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CHUGAI PHARMACEUTICAL CO., LTD.

 A member of the Roche group

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2021.12 Financial Results

February 3, 2022

Event Summary

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[Participants]		
[Number of Speakers]	5	
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	Toshiaki Itagaki	Executive Vice President & CFO
	Tetsuya Yamaguchi	Executive Vice President, Head of Project & Lifecycle Management Unit
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Presentation

Sasai: Thank you very much for participating in today's financial results briefing for the fiscal year ended December 2021.

I'm Sasai of Corporate Communications Department, and I'll be moderating today's session. Thanks.

In order to prevent the spread of the new COVID-19 infection, today's session is being conducted online. If you connect to the URL for the webcast, which can be found at the bottom of the email invitation for the conference call, you will be able to view the presentation material and video with audio. The audio will come from the conference call system, so even when you are viewing the video at the same time, please do not disconnect the line.

Conference on FY2021.12 Financial Results

Agenda



- | | | |
|---|--|---|
|  | FY2021 Overview and FY2022 Forecast | Dr. Osamu Okuda
President & CEO |
|  | FY2021 Consolidated Financial Overview (Core) | Toshiaki Itagaki
Executive Vice President & CFO |
|  | Overview of Development Pipeline | Tetsuya Yamaguchi
Executive Vice President, Head of Project & Lifecycle Management Unit |

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The agenda for today's meeting can be found on the web page and on page three of the presentation material.

Questions will be taken collectively after all presentations have been completed. The Q&A session is scheduled to last about 30 minutes.

Mr. Okuda will now give a summary of FY2021 and the outlook for FY2022.

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2021 Financial Performance

- Significant YoY increase in revenues and profits, exceeding the revised forecast for 2021
- Achieved record-high revenues, operating income, and net income for five consecutive fiscal years

Core (billions of JPY)	2020 Jan - Dec actual	2021 Jan - Dec actual	Growth (year on year)		Revised Forecast	
					Jan - Dec	Vs. 2021 actual
Revenues	786.9	999.8	+212.9	+27.1%	970.0	103.1%
Domestic sales	409.1	518.9	+109.8	+26.8%	513.0	101.2%
Overseas sales	224.2	283.9	+59.7	+26.6%	268.5	105.7%
ROOI	153.6	196.9	+43.3	+28.2%	188.5	104.5%
Operating profit	307.9	434.1	+126.2	+41.0%	400.0	108.5%
Operating margin	39.1%	43.4%	+4.3%pts	-	41.2%	-
Net income	219.4	311.5	+92.1	+42.0%	293.0	106.3%
EPS (yen)*	133.39	189.35	+55.96	+42.0%	178.00	106.4%

ROOI: Royalties and other operating income

* Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS is calculated based on the assumption that the stock split was implemented at the beginning of fiscal year 2020.

- Domestic sales significantly increased due to the growth of Tecentriq, Hemlibra, Kadcyra, Actemra, and steady market penetration of new products such as Ronapreve (supply to the government), Enspryng, Polivy, Evrysdi, and FILCDx, despite the effect of drug price revisions and generics.
- Overseas sales increased as Hemlibra far exceeded expectations, although Actemra's export to Roche decreased as expected
- ROOI increased mainly due to an increase in royalty and profit-sharing income based on the growth in overseas local sales of Hemlibra
- Achieved the full-year forecast, which was revised upward on October 22.

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Okuda: I am Okuda, the President of the Company. I will give you a summary of FY2021 and a forecast for FY2022.

Please refer to page five.

For the full year of 2021, revenues increased by 27.1% to JPY999.8 billion compared to the same period last year, and operating profit and net income each increased by more than 40%. For the fifth consecutive year, we achieved record-high revenues, operating profit, and net income.

Sales in the domestic market grew by 26.8%. Despite the impact of the price revision and generics, our mainstay products such as Tecentriq and Hemlibra, and new products such as Enspryng and Polivy, in addition to Ronapreve, a COVID-19 treatment that began to be delivered to the government in July last year, grew steadily.

Overseas sales increased by 26.6%. Exports of Actemra to Roche declined as expected, but the strong growth of Hemlibra made a significant contribution. Royalties and other operating profit increased 28.2%, mainly due to an increase in royalties based on the growth of overseas local sales of Hemlibra.

Together, these results exceeded our full-year forecast, which was revised upward substantially in October last year.

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Review of Strategic Policies for 2021 (1/2)

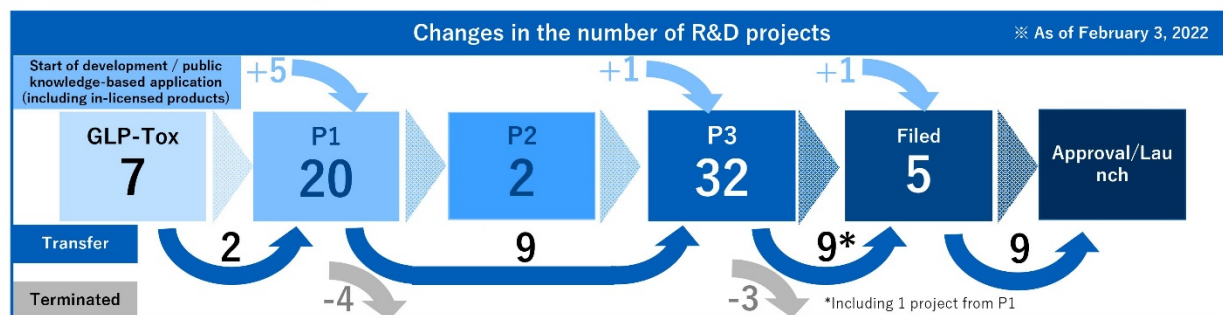
Continuous creation of R&D output

With the contribution of projects not anticipated at the beginning of the fiscal year, regulatory filings, approvals, and launches exceeded the plan

- Approval/Launch (9): Polivy (r/r DLBCL), Evrysdi (SMA), F1LCDx, Ronapreve/Actemra (COVID-19), Cellcept (GVHD), etc.
- Filed (10): Faricimab (DME, nAMD), Tecentriq (NSCLC Adjuvant), etc.

Acquired PoC in 2 projects, steady progress in early and late-stage development projects

- P3: Started GP3 for 10 projects including Roche projects and in-house projects
- PoC: Obtained PoC by the licensee for in-house developed projects CKI27 and OWL833
- P1: Started P1 of in-house proprietary technology projects for mid-size molecule LUNA18 and antibody SOF10



Next, we will review the results of our strategic policies for 2021.

First, the continuous creation of R&D output has exceeded our plans. In 2021, a total of nine projects were approved and launched, including Polivy and Evrysdi. There were a total of 10 projects that were filed, including Faricimab for diabetic macular edema and age-related macular degeneration, and the expansion of the indications of Polivy for untreated DLBCL, and the expansion of the indication of Tecentriq for non-small cell lung cancer adjuvant.

Due in part to the contribution of projects such as Ronapreve that were not anticipated at the beginning of the fiscal year, overall, we exceeded the initial plan for the fiscal year in terms of regulatory filings, approvals and launches.

As shown in the chart below, we have started Phase III of 10 R&D projects. In addition, our own projects, CKI27 and OWL833, have obtained PoC. In addition, we have started Phase I of seven early development projects, including the mid-size molecule LUNA18.

As described above, our projects progressed smoothly in each development stage.

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Review of Strategic Policies for 2021 (2/2)

Maximizing value of growth drivers

- Tecentriq: Market penetration accelerated by additional indication for hepatocellular carcinoma
- Enspryng: Approved in a total of 62 countries (as of December 2021). Domestic sales grew more than expected
- Polivy, Evrysdi: Market penetration exceeded expectations as a new product
- Hemlibra: The delay in global market penetration due to COVID-19 has gradually resolved and is now on a sustainable growth trend
- Actemra: Increase global demand and strengthen/expand supply system with COVID-19
- Distribution policy: Implemented an efficient distribution policy

Acceleration of DX

- Established antibody design technology (LI/LO*) utilizing AI technology
- Improved efficiency of clinical trial operations
- Evolution of a new customer engagement model
- Started building a production system by utilizing robotics
- Selected as a DX brand for the second consecutive year

Strengthen business foundation

- Promoted proper operation of the new personnel system (revised the position profile based on the new growth strategy)
- Achieved single-year environmental targets (waste recycling ratio, final disposal ratio, WET tests conducting ratio, chemical substances in wastewater)
- Continued selection to major ESG indices (DJSI, FTSE4Good, MSCI ESG Leaders)
- Established and built an internal system for the execution of insight business
- Prepared company-wide risk map/risk appetite statement

* LI : Lead Identification LO : Lead Optimization 7

This is followed by the main results of value maximization of growth drivers.

Tecentriq, Enspryng, Polivy, and Evrysdi each achieved market penetration faster than expected. In addition, the market penetration of Hemlibra, which had been affected by COVID-19, is gradually recovering. Global demand for Actemra due to COVID-19 has expanded greatly, and although some countries and regions have experienced shortages, we have been able to respond by strengthening our supply system.

In the area of acceleration of DX, we have made progress in each of our functions, including the establishment of molecular design technology using AI, the streamlining of clinical trial operations using eConsent, the evolution of customer engagement models tailored to customer needs using digital technology, and the use of robotics in our production system.

In terms of strengthening our business foundation, we made steady progress on our reform and improvement plans in both system and administration, including the proper operation of the new personnel system, achieving our environmental targets for FY2021, and addressing ESG issues.

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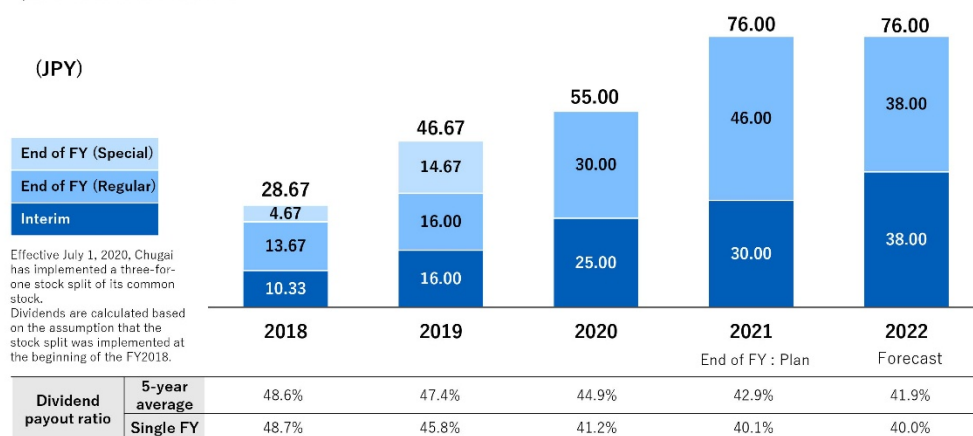
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Contribution to shareholders

■ Basic profit distribution principles

- ✓ Taking into account strategic funding needs and earnings prospects, Chugai sets a target for a consolidated dividend payout ratio of 45% on average in comparison with Core EPS, with an aim to continuously provide a stable allocation of profit to all shareholders.



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Here, we would like to inform you of the dividend.

Considering the good financial performance in 2021 and the steady progress in various priority issues, we plan to pay a year-end dividend of JPY46 per share. As a result, combined with the interim dividend of JPY30 per share, the annual dividend will be JPY76 per share.

On the next slide, I will show you the forecast of our business performance for 2022. The annual dividend for the current fiscal year is expected to be JPY76 per share, with JPY38 for both interim and year-end.

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2022 Forecast

- Revenues and profits are expected to increase due to the growth in mainstay/new products and an increase in COVID-19-related revenues
- Aiming to achieve record high financial results for six consecutive years, with over 1 trillion JPY revenues for the first time since founded

Core (billions of JPY)	2021 Jan - Dec actual	2022 Jan - Dec forecast	Growth (year on year)	
Revenues	999.8	1150.0	+150.2	+15.0%
Domestic sales	518.9	646.3	+127.4	+24.6%
Overseas sales	283.9	385.2	+101.3	+35.7%
ROOI	196.9	118.5	-78.4	-39.8%
Operating profit	434.1	440.0	+5.9	+1.4%
Operating margin	43.4%	38.3%	-5.1pts	-
Net income	311.5	312.5	+1.0	+0.3%
EPS (yen)*	189.35	190.00	+0.65	+0.3%

- In domestic sales, in addition to the significant increase in Ronapreve, new products such as Hemlibra, Polivy, Enspryng, and Evrysdi will steadily penetrate the market.
- Overseas sales are expected to increase significantly due to Actemra and Hemlibra
- Regarding ROOI, royalty income related to the initial shipment of Hemlibra will decrease, but this will be covered by the increase in export sales and royalty income related to intellectual property rights
- Revenues, operating profit, and net income will reach record-highs

* Effective July 1, 2020, Chugai has implemented a three-for-one stock split of its common stock. EPS is calculated based on the assumption that the stock split was implemented at the beginning of fiscal year 2020.

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Here is the forecast for 2022.

With further growth in mainstay products and new products, as well as an increase in COVID-19 related revenue, we expect to post record results for the sixth consecutive fiscal year, with revenues of JPY1,150 billion, operating profit of JPY440 billion, and net income of JPY312.5 billion. If we can achieve this goal, it will be the first time since our founding that our revenues exceed JPY1 trillion.

For domestic sales, we expect new products such as Hemlibra, Polivy, and Enspryng to penetrate the market steadily, and also assume a significant increase in Ronapreve sales.

Overseas sales will increase significantly, mainly in Actemra and Hemlibra.

Regarding ROOI, royalty income from initial shipments of Hemlibra will decrease, but we expect this be largely offset by higher royalty income from regular shipments and export sales.

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Strategic Policies for 2022

Continuous creation of R&D output	<ul style="list-style-type: none"> • Expansion and steady progress in mid-size molecule projects (progress of LUNA18 and subsequent projects, construction of manufacturing system) • Continuous creation of in-house new projects (accelerating drug discovery with new antibody technology and exploring new modalities) • Proof of the value of in-house Pre-PoC projects (PoC acquisition and P1 study progress) • Maximize project value of growth drivers for in-house projects (acceleration of development including expansion of indication for crovalimab, Enspryng, and Alecensa) • Steady achievement of approval/application plan: Application for Tecentriq (4 cancer types), tiragolumab (SCLC), HER/PER fixed-dose combination drug (BC), etc.
Maximize the value of growth drivers	<ul style="list-style-type: none"> • Successful introduction of new products to the market (faricimab (DME/nAMD), Tecentriq (NSCLC adjuvant), Polivy (1L DLBCL), etc.) • Accelerating market penetration of growth drivers in Japan and overseas (Hemlibra, Tecentriq, Polivy, Enspryng, Evrysdi, etc.) • Establishment of the new distribution system (further penetration of product value)
Strengthen business foundation	<ul style="list-style-type: none"> • Streamlining and strengthening the entire value chain (production, development, global regulatory, etc.) • Further strengthening of the ESG foundation (environmental investment, governance) • Development of foundations for creating innovation (human resources strategy, digital utilization)

Promote and deploy with 3 Key drivers

DX
RED* SHIFT
Open Innovation

* Research and Early Development

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The three strategic policies for 2022 are as shown.

In terms of continuous creation of R&D output, in addition to LUNA18, which is currently in Phase I, we will steadily advance a number of mid-size molecule projects that are in the non-clinical stage. In addition, we will aim to create a series of in-house projects using new antibody technologies, etc., acquire PoC, accelerate clinical development to make in-house developed products growth drivers, and steadily achieve our filing and approval plans.

In the area of maximizing the value of growth drivers, we will successfully introduce faricimab, Chugai's first product in the ophthalmology field, and Tecentriq (NSCLC adjuvant) and Polivy (first-line DLBCL) to the market. We will also work to further expand the market for growth drivers in Japan and overseas.

Thirdly, as part of our efforts to strengthen our business foundation, we will work to streamline and enhance all value chains, and promote the further strengthening of our human resources.

