



CHUGAI

CHUGAI PHARMACEUTICAL



A member of the Roche group

CHUGAI PHARMACEUTICAL CO., LTD.

Conference on FY2025.12 2Q Financial Results

July 24, 2025

Event Summary

[Company Name]	CHUGAI PHARMACEUTICAL CO., LTD.	
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[Time]	17:00 – 18:32 (Total: 92 minutes, Presentation: 40 minutes, Q&A: 52 minutes)	
[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	6	
	Osamu Okuda	President & CEO
	Iwaaki Taniguchi	Director, Executive Vice President & CFO
	Tsukasa Kusano	Executive Vice President, Head of Project & Lifecycle Management Unit
	Shinji Hidaka	Vice President, Head of Marketing & Sales Division
	Junichi Takano	Head of Marketing & Sales Division
[Analyst Names]*	Kazuaki Hashiguchi	Daiwa Securities
	Seiji Wakao	JPMorgan Securities
	Fumiyoshi Sakai	UBS Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Hidemaru Yamaguchi	Citigroup Global Markets
	Tony Ren	Macquarie Securities Capital

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Goldman Sachs

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

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Presentation

Miyata: Thank you very much for coming over to conference on financial results for Q2 for the year ending December 2025. I will be leading today's session. I am Miyata from Corporate Communications Department.

So today, we have the participants at the venue as well as on the Zoom. And today's agenda is shown on the screen at the venue as well as on page three of the presentation materials. Today's conference will be conducted in Japanese, but we are also providing English on Zoom webinar as a simultaneous interpretation.

We'll take your questions after all the presentations are completed. We plan on spending for about half an hour for Q&A session. So feel free to ask your questions.

We want to pass the floor over to Mr. Okuda to talk about overview of the Q2 results.

FY2025 Q2 Overview



Financial Overview

- Financial results with increased revenue and profit, driven by increase in both domestic and overseas sales
- Expecting to achieve the full year forecast, based on the steady progress in the first half of the fiscal year

Core (billions of JPY)	2024	2025	Growth (year-on-year)		2025	
	Jan - Jun actual	Jan - Jun actual			Jan - Dec forecast	Progress
Revenue	552.9	578.5	+25.6	+4.6%	1,190.0	48.6%
Domestic sales	217.2	223.3	+6.1	+2.8%	462.5	48.3%
Overseas sales	268.4	288.1	+19.7	+7.3%	555.5	51.9%
Other revenue	67.3	67.0	-0.3	-0.4%	172.0	39.0%
Operating profit	262.8	272.0	+9.2	+3.5%	570.0	47.7%
Operating margin	47.5%	47.0%	-0.5%pts	-	47.9%	-
Net income	189.5	193.5	+4.0	+2.1%	410.0	47.2%
EPS (yen)	115.15	117.57	+2.42	+2.1%	250.00	47.0%

- Domestic sales increased YoY due to the significant increase in new products and mainstay products, despite the effects of the NHI drug price revisions and the market penetration of generic drugs.
- Overseas sales increased YoY due to the significant increase in the export of Actemra to Roche.
- Revenue was ¥578.5 billion (an increase of 4.6% YoY) and core operating profit was ¥272.0 billion (an increase of 3.5% YoY), showing increased revenue and profit.

5

Okuda: I am Okuda, CEO of the Company. I would like to explain about our financial results for Q2 of 2025. Please take a look at page five of your handout. In Q2 of 2025, domestic and overseas product sales increased, resulting in increased revenue and profit. Compared to the previous year, revenue increased by 4.6%, operating profit increased by 3.5%, and net income increased by 2.1%. Given the steady progress made in H1, we expect to achieve our full year forecast. I will explain the details of revenue on next slide.

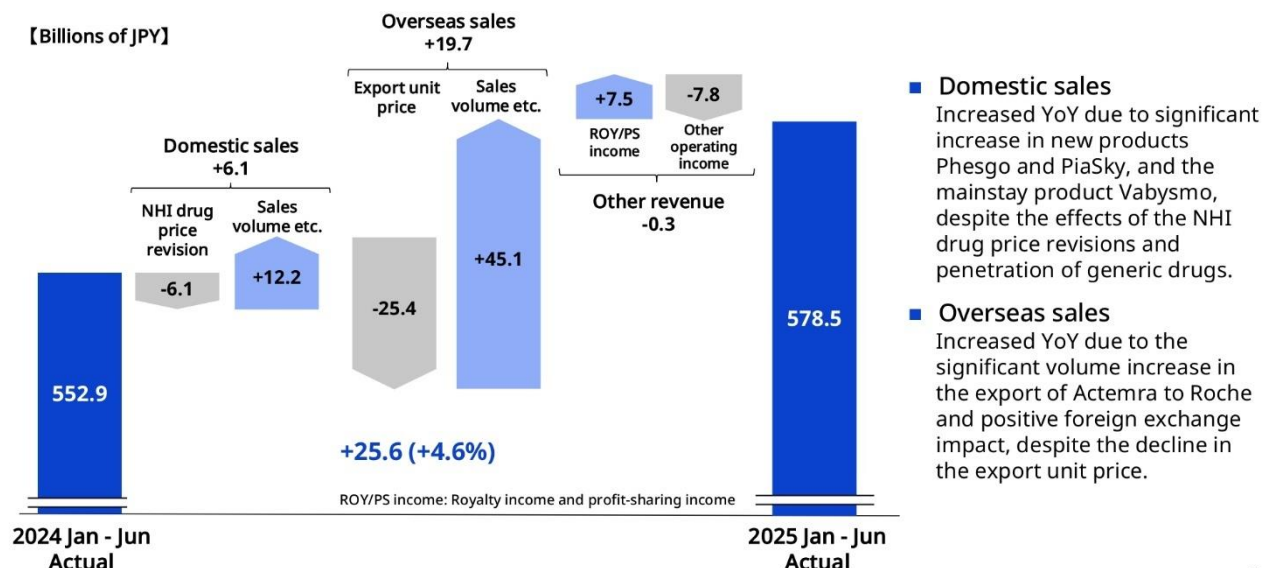
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Topline Overview



6

Compared to the same period last year, revenue increased by JPY25.6 billion, up by 4.6%. The breakdown is explained from left to right. Domestic sales were negatively impacted by NHI drug price revisions and the penetration of generics. However, sales of new products such as Phesgo, PiaSky, as well as mainstay product, Vabysmo, increased by JPY6.1 billion. Overseas sales increased by JPY19.7 billion as increases due to export volume and exchange rate and so forth far outweighed the impact of a decrease in export unit prices. In particular, exports of Actemra to Roche increased significantly.

R&D Overview

- Milestones in the first half of 2025 progressed favorably, such as the successful P3 trial of orforglipron and PoC confirmation in NXT007, which are pivotal projects for revenue contribution
- As a medium to long-term management decision focused on agile and strategic acceleration of early development, we have determined to collectively discontinue in-house development of five projects in early-stage clinical development

Letters in blue: planned in 2025

* Conducted by Eli Lilly and Company, a global licensee
 ** Conducted by Galderma, an overseas licensee
 *** Conducted by Verastem Oncology, a global licensee

Main study progress

- Started P1 for MINT91 (Solid tumors/April)
- Started P2 for GYM329 (Obesity/May)
- Started P1 for AUBE00 (Mid-size molecule) (Solid tumors/June)
- Started P3 for Hemlibra (von Willebrand disease/Additional indication/June)
- Management decision to collectively discontinue five in-house development projects (July)

Main study readout

- NXT007 (Hemophilia A/P1/2, February) : PoC confirmed
- orforglipron* (T2D/P3, April) : Achieved PE
- PiaSky (aHUS/P3)
- orforglipron* (Obesity/P3)
- GYM329 (SMA, combination with Evrysdi/P2)
- GYM329 (FSHD/P2)

Presentation in Main Medical Conference

Project	Study	Medical conference
NXT007	NXTAGE study [P1/2] (Hemophilia A)	International Society on Thrombosis and Haemostasis (ISTH 2025)
orforglipron*	ACHIEVE-1 study [P3] (T2D)	American Diabetes Association (ADA 2025)

Main regulatory filing, approval/additional indication

- Approved for NEMLUVIO*** (AD, PN/February, EU)
- Approved for AVMAPKI**** (KRAS-mutated recurrent LGSOC/May, US)
- Approved for PiaSky (PNH/May, Taiwan)
- Filed for Alecensa (ALK fusion / rearrangement gene-positive unresectable advanced or recurrent solid tumors/June, JP)
- Filing for orforglipron* (Obesity/Global)

7

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Next, I would like to explain about R&D. This slide shows the status of important R&D milestone achievements this year for in-house developed products. First, regarding orforglipron, our licensee, Eli Lilly and Company, announced the success of a global Phase III trial for type 2 diabetes in April and presented the result of that trial at the American Diabetes Association in June this year. As a result, we believe that the probability of success in development in diabetes and obesity has increased.

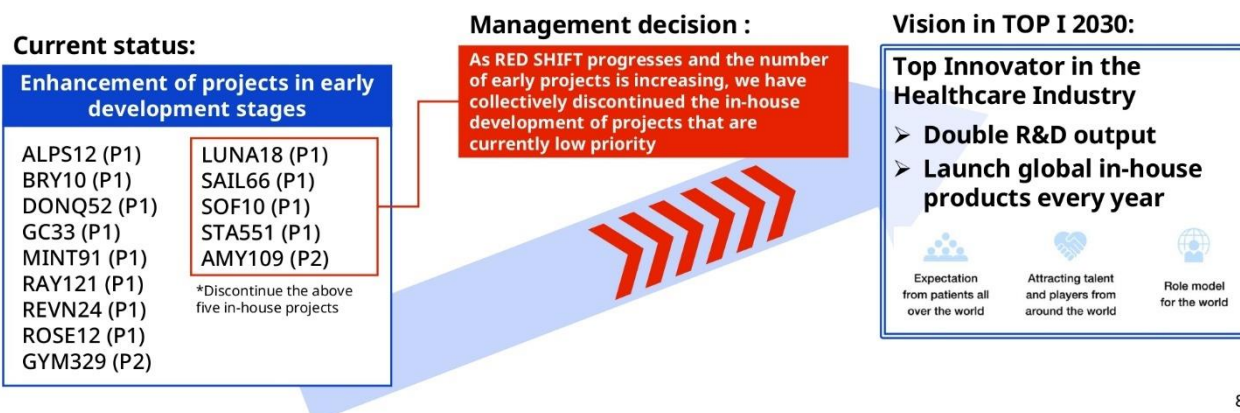
We have confirmed the PoC for NXT007. Based on this data, development is progressing with the decision to start a global Phase III trial from 2026. In addition, new in-house projects, MINT91 and mid-size molecule project, AUBE00, have begun Phase I trials. As mid- to long-term management decisions aimed at accelerating early-stage development in an agile and strategic manner, we have decided to discontinue in-house development of five projects out of our in-house pipeline that are in early stage. I will explain this in more detail in the next slide.

FY2025 Q2 Overview



Accelerating Overall Early Development Through Agile and Strategic Resource Allocation

- Since the start of TOP I 2030, early-stage development projects have been enhanced through RED SHIFT
- Based on the data obtained so far and the current portfolio situation, we have prioritized in-house projects and made a management decision to collectively discontinue the in-house development of some in-house projects. By concentrating resources on high-priority projects, we aim to maximize the success rate of achieving TOP I 2030 goals



8

Since the launch of TOP I 2030 in 2021, we have increased new projects through the RED SHIFT. As a result, in the past four years, we have enriched our early-stage projects with nine projects of in-house discovered products entering clinical trials. On the other hand, some projects were taking time to develop. As a result of prioritizing our in-house pipeline products in the early development stage, based on the data obtained to date and the overall status of our portfolio, we have decided to discontinue in-house development of five projects: LUNA18, SAIL66, SOF10, STA551 and AMY109.

This decision will enable us to focus resources on more, much higher priority projects, increasing the likelihood of achieving the goals set in TOP I 2030.

