systemizing operations related to management information creation on a global basis.

Moreover, the CFO is in charge of promoting risk management, and in FY2021, in light of the emergence of dispute related risks such as the Seagen matters and other cases, we have been working to centrally manage major disputes under the risk management system on a global basis in order to balance risk management and thorough information management. In addition, we reevaluated existing cases and reconfirmed whether or not there were any new cases.

### Forecast for FY2022

For FY2022, we expect consolidated revenue of ¥1,150.0 billion (+10.1% vs. FY2021), core operating profit of ¥105.0 billion (+15.9% vs. FY2021), and operating profit of ¥105.0 billion (+43.8% vs. FY2021). In terms of foreign exchange rates, we assume exchange rates of ¥130 to the US Dollar and ¥140 to the Euro. For depreciation of ¥1 against the US Dollar, we expect an increase of ¥2.5 billion in revenue and a decrease of ¥0.5 billion in operating profit, and for the Euro, we expect an increase of ¥1.2 billion in revenue and an increase of ¥0.3 billion in operating profit. As a result, we expect to see an increase of approximately ¥55.0 billion in revenue and a decrease of approximately ¥6.0 billion in core operating profit due to foreign exchange impact in FY2022.

Table 1: FY2022 Forecast and Key Drivers

In FY2022, we will place the highest priority on accelerating the development of 3ADCs and boosting sales growth in order to achieve our current 5-year business plan strategy to "maximize 3ADCs."

In order to bring *Enhertu* to as many patients as possible, we will accelerate our efforts to achieve market penetration and add new indications through our strategic alliance with AstraZeneca. Currently, sales are growing rapidly driven by market penetration in the United States, Europe, Japan, and other countries where the drug has been launched, and we plan to add five new indications in the U.S. and Europe in FY2022. Taking into account the recognition of regulatory milestone payments from AstraZeneca associated with the approval of these new indications and the increase in product sales driven by accelerated market penetration in each region, we expect *Enhertu* sales to double from the previous fiscal year to reach ¥159.9 billion. Excluding upfront payments, development milestone payments, and other deferred income, we expect *Enhertu* product sales to rise from ¥65.4 billion in FY2021 to ¥128.4 billion in FY2022.

Graph 1: Enhertu Sales

#### Table 1: FY2022 Forecast and Key Drivers

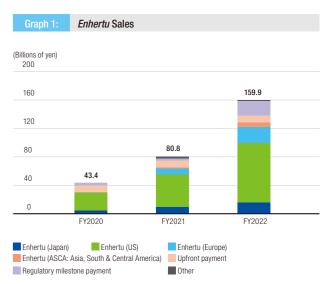
FY2022 Forecast	Key Drivers
Revenue: ¥1,150.0 billion (+10.1% vs. FY2021)	Sales of mainstay products such as <i>Enhertu</i> and <i>Lixiana</i> are expected to rise, despite negative factors such as the NHI price revision in Japan and the end of the <i>Nexium</i> <sup>®</sup> sales partnership.
Core operating profit: ¥105.0 billion (+15.9% vs. FY2021)	Expecting higher revenue and an increase in gross profit driven by an improvement in the cost of sales ratio stemming from a change in product mix to offset higher expenses associated with the concentrated allocation of resources to the oncology business, including an increase in profit-share payments to AstraZeneca for <i>Enhertu</i> and expansion of development plans for 3ADCs.
Operating profit: ¥105.0 billion (+43.8% vs. FY2021)	No temporary income or expenses expected

• We are also conducting many clinical trials for *Dato-DXd* and *HER3-DXd*, and will promote their development to promptly provide new options for cancer treatment by obtaining approval and expanding approved indications for each stage of treatment for various types of cancer.

With regard to "profit growth for current business and products," *Lixiana* is growing steadily in Japan, Europe, and the Asia, South & Central America (ASCA) region, and has surpassed its immediate target of ¥200 billion in global sales for FY2021 ahead of schedule. In FY2022, we forecast sales to grow by 15.6% year-on-year to ¥237.7 billion. In Japan, we received approval in August 2021 for additional dosage and administration for the prevention of stroke and systemic embolism in elderly patients with non-valvular atrial fibrillation who are at high risk of bleeding, and plan to expand sales in Japan from ¥92.5 billion in FY2021.

Product transfers and other initiatives are progressing in each region, and we are making steady progress in transforming toward a profit structure focused on new drugs. Going forward, we plan to shift to a business structure that supports sustainable growth by expanding the area where our strengths overlap with the expectations from society.