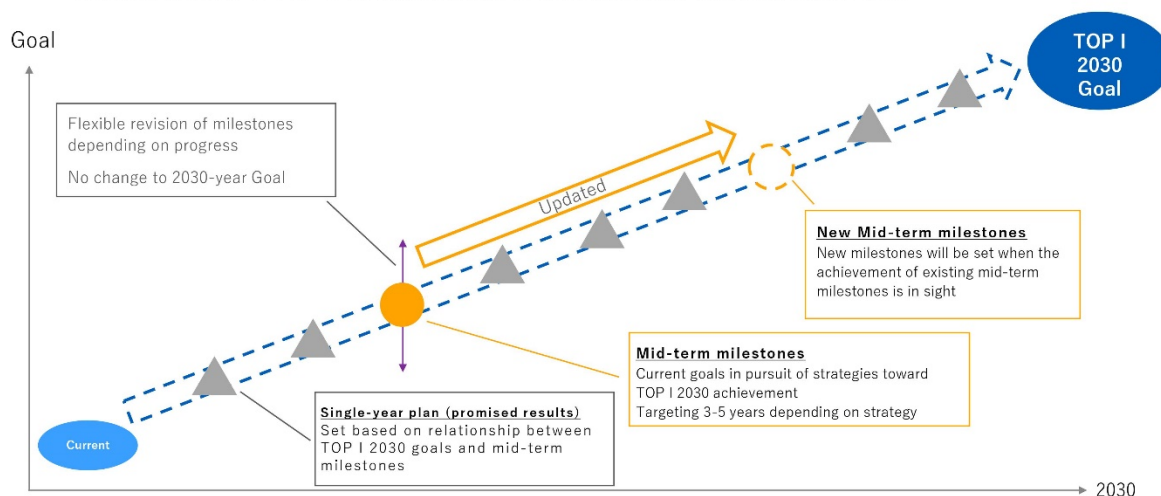
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Positioning of Mid-term milestones

- We will stop developing company-wide 3-year mid-term business plans to review and update strategies/plans in an agile manner
- Confirm validity of TOP I 2030 goals, Mid-term milestones, and Single-year plan



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From here on, I will explain the medium-term milestones.

The medium-term milestones are targets for three to five years that will be flexibly revised based on changes in the external environment and progress in a single year toward achieving TOP I 2030. We have decided to disclose as much as possible about these mid-term milestones and their progress in order to show you the path of our growth toward 2030.

The following slides show the key points in each of the five reform areas for TOP I 2030.

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Mid-term Milestones (1/5)

Milestones <Target year>		Progress
Drug Discovery	Acquisition of ePoC for LUNA18 <2024>	● On Schedule
	Continuous Creation of Drug Discovery Projects Utilizing Mid-size Molecule Technology <2023-2025> (Quantitative target for PC transition exists)	PC transition: zero* (2021)
	Establishment of New Technologies that Enhance Competitive Advantage (Acquisition of new MOA) <2023-2025>	● On Schedule
	Developing Next-Generation Antibody Technologies to Solve Drug-Wants • PC transition of new antibody engineering technologies that work selectively with tissue and cells following Switch-Ig <2023>	● On Schedule
	Establishment of a Technology Platform and New Modality Research Platform Comprising of Multiple Modalities with Competitive Advantages • PoC of new technologies through combination of protein engineering technology and new modalities <2023> • Project creation and PC transition by combining antibody engineering technologies and new modalities <2025>	● On Schedule ● On Schedule
	Strengthening the Drug Discovery Process by Utilizing Digital Technology • Antibodies: Efficiency of the discovery process through machine learning technology <2023> • Implementation of lab automation at Yokohama site <2024> • Improve drug discovery productivity by establishing a digital infrastructure (Quantitative target exists for FTE reduction) <2024>	● On Schedule ● On Schedule ● On Schedule
	Creation and Promotion of Innovative Drug Discovery Projects by Strengthening Biology • Development of a system for utilizing human clinical samples to improve the accuracy of non-clinical research <2024> • Creation of a platform for drug discovery approaches that target continuous innovation from a biological perspective <2024>	● On Schedule ● On Schedule
Capturing External Innovation • Incorporation of new modalities, technologies, numerators (Quantitative target exists for the number of projects implemented) <2024>		In-licensed: 2 projects (2021)

* PC transition in antibody / small molecule projects: total 3

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First, the field of Drug Discovery.

For each theme, we set achievement targets, milestones and their timing. For quantifiable themes, we set KPIs for them as quantitative targets. For example, the mid-sizes molecule project LUNA18 aims to obtain an ePoC in 2024. In addition, for the mid-sizes molecule, we have set a quantitative goal of entering the phase of starting GLP-TOX, which we call preclinical transition or PC transition, as a goal to continue creating subsequent projects.

In addition, we have established major milestones for drug discovery, which are listed here.

In the first year of the TOP I 2030, as indicated by the green circles, we made progress in all themes as planned.

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Mid-term Milestones (2/5)

Milestones <Target year>		Progress
Development	Strengthen the Clinical Predictability Platform and Implement Model & Simulation (M&S) Projects <ul style="list-style-type: none"> Improving clinical predictability through M&S and implementing clinical trials based on M&S <2025> <ul style="list-style-type: none"> Utilize M&S for molecular design, product candidate selection, safety range forecast, FIH dosing, etc. from the early stages of trials (Quantitative target exists for the percentage of applicable themes) Implementation of patient segmentation based on pathological biomarkers <2025> 	<p>● On Schedule</p> <p>● On Schedule</p>
	Accelerate value expansion of in-house developed products through simultaneous development of multiple diseases <ul style="list-style-type: none"> Multiple projects for simultaneous development of multiple diseases based on science and commerciality <2023> 	● On Schedule
	Proof of value of in-house projects <ul style="list-style-type: none"> Establishing general-purpose indicators that lead to true endpoint assessment of patients <2025> 	● On Schedule
	Evolution of Late-Stage Development Operations (Quantitative target exists) <ul style="list-style-type: none"> Increase workforce productivity <2023> Implementation of clinical/regulatory applications utilizing RWDs, control group data, disease registry data, etc. <2023> 	<p>● On Schedule</p> <p>● On Schedule</p>

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Next theme is the Development.

We have also set qualitative and quantitative goals for the improvement of clinical trial predictability through the implementation of Model & Simulation, the simultaneous development of multiple diseases, the establishment of indices for true endpoint evaluation of patients, and the evolution of late-stage development operations, including the improvement of productivity and the implementation of clinical development and regulatory filings utilizing various data such as real-world data.

Mid-term Milestones (3/5)

Milestones <Target year>		Progress
PT	Establishment of Manufacturing System and Process for Mid-size Molecules <ul style="list-style-type: none"> Establishment of mid-size molecule CMC technologies and production bases for API and formulations <2024> <ul style="list-style-type: none"> Start operation of FJ2 and manufacturing of investigational drugs Operation of high-difficulty formulation building and start of manufacturing for investigational drugs Establishment of initial commercial manufacturing system (FJ3) Shortening the time to PoC in collaboration with non-clinical functions <2024> 	<p>● On Schedule</p> <p>● On Schedule</p>
	Establishment of Biopharmaceutical API Manufacturing System in Response to Doubling of R&D output <ul style="list-style-type: none"> Establish a manufacturing system through facilities dedicated to APIs (FIHs) (UK4) <2024> Establish cost reduction technologies for in-house production <2024> Develop antibody pharmaceutical technologies to become the world's forerunner <2027> Shortening the time to IND in collaboration with non-clinical functions <2024> 	<p>● On Schedule</p> <p>● On Schedule</p> <p>● On Schedule</p> <p>● On Schedule</p>
	Establishment of an Efficient Manufacturing System for CPMC <ul style="list-style-type: none"> Strengthen core manufacturing technologies, establish a cost-competitive CPMC system, and firmly establish operations <2023> Establish a CMO management system for future product portfolio <2023> Launch a new operational model at other sites through the development of digital and IT infrastructure <2023> Reflecting the use of robotics in the design of new facilities <2025> 	<p>● On Schedule</p> <p>● On Schedule</p> <p>● On Schedule</p> <p>● On Schedule</p>

PT: Pharmaceutical Technology

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Next is the Pharmaceutical Technology.

Regarding the pharmaceutical technology, we have set milestones for the establishment of a manufacturing system and process for mid-size molecules, and the establishment of a biopharmaceutical API development and manufacturing system for UK4 and other biopharmaceuticals, and the enhancement of production technology to improve productivity, the development of IT infrastructure, and the use of robotics to meet our 2030 goals of doubling R&D output.

FY2021 Overview and FY2022 Forecast

Mid-term Milestones (4/5)



Milestones < Target year >		Progress
VD	Building an Engagement Model to Meet Diversifying Customer Needs <ul style="list-style-type: none"> Implement a precise individual strategy that combines in-person, remote, and digital channels <2023> <ul style="list-style-type: none"> ✓ Customer satisfaction (cancer): No. 1 in obtaining information other than MRs ✓ Customer satisfaction (MA Priority Activity Disease Area Assessment): Top 3 in all areas ✓ Customer satisfaction (providing safety information): No. 1 	No.2/No.1 * Top 2 ** (In all disease areas where products are sold) No.1***
	Creation of Unique Evidence Contributing to Personalized Medicine <ul style="list-style-type: none"> Realization of integrated use of internal and external data for predicting effectiveness and safety <2024> <ul style="list-style-type: none"> ✓ Provide to healthcare professional research papers about biomarker evidence leading to Personalized Medical & Safety Care ✓ Start research to provide solutions utilizing personalized evidence 	● On Schedule
	Functional Reforms Through Resource Shifts and Digital Use, etc. <ul style="list-style-type: none"> Systematically withdraw from mature areas and invest resources in new areas (Quantitative targets exist) <2023> Establishment of a business execution system that does not interfere with remote work, and the realization of assignments of employees with specialized knowledge from all over the country, regardless of their location <2025> 	● On Schedule ● On Schedule
	Contribute to Further Advancement of PHC by Expanding New Portfolio (monitoring the efficacy of therapies) <2024>	● On Schedule

VD: Value Delivery

* Source: MCI survey results <Owned media ranking (2nd), Medical portal site ranking (1st)>
 ** Source: INTAGE Healthcare Inc., survey results
 *** Source: The total results of all respondents of "INTAGE Healthcare Inc., 2021 questionnaire about safety information needs"

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Next, in Value Delivery, milestones are set in qualitative and quantitative terms in the four themes shown here.

For example, we use various types of customer satisfaction as KPIs in our individual approach, which combines in-person, remote, and digital channels to meet diversifying customer needs. In addition, we aim to create original evidence that contributes to personalized medicine, and to utilize internal and external data in an integrated manner.

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Mid-term Milestones (5/5)

Milestones <Target year>		Progress
Founda tion (People & Organiza tion)	Increase in active employees based on awareness survey results <ul style="list-style-type: none"> Percentage of active employees: Achieved the same level as companies with strong global performance <2024> 	(No survey conducted in 2021)
	Acceleration and penetration of D&I <ul style="list-style-type: none"> Positive response rate for employee awareness survey innovation questions (Quantitative target exists) <2024> Ratio of female managers/Ratio of female managers with subordinates: 17%/17% achieved <2023> 	(No survey conducted in 2021) 15.9%/15.0%
Founda tion (Digital)	Improve Efficiency of All Value Chains <ul style="list-style-type: none"> Improve productivity of targeted operations based on the impact of digital investment projects (Quantitative target exists) <2025> 	● On Schedule
Founda tion (Environm ent)	Strengthen the Foundation for Sustainability at the Global Level <ul style="list-style-type: none"> Continued selection for Dow Jones Sustainable Index World <2025> Scope 1 + 2 CO₂ emissions: Achieved 40% reduction (compared to 2019) <2025> Use of CFCs: Achieve 25% reduction (compared to 2020) <2025> 	DJSI World Selected ● On Schedule ● On Schedule
Founda tion (Quality)	Next-Generation Quality Management that Balances Quality and Efficiency with an Eye Toward New Modalities and New Business Processes <ul style="list-style-type: none"> Productivity improvement: Personnel and costs per product and development projects (Quantitative target exists) <2024> Establishment of a Chugai Quality System for Total Assurance of Products in New Domains <2024> 	● On Schedule ● On Schedule
Founda tion (Overseas)	Strengthen Overseas Business Foundation to Drive Growth and Maximize Chugai products Global Value <ul style="list-style-type: none"> Launch 6 in-house products globally (ACT, ALC, HEM, ENS, SKY59, CIM331) <2025> Establishment of early development and regulatory systems at U.S. and European subsidiaries in response to an increase in early-stage projects <2025> 	4 products ● On Schedule
Founda tion (Insight Business)	Search for commercialization of insight business <ul style="list-style-type: none"> Establishment of an Insight Business promotion system (infrastructure development, capabilities, and information aggregation as a hub) <2024> Start using data assets aggregated through in-house projects or Use Case related to the FMU business <2025> 	● On Schedule ● On Schedule

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Lastly, the growth foundation.

We are working on a variety of issues, such as investing in human resources, which are the source of innovation, and in DX, which is the pillar of productivity improvement, as well as achieving environmental goals, and we have set milestones for each of them as shown here. We will make steady progress here as well.

These are the mid-term milestones for TOP I 2030 and the progress made in FY2021, the first year. We will continue to disclose our progress on a regular basis and explain our path to TOP I 2030.

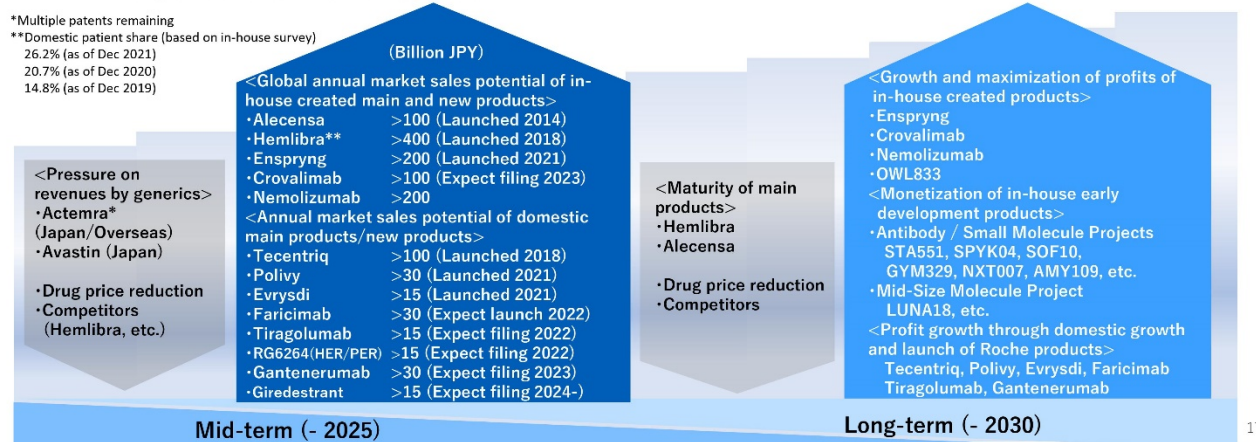
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Mid- to Long-term Revenue Outlook (Excluding Ronapreve)

- **Short-Mid-term:** Expect a growth trend in the short-mid term by making up for the decline in sales of Actemra and Avastin, both major products, through further market penetration of several major products developed in-house and the launch of new Roche products
- **Long-term:** Increased revenues and sustainable growth are expected both in Japan and overseas due to sales growth of in-house created products, launch of in-house early development products using new antibody technologies and mid-size molecules, and domestic growth and launch of Roche products



17

Next, I would like to present our medium- to long-term growth forecast for revenues.

This is an image of our company's growth excluding the revenue of Ronapreve, which is difficult to predict.

In the medium term, we expect Hemlibra to achieve annual peak revenues of more than JPY400 billion, and we see tremendous earnings potential in overseas markets for mainstay products and new products created in-house. In addition to these, there is a high potential for revenue growth of mainstay products and new products in Japan. These factors will offset the decline in revenue, and we expect to achieve sustained growth.

In the long term, in addition to maximizing revenues from products such as Enspryng and Crovalimab, which are growing into new mainstay products, and stable revenues from Roche products in Japan, we expect to achieve further growth through the fruition and market penetration of a number of in-house development projects that are currently in the GLP-Tox or Phase I stages.

By steadily realizing these growth factors, we will achieve sustainable growth over the medium- to long-term and ensure the realization of the TOP I 2030 target.