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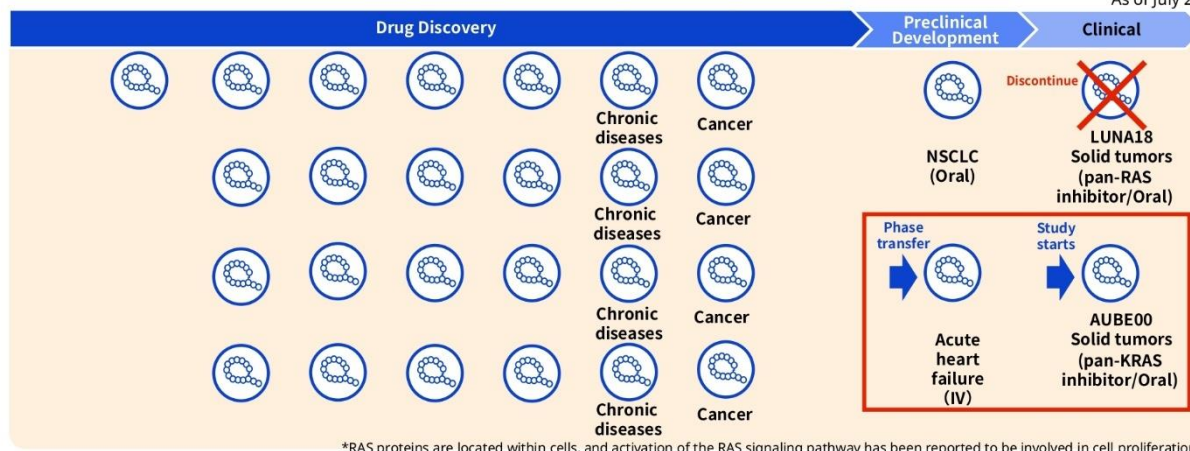
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A Robust Mid-size Molecule Portfolio

- LUNA18: Oral absorption and inhibitory activity against the RAS signaling pathway* in clinical settings have been confirmed. Meanwhile, the decision to concentrate development efforts on AUBE00 was determined based on its competitive advantage in the field of RAS inhibitors
- The research and development of mid-size molecule drugs as a whole is progressing smoothly, with new projects for indications other than cancer advancing to the preclinical development stage

As of July 24, 2025



9

Let me now cover LUNA18 and the mid-size molecule project. LUNA18 confirmed oral absorbability, an important concept for the mid-size molecule platform. Furthermore, the biomarker analysis of tumor tissues and adverse event profile suggested that LUNA18 was delivered into cells. On the other hand, concerns have risen that the pan-RAS GDP inhibitor, LUNA18, does not have a sufficient therapeutic window in clinical trials compared to competing products. According to the data accumulated from clinical trials of LUNA18 and the promising clinical trial results of competitors' pan-RAS GTP inhibitors, we have decided to shift our focus to the development of AUBE00 KRAS selective inhibitor that is likely to demonstrate a competitive advantage over LUNA18. AUBE00 is targeting solid tumors and Phase I trials began in June. Kusano will provide more details later.

In addition to AUBE00, progress is being made with the mid-size molecule portfolio as a whole, including a new project moving into the preclinical development stage for noncancer indication targeting acute heart failure. In order to meet unmet medical needs, we will continue to focus on the development of mid-size molecule drugs, which is the third modality.

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Decision to Construct a New Research Building 'UKX' at Ukima Site

■ Strengthen manufacturing process development capabilities for small, mid-size molecule drugs and biopharmaceuticals

- As high-value-added projects applying Chugai's proprietary technologies are increasing, we aim to strengthen and expand our pharmaceutical manufacturing process development capabilities to facilitate rapid entry into clinical trials and accelerate development

■ Introduction of environmentally friendly facilities

- Implementation of initiatives toward elimination of fluorocarbons and CO₂ emission reduction as part of the Mid-Term Environmental Goals 2030



[Overview of Construction Plan of UKX]

1. Total investment: 80 billion yen
2. Start of construction: May 2026
3. Completion of building: August 2028
4. Construction area: 5,047 m²
5. Total floor area: 27,136 m²

10

Finally, I would like to touch on our new investments. In order to strengthen our pharmaceutical manufacturing process development functions that apply Chugai's proprietary technologies, we have decided to build a new research building UKX at the Ukima site. The total investment amount is JPY80 billion. We'll introduce environmentally friendly equipment, such as equipment to reduce fluorocarbons and CO₂ emissions.

In order to advance the promising drug candidate substances continuously produced from drug discovery research to clinical development, it is essential to quickly establish a manufacturing method for them as pharmaceuticals. So we are confident that the construction of this new research building will further strengthen the foundation for doubling R&D output, which is the goal of TOP I 2030.

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Summary

- Financial results with increased revenue and profit, driven by increase in both domestic and overseas sales. Expecting to achieve the full year forecast, based on the steady progress in the first half of the fiscal year
- Milestones in the first half of 2025 progressed favorably, such as the successful P3 trial of orforglipron and PoC confirmation in NXT007, which are pivotal projects for revenue contribution
- As a medium to long-term management decision focused on agile and strategic acceleration of early development, we have determined to collectively discontinue in-house development of five projects currently in early clinical development stages
- LUNA18: Oral absorption and inhibitory activity against the RAS signaling pathway in clinical settings have been confirmed. Meanwhile, the decision to concentrate development efforts on AUBE00 was determined based on its competitive advantage in the field of RAS inhibitors. The research and development of mid-size molecule drugs as a whole is progressing smoothly, with new projects for indications other than cancer advancing to the preclinical development stage

11

This is a summary of my explanation, this is all for me.

Miyata: Next, I would like to invite Kusano to explain about the status of the development pipeline. He will pause for a little while at the beginning, so please take this opportunity to capture the screen.

Overview of Development Pipeline

Q2 Topics (1/2)

As of July 24, 2025

Launched	Evrysdi	Addition of dosage form (tablet)	May 2025 (Japan)
Approved	AVMAPKI™*	Adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer who have received prior systemic therapy (combination with FAK inhibitor FAKZYNJA™ (defactinib tablet))	May 2025 (U.S.)
	Elevidys	Duchenne muscular dystrophy (ambulatory) (gene therapy product)	May 2025 (Japan)
	PiaSky	Paroxysmal nocturnal hemoglobinuria	May 2025 (Taiwan)
	Vabysmo	Angioid streaks (additional indication)	May 2025 (Japan)
Filed	Lunsumio + Polivy	Relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma (additional indication)	May 2025 (Japan)
	Tecentriq	Unresectable thymic carcinoma (additional indication)	May 2025 (Japan)
	Alecensa	ALK fusion / rearrangement gene-positive unresectable advanced or recurrent solid tumors (additional indication)	June 2025 (Japan)
Initiation of Study	GYM329	Obesity (Phase II)	May 2025
	Vabysmo	Non-proliferative diabetic retinopathy (domestic Phase III)	May 2025
	Hemlibra	von Willebrand disease (Phase III)	June 2025
	AUBE00	Solid tumors (pan-KRAS inhibitor / mid-size molecule / oral) (Phase I)	June 2025
	RG6114/inavolisib	PIK3CA-mutated breast cancer (domestic Phase I/II)	July 2025

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) *Conducted by Verastem Oncology, a global licensee

13

Kusano: I am the Head of Project & Lifecycle Management Unit. I would like to explain about the status of the development pipeline. Please refer to page 13 of your handout. These are Q2 topics. In terms of the launch and approval, except for the launch of the Evrysdi tablet, everything else has already been announced.

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In terms of the approval, we have two in-house developed products and two Roche products. As for the in-house developed products, we have AVMAPKI, which has been licensed out to Verastem Oncology. This is targeting the KRAS mutation positive recurrent low-grade serous ovarian cancer, and this has been approved under US accelerated approval system.

For Roche product, we have Elevidys, which is a gene therapy product for rare intractable Duchenne muscular dystrophy, and this is now approved for the ambulatory individuals whose age is between three to seven. Additionally, following safety information regarding two fatal cases in non-ambulatory patients treated with Elevidys, and one fatal case in a study of a different investigational product from Sarepta using a similar vector, the FDA recommended that Sarepta pause the shipment of Elevidys. In Japan, ensuring patient safety is our highest priority. Therefore, we will suspend the shipment of Elevidys until the evaluation of the safety information is complete. We will continue to share information and consult with the regulatory authorities.

Now Vabysmo has been approved in Japan for the first time for the indication of angiod streaks.

In terms of the filing, we have one in-house developed product and the two Roche products as stated in the list. For Lunsumio, we have filed for an additional indication in combination with Polivy for relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma and everything else has already been announced.

In terms of the initiation of study, we have three in-house developed products and two Roche products. For in-house developed products, we have GYM329, targeting at obesity. In the combination therapy with tirzepatide, Phase II study of GYM329 has been initiated. Hemlibra has started Phase III study, targeting at von Willebrand disease. Our mid-size molecule AUBE00, which is our in-house developed product, has initiated Phase I study targeting at solid cancer. The details will be laid out later.

For Roche product, Vabysmo has started domestic Phase III study targeting at non-proliferative diabetic retinopathy. And inavolisib started domestic Phase I/II study targeting at PIK3CA-mutated breast cancer.

Overview of Development Pipeline

Q2 Topics (2/2)



As of July 24, 2025

Readout	Tecentriq + Avastin	Phase III TALENTACE study (unresectable hepatocellular carcinoma) : Met one of the primary endpoints (TACE PFS)	May 2025
	AVMAPKI^{TM*}	Phase II RAMP 205 study (pancreatic ductal adenocarcinoma): Positive results for safety and efficacy	May 2025
Conclusion of Agreement	Joint Research and License Agreement	Development of novel therapies for age-related diseases with Gero	July 2025
Removed from Pipeline	tiragolumab	Esophageal cancer (SKYSCRAPER-07 study): Discontinuation of development	
	Five early-stage in-house products	Discontinuation of in-house development: LUNA18, SAIL66, SOF10, STA551, AMY109	
Medical Conference	AVMAPKI^{TM*}	Phase II RAMP 205 study (pancreatic ductal adenocarcinoma (1st-line treatment), in combination with standard of care)	June 2025
	NEMLUVIO^{***}	Phase III ARCADIA long-term extension study (atopic dermatitis, 2-year data)	June 2025
	NEMLUVIO^{***}	Phase III OLYMPIA long-term extension study (prurigo nodularis, 2-year data)	June 2025
	NXT007	Phase I/II NXTAGE study (hemophilia A)	June 2025
	orforglipron^{***}	Phase III ACHIEVE-1 study (type 2 diabetes)	June 2025
	Lunsumio + Polivy	Phase III SUNMO study (relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma)	June 2025
Open Innovation	Investment by Chugai Venture Fund, LLC****	- Stylus Medicine - Two U.S.-based companies	April 2025 May and July 2025

Orange: in-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan) TACE: transarterial chemoembolization, PFS: progression-free survival
 *Conducted by Verastem Oncology, a global licensee **Conducted by Galderma, an overseas licensee *** Conducted by Eli Lilly and Company, a global licensee
 ****A cumulative total of 6 companies

14

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Next is readouts. AVMAPKI has a Phase II study confirming the effective add-on treatment to SOC for the first-line treatment for pancreatic ductal adenocarcinoma. In this Phase II study, we have seen ORR of 83% and confirmed efficacy signal. And next year, 2026, Phase III study will be initiated.

In terms of conclusion of agreement, we work with Gero, who has unique AI-based target discovery platform for age-related diseases. We have concluded the joint research and licensing agreement. We will be using our own antibody engineering technology to discover new antibody drug candidate for age-related disease.

Now removal from pipeline. As our CEO Okuda mentioned, with regard to the five early-stage in-house products, based on the already generated data and the status of portfolio, we have decided to discontinue in-house development. With regard to Roche product for tiragolumab, we have ongoing Phase III study targeting at esophageal cancer as a combination therapy with Tecentriq. Based on the study results so far, we have discontinued the development.

For medical conference, we have five in-house products and one Roche product. On top of the AVMAPKI, we have NEMLUVIO, which has been licensed out to Galderma. And this, we have a long-term extension study for NEMLUVIO, targeting at atopic dermatitis and prurigo nodularis, and showed positive two-year data.

Orforglipron, we are targeting at adult type 2 diabetes whose glucose control is insufficient only by diet and exercise. And we have conducted a Phase III ACHIEVE-1 study comparing against placebo in terms of efficacy and safety, and a positive result was presented in ADA 2025. Result is published in the New England Journal of Medicine.

We've submitted filing in May for Lunsumio, and in the combination therapy with Polivy targeting at relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, we have made oral presentation in international lymphoma congress. NXT007 will be explained later in details.

With regard to the open innovation last year in Boston, Chugai Venture Fund initiated full-fledged operation. In the past three months, we have made three additional investments, so since the foundation, we have completed investment into six companies so far.