Other important initiatives include the development of a COVID-19 mRNA vaccine (*DS-5670*). In light of the vaccine situation, we have placed the highest priority on conducting trials in Japan to confirm the booster effect (third vaccination) and have initiated a Phase 1/2/3 clinical trial in January 2022 aimed at providing additional doses to previously vaccinated individuals. In September 2022, we also initiated a Phase 3 clinical trial on unvaccinated healthy adults in Japan. We will do our best to supply a Japan-made mRNA COVID-19 vaccine as a Japanese pharmaceutical company in the vaccine business with the aim of bringing the vaccine to market as soon as possible.



\*Includes co-promotion sales in countries where AstraZeneca records sales.

### Cash Allocation for the Current 5-year Business Plan

During the current 5-year business plan period, we expect to allocate approximately ¥2.8 trillion in cash, which is the cash on hand at the beginning of the current 5-year business plan plus the operating cash flow before R&D expenses over the 5-year period. Of this amount, approximately ¥1.5 trillion will be allocated to R&D expenses as an investment for growth, mainly for 3ADCs, and approximately ¥500 billion will be allocated for capital investment, mainly to enhance our supply capacity for DXd-ADCs. In terms of shareholder returns, we plan to maintain the current dividend of ¥27 per share of common stock and increase the dividend in line with profit growth, while allocating cash in a balanced manner to investments aimed at building further growth pillars based on progress in the pipeline and flexible acquisition of own shares.

#### R&D investment

In the current 5-year business plan, we set a new KPI to achieve a core operating profit ratio before R&D expenses of 40% in FY2025. The aim of this is to more accurately and concretely understand our ordinary profitability as a company and our earning capacity in our core business, as well as to flexibly determine the allocation of R&D investment in accordance with the potential of our pipeline based on our "ability to finance drug discovery," in other words, our ability to fund R&D investments for sustainable growth.

Maximizing 3ADCs including *Enhertu* is the most important strategic pillar of our current 5-year business plan, and we plan to expand R&D investment centered on 3ADCs by ¥52.9 billion, from ¥254.1 billion in FY2021 to ¥307.0 billion in FY2022. In addition, we have confirmed initial efficacy signals in Phase 1 clinical trials for our fourth and fifth ADCs, *DS-7300* and *DS-6000*, and have positioned them as "Rising Stars," the new growth drivers following 3ADCs, and are promoting their development. Furthermore, as part of our multimodality strategy, we have made progress in establishing LNP-mRNA technology through vaccine development and are making steady progress in our efforts to select a post-DXd-ADC modality. We will continue to invest in R&D to identify and build further growth pillars using our proprietary ADC technologies and new modalities.

#### Capital investment

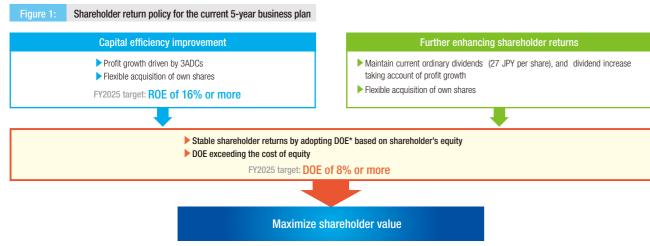
Taking into account our 3ADCs launch plan and progress in the development of DXd-ADC, which will follow *Enhertu*, we plan to allocate up to ¥300 billion in capital investment to our own production facilities in Japan and overseas, and to external contract manufacturing organizations (CMOs) by FY2025. Capital investment aimed at supplying ADC products during the current 5-year business plan period is progressing steadily, and we will determine investment allocation according to demand and work to expand ADC supply capacity in order to strengthen our production system with a view to supplying ADC products in FY2026 and beyond.

## Implementing Management Practices that Enhance Capital Efficiency to Maximize Shareholder Value

We will strive to improve capital efficiency and further enhance shareholder returns in order to maximize shareholder value.