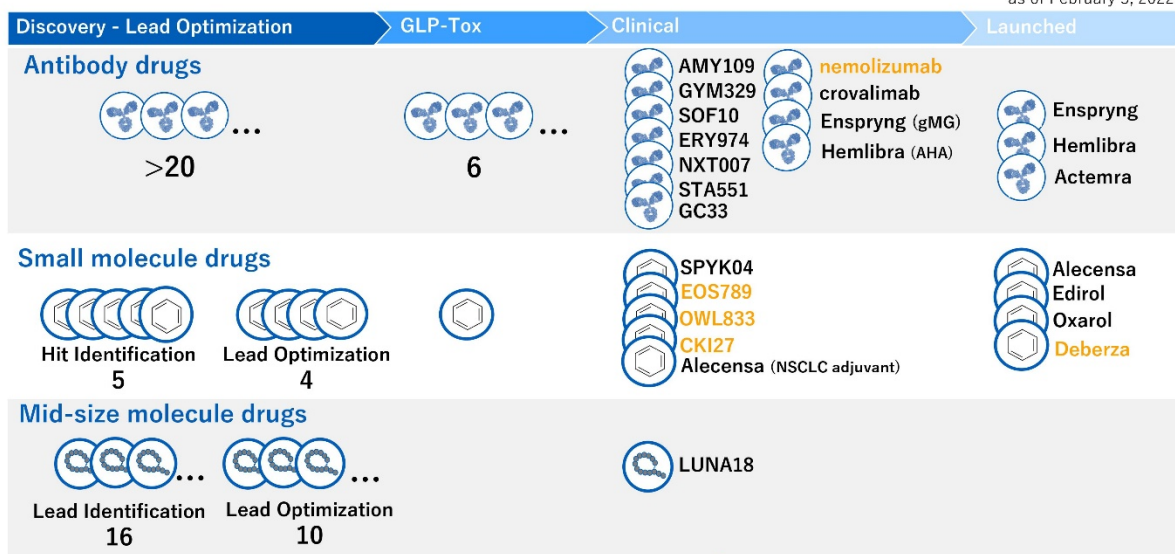
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Research Portfolio of Each Modality

as of February 3, 2022



Orange: Outsourced to a third party other than Roche

18

Next, I would like to show you Chugai's research portfolio in each modality of in-house discovery.

We have a number of innovative pharmaceutical research projects underway, as shown here.

New Management Structure

Underline: new position/role

Name	Rank	Supervisory responsibility
Osamu Okuda	Representative Director, President CEO	<u>Chairman of the Board of Directors (role)</u> <u>Corporate Planning, Partnering, External Affairs and Audit</u>
Hisafumi Yamada	<u>Director</u> , Executive Vice President	Project & Lifecycle Management (R&D), Research, Translational Research, <u>Clinical Development and Pharmaceutical Technology</u>
Toshiaki Itagaki	<u>Director</u> , Executive Vice President CFO	Finance & Accounting, Corporate Communication and Purchasing

- Hisafumi Yamada and Toshiaki Itagaki are scheduled to be appointed as directors upon approval at the 111th Ordinary General Meeting of Shareholders to be held on March 29, 2022
- Tatsuro Kosaka, Chairman and Representative Director, and Motoo Ueno, Representative Director, Deputy Chairman, will retire on March 29, 2022, and will be appointed as Senior Advisors at the Board of Directors meeting held on the same day.

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Lastly, I would like to explain the new management structure.

At a meeting of its Board of Directors held today, the Company informally decided on the following changes in directors. Tatsuro Kosaka, Chairman and Representative Director, and Motoo Ueno, Representative

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Director, Deputy Chairman, will retire on March 29, 2022, and Hisafumi Yamada and Toshiaki Itagaki will be newly appointed as Directors.

The appointment of the new directors will be formally decided at the Ordinary General Meeting of Shareholders to be held on March 29. As a result of this change, I, Okuda, will serve as the Chairman of the Board of Directors.

FY2021 Overview and FY2022 Forecast



Summary

- In 2021, revenues and profits increased for the fifth consecutive year, achieving record-high. In 2022, we expect revenue and profit increase for the sixth consecutive year, exceeding 1 trillion yen for the first time since the company's foundation
- As the first year of TOP I 2030, strategic policies were achieved almost as planned
- With abundant pipelines and steady progress in R&D, including mid-size molecules, we expect sustainable growth over the mid to long term towards the realization of TOP I 2030
- By disclosing the progress of development pipelines consisting of various modalities and the mid-term milestones, we will continue to clarify the path of growth
- Under the new management structure, we aim to become a "top innovator in the global healthcare industry"

20

To summarize the above, 2021 was a record year for the Company, with revenues and profit increasing for the fifth consecutive year. In 2022, we expect to exceed JPY1 trillion in revenues for the first time since our founding, and to increase revenues and profits for six consecutive years.

In 2021, the first year of TOP I 2030, we achieved our strategic policies almost as planned.

The Company expects to achieve sustainable growth over the medium- to long-term toward the realization of TOP I 2030 through its abundant pipeline and steady progress in R&D, including the development of mid-sized molecules.

We will continue to clearly show the path to growth by advancing our development pipeline consisting of various modalities and disclosing mid-term milestones and other information.

Under the new management structure, we will aim to become a top innovator in the global healthcare industry.

The above is a summary of the year 2021 and the outlook for 2022.

Sasai: Mr. Itagaki will now provide an overview of the consolidated financial results for the fiscal year ended December 31, 2021.

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P/L Jan - Dec (Year on Year)

(Billions of JPY)	2020	2021	Growth	
Revenues	786.9	999.8	+ 212.9	+ 27.1%
Sales	633.3	802.8	+ 169.5	+ 26.8%
Domestic	409.1	518.9	+ 109.8	+ 26.8%
Overseas	224.2	283.9	+ 59.7	+ 26.6%
Royalties and other operating income	153.6	196.9	+ 43.3	+ 28.2%
Royalty and profit-sharing income	129.6	187.2	+ 57.6	+ 44.4%
Other operating income	24.1	9.8	- 14.3	- 59.3%
Cost of sales	-272.3	-335.5	- 63.2	+ 23.2%
(cost to sales ratio)	43.0%	41.8%	-1.2%pts	-
Operating expenses	-206.7	-230.2	- 23.5	+ 11.4%
M&D and G&A ^{*1}	-93.2	-100.4	- 7.2	+ 7.7%
Research and development	-113.5	-129.8	- 16.3	+ 14.4%
Operating profit	307.9	434.1	+ 126.2	+ 41.0%
(operating margin)	39.1%	43.4%	+4.3%pts	-
Financial account balance	-3.0	-2.5	+ 0.5	- 16.7%
Income taxes	-85.5	-120.1	- 34.6	+ 40.5%
Net income	219.4	311.5	+ 92.1	+ 42.0%
EPS (JPY) ^{*2}	133.39	189.35	+55.96	+ 42.0%

Domestic sales

Significant increase due to sales growth of new products as well as mainstay products

Overseas sales

Decrease in sales of Actemra, but significant increase in export of Hemlibra

Royalty and profit-sharing income

Significant increase in income for Hemlibra

Other operating income

Decrease in one-time income

Cost of sales

Cost to sales ratio improved due to a change in product mix, etc.

Operating expenses

Increase of M&D and G&A expenses due to business tax and promotion of digital marketing
Increase of research and development expenses due to progress of projects, etc.

Operating profit

Increased due to higher royalty and profit-sharing income as well as increase in sales

^{*1} M&D: Marketing and distribution, G&A: General and administration

^{*2} Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. EPS are calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

22

Itagaki: I would like to explain the details of the financial figures.

Please refer to page 22. We will take a look at the results for this fiscal year, comparing them to the previous fiscal year.

Revenues increased by 27.1% to JPY999.8 billion.

Domestic sales increased by 26.8%, as the negative impact of price revision and generics was absorbed by volume growth of Ronapreve and mainstay products.

Overseas sales grew by 26.6%, with an increase in Hemlibra sales offsetting a decrease in Actemra sales. Royalty and profit-sharing income increased by 44.4% to JPY187.2 billion due to the increase in income related to Hemlibra. On the other hand, other operating income was only JPY9.8 billion due to a decrease in one-time income.

The cost to sales ratio improved by 1.2 percentage points to 41.8% due to changes in the product mix, despite upward pressure from the price revision.

As for expenses, SG&A expenses increased by 7.7% due to the promotion of digital marketing and an increase in business taxes. R&D expenses also increased by 14.4% due to the progress of development projects.

As a result, operating profit was JPY434.1 billion, an increase of 41.0%, and the operating margin was 43.4%, the first time it has been in the 40% range for a full year.

After deducting the financial account balance and income taxes, net income for the year was JPY311.5 billion, an increase of 42.0%.

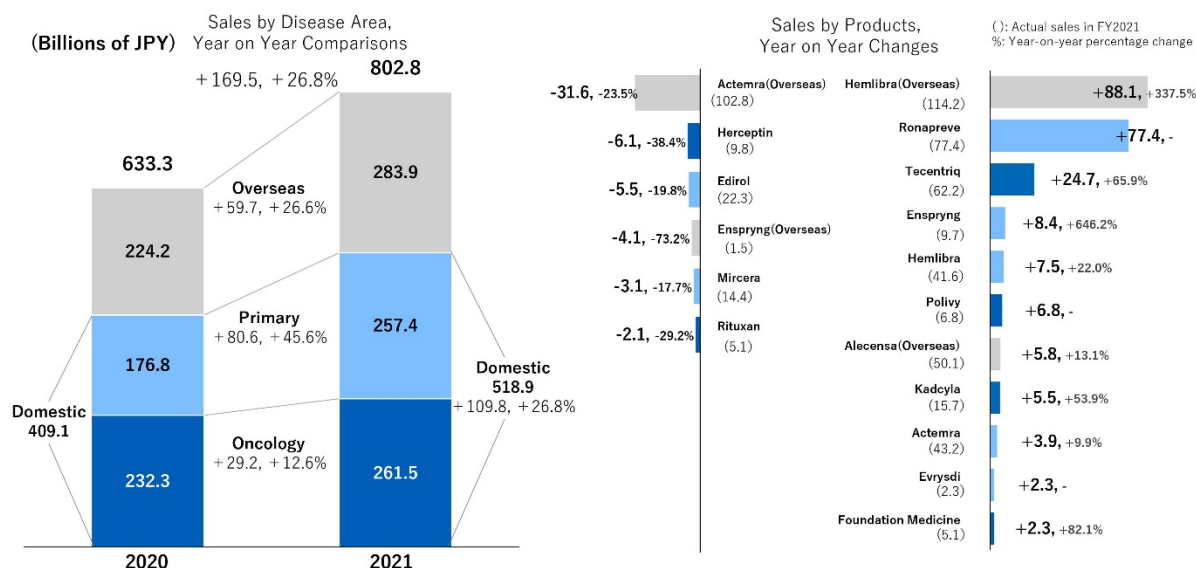
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Sales Jan - Dec (Year on Year)



23

The slide on page 23 shows the breakdown of changes in sales of products.

First, by disease area, the oncology area in Japan grew by 12.6%. Looking at the individual products on the right side, we have seen growth in Tecentriq and Kadcyla due to the expansion of indications. In addition, sales of Polivy, which was launched in May last year, totaled JPY6.8 billion. Foundation Medicine also saw an increase in sales of JPY2.3 billion with the addition of FoundationOne Liquid.

On the other hand, revenues of Herceptin and Rituxan decreased due to the impact of generics and the price revision.

The primary area grew by 45.6%. Looking at individual products, revenue of Ronapreve, which received special approval in July, totaled JPY77.4 billion. Revenues of in-house products, Enspryng, Hemlibra and Actemra, also grew steadily.

Enspryng is steadily penetrating the market and has achieved JPY9.7 billion in revenues. In April 2020, the NHI price of Hemlibra was reduced by 15% in the market expansion recalculation, and sales increased by 22%, which on a volume basis means growth in the second half of the 20% range. Evrysdi, which was launched in August, achieved JPY2.3 billion in sales.

On the other hand, sales of Edirol, for which generic versions are available, decreased by JPY5.5 billion. Mircera also saw a decrease in sales of JPY3.1 billion.

Revenues in the overseas domain increased by 26.6%. Hemlibra overseas grew 337.5%, which means that exports increased by 4.4 times. The overseas growth rate for Alecensa was 13.1%, and this was due to the impact of lower unit prices for exports. In terms of volume, this is an increase of more than 50%. This means that the number of prescriptions overseas has grown significantly.

Overseas sales of Actemra decreased by 23.5%, but this was due to the timing of shipments and the supply-demand balance, which will be explained in detail later.

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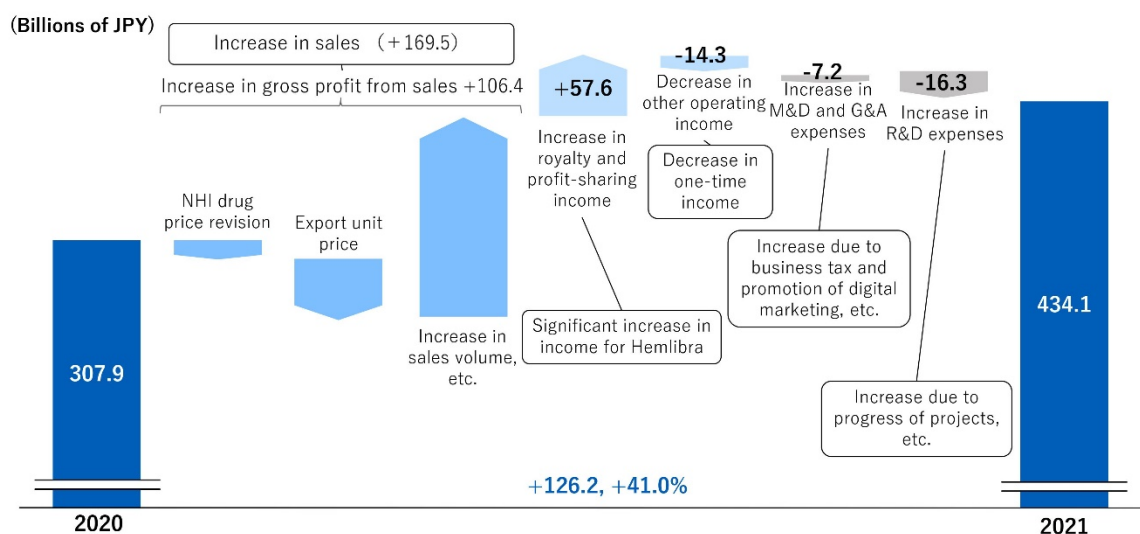
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Enspryng's overseas sales also decreased by JPY4.1 billion due to a reaction to the large number of initial shipments in 2020.

FY2021 Consolidated Financial Overview (Core)



Operating Profit Jan - Dec (Year on Year)



24

Page 24 is a breakdown of the increase in operating profit. The second to fourth bar graphs from the left show the elements of the increase in gross profit.

Net income increased by JPY106.4 billion by absorbing the negative impact of NHI price revision and export unit prices through volume growth.

Secondly, royalty and profit-sharing income increased by JPY57.6 billion, all of which contributed to the increase in profit.

On the other hand, other operating income decreased by JPY14.3 billion due to the rebound from the large one-time income in 2020, the entire amount of which was a downward factor on profit.

As for expenses, as already explained, SG&A expenses increased by JPY7.2 billion and R&D expenses increased by JPY16.3 billion.

To put it simply, gross profit from volume growth and royalty income resulted in an increase of JPY126.2 billion.

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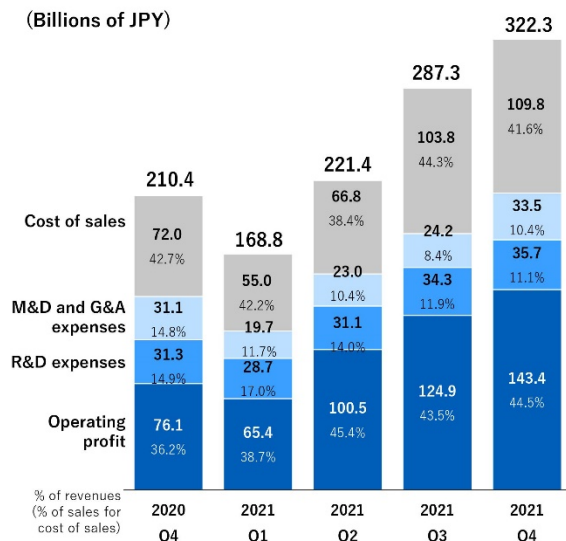
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Structure of Costs and Profit by Quarter

(Billions of JPY)



vs. Year on Year (2020 Q4)

Cost of sales ratio: improved due to a change in product mix, etc.

R&D expenses: increase due to progress of projects, etc.

Operating profit: increase of +67.3 (+88.4%)

vs. Previous Quarter (2021 Q3)

Cost of sales ratio: improved due to a change in product mix, etc.

M&D and G&A expenses: increase due to the trend of costs incurred in previous years

Operating profit: increase of +18.5 (+14.8%)

25

Starting on page 25, there are three more slides that describe quarterly trends.