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2025: Key R&D Milestones

As of July 24, 2025

	Product	Indication / Study name	Progress
Projects to be Approved	Elevydis	Duchenne muscular dystrophy (ambulatory)	Approved
	Vabysmo	angioid streaks	Approved
P3/Pivotal Readouts	PiaSky	COMMUTE-a study*: atypical hemolytic uremic syndrome (aHUS)	Achieved PE
	Lunsumio + Polivy	SUNMO study: r/r aggressive B-cell non-Hodgkin's lymphoma	
	Lunsumio	CELESTIMO study: follicular lymphoma (2nd line)	
	giredestrant	perseVERA study: HR positive breast cancer (1st line)	PoC confirmed / Decision to proceed to Phase III**
	vamikibart	evERA study: HR positive breast cancer (1st line to 3rd line)	
	vamikibart	SANDCAT study: noninfectious uveitic macular edema (UME)	
P2 Readouts	GAZYVA	INShore study: pediatric nephrotic syndrome	Decision to proceed to Phase III
	GYM329 + Evrysdi	MANATEE study: spinal muscular atrophy (SMA)	
	GYM329	MANOEUVRE study: facioscapulohumeral muscular dystrophy (FSHD)	
P1/2 Readout	NXT007	hemophilia A	Study initiated
	trontinemab	Brainshuttle™ AD study: Alzheimer's disease	
Initiation of study	GYM329	obesity (Phase II study)	

Orange: In-house projects (development in global) Blue: In-licensed from Roche (development and distribution in Japan)

*Adult/Adolescent patients, **Three phase 3 studies scheduled to initiate in 2026 (vs. FVIII products, vs. Hemlibra, and pediatric patients)

r/r: relapsed or refractory, PE: primary endpoint, HR: hormone receptor, PoC: Proof of Concept

Underlined: Changes since April 24, 2025

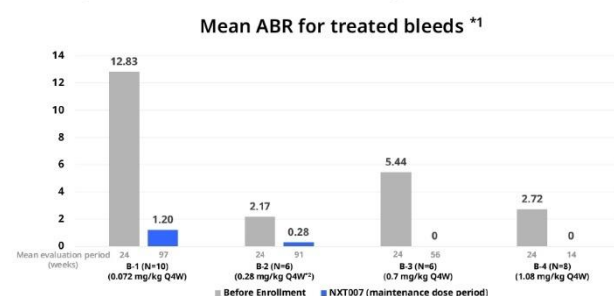
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This is a list of major R&D events in 2025. The underlined parts are the changes from the previous earnings call. As I have explained earlier, with regard to Elevydis, Vabysmo, we have been granted approval. In terms of the initiation of the study, as I mentioned earlier, GYM329 has started a Phase II study for obesity.

NXT007: P1/2 Study for Severe Hemophilia A Without Inhibitors

- First clinical data of NXT007 in people with hemophilia A. Hemlibra-naïve people enrolled
- In the high dose cohorts (B-3, B-4), plasma concentrations reached the predicted normal range of FVIII-equivalent activity, with no treated bleeds observed. NXT007 was well tolerated, based on data up to date
- Three Phase III studies to be initiated in 2026, including H2H with Hemlibra. In addition to efficacy, safety including ADA (anti drug antibody) will be further evaluated

Efficacy (ABR : Annualized Bleeding Rate)



*1 Bleeding information before study was collected from 24 weeks before the study in a retrospective manner.

ABR was calculated by annualizing the number of bleeding episodes observed during the evaluation period

*2 Dosing regimen was switched from 0.14 mg/kg Q2W to 0.28 mg/kg Q4W to reflect study protocol amendment

Safety

- No dose-dependent increases in AEs were observed. No serious adverse events related to NXT007, or thromboembolic events were observed
- ADA was observed in 22 out of 30 patients; the number of ADA positive patients at the final observation before the data cutoff was 10. ADA impacting PK was observed in 2 patients. No ADA cross-reacting with emicizumab was observed

	B-1 (N=10)	B-2 (N=6)	B-3 (N=6)	B-4 (N=8)	Total (N=30)
ADA post-baseline incidence *3	7	6	4	5	22
ADA impacting PK	1	0	1	0	2
ADA cross-reacting with emicizumab	0	0	0	0	0

*3 No patients were ADA positive at baseline.

16

Now this is the result of Phase I/II study for NXT007. NXT007 has been under development as a next-gen treatment for hemophilia A. For the first time, we have presented the efficacy and safety data targeting people with hemophilia A in ISTH in June. First of all, efficacy. The graph to your left shows ABR, annualized

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bleeding rate, targeting people with hemophilia A who have not been treated with Hemlibra . In across all cohorts prior to the administration, ABR has been dropped.

In high-dose cohort B-3, B-4, the plasma concentrations reached the predicted normal range of FVIII-equivalent activity with no treated bleeds observed.

Next is safety. The tolerability of NXT007 is good and no serious adverse events related to NXT007, or thromboembolic events were observed.

Anti-drug antibody, ADA, was observed in 22 out of 30 patients. However, most of ADAs did not impact PK. The number of ADA-positive patients at the final observation before the data cutoff was reduced down to 10. As it shows, half of the ADA was transient. The ADA was observed in two patients in a way that affected the PK. However, ADA impacting PK, no ADA cross-reacting with hemophilia was observed. In three Phase III studies, which are expected to start in 2026, we are going to evaluate efficacy and ADA-related safety.

Overview of Development Pipeline

AUBE00 (Pan-KRAS Inhibitor)



- Second clinical-stage project applying mid-size molecule technology. Phase 1 trial initiated for solid tumors.
- Expecting superior efficacy compared to the pan-RAS inhibitor LUNA18, resulting from a wide therapeutic window based on KRAS-selective inhibitory activity.

■ Characteristics of AUBE00

- Expected to deliver anti-tumor effects and favorable safety profiles through selective inhibitory activity against KRAS-GDP
- Anticipated to target a wide range of KRAS genetic mutations. No such drugs have been approved yet, representing high unmet medical needs

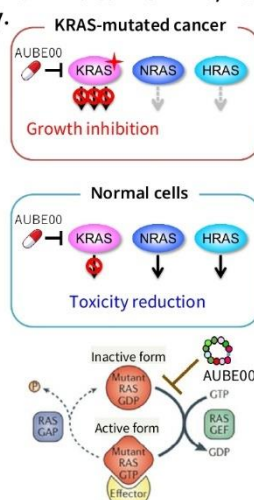
■ What is KRAS ?

- One of the most frequently mutated oncogenes that contribute to tumor development and progression

■ Characteristics of mid-sized molecule technology

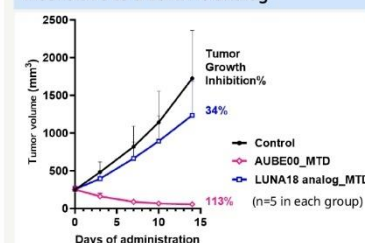
- Cyclic peptides containing non-natural amino acids
- Expected to improve binding affinity by interacting with broad interfaces of target proteins
- Possess high membrane permeability and metabolic stability, making oral administration feasible

GTP: guanosine triphosphate, GDP: guanosine diphosphate, GAP: GTPase activating protein, GEF: guanine nucleotide exchange factor



Anti-tumor effects in a xenograft mouse model inoculated with a human KRAS-mutated non-small cell lung cancer (Source: Internal data)

AUBE00 demonstrated robust tumor regression in a xenograft model that was insensitive to a LUNA18 analog



Tumor growth inhibition (%): This represents the tumor inhibition effect against tumor growth in the control group. 100% indicates tumor growth is completely stopped, while values exceeding 100% indicate tumor shrinkage

MTD (Maximal tolerable dose)

Reference : Nat Rev Drug Discov. 2014;13:828-51, modified

17

Next, let me introduce AUBE00, a pan-KRAS inhibitor discovered in-house. This is our second mid-size molecule project that has advanced to clinical trials. As explained by Okuda earlier, we have decided to shift our focus from the pan-RAS inhibitor, LUNA18 to AUBE00 for cancers involving the RAS gene. Let me elaborate the background to this decision.

There are three types of RAS genes, KRAS, NRAS and HRAS. KRAS is one of the most frequently mutated oncogenes with genetic abnormalities. KRAS-mutated cancers are highly dependent on KRAS with active mutations to survive and grow. So inhibiting KRAS is expected to have an antitumor effect, whereas normal cells survive and proliferate using signals not only from KRAS, but also from NRAS and HRAS. Therefore, AUBE00 was designed to selectively target KRAS and a wide range of KRAS genetic mutations.

As a result, even if AUBE inhibits KRAS, NRAS and HRAS will act instead, minimizing the impact on normal cells. As a result, AUBE is expected to have a broad therapeutic window and to have a higher efficacy than LUNA18, which inhibits all RAS, including NRAS and HRAS.

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The non-clinical data on the right shows that in a xenograft model of non-small cell lung cancer, where a LUNA analog is not sufficiently effective, AUBE00 induced tumor regression, demonstrating strong efficacy. As a result, we'll continue to work to deliver innovative medicines to patients as soon as possible in order to overcome KRAS-mutated cancers, which have high unmet medical needs.

Overview of Development Pipeline



ROSE12: Anti-CTLA-4 Switch Antibody

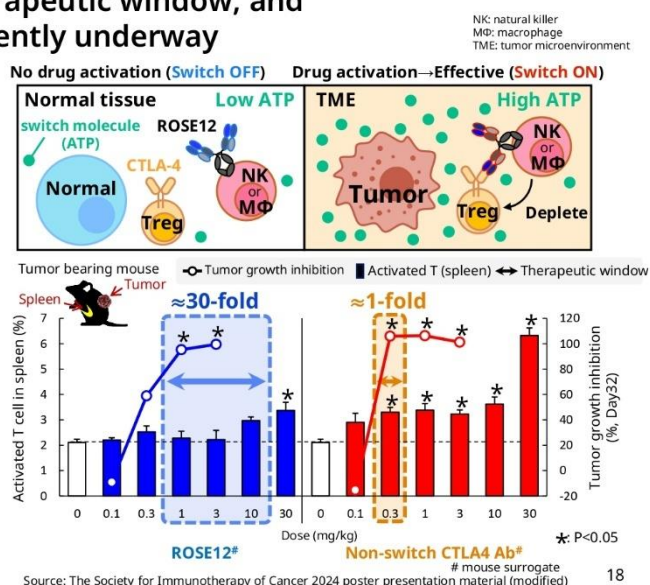
- ROSE12 is expected to have a wide therapeutic window, and its phase 1 trial for solid tumors is currently underway

ROSE12:

- Selectively depletes immunosuppressive regulatory T cells (Tregs) in tumors and increases activated T cells, **demonstrating anti-tumor effects while reducing systemic side effects**
- Shows anti-tumor effects without increasing activated T cells in normal tissues in non-clinical studies
- A phase 1 clinical trial for patients with locally advanced or metastatic solid tumors as monotherapy and in combination with Tecentriq is ongoing in Japan and the U.S. (NCT05907980)

CTLA-4:

- Membrane protein highly expressed on Treg which has strong immunosuppressive function
- ROSE12 binds to Treg via CTLA-4 only in the presence of the switch molecule (extracellular ATP)



Next is our in-house developed product, ROSE12. Since its mechanism of action is now available, we would like to take this opportunity to explain this. ROSE12 is an anti-CTLA-4 antibody that uses our proprietary switch antibody technology. CTLA-4 is one of the membrane proteins highly expressed in highly immunosuppressive regulatory T cells. It is known as an important therapeutic target in cancer, but controlling systemic side effects is a challenge when using drugs that target this molecule. ROSE12 is expected to exert an antitumor effect, while suppressing systemic side effects by acting selectively on tumors using switch technology.

In non-clinical trials using mice, the effective and safe doses of non-switched anti-CTLA-4 antibodies were similar, whereas the effective and safe doses of switched antibodies were approximately 30-fold higher, demonstrating a wide therapeutic safety margin. In the ongoing Phase I study, we are evaluating ROSE12 as a monotherapy and in combination with Tecentriq, and we hope that the switch antibody technology will provide high efficacy while providing a favorable safety profile.

