# Value Chain Activities

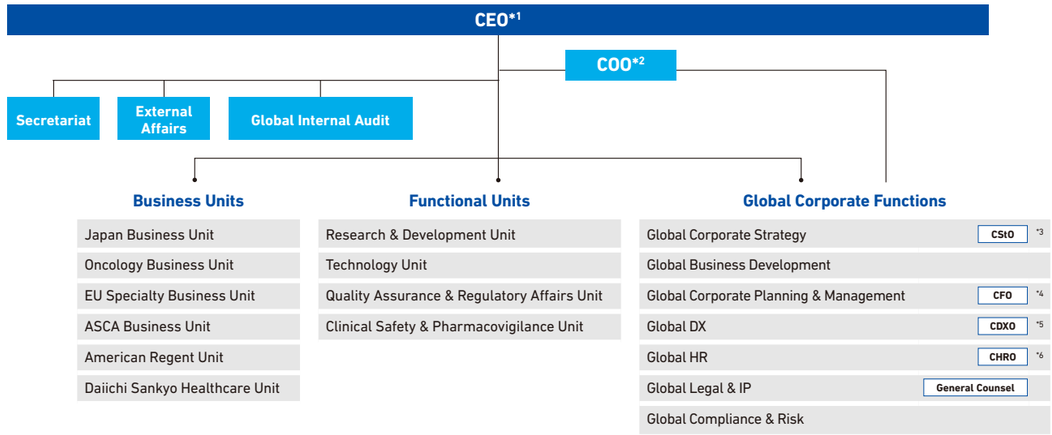
Starting from FY2023, we made some changes to our global management structure: we established the Technology Unit comprising the Biologics, Pharmaceutical Technology, and Supply Chain functions and we reorganized our corporate units into seven global corporate functions. In order to provide better treatment to patients worldwide at the earliest possible opportunity and to expand our business, we work with a global network of members across various functions and regions. In this section we introduce the value chain activities undertaken in FY2022.

## Business Units

| Organization | Role and Mission | FY2022 Results |
|---|---|---|
| **Japan Business Unit** | The Japan Business Unit aims to comprehensively expand the Company's offerings of innovative pharmaceuticals, including in the oncology field, as well as vaccines and generic drugs, and maximize profits and contribute to the medical community in our Mother Market. | We contributed to medical care by popularizing our major products (*Lixiana*®, *Tarlige*®, etc.) and provided new treatment options to patients with the addition of indications for *Enhertu*® and the launch of *Reyvow*® and *Ezharmia*®. Also, the activities of our medical representatives, medical affairs and the product information center were ranked number one in a third-party questionnaire survey. |
| **Oncology Business Unit** | The Oncology Business Unit (OBU) paramount responsibility is to ensure our cutting-edge medicines are accessible to the right patient at the right time so that healthcare professionals and payors in the US, Europe, and Canada can make the best treatment and access decisions for the people they serve. The OBU also provides information about medicines and diseases, as well as a robust support service, as a way of fully supporting patients and caregivers. In addition, the OBU makes decisions on global commercialization strategies. | Due to the US. and EU demand for *Enhertu*, revenue from the OBU increased more than 166% year-over-year one and we have become a market leader for all its indications within 12 months of each launch. With revenue globally in excess of $1.4 billion, *Enhertu* was prescribed to approximately 22,000 patients. The treatment of HER2 low breast cancer with *Enhertu* (post-chemotherapy treatment), which was approved in August 2022 based the groundbreaking data from DESTINY-Breast04, which received a standing ovation when presented at ASCO 2022, will completely transform the way certain breast cancers are treated for thousands of patients and we will continue to support medical facilities, doctors, and customers in this area. We also supported TGCT and IDA patients through delivering *TURALIO*™ and *Injectafer*®. |
| **EU Specialty Business Unit** | The EU Specialty Business Division's goal is to protect people from cardiovascular disease – Europe's leading cause of death – through our expertise in providing innovative pharmaceuticals and help those who suffer from it to enjoy every precious moment of life. | We achieved 1 billion Euro in market performance for *Lixiana*. This means that 1.7 million patients in Europe use *Lixiana*, benefit from it and live their lives with improved protection from stroke.<br>In March we reached 100,000 patients on *Nilemdo*® / *Nustendi*® in Europe, an add-on treatment option to take back control over LDL-C (low-density lipoprotein-cholesterol) management.<br>With our portfolio of medicines that help protect from cardiovascular disease, we live up to our commitment: we care for every heartbeat. |
| **ASCA Business Unit** | ASCA Business Unit aims to deliver DS products to more patients by making full efforts to promote primary business and to maximize oncology business for the business expansion in ASCA region. | Sales revenue recorded a year-on-year increase of 25.1% climbing up to 142.8 billion JPY, mainly due to growth of *Lixiana* and *Enhertu*. *Lixiana* achieved the No. 1 market share of sales in Taiwan following South Korea. Further, *Enhertu* was launched in Taiwan and South Korea following Brazil and Hong Kong. Operations of new company started in Australia and Singapore, and we are committed to sustainable business growth together with ASCA Affiliates in each region. |
| **American Regent Unit** | The American Regent Unit strives to improve human and animal health through the development, manufacture, and delivery of innovative, accessible, and high-quality sterile injectable products.. | During 2022, we strengthened our pipeline and expansion in the US with our acquisition of HBT Labs with the anticipation of launching Paclitaxel in 2023. We also met increased demand for our *Venofer*® business and continued our Capital Expansion efforts in Ohio, New York, and Daiichi Sankyo Altkirch Sarl, including our first product shipments out of our New Albany facility. Additionally, we continued advancing our pipeline with seven product launches, 13 FDA submissions, and six approvals. |
| **Daiichi Sankyo Healthcare Unit** | The Daiichi Sankyo Healthcare Unit contributes to quality-of-life improvements for people who aspire to be healthier and more beautiful with a wide range of products and services, including OTC drugs, functional skincare and oral care, and food products. | Driven by our major new products of *Lulu Attack Premium* and *Loxonin EX* (topical medication), we posted record-high sales revenue and clinched the second-biggest share (among manufacturers) of the OTC market (all categories) for the very first time. Also, as an initiative aimed at recycling resources, we launched a pilot program "OKUSURI SHEET RECYCLE PROGRAM" for Japan's first-ever consumer-driven scheme to recycle used tablet blister packs. |