The first slide shows the cost structure. Comments comparing the performance of the fourth quarter under review to the previous year's fourth quarter are shown in the upper right-hand column, and comments comparing the performance of the fourth quarter to the prior third quarter are shown in the lower right-hand column.

In common with both, the cost to sales ratio has improved due to a change in product mix. In addition, both SG&A and R&D expenses increased, but the ratio of expenses to sales decreased due to the increase in revenues themselves.

Operating profit grew significantly, reaching a profit margin of 44.5% in the most recent quarter, a very high level.

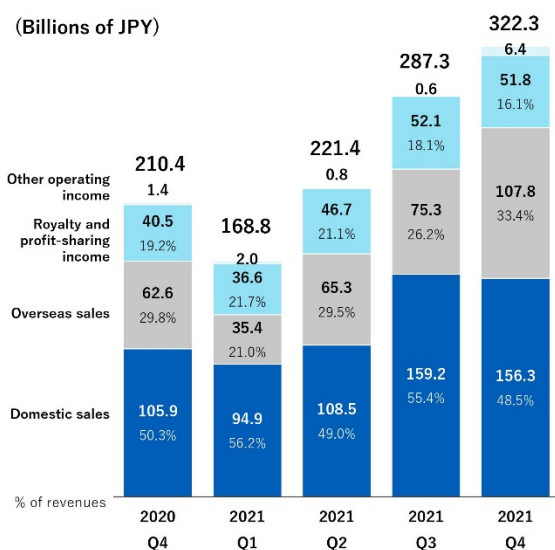
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Structure of Revenues by Quarter



vs. Year on Year (2020 Q4)

Domestic sales: steady increase due to sales of new products and mainstay products grew despite impact of generic drugs

Overseas sales: significant increase in export of Hemlibra

Royalty and profit-sharing income: increase in income for Hemlibra and Actemra

vs. Previous Quarter (2021 Q3)

Domestic sales: slight decrease (See next slide)

Overseas sales: significant increase in export of Hemlibra and Actemra

26

Page 26 shows the revenue structure.

Compared to the same period of the previous year, domestic sales, overseas sales, and royalty income all grew significantly.

In Japan, growth in sales of new mainstay products, especially Ronapreve, contributed significantly to the increase in sales. Overseas, exports of Hemlibra have increased substantially. Royalty and profit-sharing income increased in relation to Hemlibra and Actemra.

Compared to the third quarter, domestic sales and royalties were almost the same, but overseas exports of Hemlibra and Actemra increased, and the composition ratio of overseas sales rose significantly to 33.4% in the fourth quarter.

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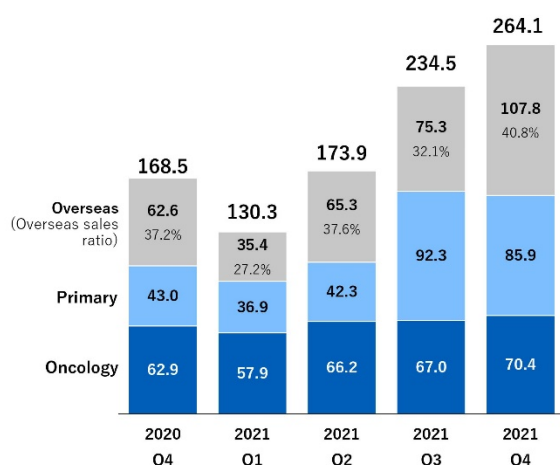
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Structure of Sales by Quarter

(Billions of JPY)



vs. Year on Year (2020 Q4)

Oncology	Tecentriq:	+4.1	Polivy:	+3.3
	Kadcyla:	+1.3	Herceptin:	-1.3
Primary	Ronapreve:	+34.6	Hemlibra:	+2.8
	Enspryng:	+2.5		
Overseas	Hemlibra:	+48.0	Actemra:	+2.5
	Enspryng:	-3.7		

vs. Previous Quarter (2021 Q3)

Oncology	Polivy:	+0.7	Tecentriq:	+0.6
	Ronapreve:	-8.2	Edirol:	-5.0
Primary	Tamiflu*:	+1.9	Hemlibra:	+1.7
	Evrysdi:	+1.5		
Overseas	Hemlibra:	+24.0	Actemra:	+13.7
	Alecensa:	-5.4		

* Govt. stockpiles, etc.

27

Page 27 is the last page of the quarterly trends and shows the sales by product area.

Whether oncology, primary, or overseas, sales performed very well in the fourth quarter. The details are as described on the right.

P/L Jan - Dec (vs. Forecast)

(Billions of JPY)	2021		+/-	Achiev.
	Forecast*	Actual		
Revenues	970.0	999.8	+ 29.8	103.1%
Sales	781.5	802.8	+ 21.3	102.7%
Domestic	513.0	518.9	+ 5.9	101.2%
Overseas	268.5	283.9	+ 15.4	105.7%
Royalties and other operating income	188.5	196.9	+ 8.4	104.5%
Royalty and profit-sharing income	179.5	187.2	+ 7.7	104.3%
Other operating income	9.0	9.8	+ 0.8	108.9%
Cost of sales	- 339.0	- 335.5	+ 3.5	99.0%
(cost to sales ratio)	43.4%	41.8%	-1.6pts	-
Operating expenses	- 231.0	- 230.2	+ 0.8	99.7%
M&D and G&A	- 99.5	- 100.4	- 0.9	100.9%
Research and development	- 131.5	- 129.8	+ 1.7	98.7%
Operating profit	400.0	434.1	+ 34.1	108.5%
(operating margin)	41.2%	43.4%	+2.2pts	-
Net income	293.0	311.5	+ 18.5	106.3%
EPS (JPY)	178.00	189.35	+ 11.35	106.4%

* Revised Forecast (Announced on October 22, 2021)

Domestic Sales

Various products outperformed the forecast (see next slide)

Overseas sales

Exports of Hemlibra exceeded the forecast

Royalty and profit-sharing income

Income for Actemra and Hemlibra exceeded the forecast

Cost of Sales

Cost to sales ratio improved due to a change in product mix from the forecast, etc.

Operating expenses

Progress almost as expected

Operating profit

Actual profit exceeded forecast by +34.1 (+8.5%) due to higher sales, royalty and profit-sharing income

28

Next is a comparison with forecast. Please refer to page 28.

When we announced the financial results of the third quarter, we revised our full-year forecast upward. This is a comparison with that forecast. In general, there has been no major difference. However, we have

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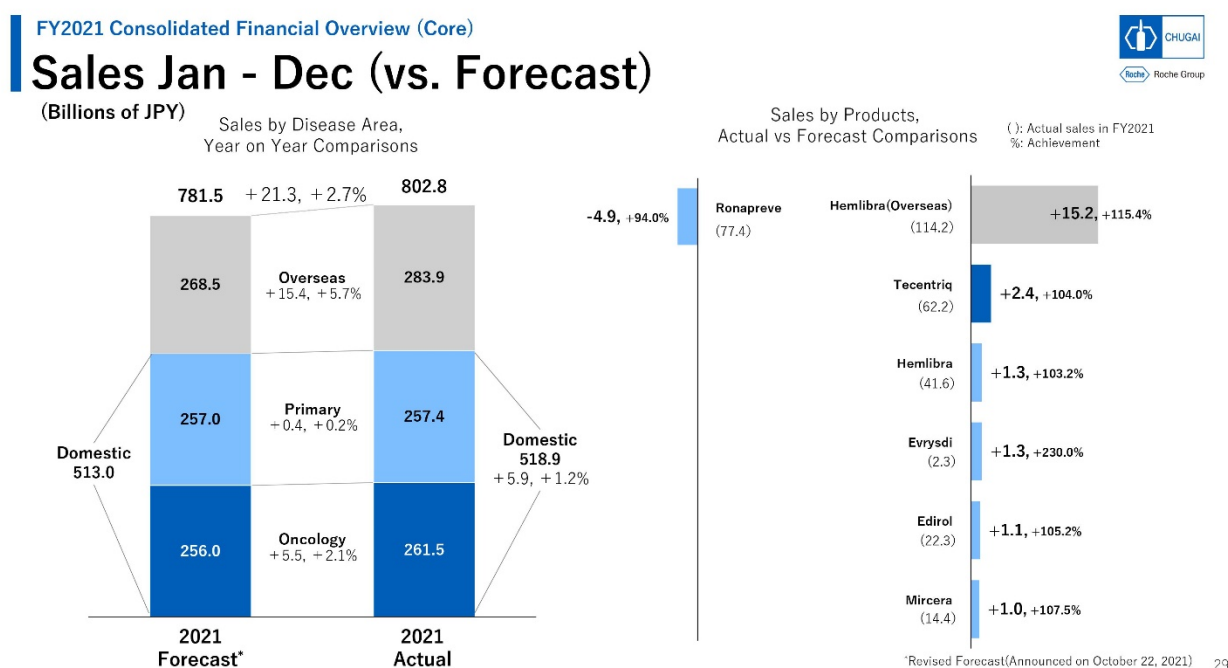
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overachieved the forecast of revenues and operating profit by around JPY30 billion, and I will explain the reasons in brief.

First, in overseas sales, several lots of Hemlibra were accepted by Roche earlier than expected, resulting in an overachievement of JPY15.4 billion. As a result, we have reduced our plans for the current year's export of Hemlibra, which means that last year and this year will offset each other.

The second point is royalty income. Overseas sales of Hemlibra and Actemra were very strong in the fourth quarter, exceeding our expectations, and as a result, the royalty income we received exceeded our forecast by JPY7.7 billion. This is a positive trend for the current year's revenues as well, as it doesn't depend on the time.

As a result, revenues were 103.1% of the revised forecast, and operating profit was 108.5%.



The slide on page 29 shows sales compared to the forecast by product.

The biggest difference was the overseas sales of Hemlibra, which the timing of the acceptance inspection was accelerated for. In addition, sales of domestic products have all been slightly higher than expected. As you can see on the left, both the oncology and primary areas have exceeded our expectations.

On the other hand, the product that did not reach the forecast was Ronapreve, due to the fact that the delivery of some lots to the government was postponed to the current fiscal year. The quantity to be delivered has been agreed upon with the government, so if we combine last year's and this year's deliveries, it will be as planned.

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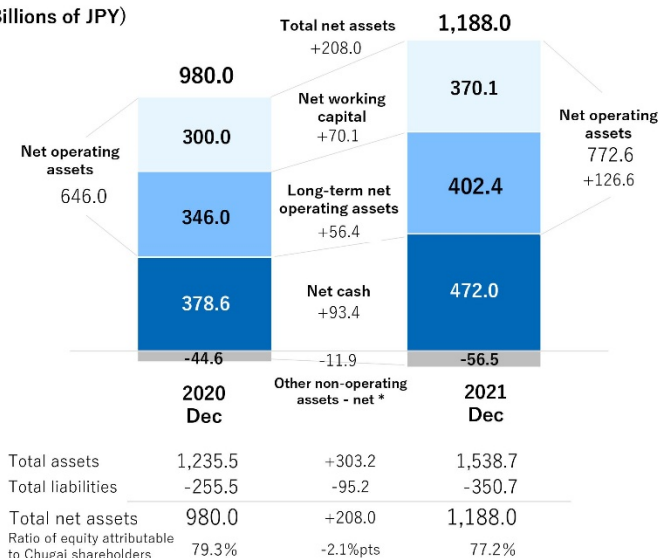
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Financial Position (vs. 2020 Year End)

(Billions of JPY)

**Increase in net working capital**

Increase mainly in trade accounts receivable

Increase in long-term net operating assets

Increase mainly in property, plant and equipment

Increase in net cash

(See next slide)

Decrease in other non-operating assets – net

Increase mainly in accrued corporate tax

* E.g., deferred income tax assets, accrued corporate tax, etc.

30

Page 30 shows the balance sheet.

Please see from the top of the figure on the left. Total net assets at the end of last year were JPY1,188 billion. As shown in the figure, net operating assets increased by JPY126.6 billion to JPY772.6 billion, and net cash increased by JPY93.4 billion to JPY472 billion, due to the increase in trade receivables and property, plant and equipment.

As you can see at the bottom left, ratio of equity attributable to Chugai shareholders remained at a very high level of 77.2%.

We will look at the breakdown of the increase in net cash on the next page.

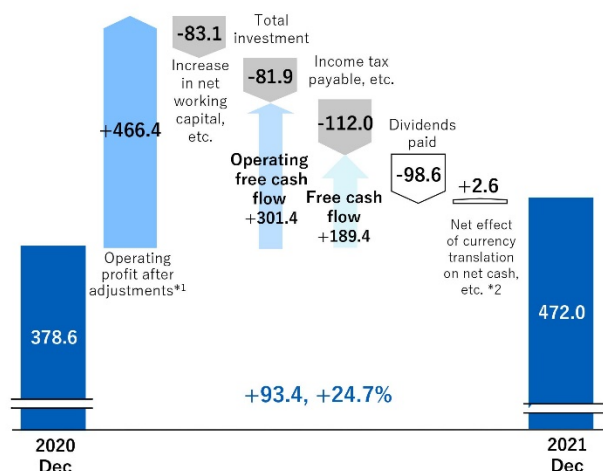
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Net Cash (vs. 2020 Year End)

(Billions of JPY)



Operating profit after adjustment *1	+466.4
Operating profit *1	+421.9
Depreciation, amortization and impairment *1	+37.2
Increase in net working capital, etc.	-83.1
Total investment	-81.9
Property, plant and equipment	-66.0
Payment for lease liabilities	-9.0
Intangible assets	-6.9
Operating free cash flow	+301.4
Income tax payable, etc.	-112.0
Income tax payable	-104.1
Free cash flow	+189.4
Dividends paid	-98.6
Net effect of currency transaction on net cash, etc. *2	+2.6

*1 Including Non-Core (IFRS results)

*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + Purchase of non-controlling interests + Net effect of currency translation on net cash(*3)

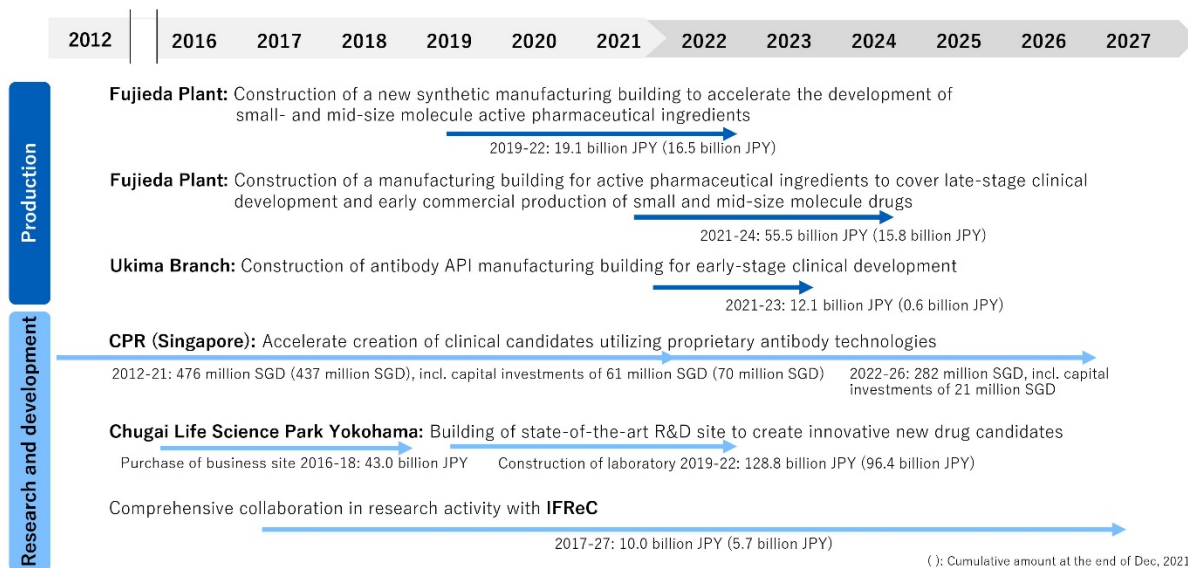
*3 Results from using different types of exchange rates when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flows using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

31

Cash flow in from operating activities was JPY466.4 billion from the end of 2020. After deducting the increase in net working capital and payments for the construction of new laboratories and manufacturing facilities, operating free cash flow was positive JPY301.4 billion.

After deducting the income tax payable of JPY112 billion and the dividends paid of JPY98.6 billion, net cash increased by JPY93.4 billion, resulting in a balance of JPY472 billion at the end of the fiscal year.