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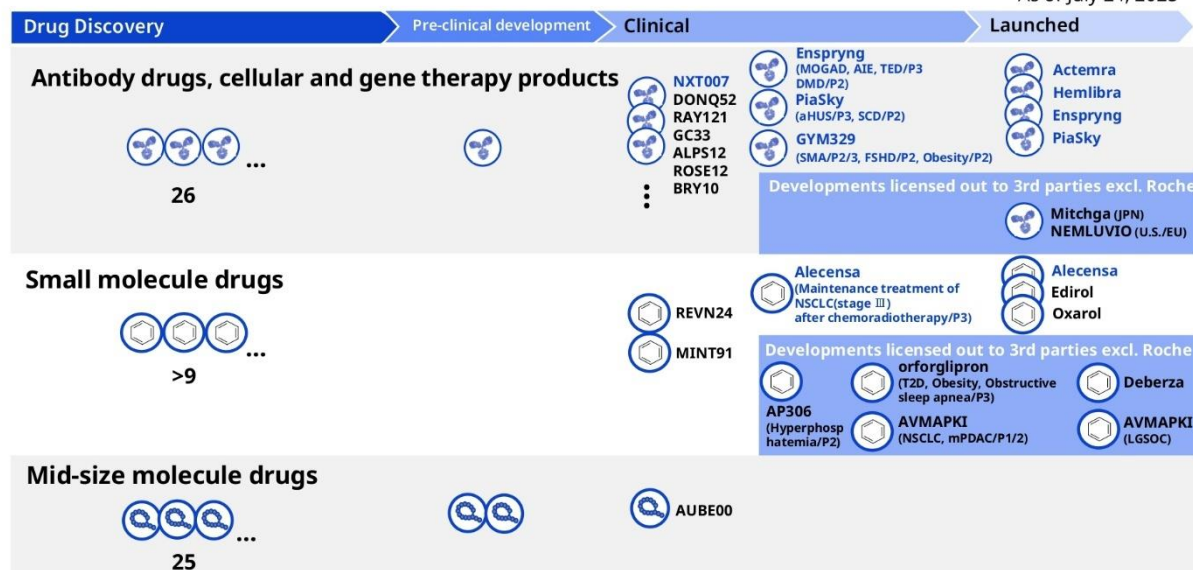
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Portfolio of Each Modality

As of July 24, 2025



Blue: Joint development with Roche 19

In light of the collective project cancellation, we would like to present the status of our portfolio for each modality. We continue to have a wealth of in-house developed projects. In particular, in mid-size molecule drugs, which we are focusing on as our third pillar, 2 projects are in a preclinical development stage and another 25 projects are in the drug discovery stage. We recognize that progress is proceeding smoothly.

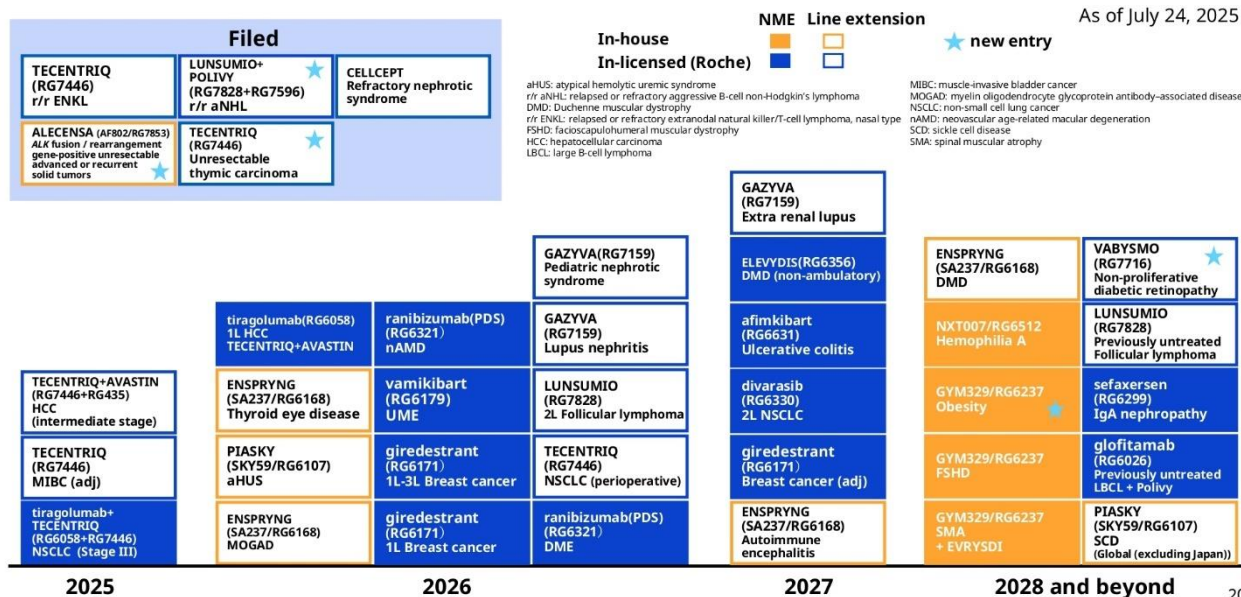
As reference materials, we have attached slides at the back of this presentation that provide detailed information on small molecule drugs, mid-size molecule drugs, antibody drugs, and cell and gene drugs, so please review them as well.

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Projected Submissions (Phase II & Later Programs and Products)



20

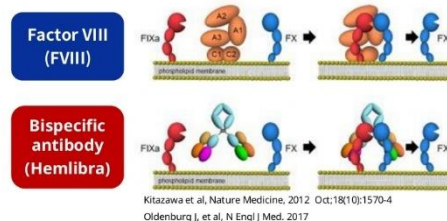
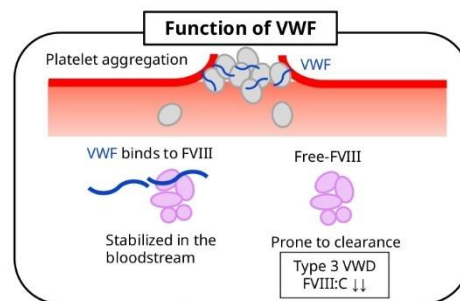
Finally, here's our projected submissions. Projects with light blue stars are newly added projects.

The following slides are attached as reference materials.

Advance Hemlibra into Global PhIII Development for von Willebrand Disease (VWD)

■ Hemlibra is expected to prevent bleeds for people with Type 3 VWD due to its mode of action

- von Willebrand factor (VWF) is a plasma protein that mediates platelet adhesion and aggregation at sites of vascular injury and also binds and stabilizes the blood clotting factor VIII (FVIII) in the circulation
- VWD is an inherited bleeding disorder caused by quantitative deficiency, dysfunction, or absence of VWF (Type 1, 2, and 3 respectively), characterized mainly by mucosa-associated bleeding (e.g. nose bleeds, oral-cavity bleeds, easy bruising) and heavy menstrual periods
- FVIII mimetic function of Hemlibra is expected to prevent the bleeds for people with Type 3 VWD, who can experience bleeding in joints and muscle due to reduction in FVIII activity caused by VWF absence.
 - ✓ Current replacement therapy with VWF has several issues: i.v. infusion, frequent injection due to short half life, development of alloantibody



23

The appendix explains von Willebrand for which Hemlibra has now begun its Phase III trial, so please review them as needed. This concludes my presentation.

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P/L Jan – Jun (Year on Year)

(Billions of JPY)	2024	2025	Growth	
Revenue	552.9	578.5	+ 25.6	+ 4.6%
Sales	485.5	511.4	+ 25.9	+ 5.3%
Domestic	217.2	223.3	+ 6.1	+ 2.8%
Overseas	268.4	288.1	+ 19.7	+ 7.3%
Other revenue	67.3	67.0	- 0.3	- 0.4%
Cost of sales	-160.2	-175.2	- 15.0	+ 9.4%
(cost to sales ratio)	33.0%	34.3%	+1.3%p	-
Research and development	-84.0	-86.3	- 2.3	+ 2.7%
Selling, general and administration	-46.6	-45.4	+ 1.2	- 2.6%
Other operating income (expense)	0.8	0.4	- 0.4	- 50.0%
Operating profit	262.8	272.0	+ 9.2	+ 3.5%
(operating margin)	47.5%	47.0%	-0.5%p	-
Financial account balance	0.5	-1.5	- 2.0	-
Income taxes	-73.8	-77.0	- 3.2	+ 4.3%
Net income	189.5	193.5	+ 4.0	+ 2.1%
EPS (JPY)	115.15	117.57	+2.42	+ 2.1%

Domestic sales

Increase due to significant growth of new products and mainstay products, despite decrease due to the NHI drug price revisions and the market penetration of generic drugs

Overseas sales

Increase due to significant growth of Actemra

Other revenue

Decrease in the one-time income, despite increase in the income related to Hemlibra

Cost of sales

Increase in cost to sales ratio due to a change in product mix, etc.

Research and development expenses

Increase due to investments in research and early development, and progress of development projects, etc.

Selling, general and administration expenses

Decrease in various expenses, etc.

32

Taniguchi: I am Taniguchi, CFO of the Company. I would like to explain about the consolidated result for Q2 of 2025. First of all, the Q2 2025 revenue was JPY578.5 billion, up by 4.6% or JPY25.6 billion. OP was JPY272 billion, up by JPY 9.2 billion or 3.5%.

Let me explain about the breakdown of revenue. Now out of revenue, sales was JPY511.4 billion, which was up by JPY25.9 billion or 5.3%. If we look at sales by region, domestic sales was JPY223.3 billion, up by 2.8% or JPY6.1 billion. The strong performance of new products and mainstay products outweighed the negative impact of the NHI drug price revision and penetration of generics.

Overseas was JPY288.1 billion, up by 7.3%, or JPY19.7 billion. If we look at Q2 alone, Actemra export was extremely strong.

And other revenue was JPY67 billion, almost flat to the previous year. Although we have seen an increase in income related to Hemlibra, but milestone payments, one-time income has dropped and that's the reason why other revenue stayed flat to the previous year.

Now moving on to expense. Cost of sales was JPY175.2 billion, up by 9.4% or JPY15 billion. The sales increased and the cost of sales also increased as a result. The cost to sales ratio compared to the previous year went up by 1.3 points, and now it has become 34.3%. The background is Actemra composition, which has relatively higher cost has increased in Q2.

SG&A has been impacted by the inflation and the personnel cost increase, but we've increased the operational efficiency and it has come down by JPY1.2 billion from the previous year. R&D cost reflected the progress of the early development projects and drug discovery researches and went up by JPY2.3 billion from the previous year. Other operating income was down by JPY400 million YoY. As a result, Core OP was JPY272 billion, up by JPY9.2 billion. OP margin was 47%. Net income was JPY193.5 billion, up by 2.1% or JPY4 billion.

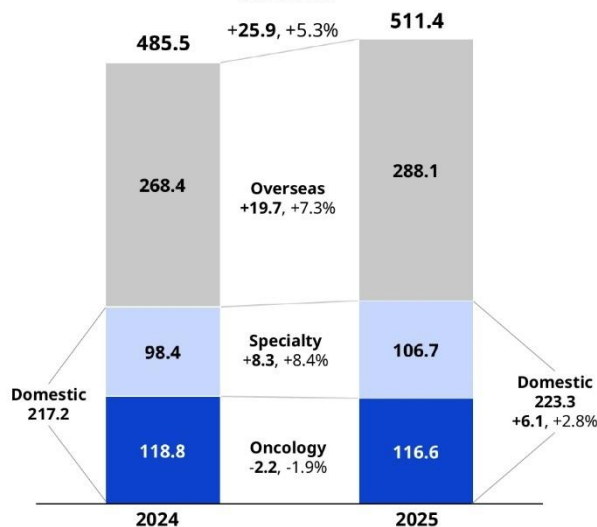
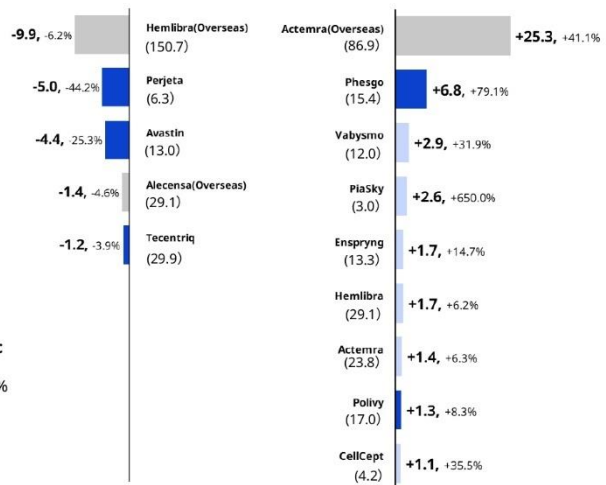
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Sales Jan – Jun (Year on Year)

(Billions of JPY)

Sales by Disease Area,
Year on YearSales by Product,
Year on Year
 (): Actual sales in FY2025
 %: Year-on-year percentage change


33

Next, this is the sales by product YoY. First, domestic oncology. It was JPY116.6 billion, down by JPY2.2 billion or 1.9% from the previous year. Avastin was negatively impacted by the penetration of generics. However, new product Phesgo sales outweighed the decline in Perjeta. Now specialty was JPY106.7 billion, up by JPY8.3 billion or up by 8.4%. We were impacted by the NHI drug price revision in general. However, our mainstay products such as Hemlibra, Actemra and Enspryng, Vabysmo, and new product, PiaSky have grown the sales.