#### • Capital efficiency improvement (FY2025 target: ROE of 16% or more)

We aim to achieve a ROE of 16% or more in FY2025 by increasing profitability through growth in 3ADCs and improving capital efficiency through flexible acquisition of own shares, and other measures. Our ROE in FY2021 was only 5%, but when analyzing our Group's ROE trends, there was no significant change in total capital turnover or financial leverage, and the biggest impact factor was net profit margin, which was mainly influenced by continued up-front R&D expenditures. We plan to achieve substantial revenue and profit growth by further growing 3ADCs, maximizing earnings from Lixiana, and shifting to a profit structure focused on new drugs by quickly ramping up *Tarlige*, *Nilemdo*<sup>®</sup>/*Nustendi*<sup>®</sup>, and other drugs, as well as by optimizing the cost of sales and expenses. In addition, our equity ratio as of the end of FY2021 is 60.8%, which ensures sufficient financial safety, but we believe this is near the upper limit from the perspective of capital efficiency, and we intend to maintain this level through flexible acquisition of own shares and other



\* Dividend on Equity = Total dividend amount / Equity attributable to owners of the Company

measures. We have been reducing our non-core assets by selling non-business fixed assets, dissolving cross-shareholdings, and selling current products.

With regard to cross-shareholdings, we have adopted a policy of not holding listed stocks in principle unless we determine that it will help maintain and strengthen long-term business relationships and enhance our corporate value, and we will continue to sell stocks that we cannot reasonably justify owning. Regarding real estate, we sold our Osaka logistics center in FY2021. Going forward, we will continue to make decisions on whether or not to sell real estate based on its importance to our business activities and replaceability. as well as life cycle costs such as maintenance and renovation costs and our business continuity plan (BCP), while also carefully taking into account appropriate timing. Furthermore, in FY2021, we signed an agreement to sell current products in the US and an agreement to sell our *Cravit* drug formulation and production company. Daiichi Sankyo Pharmaceutical (Beijing) Co., Ltd. in China. We will continue to work on reducing non-core assets, including by reviewing our business portfolio, to free up capital for growth investments and shareholder returns.

#### • Further enhancing shareholder returns

In order to maintain and expand our relationship of creating shared value with our shareholders over the long term, we believe it is essential to carefully consider dividends by combining capital efficiency and shareholder return with a strong focus on cost of capital. In line with this, we have adopted dividend on equity (DOE), which is calculated by multiplying ROE and dividend payout ratio, as a key indicator of shareholder return. In FY2025, we aim for a DOE of 8% or more, which is above the cost of shareholders' equity. By establishing DOE as an indicator, which takes shareholders' equity into account, we are committed to providing stable returns to shareholders, and we intend to maintain the current dividend of ¥27 per share of common stock and raise the dividend in line with profit growth, while also flexibly acquiring our own shares.

Figure 1: Shareholder return policy for the current 5-year business plan

## Non-financial Capital that Sustains the Competitiveness of our Business Model built on our Strength in Science & Technology

We believe that the assets that are most important for creating corporate value are not the ones that appear in our financial statements, but rather those that do not appear in financial statements. Our Japanmade business model built on our strengths in Science & Technology, our technologies and expertise in creating pharmaceuticals, and our patents on substances and drug formulations are unique and important assets that were established within the Group and were not purchased externally through M&A deals or product in-licensing. These can be described as non-financial values that can be called "invisible assets," as they cannot be found in financial statements. Furthermore, we believe that human capital, including the researchers who create these assets, is the most important capital for sustaining our competitiveness, and to strengthen it, we will promote materiality on business (promoting the success and development of a diverse range of people who create competitive advantages) by continuously enhancing our investment in human resource development. In addition, we will enhance the disclosure of our non-financial values and invisible assets. In FY2022, we reviewed our disclosure information based on the recommendations of the TCFD, and enhanced our financial impact and other disclosures in this report.

Figure 2: Daiichi Sankyo's Vision for ESG Management

# Maximizing Corporate Value

The ESG management that we drive represents "management based on a long-term perspective that enhances both financial and non-financial value by reflecting ESG elements in business strategies." We believe that such long-term focused management translates into sustainable growth of both our company and society. As the capital market's evaluation of our product potential grows along with the positive clinical trial data coming out for *Enhertu* and our ADCs pipeline, our stock price began to rise from around 2018, reaching a market capitalization of over ¥6 trillion as of the end of June 2022. In comparison, the total equity of our consolidated statement of financial position was approximately ¥1.4 trillion and our Price Book-value Ratio was over 4x, which we believe is an indication that the market appreciates the value of our innovative pharmaceuticals pipeline as well as the non-financial value of our contributions to patients, shareholders and investors, employees, society, and the natural environment.

In response to various demands from society, such as addressing unmet medical needs and environmental issues, we will create economic and social value through materiality initiatives, etc., by leveraging our strengths in Science & Technology as our greatest source of competitive advantage. We will continue to engage in active dialogue with our shareholders, investors, and other stakeholders to improve our corporate management.