Current Status / Plan for Major Investments



(): Cumulative amount at the end of Dec, 2021 32

The funds on hand will be used for future investments. Page 32 shows the status of major investments.

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This is an update of our investment performance from what we disclosed at the time of our third quarter results. There are no new additional projects at this time.

At the top of the page is the Fujieda Plant's synthetic active pharmaceutical ingredient (API) manufacturing building, which we call FJ2. Also, as described in the second line from the bottom, Chugai Life Science Park Yokohama will finally be completed this year. The construction of Fujieda Plant's third building for the production of APIs called FJ3, which is described in the second line from the top, and of UK4, the fourth antibody API manufacturing building in Ukima, started last year and are progressing smoothly.

FY2021 Consolidated Financial Overview (Core)

P/L 2022 Forecast



(Billions of JPY)	2021 Actual	2022 Forecast	Growth	
Revenues	999.8	1150.0	+ 150.2 + 15.0%	
Sales	802.8	1031.5	+ 228.7 + 28.5%	
Domestic	518.9	646.3	+ 127.4 + 24.6%	
Overseas	283.9	385.2	+ 101.3 + 35.7%	
Royalties and other operating income	196.9	118.5	- 78.4 - 39.8%	
Royalty and profit-sharing income	187.2	114.0	- 73.2 - 39.1%	
Other operating income	9.8	4.5	- 5.3 - 54.1%	
Cost of sales	- 335.5	- 460.0	- 124.5 + 37.1%	
(cost to sales ratio)	41.8%	44.6%	+ 2.8%pts	
Operating expenses	- 230.2	- 250.0	- 19.8 + 8.6%	
M&D and G&A	- 100.4	- 100.5	- 0.1 + 0.1%	
Research and development	- 129.8	- 149.5	- 19.7 + 15.2%	
Operating profit	434.1	440.0	+ 5.9 + 1.4%	
(operating margin)	43.4%	38.3%	- 5.1%pts	
Net income	311.5	312.5	+ 1.0 + 0.3%	
EPS (JPY)	189.35	190.00	+ 0.65 + 0.3%	

Domestic sales

Despite impact from NHI drug price revision and launch of generic drugs, increase due to sales growth of new products as well as mainstay products, including Ronapreve

Overseas sales

Increase in income for Hemlibra and Actemra

Royalty and profit-sharing income

Decrease in royalty income for Hemlibra regarding initial shipping inventory

Other operating income

Decrease in one-time income

Cost of sales

Cost to sales ratio increase due to a change in product mix, etc.

Operating expenses

Increase of research and development expenses due to progress of projects, etc.

Operating profit

The increase in sales will offset the decline in royalties and other operating income and the rise in operating expenses.

33

From page 33, I will explain the forecast for the next fiscal year, 2022.

We are forecasting an increase in both revenues and profits this year as well, and we hope to achieve a record high for the sixth consecutive year.

Revenues will reach JPY1.15 trillion, over the trillion yen mark. The Company plans to absorb the decline in Hemlibra's Royalty 2 by increasing domestic and overseas sales.

The cost to sales ratio is expected to increase by 2.8 percentage points to 44.6% due to product mix.

Marketing, general, and administrative expenses will be kept flat, while we will increase investment in R&D. We have budgeted for a total increase in expenses of approximately JPY20 billion, to JPY250 billion.

Operating profit is expected to be JPY440 billion, with an operating profit margin of 38.3%.

Support

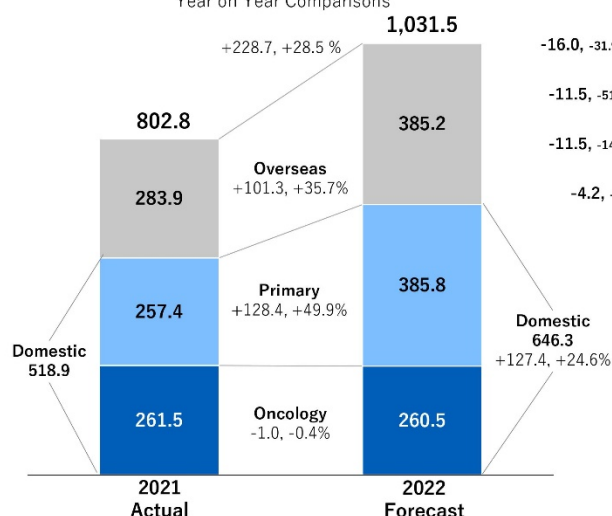
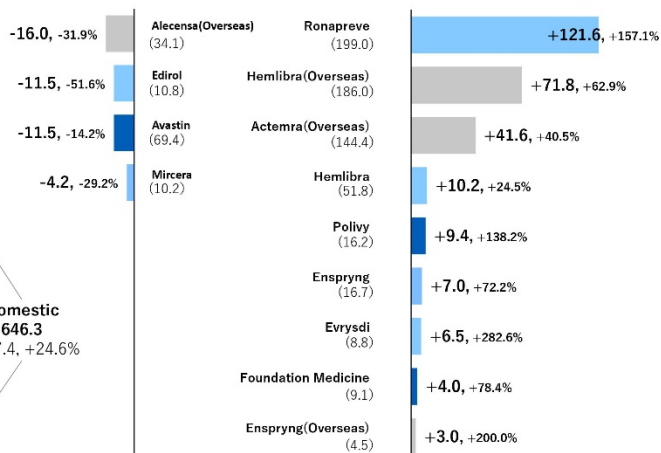
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Sales 2022 Forecast

(Billions of JPY)

Sales by Disease Area,
Year on Year ComparisonsSales by Products,
Year on Year Changes(); Forecast sales in FY2022
%; Year-on-year percentage change

34

Domestic and overseas sales are expected to increase 24.6% and 35.7%, respectively, continuing the trend of last year.

In oncology area in Japan, the impact of biosimilars will be offset by growth in new products and products with additional indications. In primary area in Japan, sales are also expected to increase by 49.9% due to the addition of Ronapreve sales, offsetting the impact of generics with growth in new products.

Overseas, we plan to see a large increase by JPY71.8 billion in Hemlibra exports. Exports of Actemra are also expected to increase by JPY41.6 billion to cover the tight inventory situation at Roche.

I would like to discuss the background behind this premise in the next page.

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Export of Actemra to Roche

(Billions of JPY)

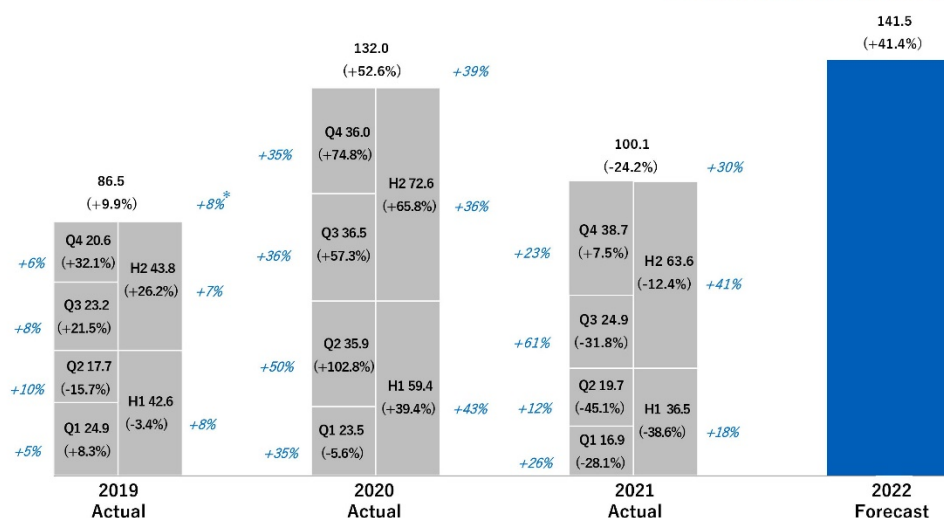


%, year on year growth

black: Chugai sales to Roche

blue*: Roche sales excluding Japan (for reference)

*Growth rates in blue are calculated with the effects of exchange rate fluctuations eliminated.



35

Please refer to page 35.

In this slide, exports of Actemra to Roche are listed in chronological order from the left, and in quarterly order from the bottom. The figures in blue on both sides of the chart are the percentage increase in sales of Actemra by Roche.

First of all, if you look at the full year results written on the top of the chart, in 2020, the year before last, exports increased by 52.6%, which is 14 percentage points higher than Roche's sales increase, which was 39% written in blue, which means that exports were ahead of the overseas demand.

That adjustment occurred the following year, 2021, and if you look at the results for the first half of 2021, you will find that Roche's sales grew by 18%, while our export sales declined by 38.6%.

In the second half of the fiscal year, overseas demand surged due to the spread of the Delta strain, and Roche's sales increased by 41%, but due to production, lead time, and capacity constraints, our exports have not been able to keep up. Our exports in the fourth quarter have increased by 7.5% compared to the same period last year, but looking at the full year results, our exports have decreased by 24.2% compared to Roche's growth rate of 30%, leaving a growth gap of 54 points.

Even taking into account the inventory adjustment caused by the accelerated exports in 2020 and the decline in export unit prices, we believe that there is still room for exports of about 30 percentage points. Against this background, and referring to the rolling forecast from Roche, we are forecasting Actemra exports of JPY141.5 billion this year.

Support

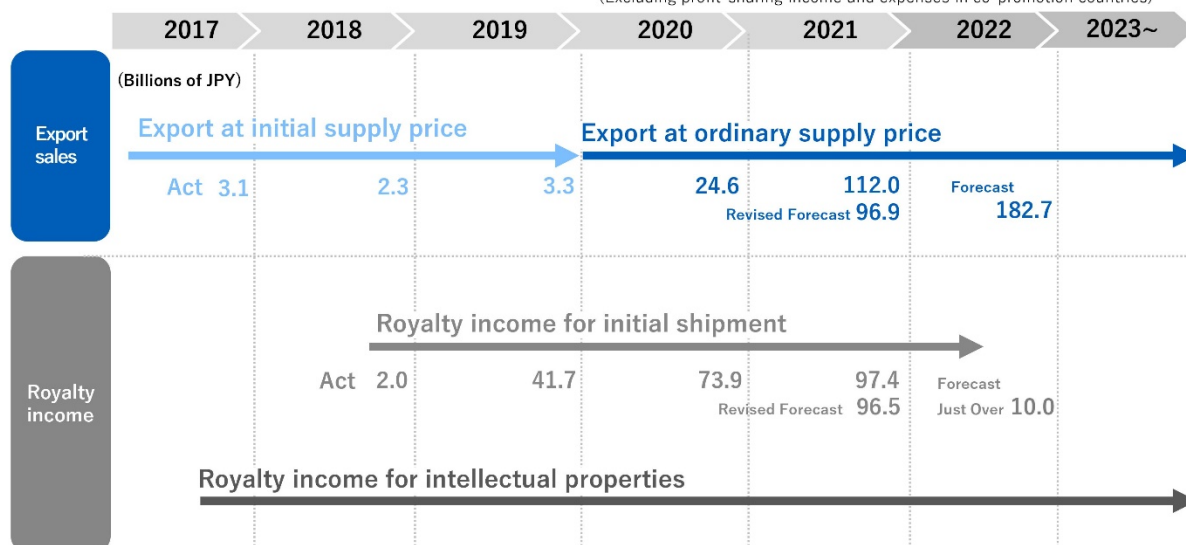
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Outline of Hemlibra Sales to Roche

(Excluding profit-sharing income and expenses in co-promotion countries)



36

Please refer to page 36. This is about the Hemlibra transaction for Roche.

Today will be the last time for this slide that we have been familiar with for a long time. First of all, the export sales in the upper row were JPY112 billion. We raised our forecast by 10% from JPY88 billion at the beginning of the fiscal year to JPY96.9 billion, but the timing of Roche's acceptance inspection was accelerated, resulting in a higher result of JPY15.1 billion. Exports for the current year are expected to be JPY182.7 billion.

The royalty income from initial shipments, so-called Royalty 2, shown in the bottom row, also exceeded our forecast at JPY97.4 billion. For this year, we are forecasting a little over JPY10 billion.

Support

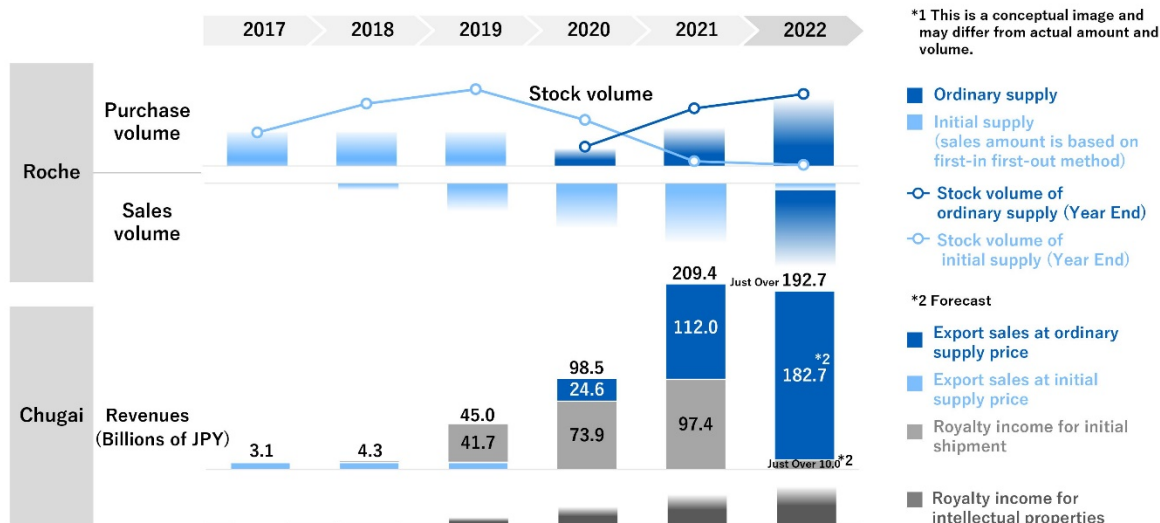
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Outline of Hemlibra Sales to Roche

Image for Timing of Export Sales and Royalty Income*1



37

These are illustrated in the image on page 37. Please see the Chugai's revenues in the bottom row.

Last year, income from Royalty 2 in gray was JPY97.4 billion, and exports in blue were JPY112 billion. This year, Royalty 2 will drop to just over JPY10 billion, but exports will grow to JPY182.7 billion.

Adding up both of these figures, revenues will be JPY192.7 billion this year. It is a little short of last year's total of JPY209.4 billion, but if we take into account the increase in regular royalty income shown in dark gray at the bottom, it will be almost the same as last year.

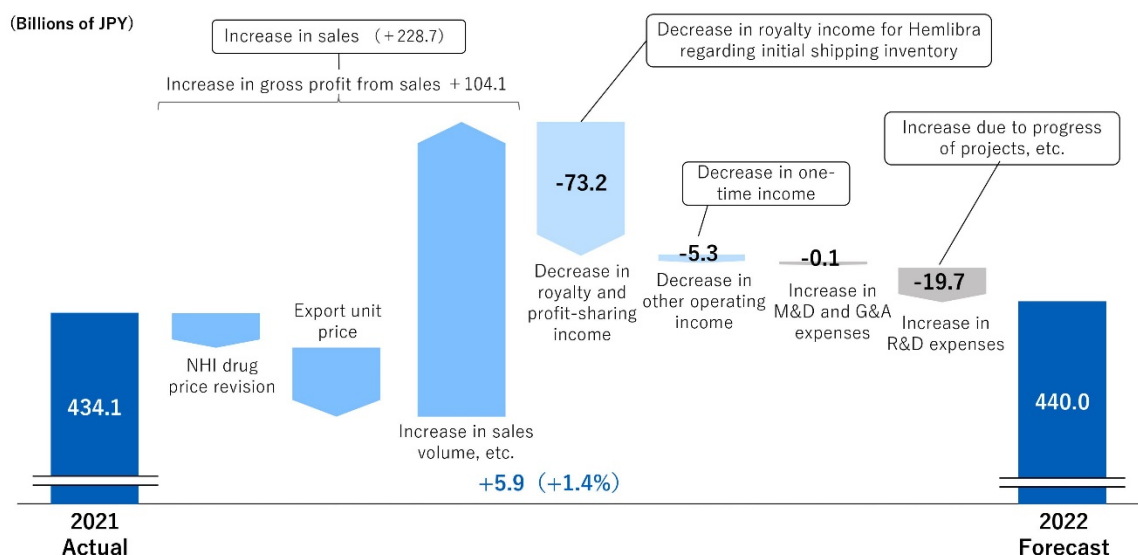
However, if we take into account the fact that the timing of acceptance inspection was accelerated and JPY15.1 billion was recorded in last year's results, we can say that the actual situation is on an upward trend.