Now overseas sales. As I mentioned earlier, Actemra increased, and we were able to increase overseas sales to JPY288.1 billion, up by 7.3% or JPY19.7 billion.

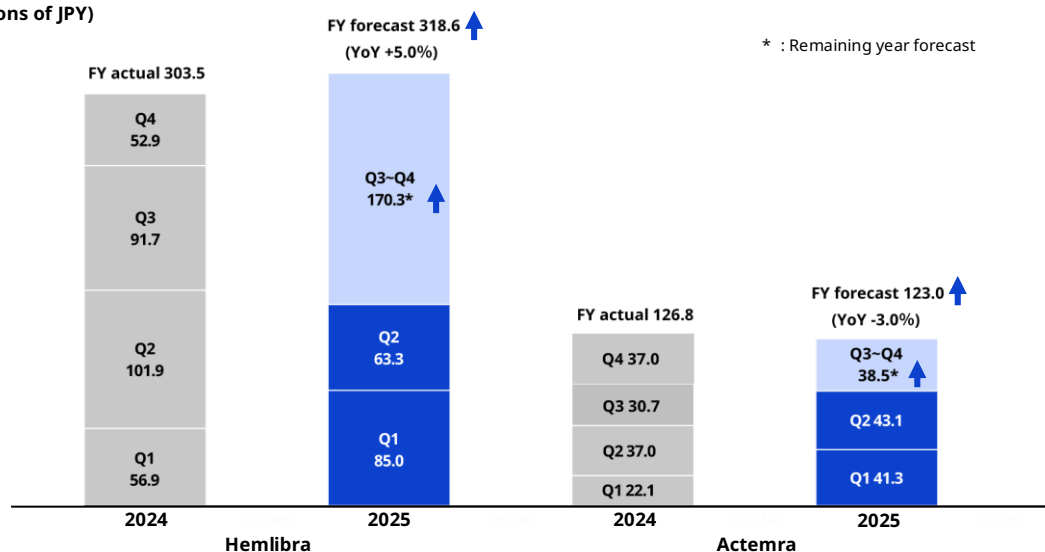
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Export of Hemlibra and Actemra to Roche

(Billions of JPY)



34

This page shows the forecast of our mainstay product, which is Hemlibra and Actemra. This is the full year forecast for those two products.

Now Hemlibra, in Q2, the revenue of approximately JPY38 billion, which was scheduled to be recorded or recognized in late June was delayed to July, due to a delay in delivery procedures. This happened in the past, but we've had this in Q2.

Now Hemlibra global sales has been growing steadily and based on the current shipment schedule, we are expecting to go above the initially forecasted revenue of JPY318.6 billion by more than JPY10 billion.

For Actemra, biosimilar penetration is delayed and based on the current shipment trend and based on the strong inventory needs, we believe on a full year basis, we can overshoot our initial forecast of JPY123 billion by more than JPY10 billion.

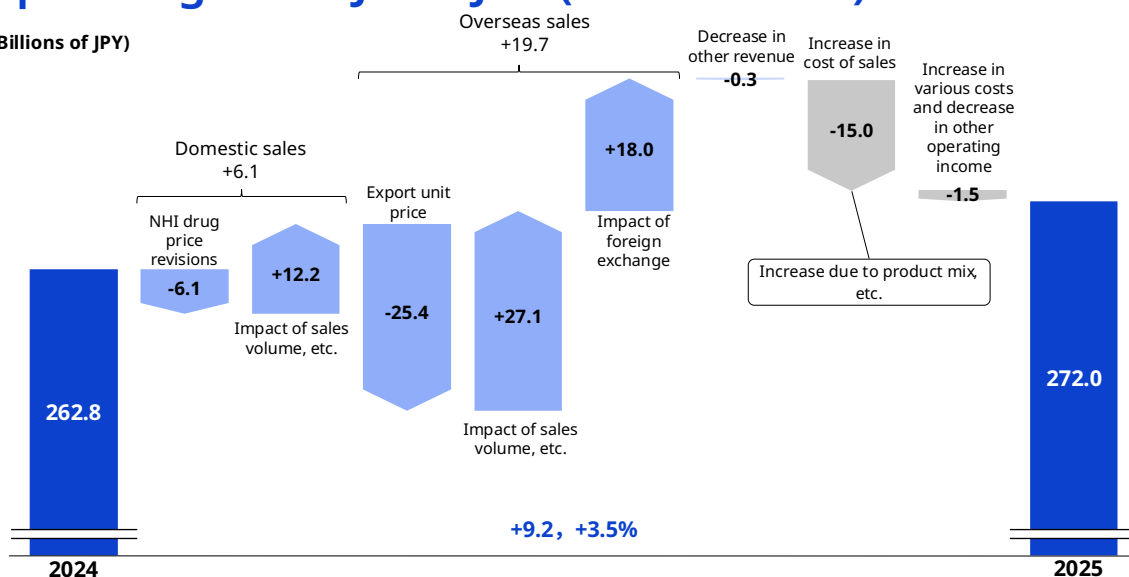
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Operating Profit Jan – Jun (Year on Year)

(Billions of JPY)



35

Next page shows changes in OP. Last year was JPY262.8 billion and there was an increase by JPY9.2 billion this year. Now domestic sales volume outweighed the negative impact of NHI drug price revision, and resulted in an increase of JPY6.1 billion in OP.

And as for overseas sales, export unit price has come down. Hemlibra sales is growing, particularly in emerging market. But volume is actually growing more than that. We also have positive impact from FX, resulting in JPY19.7 billion increase in OP.

A slight negative impact of JPY 0.3 billion, in other revenue.

Sales itself is growing. So cost of sales is also growing by JPY15 billion.

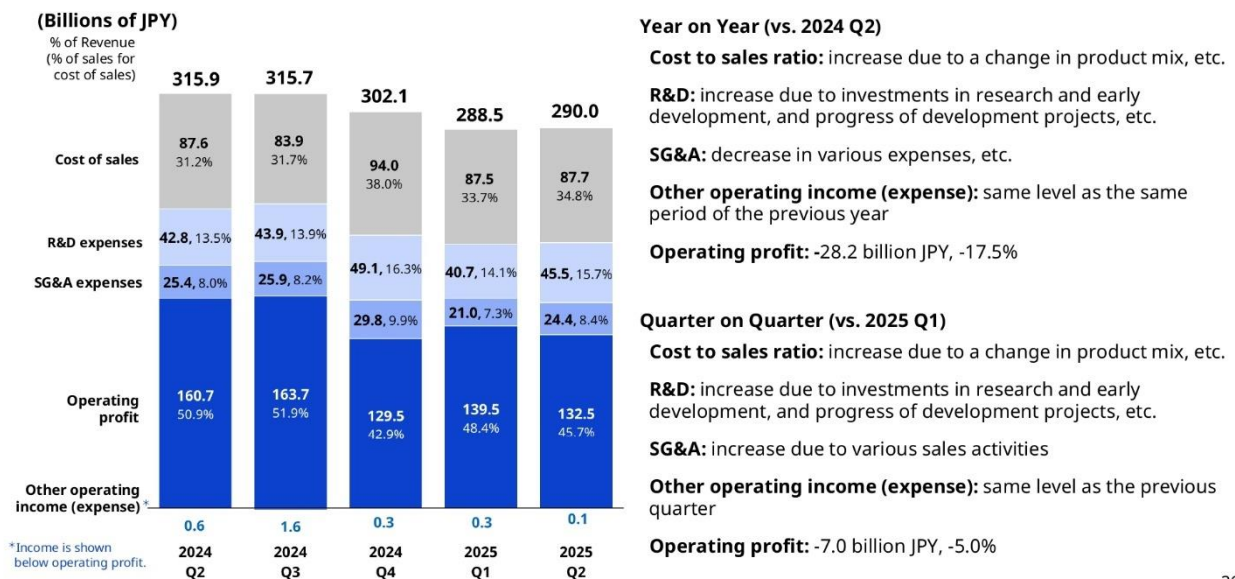
So total, OP increased by JPY9.2 billion from the previous year.

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Structure of Costs and Profit by Quarter



36

Now this is the structure of cost and profit by quarter. So these are the quarterly numbers.

There tend to be quarterly fluctuations as a result of delayed revenue recognition due to the timing of export. If we compare Q2 this year and last year Q2, last year Q2, we had a strong sales of Hemlibra. So, In terms of comparison on a second quarter basis, OP has decreased for this second quarter.

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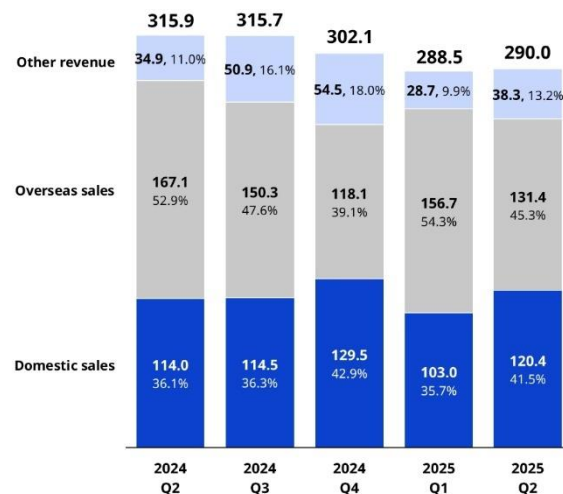
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Structure of Revenue by Quarter

(Billions of JPY)

% of Revenue



Year on Year (vs. 2024 Q2)

Domestic sales: increase due to growth of new products and mainstay products

Overseas sales: decrease due to the timing of shipment of Hemlibra

Other revenue: increase mainly in the royalty income of Hemlibra

Quarter on Quarter (vs. 2025 Q1)

Domestic sales: increase due to growth of new products and mainstay products

Overseas sales: decrease due to the timing of shipment of Hemlibra

Other revenue: increase mainly in the royalty income of Hemlibra

37

This page shows the structure of revenue by quarter.

Looking at the domestic, we saw the increase by JPY6.4 billion YoY, but as I mentioned earlier, because of the impact of booking timing for the export, we have confirmed the drop in overseas sales here.

P/L Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2024
	2025 Jan - Jun	2025 Jan - Dec	Progress	Progress*
Revenue	578.5	1,190.0	48.6%	47.2%
Sales	511.4	1,018.0	50.2%	48.7%
Domestic	223.3	462.5	48.3%	47.1%
Overseas	288.1	555.5	51.9%	50.0%
Other revenue	67.0	172.0	39.0%	39.0%
Cost of sales	- 175.2	- 341.0	51.4%	47.4%
(cost to sales ratio)	34.3%	33.5%	-	-
Research and development	- 86.3	- 178.0	48.5%	47.5%
Selling, general and administration	- 45.4	- 101.0	45.0%	45.6%
Other operating income (expense)	0.4	-	-	29.6%
Operating profit	272.0	570.0	47.7%	47.3%
(operating margin)	47.0%	47.9%	-	-
Net Income	193.5	410.0	47.2%	47.7%
EPS (JPY)	117.57	250.00	47.0%	47.7%

* Jan - Jun 2024 progress versus Jan - Dec 2024 actual

Domestic sales

Steady progress in mainstay products and new products

Overseas sales

Steady progress in Actemra exports to Roche, despite a partial shift in the shipment timing of Hemlibra from June to July

Other revenue

Mostly in line with the forecast

Cost of sales

Cost to sales ratio from January to June was mostly in line with the forecast

Research and development

Mostly in line with the forecast

Selling, general and administration expenses

Mostly in line with the forecast

38

This slide, as of Q2 results comparing to the forecast number announced at the beginning of the year. So we are showing the progress against the forecast here.

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Comparing to the progress rate as of last year, revenue, expenses, and operating profit are showing better progress. So in terms of progress, I think we are having pretty good progress so far.