▶ See P95 for information on financial data of each business unit.

**Global Management Structure**




*1 Chief Executive Officer
*2 Chief Operating Officer
*3 Chief Strategy Officer
*4 Chief Financial Officer
*5 Chief Digital Transformation Officer
*6 Chief Human Resources Officer

## Functional Units

| Organization | Role and Mission | FY2022 Results |
|---|---|---|
| **Research & Development Unit** | The Research & Development Unit will continuously promote the creation of competitive pipelines and innovative novel medicines that revolutionize the standard of care, as well as the accelerated submission and secure approval in each country and region. To this end, strategic R&D activities are planned and executed to maximize the value of our 5DXd-ADCs and develop further growth pillars to follow DXd-ADCs. | *Enhertu* has been approved for the following indications: second-line treatment of HER2-positive breast cancer (Japan, the US, Europe, and China), HER2- low breast cancer in patients previously treated with chemotherapy (Japan, the US, and Europe), second-line treatment of HER2-positive gastric cancer (Europe), followed by second-line treatment of HER2 mutated non-small cell lung cancer as the third cancer type for *Enhertu* treatment (the US). In addition, there were notable progress in a number of pipelines, including for *Dato-DXd*, the initiation of a global Phase 3 clinical trial for the first-line treatment of non-small cell lung cancer in combination with an immune checkpoint inhibitor, and for the mRNA vaccine *DS-5670*, the filing for additional immunization for the prevention of COVID-19 (Japan). |
| **Technology Unit** | We consistently manage the manufacturing life cycle, from early development, investigational drug/commercial manufacturing to post-marketing change including CMC regulatory affairs. We realize stable product supply, assuring quality, and low-cost production by developing advanced manufacturing technology/process with continuous improvement. | In the situation where demand for *Enhertu* is expanding rapidly, we continued to ensure the steady supply of the product to each country. In addition to shortening the supply lead time and promoting timely/appropriate application for post approval change in each country and region, we promoted the expansion of internal and external manufacturing facilities and technology transfer, in order to expand the clinical trial and commercial supply capacity of 5DXd-ADCs, leading to stable supply over the mid-to-long-term. We also worked on the development of a COVID-19 vaccine that utilizes LNP-mRNA technology as the first Japanese company, established manufacturing technology and analysis methods, and realized the marketing authorization application in January 2023. |
| **Quality Assurance & Regulatory Affairs Unit** | The Quality Assurance & Regulatory Affairs Unit adheres to the fundamental principle of "quality first" to ensure the reliability of products and to provide products that are safe and effective. Under compliance, the unit contributes to the maximization of the product value through planning and promoting the pharmaceutical regulatory strategies. | We achieved stable supply by completing pharmaceutical regulatory actions to add new *Enhertu* manufacturing sites, acquiring GMP certifications, and promoting quality assurance measures. Also, in response to the increase in clinical trials and regulatory filings for mainly 3ADCs, we ensured the reliability of application data and completed regulatory inspections by health authorities successfully. We obtained regulatory approval ahead of schedule to add new manufacturing site for regenerative medicine, which consequently contributed to stable supply. |
| **Clinical Safety & Pharmacovigilance Unit** | The Clinical Safety & Pharmacovigilance Unit contributes to ensuring patient safety by promptly providing high-quality safety information in a timely manner for all products while expanding oncology products and new modality from development to post-marketing. | Operations under the new global management structure has been started. We ensured global ILD monitoring and management under further expanding the new indication and approved countries with *Enhertu*. We also proceeded to enhance fundamental Pharmacovigilance system by the use of new safety analysis tools and pursuing the global harmonization of the adverse event case management process. |