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Operating Profit 2022 Forecast



38

Page 38 is my last slide, and it shows the forecast for the change in operating profit.

This year, we expect to increase gross profit by JPY104.1 billion by absorbing the negative impact of the NHI price revision and the decline in export unit prices through an increase in volume.

Since Hemlibra's Royalty 2 will decrease by about JPY87 billion, the total royalty income will decrease by JPY73.2 billion. One-time income is also expected to decrease by JPY5.3 billion, and the total ROOI is expected to have a negative impact of JPY78.4 billion on operating profit.

We will invest JPY19.7 billion more in R&D while keeping SG&A expenses low, but we believe that we will be able to secure an increase in operating profit.

That is all. Thank you very much.

Sasai: Next, Mr. Yamaguchi will explain the status of the development pipeline.

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Q4 Topics (1/2)



As of February 3, 2022

Approved	Ronapreve	Prevention of symptomatic COVID-19, Subcutaneous administration	November 2021
	Herceptin	Advanced or recurrent HER2-positive salivary gland cancer not amenable to curative resection	November 2021
	FoundationOne CDx	pembrolizumab* : advanced or recurrent solid tumors with Tumor mutational burden-high	November 2021
	Rituxan	Refractory pemphigus vulgaris and pemphigus foliaceus	December 2021
	Actemra	COVID-19 pneumonia (EU)	December 2021
	Actemra	COVID-19 pneumonia (JP)	January 2022
Filed	Hemlibra	Acquired Hemophilia A	November 2021
	Polivy	Previously untreated diffuse large B-cell lymphoma (DLBCL)	December 2021
	FoundationOne CDx	- dacomitinib hydrate: NSCLC (Activated <i>EGFR</i> gene alterations)	December 2021
		- brigatinib: NSCLC (<i>ALK</i> fusion genes)	
Phase transition	RG7828/ mosunetuzumab	Follicular lymphoma	P3 study (October 2021)
	RG6396/pralsetinib	Non-small cell lung cancer (NSCLC)	P3 study (November 2021)

Letters in orange : in-house projects Letters in blue : in-licensed (Roche)

* Application under review and not yet approved for the drug indication

44

Yamaguchi: I would now like to explain the status of our development pipeline.

Please refer to page 44. First, I would like to explain the major topics in the fourth quarter from the previous announcement to today on two slides.

Three of the approvals were related to COVID-19. First of all, for Ronapreve, additional indications for prevention of symptomatic COVID-19 and subcutaneous administration were approved last November. In addition, Actemra received additional indications for COVID-19 pneumonia in Europe in December 2021 and in Japan in January 2022. In addition, in November, Herceptin was approved for an additional indication for HER2-positive advanced or recurrent salivary gland cancer, and FoundationOne CDx for CDx functions with pembrolizumab. In December, the indication for Rituxan was expanded to include pemphigus vulgaris and pemphigus foliaceus.

As for the application, first of all, we filed for Hemlibra for acquired hemophilia A in November. Also, in December, we filed an application for Polivy for untreated DLBCL based on the results of the POLARIX study. For FoundationOne CDx, we have applied for four CDx functions.

As for phase transition, mosunetuzumab, a CD3/CD20 bispecific antibody, has started Phase III trials for follicular lymphoma. In addition, pralsetinib, a RET kinase inhibitor, has started Phase III trials for non-small cell lung cancer.

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Q4 Topics (2/2)



As of February 3, 2022

Pipeline entry	SKY59/crovalimab	Atypical hemolytic uremic syndrome (aHUS)	P3 study (October 2021)
Development discontinued	PCO371	Hypoparathyroidism	
	RG6422 (AT-527)	COVID-19	
	Suvenil	Knee osteoarthritis/Shoulder periarthritis (China)	
	AMY109	Solid tumors	
Medical conference	Hemlibra	HAVEN 6 study: interim data	ASH (December 2021)
	Polivy	POLARIX study: previously untreated DLBCL	ASH (December 2021)
Others	Edirol	Osteoporosis	Launch of authorized generic version of Edirol by Towa Pharmaceutical (December 2021)
	OWL833	Type 2 diabetes: advanced to Phase 2**	September 2021
	OWL833	Obesity: initiation of Phase 2 study**	September 2021
	SRP-9001/RG6356*	Duchenne muscular dystrophy (DMD)	License-in agreement (December 2021)
	faricimab	DME: P3 studies (YOSEMITE / RHINE)	Published in Lancet
	faricimab	nAMD: P3 studies (TENAYA / LUCERNE)	Published in Lancet

Letters in orange : In-house projects Letters in blue : In-licensed (Roche)

DME: diabetic macular edema nAMD: neovascular age-related macular degeneration

* Global P3 study for DMD is managed by Sarepta Therapeutics including Japan, while Chugai will be responsible for the regulatory filing and marketing in Japan.

** Conducted by licensee, Eli Lilly and Company

45

Please move on to page 45.

As a pipeline entry, we have initiated a new Phase III study for in-house antibody project, crovalimab, for atypical hemolytic uremic syndrome (aHUS).

As for discontinuation of development, development has been discontinued for PCO371, AT-527, Suvenil in China, and AMY109 for solid tumors. AMY109 will continue to be developed for endometriosis.

For the other OWL833 and RG6356, I will explain the details later.

In addition, we have published in *The Lancet* the results of four Phase III studies of faricimab for diabetic macular edema and neovascular age-related macular degeneration.

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Advances in Chugai Originated Projects Licensed Out to the 3rd Party

★: changes since July 26, 2021

As of February 3, 2022

Development code Chugai/generic name (partner code)	Licensee	Indication	Stage	Mode of Action	Progress
CKI27 (VS-6766)	Verastem Oncology	Ovarian cancer	global: P2	RAF/MEK inhibitor	<ul style="list-style-type: none">US FDA BTD (recurrent LGSOC* in combination with defactinib)
		NSCLC	global: P2		<ul style="list-style-type: none">RAMP 203 trial (in combination with KRAS G12C inhibitor sotorasib) to be initiated in Q1 2022 ★RAMP 204 trial (in combination with KRAS G12C inhibitor, adagrasib) to be initiated in Q2 2022 ★
			global: P1/2★		
CIM331/ nemolizumab	Global (Galderma) Japan (Maruho)	Atopic dermatitis	global: P3	Anti-IL-31 receptor A humanized monoclonal antibody	<ul style="list-style-type: none">US FDA BTD
		Prurigo nodularis	Japan: Filed		
			global: P3		
			Japan: P2/3		
OWL833 (LY3502970)	Eli Lilly and Company	Type 2 diabetes	global: P2★	Oral non-peptidic GLP-1 receptor agonist	<ul style="list-style-type: none">Conduct a 12-week proof of concept study in type 2 diabetes (P1b)✓ Highest dose group of OWL833 shows 4.71 kg weight loss and 1.77% lowering of HbA1c ★Initiated P2 study in September 2021 ★
		Obesity** ★	global: P2		<ul style="list-style-type: none">Initiated P2 study in September 2021

*LGSOC: low-grade serous ovarian cancer **In 2016, more than 1.9 billion adults, 18 years and older, were overweight. Of these, over 650 million were obese. Worldwide, obesity has nearly tripled since 1975.
(Source: WHO Obesity and overweight Fact sheet <https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>)

46

On page 46, you will see the progress of projects licensed out to the third-party.

CKI27 is an RAF/MEK inhibitor discovered and developed by our company and licensed out to Verastem in the US. Verastem is planning to start Phase I/II studies in combination with KRAS G12C inhibitors, sotorasib and adagrasib, for non-small cell lung cancer in the first half of this year, respectively.

In September last year, Eli Lilly and Company started Phase II trials of OWL833 for the treatment of type 2 diabetes, and also started Phase II trials for the treatment of obesity in September.

The following slide shows the results of the proof-of-concept study that was conducted ahead of those trials.

Support

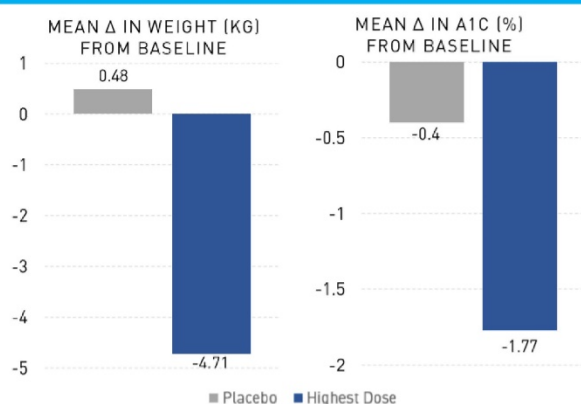
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OWL833: Favorable Efficacy and Safety in T2D

■ Potential contribution to T2D patients as a more convenient treatment option

12-WEEK PROOF OF CONCEPT IN T2D



T2D: Type 2 Diabetes
Source: materials of 2021 Investment Community Meeting by Eli Lilly and Company on December 15, 2021

- **A 12-week proof of concept study in T2D (P1b)**
 - ✓ Suggests possible equivalence to subcutaneous GLP-1 receptor agonists
 - Weight loss 4.71kg
 - HbA1c lowering up to 1.77% points
 - Safety and tolerability consistent with other GLP-1 receptor agonists
- **Expected features of a small molecule, OWL833**
 - ✓ Better bioavailability
 - ✓ Better manufacturing cost structure
 - ✓ Easier administration with no requirement to fast
 - ✓ Once daily oral administration

47

Page 47.

The graph shows the results of a 12-week administration study of OWL833 in patients with type 2 diabetes. In the dark blue OWL833 arm, there was a weight loss of 4.71 kilograms and a decrease in HbA1c of 1.77%. This is considered to be a decrease in the number at the same level as that of subcutaneously injected GLP-1 receptor agonists.

OWL833 is being developed as a once-daily oral administration that does not require any food or drink restrictions after taking the drug. It has better bioavailability and production cost compared to the current oral peptide preparations. As a highly convenient treatment option, it is expected to contribute to the treatment of diabetes and obesity.

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Development Status of Treatments for COVID-19

Treatment	Development status
Actemra (Moderate II to Severe)	<p><Japan></p> <ul style="list-style-type: none"> ● Additional indication for SARS-CoV-2 pneumonia (limited to patients requiring oxygen intervention) (Filed in December 2021, Approved in January 2022) <p><Overseas></p> <ul style="list-style-type: none"> ● US: FDA Emergency Use Authorization granted (June 2021) ● EU: Approved for severe COVID-19 treatment (December 2021) ● WHO: <ul style="list-style-type: none"> ✓ recommended IL-6 receptor blockers including Actemra for treatment in severe COVID-19 patients receiving corticosteroids (July 2021) ✓ announced that IL-6 receptor blockers are expected to remain effective for the management of patients with severe or critical Omicron-associated COVID-19 (November 2021)
Ronapreve (Asymptomatic to Moderate I)	<ul style="list-style-type: none"> ● SARS-CoV-2 infection and prevention of symptomatic SARS-CoV-2 infection (First approval in July, additional indications in November 2021, respectively) ● Neutralizing activity against Omicron variant (B.1.1.529/BA.1) was confirmed to be diminished, and revised the package insert based on the data (December 2021) ● On the other hand, Ronapreve has shown to retain its efficacy against other variants of concern, including Delta. Efficacy against future emerging variants has not been denied.
AT-527	<ul style="list-style-type: none"> ● Decision was made to discontinue development in December 2021

48

Next, on page 48, we have summarized the status of the development of treatments for COVID-19.

As you know, we filed an application for Actemra in Japan in December last year, and received approval in January. Moderate II to Severe cases of pneumonia caused by SARS-CoV-2 requiring oxygen intervention will be covered.

In addition, the approval of the drug in Europe was granted in December last year, and it is now under review and regulatory approval in dozens of countries around the world. The WHO has also stated that IL-6 receptor inhibitors, including Actemra, will continue to be effective even after the emergence of Omicron variant.

Next, as mentioned earlier, Ronapreve was approved in July last year for mild to Moderate I with a risk of severe disease, and in November, prevention of symptomatic COVID-19 and subcutaneous administration were added. Unfortunately, the neutralizing activity against the Omicron variant/BA.1 was confirmed to be diminished, but we believe that the neutralizing activity of newly emerging variants cannot be denied in the future.

The development of AT-527 was discontinued at the end of last year.

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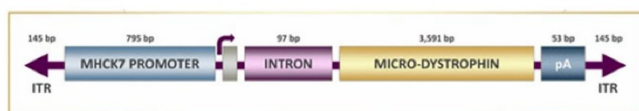
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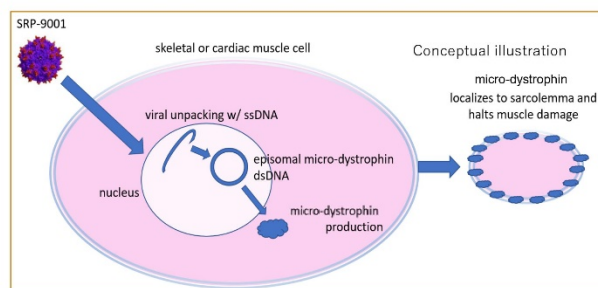
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Micro-dystrophin Gene Therapy SRP-9001/RG6356

- **Express a shortened, functional dystrophin protein inside the targeted muscle**
 - ✓ Delandistrogene moxeparvovec (SRP-9001/ RG6356) is an investigational gene transfer therapy developed for targeted muscle expression of micro-dystrophin, a shortened, functional dystrophin protein, that addresses the genetic cause of DMD.



- Aims to express **micro-dystrophin** – a smaller but still functional version of dystrophin, used because naturally-occurring dystrophin is too large to fit in an AAV vector¹.
- Employs the **AAVrh74 vector**, which has a robust affinity for muscle cells, making it an ideal choice for delivering the micro-dystrophin transgene. AAVrh74 also has a relatively low level of pre-existing immunity¹.
- The **MHCK7 promoter** drives the expression of the micro-dystrophin transgene selectively in skeletal and cardiac muscle, and contains an **α-MHC enhancer** that has been shown to drive high protein expression, particularly in cardiac muscle.^{1,2}



Source: Roche internal materials

1. Asher D, et al. Clinical development on the frontier: gene therapy for duchenne muscular dystrophy. Expert Opinion on Biological Therapy. 2020; 20:263-274;
2. Salva MZ, et al. Design of Tissue-specific Regulatory Cassettes for High-level rAAV-mediated Expression in Skeletal and Cardiac Muscle. Mol Ther. 2007; 15:320-9;

Next, on page 49, you will find an introduction of RG6356, a gene therapy drug introduced by Roche at the end of last year.

RG6356 is currently being investigated in a global Phase III study, EMBARK, by Sarepta in the US, including Japan, for Duchenne muscular dystrophy. Chugai is responsible for the regulatory filing and marketing in Japan.

Duchenne muscular dystrophy is a serious disease characterized by progressive muscle atrophy caused by mutations in the dystrophin gene on the X chromosome. RG6356 is designed to efficiently express shortened, functional dystrophin in muscle cells. Specifically, we have adopted vectors with high affinity for myocytes, as well as a promoter and enhancers that drive gene expression in myocytes. We hope that this will be the Chugai's first gene therapy.

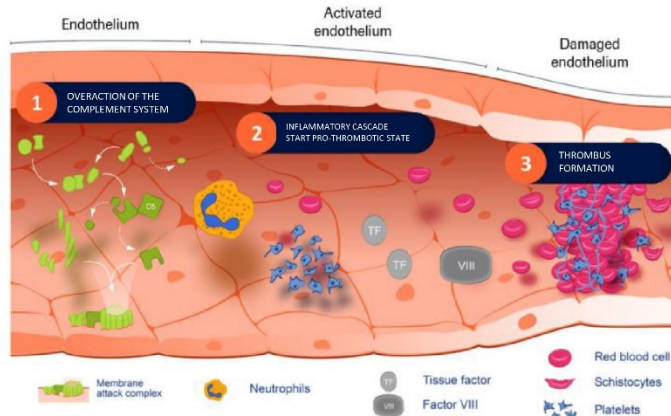
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Atypical Hemolytic Uremic Syndrome (aHUS)

- **Crovalimab:** Binds to C5 and inhibits the cleavage of C5a and C5b, thereby blocking the activated terminal complement cascade completely



- aHUS is caused by uncontrolled complement activation in the alternative pathway. A variety of genetic defects in complement-related factors or acquired autoantibodies to the complement regulators are associated with the onset.
- Ultra-rare disease characterized by severe and life-threatening acute kidney damage, decreased platelets, and MHA*
- Many people with aHUS form the membrane attack complex (MAC) due to complement abnormalities, and cause endothelial disorders, activated platelets and thrombosis.
- Children with aHUS account for 40% of all cases
- About 200 patients are estimated in Japan (Source: aHUS registry cohort; Survey conducted by research team at the Ministry of Health, Labour and Welfare 2018)

* MHA: microangiopathic hemolytic anemia

Adapted from Feitz WJ et al. Med Genet. 2018;30:400
Source: materials of Roche Pharma Day 2021 held on September 14, 2021

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As for anti-C5 antibody crovalimab, we started Phase III trials for aHUS in October last year as a follow-up indication to PNH.

aHUS is caused by mutations in complement-related genes or autoantibodies against complement regulators, and results from uncontrolled activation in the alternative complement pathway. It is an extremely rare disease characterized by severe and fatal acute kidney injury, thrombocytopenia, and hemolytic anemia.