FY2025 Q2 Consolidated Financial Overview (Core)



Sales Jan – Jun (vs. Forecast)

(Billions of JPY)	Actual	Forecast		2024
	2025 Jan - Jun	2025 Jan - Dec	Progress	Progress *
Sales	511.4	1,018.0	50.2%	48.7%
Domestic	223.3	462.5	48.3%	47.1%
Oncology	116.6	239.2	48.7%	48.0%
Tecentriq	29.9	62.0	48.2%	47.6%
Polivy	17.0	35.8	47.5%	46.0%
Alecensa	15.8	34.0	46.5%	48.1%
Phesgo	15.4	31.6	48.7%	36.6%
Avastin	13.0	25.5	51.0%	51.5%
Kadcyla	7.8	16.6	47.0%	47.0%
Perjeta	6.3	11.9	52.9%	56.5%
Lunsumio	1.0	3.7	27.0%	-
Herceptin	0.7	1.4	50.0%	58.3%
Foundation Medicine	3.9	7.1	54.9%	47.4%
Other	6.0	9.6	62.5%	53.4%

(Billions of JPY)	Actual	Forecast		2024
	2025 Jan - Jun	2025 Jan - Dec	Progress	Progress *
Specialty	106.7	223.3	47.8%	46.1%
Hemlibra	29.1	59.4	49.0%	46.4%
Actemra	23.8	50.0	47.6%	46.7%
Enspryng	13.3	26.0	51.2%	47.0%
Vabysmo	12.0	23.5	51.1%	42.3%
Evrysdi	7.9	15.9	49.7%	47.2%
CellCept	4.2	5.8	72.4%	45.6%
Mircera	2.4	5.0	48.0%	49.2%
PiaSky	3.0	4.4	68.2%	15.4%
Other	11.1	33.2	33.4%	47.7%
Overseas	288.1	555.5	51.9%	50.0%
Hemlibra	150.7	324.2	46.5%	52.2%
Actemra	86.9	127.6	68.1%	46.7%
Alecensa	29.1	67.0	43.4%	48.6%
Enspryng	6.1	12.6	48.4%	37.0%
Sigmart	4.5	7.8	57.7%	52.5%
Neutrogin	4.6	6.5	70.8%	53.5%
Other	6.3	9.8	64.3%	43.6%

* Jan - Jun 2024 progress versus Jan - Dec 2024 actual

39

This is shown by different segment and by product, in terms of progress against the initial forecast as of now.

As you can see, we see the progress is uneven.. But for the domestic oncology, domestic specialty, and overseas, comparing to last year progress, they all show positive results. So they're all showing good progress.

FY2025 Q2 Consolidated Financial Overview (Core)



Impact from Foreign Exchange Jan – Jun

(Billions of JPY)	vs.2024 Actual rate	vs.2025 Forecast rate
	[C] vs. [A]	[C] vs. [B]
Revenue	+23.3	-0.8
Sales	+18.0	-0.1
Other revenue	+5.3	-0.6
Cost of sales	-1.4	+0.0
Other than above *1	+0.1	+0.4
Operating profit	+22.0	-0.3

Exchange Rate (JPY)	2024 Actual rate*2 Jan - Jun [A]	2025 Forecast rate Jan - Jun [B]	2025 Actual rate*2 Jan - Jun [C]	2025 Market average rate*3 Jan - Jun	2025 Forecast rate Jan - Dec
1CHF	160.90	171.36	171.31	172.12	171.00
1EUR	164.63	160.00	162.19	162.03	160.00
1USD	135.45	146.13	146.56	148.57	148.00

*1 Total of R&D, SG&A and other operating income (expense)

*2 Weighted average of the exchange rates used to record foreign currency transactions included in categories from revenue to operating profit

*3 Market average rates in during the fiscal period

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This is FX impact. The far left, comparison with last year's actual rates, is quite important. On revenue, we are showing plus JPY23.3 billion, and on OP, JPY22 billion positive impact. Comparing to last year, especially Swiss franc, we saw the yen depreciation. That is the major reason. And Swiss franc is our largest trading currency. And last year, Swiss franc was JPY160.90 to a Swiss franc, and this became JPY171.31 this year, so it depreciated more than JPY10.

FY2025 Q2 Consolidated Financial Overview (Core)



Financial Position (vs. 2024 Year End)

(Billions of JPY)

Total assets	2,208.4	+ 69.9	2,278.3
Total liabilities	-306.9	+13.7	-293.2
	1,901.5	Total net assets +83.6	1,985.1
Net operating assets 947.6	448.7	Net working capital -7.0	441.7
	498.9	Long-term net operating assets +51.0	991.5
	996.3	Net cash +31.3	1,027.6
	-42.5	+8.5	-34.0
	2024 Dec	Other non-operating assets - net *1	2025 Jun
Ratio of equity attributable to Chugai shareholders	86.1%	+1.0%p	87.1%

Decrease in net working capital

Increase in accounts payable, etc., despite decrease in accounts payable for property, plant and equipment

Increase in long-term net operating assets

Increase in property, plant and equipment mainly due to the investment in

- the manufacturing building for bio drug substance (UT3) at Utsunomiya Plant
- the manufacturing building for injectables (UTA) at Utsunomiya Plant

Increase in net cash

(See next slide)

Increase in other non-operating assets - net

Increase mainly due to a decrease in accrued corporate tax

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

41

Next, the balance sheet situation. Total assets amounted to JPY2,278.3 billion, reflecting an increase in cash and deposit and increase in tangible fixed assets such as factory facilities. It went up by JPY69.9 billion. Total net assets increased as well by JPY83.6 billion to JPY1,985.1 billion, reflecting accumulation of equity capital through profits. And this pushed up the shareholders' equity ratio to 87.1%. Net cash increased by JPY31.3 billion from the end of 2024 to JPY1,027.6 billion.

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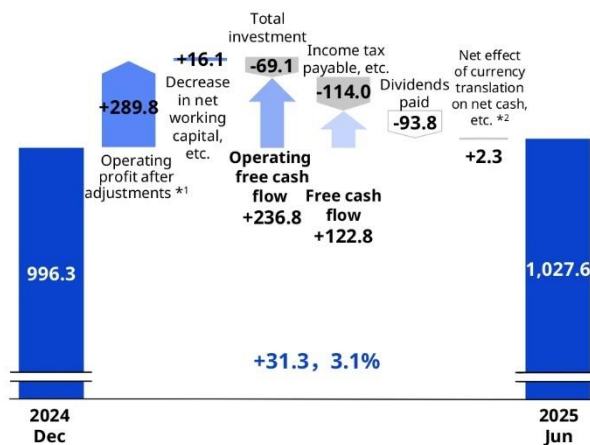
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Net Cash (vs. 2024 Year End)

(Billions of JPY)



*1 Including Non-Core (IFRS results)

*2 Net effect of currency translation on net cash, etc. = Transaction in own equity instruments + 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)

Operating profit after adjustment *1	+289.8
Operating profit *1	+273.3
Depreciation, amortization and impairment *1	+16.1
Decrease in net working capital, etc.	+16.1
Total investment	-69.1
Property, plant and equipment	-48.9
Payment for lease liabilities	-4.0
Intangible assets	-16.2
Operating free cash flows	+236.8
Income tax payable, etc.	-114.0
Income tax payable	-107.2
Free cash flows	+122.8
Dividends paid	-93.8
Net effect of currency transaction on net cash, etc.	+2.3

42

This slide shows the change in net cash, which I just mentioned, showing some breakdown since last year. Net cash increased by JPY31.3 billion. As a result of the cash inflow from operating profit, the increase due to the decrease in net working capital, and a decrease due to investment, operating free cash flow came to be JPY236.8 billion. And after deducting corporate taxes and dividend, cash increased by JPY31.3 billion over the past six months.

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Current Status / Plan for Major Investments

			~2024	2025	2026	2027	2028	2029	2030~	Planned investment			Period*	
										Total amount	Investment to-date	Unit		
Manufacturing	Utsunomiya plant	UT3: Manufacture bio drug substance for middle to later- stage clinical development and early commercial use								37.4	29.9	billion JPY	2023	2026
	Utsunomiya plant	UTA: Manufacture sterile injectables for early commercial use								19.0	15.3	billion JPY	2023	2025
	Ukima plant	UK3(modification): Manufacture bio drug substance								20.3	5.7	billion JPY	2024	2027
Research and development	CPR	Move and renovate facilities to enhance research functions								60	15	million SGD	2024	2026
	IFReC	Funding to IFReC per comprehensive collaboration agreement								10.0	8.3	billion JPY	2017	2027
	Ukima Site	UKX: Strengthening the process development function of small-and-mid-size molecule drugs and biopharmaceuticals								80.0	0.8	billion JPY	2026	2028
Environment	Environmental Investment**	Equipment upgrade to achieve Mid-Term Environmental Goals 2030								135.9	5.5	billion JPY	2022	2032
										estimated total amount				

*For capital investments, the period indicates the years from project start to planned completion

** Incl. part of investments described in the schedule above

43

This slide shows, we show this every time, but this is showing our capital investment plan, which has been approved internally. It includes the new capital investment project of JPY80 billion at Ukima site that was announced today.

P/L Jan – Jun (Non-core adjustment)

(Billions of JPY)	IFRS results	Non-core items		Core results	Non-core items	
		Intangible assets	Others		Factors affected operating profit	
Revenue	578.5			578.5	Intangible assets	
Sales	511.4			511.4	Amortization	+0.8
Other revenue	67.0			67.0	Impairment	+0.1
Cost of sales	-175.9	+0.6	+0.1	-175.2	Others	
Research and development	-86.6	+0.2	+0.1	-86.3	Business rebuilding expenses	+6.3
Selling, general and administration	-51.6		+6.3	-45.4	Restructuring expenses, etc. including gain on disposal of assets	-8.4
Other operating income (expense)	9.0		-8.6	0.4		
Operating profit	273.3	+0.8	-2.1	272.0		
Financial account balance	-1.5			-1.5		
Income taxes	-77.4	-0.3	+0.7	-77.0		
Net income	194.4	+0.6	-1.5	193.5		
EPS (JPY)	118.12			117.57		

44

Next page, we've been only talking about on a core basis. This is IFRS basis results. So what the adjustment looked like here: intangible asset amortization, impairment, the business rebuilding cost which is ERP

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implementation, and also the asset sales gain. In Q1, we sold the R&D site, ex-R&D site in Kamakura. So those are all considered as adjustment.

FY2025 Q2 Consolidated Financial Overview (Core)



Summary of Chugai Originated Global Products

(Billions of JPY)

Product (Billions of JPY)	FY2025 Q2 Results	Y on Y	FY2025 Forecast	Comments	
Hemlibra®	Domestic:	29.1	+6.2%	59.4	<ul style="list-style-type: none">Japan: Sales increased year on year as domestic market share steadily increased.Overseas: Sales increased in all regions. Expect to exceed export forecast for the full year.We provide value to patients worldwide through its convenience and accumulated clinical evidence.
	Export:	150.7	-6.2%	324.2	
	Overseas local:	2,238mCHF	+17%	-	
Actemra®	Domestic:	23.8	+6.3%	50.0	<ul style="list-style-type: none">Japan: Continued to obtain new prescriptions for rheumatoid arthritis. Other indications also penetrated.Overseas: Sales increased in the U.S. and International, while decreasing in EU. Exports greatly increased year on year.We provide value to patients through the established evidence as an originator of IL-6 inhibitor.
	Export:	86.9	+41.1%	127.6	
	Overseas local:	1,126mCHF	+3%	-	
Alecensa®	Domestic:	15.8	+6.0%	34.0	<ul style="list-style-type: none">Japan: Maintains its high share in the first-line therapy despite competitors' entry since 2021.Overseas: Sales increased especially in the U.S. and International. No change in export forecast for the full yearWe provide value to patients for early-stage NSCLC as the first ALK inhibitor, in addition to advanced NSCLC.
	Export:	29.1	-4.6%	67.0	
	Overseas local:	702mCHF	+8%	-	
Enspryng®	Domestic:	13.3	+14.7%	26.0	<ul style="list-style-type: none">Japan: Sales increased year on year as the switching from other drugs progressed steadily, despite the significant drug price revision implemented in 2024*1.Overseas: Sales increased in all regions. Exports also performed favorably.We provide a convenient treatment option for patients who wish to avoid steroids.
	Export:	6.1	+19.6%	12.6	
	Overseas local:	98mCHF	+38%	-	
PiaSky®	Domestic:	3.0	+650.0%	4.4	<ul style="list-style-type: none">Japan: The product successfully penetrates the market, gaining favorable evaluation in medical facilities due to the convenience of subcutaneous administration and reduced hospital time.Overseas: Market introduction is progressing in EU. We aim to penetrate markets in various countries worldwide.We provide an improved convenience and a broad range of treatment opportunities for patients including C5 gene polymorphisms.
	Export:	-	-%	-	
	Overseas local:	3mCHF	-%	-	

Export in the table includes Taiwan local sales in the Chugai territory.

Overseas local refers to overseas local sales by Roche, and Year on Year (%) is on a constant exchange rate basis.