The number of patients in Japan is estimated to be about 200, of which 40% are children. The two global Phase III studies, COMMUTE-a in adolescents and adults and COMMUTE-p in pediatric patients, have been initiated in collaboration with Roche. The application is scheduled for 2024 or later.

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Potential Market Sales of Post PoC Projects

[Expected year when each project will reach its peak-sales] **projects in black:** between 2022 to 2029; **projects in purple:** 2030 and beyond.

In-house projects	★★★★★ Global over 400 bn yen	★★★★ Global over 200 bn yen	★★★ Global over 100 bn yen	★ Global below 100 bn yen
	Hemlibra (Hemophilia A, acquired hemophilia A)	Enspryng (NMOSD, gMG, etc.) nemolizumab* (Prurigo nodularis, atopic dermatitis)	Alecensa (NSCLC, NSCLC adjuvant, ALCL, etc.) crovalimab (PNH, aHUS, sickle cell disease, etc.)	
In-licensed (Roche)	★★★★★ Domestic over 60 bn yen	★★★★ Domestic over 30 bn yen	★★★ Domestic over 15 bn yen	★ Domestic below 15 bn yen
	Tecentriq [over 100 bn. yen] (NSCLC, SCLC, urothelial carcinoma, RCC, prostate cancer, HCC, triple negative breast cancer, ovarian cancer, head and neck carcinoma, esophageal cancer, pancreatic adenocarcinoma, etc.)	Polivy (DLBCL) faricimab (nAMD, DME, RVO) gantenerumab (Alzheimer's disease)	Evrysdi (Spinal muscular atrophy) HER/PER fixed-dose combination (Early breast cancer, metastatic breast cancer) tiragolumab (NSCLC stage III, NSCLC (1L), SCLC (1L), esophageal cancer) giredestrant (Early breast cancer, metastatic breast cancer)	Gazyva (Follicular lymphoma, etc.)

* Licensed out to Galderma (global) and Maruho (domestic), respectively. Based on the forecasts by Galderma and Maruho NOTE: expected indications based on peak-sales forecast are noted in brackets

NMOSD: neuromyelitis optica spectrum disorder, gMG: generalized myasthenia gravis, NSCLC: non-small cell lung cancer, ALCL: anaplastic large cell lymphoma, PNH: paroxysmal nocturnal hemoglobinuria, aHUS: atypical hemolytic uremic syndrome, RCC: renal cell carcinoma, HCC: hepatocellular carcinoma, DLBCL: diffuse large B-cell lymphoma, nAMD: neovascular age-related macular degeneration, DME: diabetic macular edema, RVO: retinal vein occlusion

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Page 51 shows the potential market sales of post PoC projects.

This kind of slide was presented at the financial results briefing for the first half of 2021, but we have changed the display in order to show the peak-sales period and the indications included in the sales forecast. We believe that this indicates the sales potential of late-stage development products, which are the key to growth, but please note that this is only a forecast at this point in time and there is a high degree of uncertainty.

For our own products, we have categorized them according to the scale of sales in the global market including Japan. We expect sales of over JPY400 billion for Hemlibra, over JPY200 billion for Enspryng and nemolizumab, and over JPY100 billion for Alecensa and crovalimab.

Roche's in-licensed products are categorized by the scale of domestic sales. Sales of Tecentriq are expected to be over JPY60 billion, but we actually believe this will exceed JPY100 billion. In addition, sales of Polivy, faricimab, and gantenerumab are expected to exceed JPY30 billion.

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2022: Key R&D Milestones

Projects to be approved	Actemra	COVID-19 pneumonia	✓
	nemolizumab	Atopic dermatitis	
	Herceptin/Perjeta	HER2 positive colorectal cancer	
	faricimab	Neovascular age-related macular degeneration (nAMD)	
	faricimab	Diabetic macular edema (DME)	
	Tecentriq	Non-small cell lung cancer (NSCLC) [adjuvant]	
	Hemlibra	Acquired hemophilia A	
P3/Pivotal readouts	Polivy	Previously untreated diffuse large B-cell lymphoma (DLBCL)	
	Alecensa	ALINA Study: NSCLC [adjuvant]	
	gantenerumab	GRADUATE1/2 Study: Alzheimer's disease	
	Tecentriq	IMpower030 Study: NSCLC [neoadjuvant]	
	Tecentriq	IMmotion010 Study: RCC [adjuvant]	
	Tecentriq	IMvove010 Study: HNC [adjuvant]	
	Tecentriq + Avastin	IMbrave050 Study: HCC [adjuvant]	
	Tecentriq + tiragolumab	SKYSCRAPER-01 Study: NSCLC [1st line]	
	Tecentriq + tiragolumab	SKYSCRAPER-02 Study: SCLC	

Letters in orange : in-house projects, Letters in blue : in-licensed(Roche)

52

Next, on page 52, we have presented the schedule of major projects to be approved and pivotal readouts in 2022.

Eight products are scheduled to be approved. In addition to Roche products such as faricimab, which we are entering the ophthalmology field with for the first time, and Polivy, which is aimed to expand to a first-line DLBCL treatment, we expect approval of our own products, nemolizumab, which is currently under review in Japan, and Hemlibra for acquired hemophilia A.

As for the pivotal study readouts, the results of the ALINA study for Alecensa for the adjuvant treatment of non-small cell lung cancer (NSCLC) will be revealed, and readouts are scheduled for Roche products such as gantenerumab, Tecentriq, and tiragolumab.

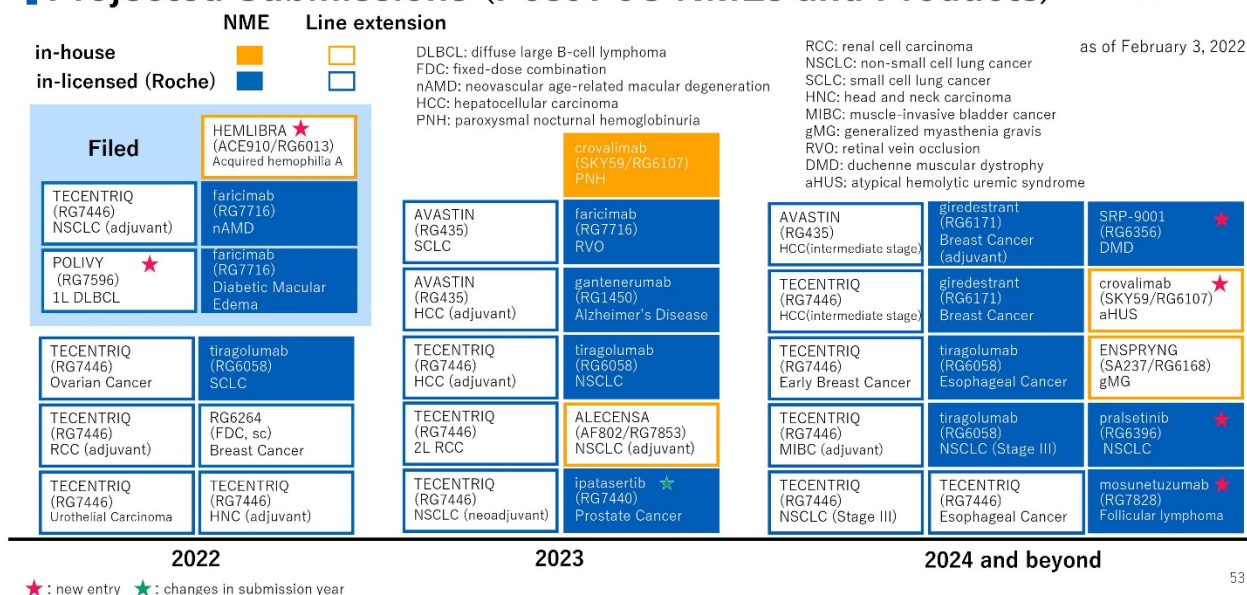
The pivotal trials are listed in alphabetical order, and the projects to be approved are listed in order of application.

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Projected Submissions (Post PoC NMEs and Products)



53

Moving on to page 53, here is the schedule for future applications.

The red star indicates that the application was added this time, and the green star indicates that the application year was changed.

We believe that we will continue to be in a very good position regarding applications for both in-house products and Roche products.

The following slides show the development pipeline, the status of the companion diagnostic function of FoundationOne CDx and FoundationOne Liquid CDx, and our research portfolio in small molecule, mid-size molecule and antibody drug discovery. Please refer to it as necessary.

Thank you for your attention.

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Question & Answer

Sasai [M]: We will now move on to the question-and-answer session.

Mr. Hidaka, Vice President and Head of Marketing & Sales Division, will also be joining us.

In order to allow as many people as possible to ask questions, we would like to limit the number of questions to two per person. Please note that the content of your questions will be posted on our website at a later date along with the presentation.

When it is your turn to ask a question, we will call your name. When asking a question, please let us know your company name and your name. Thank you.

Now let's get to your first question. Mr. Wakao, please go ahead.

Wakao [Q]: This is Wakao of JPMorgan. Thank you.

I was surprised to see a very high level of profit growth. First, please tell us about the impact of the COVID-19 pandemic this fiscal year and future growth potential. Sales of Ronapreve were better than I expected this fiscal year, but is this because of the JPY199 billion in contracts that were initially signed when it was released last year? Are there any additional contracts after that that have been factored in here?

In the future, I think that sales of Ronapreve and Actemra will decline as the COVID-19 pandemic comes to an end. On the other hand, I think that after that, Hemlibra exports will drive growth. Do you envision a peak in profits this fiscal year and a dip next fiscal year before that move back to growth? Sales of Ronapreve are large, but it is also a sublicensed product, so thinking on a profit basis, I was wondering if you could get back on track to increasing profits again faster than sales.

Okuda [A]: Thank you for your question, Mr. Wakao. I'd like to give you my answer, and then Mr. Itagaki will say a few words too.

The sales forecast for Ronapreve for the current fiscal year is as you say. We anticipate a carry-over of last year's delivery schedule. In addition, the forecast includes the expected sales of Ronapreve associated with a new contract we are aiming to agree.

It is difficult to foresee what will happen in the future with Ronapreve with respect to the COVID-19 pandemic. The situation is similar with Actemra. In the future, both globally and in Japan, it is expected that new COVID-19 variants will emerge and spread, and effectiveness against these is unknown. It is assumed that the demand of Actemra will vary depending on the severity of the mutant strain.

So, in summary, it is very difficult to forecast. I gave an explanation of the medium- to long-term outlook, and I explained about the exclusion of Ronapreve.

Mr. Itagaki may want to say something about the profit margin.

Itagaki [A]: Thank you. Last year, the operating profit margin was in the 40% range, while this year's forecast is 38.3%. We are not expecting to reach the 40% mark. It is notable that Ronapreve makes up a larger percentage of the total this year.

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However, although to some extent we have included some assumptions based on COVID-19 forecasts in the figures for Ronapreve and Actemra, as mentioned earlier, there may be some variability. Regardless of this, the baseline sales and profit trends of our company remain strong. While it would be foolish to make specific predictions for FY2023, we anticipate that this solid trend will continue.

Wakao [Q]: Thank you very much. Thank you for your clear explanation.

Secondly, I would like to know what your thoughts about the outlook for the hemophilia segment, including Hemlibra. This time, the export sales of Hemlibra have been very large. I am aware that export sales will grow in parallel with the growth of Hemlibra, but I wonder about these figures. The potential figure listed here is over JPY400 billion, and I feel like it's about to reach that point. Please tell us how you see the upside of global sales for Hemlibra going forward.

In addition, what is the status of NXT007 now? I'm looking forward to seeing the data, so if you can comment on that it would be appreciated.

Okuda [A]: I would like to give you my answer first about the prospects for Hemlibra, and then Mr. Yamaguchi will add some further explanation if necessary.

Regarding the growth potential of Hemlibra, we have announced a sales forecast of over JPY400 billion. Roche just announced its financial results, and the market share in the second quarter was 29%, in the third quarter 31%, and in the fourth quarter 33%. These are the total market share figures for the five European countries and the US, and they have been increasing by 2% each.

Then there is the market share in Japan. As you can see in the slide, the percentage was 20.7% in December 2020, 26.2% in December 2021, one year later, and 14.8% going back to December 2019. So, it has been increasing over 5% per year, even during the COVID-19 pandemic. We have also observed that when the COVID-19 infection subsided slightly in the fourth quarter here, the switch to Hemlibra was a little quicker, so we believe that there is still room for growth.

Mr. Yamaguchi will explain about NXT007.

Tetsuya Yamaguchi [A]: Thank you.

The Phase I study is underway as planned, and we are in the process of increasing the dose. Unfortunately, there is nothing more that we can disclose at this time.

That is all.

Wakao [Q]: So, there isn't any hope of seeing Phase I data at present?

Tetsuya Yamaguchi [A]: I'm afraid we're not at the stage for disclosing data.

Wakao [M]: I understand. Thank you.

Sasai [M]: That brings us to the next question. Mr. Hashiguchi of Daiwa Securities, please go ahead.

Hashiguchi [Q]: This is Hashiguchi. Thank you.

Regarding sales of Ronapreve and Actemra relating to COVID-19, as you mentioned, I think it is very important to see what happens with mutant strains. In the long term, I think sales will be determined by actual demand, but in the short term, I think it will be greatly affected by how the Japanese government (in the case of Ronapreve) and Roche (in the case of Actemra) read the situation relating to mutant strains.

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I was wondering if you could share your current observations on how the Japanese government and Roche are building up inventories for future mutant strains, and how much upside and downside risk you see in this forecast.

Okuda [A]: Thank you for your question, Mr. Hashiguchi. In the case of Ronapreve, I think this relates to the accuracy of the sales forecast for the current fiscal year.

Experts are saying that new coronavirus variants are de novo. This means that rather than coming out as an addition to the Delta strain or a descendant of the Omicron strain, they often seem to appear as completely new variants. As a result, there is a good chance that new variants will emerge.

It is also difficult to predict whether or not Ronapreve will be effective against new variants, so we will conduct in vitro experiments to confirm the effectiveness of Ronapreve as they emerge.

The reason why we have included it in our forecast this time is that, looking back on the last year, we did not include the sales of Ronapreve in our forecast last year. This was not included in last year's sales forecast due to various factors that introduced uncertainty, such as the fact that Ronapreve was still under development at that time, we did not know if it would be approved, and we had not yet signed a delivery contract with the government.

This year, as you can see, things are a little different. Last year, we signed a contract with the government. In addition, we received special approval in July and started sales. These are the sort of results we have accumulated to date. In addition, we have been discussing with Roche about the delivery for this fiscal year. They appreciate the situation relating to delivery, and we have working to accommodate their requests. Under these circumstances, we expect to have a certain degree of certainty in sales for this fiscal year.

With regard to Actemra, the underlying factor is difficult to predict; that is, the number of patients on a global basis who become severely ill with COVID-19 or require oxygen administration. I think it is helpful to keep this point in mind.

Mr. Itagaki can say a few words if there's anything to add.

Itagaki [A]: In the slides that Roche presented today, they are unsure of what kind of impact Delta, Omicron, and other strains will have in the medium to long term, and they give two scenarios. On the other hand, with regard to Ronapreve, as Dr. Okuda explained, it is not a matter of how the government sees it, but rather, based on the state of negotiations with the government, the level we believe that we can achieve. Thereby we have incorporated this into the plan.