Y on Y: year on year, NSCLC: non-small cell lung cancer

*1Market expansion re-pricing in April 2024 (-25.0%)

[Hemlibra] Domestic Hemophilia A Patient Share Trends

Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025
33.8%	34.9%	35.3%	36.2%	37.0%

45

Last page, this is in-house global products. We have five products, including PiaSky. So showing the six months sales at Roche, outside of Japan. And I hope you can use this info for your reference. This concludes my explanation. Thank you so much.

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Question & Answer

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities. My first question is related to tariff. From a medium- to long-term perspective, when you think about supply chain, is there any possibility that you're going to make some changes? And also it seems like the tax rate may gradually go up, but if higher percentage of tariff is going to be imposed on the pharmaceuticals in the future, are you planning to ship out the pharmaceutical products to US as a preparation, I mean, to prepare for that to happen?

Okuda [A]: Thank you very much, Hashiguchi-san, for your question. That was a question on the supply chain, related to tariff. Yesterday, Japan and US have come to an agreement regarding the reciprocal tariff. So 15% is the decided percentage. In our understanding, pharmaceuticals are not within the scope of this 15% tariff. In early July, President Trump, for pharmaceuticals, the US is conducting a survey towards imposing tariff on pharmaceuticals based on section 232 of the trade law and maybe like 200% or so according to news reports. It has also been said that there will be one or one and a half year duration until imposing the tariff. We understand that this is based on the understanding that it will likely take a considerable amount of time for the technology transfer of pharmaceutical production, or to establish a production base in the United States.

To your second question, under such circumstances for the pharmaceuticals product, what level of tariffs are going to be imposed? I mean it's very difficult for us to foresee the expected percentage of tariffs. So as Hashiguchi-san mentioned, we don't believe that the tariff percentage will gradually go up, but as Prime Minister Ishiba commented last night, if in the future, when tariff is imposed, our country, our priority will not be lowered compared to the other countries but still, for pharmaceuticals, I mean, we still need to carefully monitor how things will go. And then coming back to your first question again, are we going to relocate production site to US? Or are we going to do a technology transfer to US? Are we considering that? We are exploring and considering various options right now.

Hashiguchi [Q]: My second question, so you are considering about the second point, is that right? So making changes in the supply chain, you are currently contemplating, but about increasing the production volume and shipping out those produced product to US in early phase to mitigate the potential risk of higher tariff percentage, you don't think about that option?

Okuda [A]: Well, again, I would like to just say that we are exploring different options.

Hashiguchi [Q]: My second question is related to Hemlibra improvement of convenience. At ISTH, Novo Nordisk with regard to the Mim8 device, the patients who are enrolled in a clinical trial said that it's easier to use compared to Hemlibra and that data was presented. What's your takeaway of this and the current initiative to improve the convenience of Hemlibra? What's the current status?

Okuda [M]: So Mim8 information and our efforts to improve the convenience of Hemlibra. Those are the questions. Kusano-san, can you respond?

Kusano [A]: Thank you, Hashiguchi-san, for your question. Currently, for Hemlibra, we are developing AI. The timing is difficult for us to comment clearly. But in one or two years, maybe about in two years, we might be able to complete the development. And NXT007, we are developing the device for easy administration. So we should be able to fairly compete against Mim8. So that's the status right now.

Wakao [Q]: Wakao from JPMorgan. My first question on slide 34 is about the export of Hemlibra. Looking at Roche results today, they show very good results. But in Chugai Q2, number was low. There was a surprise.

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According to Investor Relations, a large amount actually got delayed into July. That's what we heard. So the amount was quite big, how much was it? If it came into June, then what would have been like in second half? And because of this delay, what happens to second half? So please share those information.

Taniguchi [A]: In Q2, in June, about JPY38 billion or so was originally planned, but that got delayed into Q3 in July. So if we had this JPY38 billion in Q2 and what happens for the remaining six months? The remaining six months, as I mentioned earlier, compared to the full year forecast, it looks like we have an upside of over JPY10 billion. So JPY38 billion, even if you deduct JPY38 billion from this number, then still you see a positive upside.

Wakao [Q]: So originally, if you had JPY38 billion in June for the second half, you had a bigger upside?

Taniguchi [A]: No. Compared to JPY318.6 billion for the full year, in either way, we would have seen over JPY10 billion upside.

Wakao [Q]: So this delayed JPY38 billion would be the incremental for the second half?

Taniguchi [A]: Yes, that's right.

Wakao [Q]: So what was the reason for delay? So basically, I believe you have to catch up with the demand because there's a very strong demand. So why was there a delay?

Company Representative [A]: We did see such a timing delay in the past several, a few times. So because of the booking, revenue booking according IFRS, not just according to the shipping, they have to be delivered and the risk must be transferred over to the other party to book revenue. And you're going to have to go through a very complicated documentary process. You have to go through the custom duties because of the cross-border procedure, and you have to go through the quality check, and we need to prepare resources or many other reasons, it is possible to see a potential delay for this process, and it's just happened this time.

Wakao [Q]: So this upside of over JPY10 billion, is it because of the strong demand in the market?

Taniguchi [A]: Yes, overall. Yes. The end market strength is seen and we are also seeing demand for inventory.

Wakao [Q]: So you're not adding the inventory because of the tariff situation?

Taniguchi [A]: No, that's not the case.

Wakao [Q]: My second question is on LUNA18. So the reason for the failure of LUNA18, can you clarify that? Because of the pan-RAS, you weren't able to get a good balance between the safety and efficacy? Or what is the reason? Can you clarify that? And AUBE00, compared to LUNA18, looks like it is a better product potentially. But A KRAS inhibitor that's been developed right now, compared to that, what would be the profile expected for AUBE00?

Kusano [A]: Wakao-san, thank you very much for your question. LUNA18, regarding its negative aspect, exactly as you mentioned. LUNA18 with the pan-RAS inhibitor, not just for KRAS, but also NRAS and HRAS, all RAS will be inhibited. And so for many kinds of different cancer types, we can expect a potential impact. But the safety window, extensive enough, whether that can be insured or not was a major challenge. But at the same time, looking at the competitive product in the market status, the competitive products are showing pretty good results in the clinical studies.

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So according to the results obtained from the current clinical studies comparing to those competitors' study results, we started to see a concern of not being able to ensure enough amount of the treatment window, so that's why making it more difficult for us to differentiate from the others. Therefore, as we reconsider the portfolio as introduced in today's presentation, compared to LUNA18, we believe there is higher possibility of being able to show the competitive advantage as pan-KRAS inhibitor with this AUBE00, that's why we decided to switch to that project.

And AUBE00, this is the second mid-size molecule drug discovery. So what did we learn from LUNA18 is going to be quite important to develop this AUBE00. As we were going through development of LUNA18, we were able to confirm a good oral absorption ability. Also, we have seen the indication of transfer into, inside the cells. Especially the oral absorption ability, along with the dose increase of LUNA18, we were able to confirm the increased level of the dose inside the blood. And also, we were able to confirm that the drug can be absorbed in humans up to concentrations that exceed the effective pharmacological exposure levels anticipated from the mouse results. Additionally, regarding transfer into the cells, we have observed a tendency for decreased mRNA expression levels in multiple molecules downstream of the RAS/MAP kinase signaling pathway in tumors. Therefore, with our mid-size molecule, both oral absorption and transfer into cells were indicated. These will also be implemented on AUBE00. That's why we still maintain very high expectation for mid-size molecules.

Wakao [Q]: Is it correct to understand that [inaudible]?

Kusano [A]: So right now, we have to see how it goes, unless we go through the clinical trials. But what we learned from LUNA18, all this based on this experience, we will verify them in a Phase I study.

Wakao [Q]: So in conclusion, Kusano-san also mentioned making good progress for the mid-size molecules. But on the other hand, of Phase I, ending timing would be in 2030. So it seems like it's going to be delayed by about five years. Looking from outside as an outsider perspective, I don't think it's making a smooth progress. What is your intention of mentioning that you're making good progress so far? What is the difference from my understanding?

Kusano [A]: For each drug, there may be delays, but we have now two projects in the preclinical stage, one is cancer -related, one is noncancer related. And we have 25 research level drug projects. So of course, we haven't been able to introduce the drugs to come to the clinical stage. However, there are many mid-size molecule projects going on at the preclinical stage or in the earlier stage.

Wakao [Q]: So you're saying it's taking longer time, but you have increased the number and quality of potential projects?

Kusano [A]: Thank you.

Yokoyama [Q]: I am from Nikkei BP. My name is Yokama. I have a question on TALENTACE. Based on this data, you're going to submit filing. The primary endpoint, TACE PFS has been met, but at 18 months, Kaplan-Meier curve is almost overlapping, and for OS, there is no significant difference. It's immature. But hazard ratio is 0.96, and compared to LEAP, it's not as good. So what's your expectation on this?

Kusano [A]: Thank you very much. For your question regarding TALENTACE. So for TACE PFS is met, but OS is not met. So currently, we are not submitting a filing. We are going to look at the result of the analysis next time and if OS looks good, we are going to move on to the actual filing.

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Yokoyama [Q]: Inavolisib finally started to move. I was expecting earlier move. But for inavolisib, you have a proven data. And I was hoping to get this product available in Japan. But you don't list this in the filings list. I was wondering when is the expected timing for the submission of filing?

Kusano [A]: Thank you very much for your question on inavolisib. Currently, Phase I/II study has been initiated, and we are promoting the clinical trial in a rush manner. And as you have pointed out, this has been approved outside of Japan and also in Europe. And at ASCO, OS data was presented, so we would like to bring this product as soon as possible to Japanese patients. We would like to complete Phase I/II study, and we would like to do a bridging to Phase III study, so that we can submit filing. We do our best.

Yokoyama [Q]: So sometime next year?

Kusano [A]: Sorry, I cannot comment on the timing, but we will take actions as soon as possible.

Ueda [Q]: Ueda from Goldman Sachs Securities. My first question is about LUNA18 and AUBE00. LUNA18, I think it seems like you're making very cautious steps in moving forward the clinical studies, including safety profile, and this will be the very first mid-size molecule technology. I guess you've been quite cautious in proceeding with this project so looking at, has there been any concern about the safety and also the mid-size molecule so far? And I think it's possible, do you think you can obtain a data result for AUBE00 smoothly? It states the completion is planned in 2030 in ClinicalTrials.gov, but you may expect to see the results earlier than that?

Kusano [A]: Ueda-san, thank you very much for your question. For LUNA18, as we have been talking about regarding safety profile, there was a concern on therapeutic window. So that's why, as mentioned in the past several times, in Phase I study, so the confirmation of maximum tolerated dose (MTD) and dose limit toxicity (DLT) was also conducted with a cautious manner, and that's what took so long, and the more detailed result to come out on papers or to be presented at the academic conference.

I believe that it is likely producing effective side effects related to the drug's mechanism, as it shows the typical skin symptoms and gastrointestinal symptoms that occur due to RAS/MAP kinase inhibition, similar to what we've seen with previous treatments.. Also some mid-size molecule specific side effects are not confirmed, so I don't think there is any concerns on that point. But more details to be shown at the academic conference or on our papers.

For the AUBE, we have learned a lot from LUNA, so we have conducted many Phase I trials for the different antitumor drugs, so we are trying our best so that we can complete this Phase I trial as soon as possible earlier than LUNA.

Ueda [Q]: Thank you for your answer. And second question is about the US tariff situation. Just a qualitative information. So you're part of Roche Group, so reviewing the production footprint or the supply chain, will there be any merits or advantage, or if you can actually take some flexible actions to address those areas?

Okuda [A]: Thank you for your question. You may already know, as part of the Roche Group, there are multiple manufacturing operations in the US market. There is naturally an option for Chugai to utilize such facilities as a member of the Roche Group. As I mentioned, there are many different options. So including them, we will look into different options.

Sakai [Q]: I am Sakai from UBS. ROSE12, the mechanism seems to be very complicated and difficult. So Treg is like a boom. Nowadays, it's gaining a lot of attention, but I think there is a difficulty being reported. So you have a switch antibody technology, so you can make switch on and off clear without increasing Treg, you can

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improve the immunity. Is it correct to understand that by combining Tecentriq, it involves targeting CTLA-4 as well, thus attacking the cancer through two different mechanisms?

Kusano [A]: Thank you very much, Sakai-san, for ROSE12 question. Switch antibodies determine whether the antibody attaches or not depending on the presence or absence of ATP (adenosine triphosphate), which is abundant in tumors. Rather than affecting whether T-regs appear in high or low numbers, it's about whether this ROSE12 has a higher or lower probability of attaching to T-regs. So in tumor cells, when ATP is large or big in quantity, we can catch Treg more. And in normal cell, ROSE12 does not function, and that is the mechanism of action. So while maintaining good safety, we can dose up. That's the drug design.