As for Actemra, as I explained earlier, there is already a slight inventory crunch in the supply and demand area, and demand is still strong because there are still a certain number of patients with severe disease even though we have seen changes in the makeup of strains globally. There is also the rolling forecast from Roche, which is how much they want to import from us in the future. Our current estimate is based on a comprehensive consideration of these factors.

Therefore, we are not considering this in terms of the impact or scale that COVID-19 itself will have in the future, but we are looking at it on the basis of business contracts, contracts with Roche, negotiations with the government, and so on.

Hashiguchi [Q]: Thank you very much.

My second question is about dividends. As you can see in the slide on page eight, the dividend payout ratio for a single year is 40% in both the previous and current fiscal year, with a dividend of JPY76. Compared to

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the current policy of aiming for 45%, the dividend payout ratio appears to be low. Could you explain the reasoning behind this? It seems to me that you have set this figure based on the fact that there is a reasonable possibility that profits will decline in the next fiscal year and beyond.

Itagaki [A]: This is Itagaki.

Our dividend policy is, of course, to pay stable dividends on an ongoing basis, taking into account the uncertainties of the business environment and fully taking into account our future performance and other factors. As a guideline, we are aiming for an average of 45% over the next five years, while considering past and future performance. The dividend for FY2021 was JPY76 yen, and we expect it to be JPY76 yen for this fiscal year as well. For a single year, the rate is 40%, and over five years, it is 42.9 or 43%, which is almost in line with our policy.

Although we have accumulated a large amount of cash, the business environment is changing rapidly, and as we continue to grow, we will need to make investments in the evolution of drug discovery technologies, in digital technology, and in the environment in terms of ESG. We will continue to have a high need for funds, and we would like to maintain a balance between returning profits and investing for the future.

Hashiguchi [M]: Thank you very much.

Sasai [M]: Thank you very much.

The next speaker is Mr. Sakai from Credit Suisse Securities.

Sakai [Q]: This is Sakai from Credit Suisse. I would like to ask two questions about Actemra.

I didn't have time to look at Roche's financial results, so I'd like to ask you about it. Your Company's Actemra exports to Roche this fiscal year are JPY141.5 billion, I think. I'm sure that during production, your Company is in ongoing discussions with Roche. Last year, before the Omicron strain emerged, Roche stated that they estimated 200 million to 300 million COVID-19 infections.

I remember that it was said on an IR basis that the demand for Actemra would continue to be strong, but assuming that JPY141.5 billion estimate, some percentage of that that estimated 200 or 300 million people were assumed to become seriously ill and use Actemra. Is that how the figure was calculated?

Itagaki [A]: This is Itagaki. Thank you.

Of course, we have assumptions about Actemra use in Roche's territory. However, as I explained earlier, our JPY141.5 billion in exports is based on two factors. Production capacity was confirmed in the latter half of last year, and we are following up on the part where the inventory is a little tight. Then there is a rolling forecast, which Roche uses to calculate how much to order, and the figures are based on these two factors.

As I mentioned earlier, a certain amount of assumption has been made by Roche, presumably reflected in a rolling forecast. With regard to scenarios A and B mentioned earlier, there are a lot of variability depending on the case.

On the other hand, I would like to reiterate that for a period of time in the future, they will place firm orders with us, so at least for our exports, this figure of JPY141.5 billion will not fluctuate too much.

Sakai [Q]: Thank you very much.

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Another question is that looking at the presentation materials, the Company's financial results are watertight, but in spite of that, the stock price is in its current difficult spot. It seems the biggest risk is the entry of a biosimilar to Actemra.

This is more a request than a question, but would you be able to provide something like a list of medium- to long-term KPIs, which reflect how you are going to defend Actemra's territories and franchises, including for example IPs? Or if areas appear where you are no longer able to do so. That would be very helpful for us in recognizing the risks. Would something like that be possible?

Okuda [A]: Thank you for your question.

Regarding the status of Actemra biosimilars and the patent situation, as I made clear in the slides of this presentation, there are several Actemra patents remaining. The substance patent and the application patent for rheumatoid arthritis have expired, but several other patents remain.

As for your request for quarterly updates on the status of patents, please understand that we have a long-standing policy of not disclosing the status of IP.

However, we are aware that there are about eight companies developing biosimilars, with two companies leading the group. As for this, I think you can infer the status of Actemra's patents if you refer to the information about them as it becomes public. Thank you.

Sakai [Q]: I'm not asking you to give us all the patent information, but if you could tell us your Company's view, it would be very helpful to us. I will of course do what I can to obtain other indirect information as well. That was the gist of what I was asking. Thank you very much.

Sasai [M]: Thank you very much.

Let's move on to the next question. Mr. Ueda from Goldman Sachs, please go ahead.

Ueda [Q]: I'm Ueda from Goldman Sachs.

The first thing I would like to ask is about the export of Alecensa. I understand that you are anticipating a decrease in sales, but with regard to competition, and factors behind your inventory levels, price assumptions, and so on, how do you predict sales changing in the future?

Itagaki [A]: Thank you very much for your question. This is Itagaki.

In 2022, the forecast for Alecensa export is negative. I think the figure was -31.9%. If you break it down, the export volume is decreasing. It is assumed that the unit price of exports is also declining. We expect global sales to grow steadily, but the buildup of inventory up until last year has reached a safe, or rather, expected level, and adjustments are being made from this year. As a result, the volume of exports is expected to decline.

In addition, we are also seeing a steady growth in sales outside the US, especially in China. This has inevitably led to a one-year delay in the decline in unit prices for exports. As for external sales, if you look at Roche's actual results, the global sales increased by 18%, and the figure for Alecensa is growing, with the US and Europe each accounting for over 10%, and international sales at 40%. As I mentioned earlier, due to the two special factors of inventory adjustment and unit price, exports are expected to decline this fiscal year.

Ueda [Q]: Thank you very much.

Secondly, I would like to ask you about the medium-term milestones on page 12. At the top of this page, where it says that the acquisition of ePoC for LUNA18, what is the definition of ePoC here, and what about

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the 2024 date for acquisition? Is it because this is a new modality, so your Company is proceeding with caution in Phase I, for example? What are your thoughts on this?

Tetsuya Yamaguchi [A]: Thank you for your question.

As for the acquisition of the early proof of concept for LUNA18, the concept of early proof of concept is defined as the stage where a certain concept has been proven in a small number of patients.

In this regard, Phase I of the project started in October last year, and the 2024 date is when we anticipate actually increasing the dose.

Ueda [Q]: Thank you very much. In that case, if you look at the development of other drugs in the same field, the subsequent process seems to be relatively smooth. About the later stage of development, such as the schedule of launch, how long do you think it will take?

Tetsuya Yamaguchi [A]:

It depends on the actual clinical data. For example, G12C inhibitor showed very effective clinical results, and was approved in a very short time, especially in the US with Accelerated Approval. However, there are some cases that need to be looked at in combination with other drugs, so I think that the development plan is based on the response seen in the clinical results depending on the doses used.

Ueta [M]: I understand. Thank you very much. That is all.

Sasai [M]: Thank you very much.

Next, Mr. Yamaguchi from Citigroup, please go ahead.

Hidemaru Yamaguchi [Q]: This is Yamaguchi from Citigroup. Thank you.

It would be highly appreciated if you could update the mid-term milestones, regardless of numerical targets or not. Next year will be the second year of the mid-term milestones, and I would like to confirm the approach to these. For example, do you intend to take another look at the situation, and if there are things that are not working, revise them?

Okuda [A]: Yes, that's right. However, if the environment or own progress changes, we may revise the mid-term milestones themselves. We will provide updates on the pipeline as well, so you can check the progress there.

Hidemaru Yamaguchi [Q]: One more thing, in this medium- to long-term sales revenue forecast, the medium-term part has a peak sales in the figures, but the long-term part does not yet. How far would the timing of this entry have to go before your Company would be willing to disclose it to the public?

Okuda [A]: Mr. Yamaguchi, I understand.

You asked when potential figures regarding in-house products and in-licensed Roche products listed on the right-hand side would be released.

We gradually learn more as each project progresses, and when we know more and can disclose it, we would like to share it with you. We would like to periodically disclose this information when it becomes available.

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Hidemaru Yamaguchi [Q]: Thank you very much.

I'd like to ask one more thing, does the JPY100 billion figure Alecensa include adjuvants?

Okuda [A]: Yes, it's in there.

Hidemaru Yamaguchi [M]: I see. Thank you very much. That's all.

Sasai [M]: Thank you very much.

Next, Nihon Keizai Shimbun, Mr. Yamada, please go ahead.

Yamada [Q]: Thank you. This is Yamada from the Nikkei Shimbun.

The first question I have is about Actemra. You mentioned that you have doubled your production capacity with Roche and other contractors compared to before the COVID-19 pandemic, and I was wondering if you have a strategy to further increase your production capacity in the future? If you were to further increase your production capacity, would you do so internally or would you seek outside help?

Okuda [A]: Thank you for your question, Mr. Yamada.

Compared to before COVID-19 spread, we have internal production and production outsourced to Roche. We also outsource manufacturing to third parties, and we have doubled our production volume. There is one more company that will start contract manufacturing in the future, so please understand that the figure will increase a little more.

Yamada [Q]: Thank you very much.

One more point, and I'm sorry to keep repeating this question, but the Company has been making large double-digit profit increases, and I think that this is another great financial result. However, I think that core net income will remain flat. Is it correct to assume that the rate of profit growth will slow in the future? Please let me know how to interpret this part.

Itagaki [A]: This year will be the sixth consecutive year of increased revenues and profits. However, the range of operating profit and profit growth is small, which may lead to the question of what will happen after that.

However, if we take this year as the starting point, next year we will not have Royalty 2, so exports will equate to in-house products. In addition, if the products are sold outside the country, not only the gross margin of manufacturing, but also the royalty, or in some cases the profit-sharing, will be included. That is the general structure.

So, as I mentioned earlier, if you look at the baseline excluding COVID-19 use of Ronapreve and Actemra, I think we can expect strong business growth and profit momentum.

When we exclude Ronapreve from the results, we can still get a good idea of sales, for example, but in the case of Actemra, it is difficult in the first place to identify how much revenue is from COVID-19. The same is true on a profit basis, since there are various factors, such as purchases for increasing stocks. In any case, I hope you can appreciate the general trend.

Yamada [M]: Understood. Thank you.

Sasai [M]: Thank you very much.

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The next speaker is Mr. Muraoka from Morgan Stanley Securities.

Muraoka [Q]: Hello, this is Muraoka, Morgan Stanley. Thank you.

In the PL plan for this fiscal year, SG&A expenses are almost flat at JPY100.4 billion. I was a little surprised that you were able to keep SG&A expenses flat after achieving such excellent results.

What I would like to ask is that, for example, with the Company making the current level of profit, what are your thoughts about employee remuneration? It's impressive that SG&A expenses have been controlled, and I understand the desire to increase profits, but how about the option of increasing SG&A spending?

Itagaki [A]: This is Itagaki.

We are planning to use it, or rather, we have budgeted to do so. For example, SG&A expenses increased last year, but if you look at the breakdown, you will see that the profit itself increased, and business tax increased, which so you could see as a sort of value-added tax. Also, in the future, we are planning to create a hybrid sales system, or a hybrid of remote, real, and digital data, and we have been increasing our SG&A expenses while making investments.

The office space has also become much more efficient, and rental costs are decreasing, so we think we can go ahead with a flat budget here.

Muraoka [Q]: I understand. Thank you.

Also, the figure for Ronapreve, which was mentioned earlier, was JPY199 billion. I don't know how to ask this, but is there anything you can say about the portion that is almost fixed and the portion that your Company thinks will be variable? For example, is half of it fixed, or is it almost totally fixed?

When I watch the news, I wonder about whether the unit price will be reduced due to political pressure or something like that.

Okuda [A]: I couldn't catch the last part, but it's hard to give you a breakdown. One thing I can tell you is that there are some things that are carried over from last year's contract. There is also a new part that we are talking about with the government now. I'm sorry.

I didn't hear the second half of the question, so I'm not sure if I answered it correctly.

Sasai [M]: Mr. Muraoka, is that alright?

Muraoka [M]: Yes, thank you. I'm sure there's probably not much you can freely say. Thank you. That's all.

Sasai [M]: Thank you very much.

Next, Numata from MIX, please go ahead.

Numata [Q]: I'm Numata from Monthly MIX.

In today's presentation by Dr. Okuda, he explained the maximization of value as a growth driver, but one part was skipped over. I was wondering what he meant when he talked about having implemented an efficient distribution policy. Also, the priority policy for FY2022 mentions a new distribution system. Could you describe what new is referring to here?

Okuda [M]: I will pass this question to Mr. Hidaka.

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Hidaka [A]: Thank you for your question.

One of the new distribution policies is to break away from the conventional style of manufacturers asking wholesalers to promote their products. In particular, our company has many hospital products in our pipeline, so we would like to move forward with the idea of changing these products to a new style. We would like to discuss this with wholesalers as we move forward.

I hope I have answered your question.

Numata [Q]: So, are you talking about revising the contract a little in terms of, for example, sales promotion and promotion expenses?

Hidaka [A]: That's right. I think it's safe to say that we will create systems based on such considerations, while consulting with various wholesalers.

Numata [Q]: Okay. Thank you.

One more question: in the Value Delivery section of the mid-term milestones, there is a section on functional transformation through resource shifting and digitalization. In that section, there is a part on realizing the assignment of employees with specialized knowledge across the country, regardless of their location. Does this mean that you will be using digital technology in the future so that staff such as MRs will not be located in a physical area and will only do business remotely? I was wondering if you could give some specific examples of this.

Hidaka [A]: I think the question of how much we can expand the scope of our business will depend on the future environment. For example, I believe that it is now possible for sales staff to work remotely without having to choose where to work.

In particular, there are some staff members who are unable to move around while they are in the local area, so I think it is possible for them to do a variety of work without being restricted, and to do it remotely. I would like to change to such a system.

Numata [M]: Thank you very much.

Sasai [M]: Thank you very much.

Due to time constraints, the next question will be the last. Thank you. Mr. Yokoyama of Nikkei BP, please go ahead.

Yokoyama [Q]: I would like to ask you two questions about oncology.

First, on the development side, I would like to ask about pralsetinib. You explained that Phase III study had been started and Chugai is scheduled to file in 2024 or later. Is it correct to say that Japan will participate in the AcceleRET Lung study, which compares with chemotherapy? Will your Company wait for the results of this study before submitting an application in Japan?

Tetsuya Yamaguchi [A]: I will take your question.

As you said, we are going to participate in AcceleRET Lung. In addition to this, we would like to consider a variety of other possibilities.

Yokoyama [Q]: Does that mean there is a possibility that you will do a small-scale Phase II and the application will be moved up?

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Tetsuya Yamaguchi [A]: It is quite difficult to recruit patients with cancer types that have RET mutations. There are challenges, but we will try various approaches.

Yokoyama [Q]: If that's the case, is it possible to apply before 2024?

Tetsuya Yamaguchi [A]: We will of course aim to apply as soon as possible, but we also need to carefully assess efficacy, so we would like to keep a balance between the two.

Yokoyama [Q]: I see. Would you like to use FoundationOne as a companion diagnostic?

Tetsuya Yamaguchi [A]: We would like to make it possible to measure a wider range of things, including this, but I think we will proceed as you have pointed out.

Yokoyama [Q]: I understand.

Also, I would like to ask you about sales. I saw that the oncology sales for this year were down, but is it correct to assume that sales of Tecentriq as a lung cancer adjuvant are included in the forecast figure?

Hidaka [A]: I will take your question. Thank you for your question.

The adjuvant of Tecentriq is included, but of course, we are expecting approval during the term. In addition, the adjuvants give results based on accumulated administration over a certain period of time, so I hope you understand that these figures are based on such factors.

Yokoyama [Q]: I'm expecting that the amount will be quite large, but is your Company not expecting that much?

Hidaka [M]: Bigger than forecast, you mean?

Yokoyama [M]: Yes.

Hidaka [A]: Of course, this is the figure for this year, but of course we are expecting a lot from adjuvants, so of course we will expect more from next year.

Yokoyama [M]: I understand. Thank you very much.

Okuda [A]: Just to add a few words, Tecentriq received a market expansion recalculation in August last year, so the NHI price has been reduced by about 10%, I think. The sales forecast includes that.

Yokoyama [M]: Thank you very much.

Sasai [M]: Thank you very much.

This concludes today's financial results briefing for CHUGAI PHARMACEUTICAL. If you have any questions that we were unable to answer due to time constraints, please feel free to contact our Corporate Communications Department.

Thank you very much for taking time out of your busy schedule to join us today. Thank you.

[END]

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