Sakai [Q]: So you're talking about solid tumor this time. So the expression of Treg does matter when we talk about solid tumor, right?

Kusano[A]: Yes.

Sakai [Q]: Does that mean you're going to aim for around that area?

Kusano [A]: Yes.

Sakai [Q]: 30 times, efficacious, that was proven in the mouse?

Kusano [A]: Yes.

Sakai [Q]: You have dropped six R&D development projects?

Kusano [A]: No, not six. Five.

Sakai [Q]: I've been following your company for a long time, but I think this is your first time to drop so many development projects at the same time. What's the reason behind? I know you have richer early pipeline, as Okuda-san said. Is that the only reason? Or is there any changes in your R&D policy? If there is any particular background, please enlighten me.

Okuda [A]: Thank you, Sakai-san, for your question. Dropping this number of projects at once has never been done before in Chugai, as far as I know. TOP I 2030 started in 2021. And the core strategic concept is RED SHIFT. We reinforced RED function, and we are going to increase the R&D project number. And at the end of the day, we are going to launch one global product per year. That's the strategy.

But now we've generated a lot of projects and they went into preclinical and clinical phase. In the past, you have pointed this out, and we've had discussion internally, but depending on the project, we had to proceed R&D development very thoroughly. We had to generate a lot of data. But as a result, in some projects, the time frame got longer than our initial expectation. And in order to address that, it has been explained for each project go or no-go decision criteria, what's clearly set, and when a milestone is met based on the data and based on the competitors' data, we make go or no-go decision. So that's the strategy we've been upholding.

But then in the meanwhile, the number of projects has gone up quite a bit. The question is, do we want to stay fully focused on the development of all those many projects with the full resources? Well, even before go/no go decision or milestone achievement timing, we look at the clinical and non-clinical data, especially safety, efficacy, competitiveness, and PK. We look at those data and then we prioritize the different projects.

And then if, and then we've decided to discontinue those five projects who have the least priority.

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Sakai [Q]: Is there an aspect where this incident served as a strong wake-up call to researchers?

Okuda [A]: As a result, I guess the researchers were, in a way, inspired. Well, as we did the prioritization work, well, our research has been working on the development project based on the science. So based on the data, we say, I mean, we look at competitiveness, safety, efficacy assessment, and then we did the prioritization work, and that was well understood. And by doing this prioritization work, we were able to narrow down on more promising projects.

By doing this, what remains are more promising projects, and we can accelerate the development of these projects. We can design ways to accelerate development by allocating additional resources or investing more money, which opens up various possibilities. With these aims in mind, we made this management decision to discontinue multiple projects at once

Sakai [Q]: Thank you. Understood.

Banno [Q]: This is Banno from Nihon Keizai newspaper. My question is about the construction of the R&D facility.

So JPY80 billion investment is quite a large number, I believe. So for the mid-size molecule, the antibody modality research that would require this level of investment, what is the reason for this amount of the investment?

And also, you are trying to reinforce the development function, but what do you expect as a result of having this new facility?

Okuda [A]: Regarding whether the 80 billion yen investment in UKX is appropriate, I said, within the RED SHIFT strategy, now we're starting to increase in number of projects and antibody drugs and mid-size or small molecules are being focused more. In order to appropriately produce all these clinical drugs at the appropriate timing, and the compounds that we are developing are quite complex at the same time. And much faster delivery also, we need to establish a manufacturing method as quickly as possible. And that was the major challenge. And of course, antibody and mid-size molecule projects are increasing, and we need more spaces. We need more resources at the same time.

In the existing facility, we won't be able to accommodate them all. Therefore, we decided to build this UKX at this size. This is an R&D facility to develop production and engineering technology. So if JPY80 billion is appropriate or not, I know it is a quite large figure. And we, of course, went through the bidding process and compared different prices, and we selected a more reasonably sized project. And we also looked into similar facilities outside of Japan and how much it cost to those facilities, and we compare to their figures.

And we confirm this figure, we are talking about isn't too far off of what was invested in other facilities. And lately, we are experiencing inflation, price increases, and labor cost increases. And the construction cost has increased a lot compared to a few years ago. That is also another truth. And we got quotes, we actually received quotes a few years ago but even since then, we got requotes recently, we saw huge increases in the actual costs.

So just because having this investment is very high doesn't really lead us for not making this decision to investment. And we think this is an essential part of accomplishing TOP I 2030 targets.

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Taniguchi [A]: And just to elaborate more, also in Ukima facility, there are several buildings available. And since they are getting older, so we want to consolidate them into a bigger facility so we can be more efficient in communication at the same time. That is another purpose.

Okuda [A]: I forgot to mention this. In this UKX research facility is also being friendly to environment. We try not to utilize fluorocarbons as much as possible. We want to have zero exposure to fluorocarbons and zero CO₂ emissions. And we have factored, we have tried to accommodate those impacts into this building, and that is also another reason for seeing higher cost.

Muraoka [Q]: My name is Muraoka from Morgan Stanley. My first question is related to the export of Actemra and Hemlibra. On a full year basis, there is a possibility to overshoot the forecast by 20 billion in total, both Hemlibra and Actemra will overshoot initial target by JPY10bn each. On top, I was looking at the numbers presented by Galderma. NEMLUVIO seems to be selling quite well. Can we expect upside by JPY10bn of NEMLUVIO?

Since this is a medication for which a large inventory needs to be secured at present, with this momentum, I thought it might have a significant impact on the current fiscal period as well. Am I being too eager in thinking this way?

Taniguchi [A]: Thank you so much, Muraoka-san. This is Taniguchi speaking. Hemlibra, Actemra, I said more than 10 billion, not 10 billion. So the export to Galderma, based on the current sales pace of Galderma, it's actually been accelerated but we haven't quantified the potential upside impact as a result. So if we have more visibility and information, we would like to update you in the next earnings call. NEMLUVIO is growing more than I have expected.

Muraoka [Q]: Yes. Thank you. GYM329, when I look at the presentation by Roche, about Zepbound combination therapy Phase II, GYMINDA study, details have been laid out. And I looked at the clinicaltrial.gov site, and I thought this is quite interesting, 48-week Zepbound combination therapy study, 24 weeks extension is going to be GYM329, monotherapy. So combination therapy only 48 weeks and remaining is monotherapy.

Compared to the other myostatin, this is quite a unique way of using the drug or design. What is the reason for this unique study design? And what is the expected best-in-class unique profile? Can you explain about your intention behind this unique study design?

Kusano [A]: Thank you very much, Muraoka-san. Yes, GYM329 Phase II study, initially, for 48 weeks, the investigational drug will be administered together with tirzepatide low dose, mid dose, high dose, there are three doses to be compared. And on top, we have a placebo arm. And then following 24 weeks, in all arms, tirzepatide will be suspended. But for high dose, only GM329 will be extended for 24 weeks. That's the clinical trial design.

Incretin, as you know, once administration is stopped, body weight is expected to increase. But then GM329, follow-up is given, the body weight increase can be suppressed. So that's something we are expecting to see in the maintenance therapy period.

Muraoka [Q]: When the mass goes up, and then we don't see any rebound of the body weight. Correct?

Kusano [A]: Yes. That's right.

Muraoka [Q]: Sorry, one quick question. For the actual financials in export, you didn't have any impact from tariff, meaning that Roche did decide to increase the inventory volume in April to June.

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Taniguchi [A]: As far as I understand, Roche didn't do that.

Muraoka [Q]: Thank you. That's all from me.

Yamaguchi [Q]: I'm Yamaguchi from Citi. The canceled project among them, the switch antibody was one of them, I believe. And now you are talking about the switch antibody project. STA551, I believe, the reason for the cancellation of this, can you explain? And also the concept of switch antibody, was it also available in the project or not? Can you comment on this project?

Kusano [A]: Yamaguchi-san, thank you for your question. STA551 regarding this project, the target molecule was the T cell CD137. So STA551 to be combined with CD137 in the presence of ATP, which has a high concentration in tumor tissues, that was the mechanism. And as a result, in a clinical study, result cannot be disclosed at this point. We have been able to confirm tolerability up to dosage levels that would likely be unattainable with CD137 antibodies without switch functionality. So I think the efficacy was confirmed to some level, but more details will be presented at the academic conference anyway. But on ROSE12, as mentioned before, the CTLA-4 is targeted on the Tregs, so it's a completely different target. So with this STA551 cancellation, looking at the portfolio level, and we made a decision. The switch antibody expectation, also the ROSE12 expectation won't be affected.

Yamaguchi [Q]: So the details to be confirmed in data. As we see, so you saw improved tolerability, but you didn't see a clear efficacy, I believe, that's what you saw.

Kusano [A]: As of now, at this point, we are not able to disclose detailed data yet. And so later, please refer to them in the papers or the academic conference.

Yamaguchi [Q]: Another quick question. Muraoka-san also asked this. NEMLUVIO, so this is part of the other revenue, right?

Taniguchi [A]: Yes. This is part of the overseas. There's other section. And so that's part of this other, under overseas.

Yamaguchi [Q]: Looking at this, this number, it seems like there's no major change in Q1 and Q2. So what Galdema is saying to the investors are not really reflected into these numbers or there is, because of the other, under the other sector, is it invisible?

Taniguchi [A]: I think it's going to come stronger towards the end of the year.

Yamaguchi [Q]: Okay. So there is a potential increase expected towards the end. It could be actually stronger than what you expected.

Taniguchi [A]: There is, yes, such a potential.

Ren [Q]*: Can you hear me? Okay. Perfect. So this is Tony Ren from Macquarie. A couple. So first, a couple of questions on your Hemlibra next-generation product, NXT007. Specifically, I want to ask about the dosing. So in the Phase I/II study, you guys used every four-week dosing. Previously, you guys had hinted that you might be able to dose it at much longer intervals, possibly every two to three months. So just wanted to see why did you decide to settle with a far more frequent monthly, every four-week dose? Would that be the dose you will take into Phase III trials?

And also in the future, do you think you can get an extended dosing interval longer to more than four weeks? So that's on NXT007.

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The second question is on the gene therapy Elevidys. So you guys had it approved in May in Japan, in ambulatory patients. So I just want to see how many patients have you dosed, have you given the gene therapy to in Japan? And have there been any patients in the non-ambulatory situation receiving the gene therapy? Thank you.

Kusano [A]: Thank you very much, Mr. Tony Ren, for your question. With regard to dosing frequency of NXT007, in terms of the future regimen, unfortunately, there is nothing I can comment on. We are sorry about that. But half-life is quite long, so there is a possibility that we can extend the interval between dosings. And with the high half-life, the change in PK between peak and trough can be controlled better, which can contribute to stability of effect. So in the future trials, we will be investigating into the dosing frequency. Now if I may, I would like to move on.

Ren [M]*: Sure, please.

Kusano [A]: And next, Elevidys, Japan, Japanese dosing experience or usage experience. Currently, in Japan, from age four to seven, ambulatory Duchenne muscle dystrophy patient is enrolled in the clinical trial. And actually, we have enrolled five patients as such so far. Those are the five ambulatory patients. And non-ambulatory patients targeted clinical trial is participated by Japan and four Japanese subjects have been enrolled. But the clinical trial targeting non-ambulatory patients are blinded, so we do not know whether they are randomized to placebo group or active drug group. That's all.

Sogi [Q]: US tariff impact. So you're looking at different options right now. So this is a question related to the assumptions you have. So the cost came out to be quite high this time because Actemra overseas export was high, I think you mentioned. So US Genentech facility was utilized and you outsourced manufacturing for Actemra. I think you mentioned that before. Is that the reason why you saw the higher cost? If that's the case, now in the US, if pharmaceutical is going to be also in the scope of the tariff in the future and Hemlibra production could be also transferred over to US potentially. And when that happens, as far as we heard from Roche, they're saying that manufacturing capacity wise, it seems like they have enough capacity right now. And compared to the capacity by Roche, you may outsource the manufacturing to Roche capacity. Would that be also possible? If that's the case, just like with Actemra, that could actually increase the cost at the same time. Would that be true? Of course, this is just one of the options. And I just wanted to know if there is such a possibility as well.

Taniguchi [A]: Sogi-san, thank you very much. For Actemra cost, it came out to be higher from a relative perspective. It's not just because of the genetic site issue. There's a multiple impact. So antibody production of Actemra cost was high regardless of the site location, so there are other elements as well. And regarding manufacturing sites, as Okuda mentioned earlier, there are different options available and we are looking at them from different perspectives right now, so we haven't really decided to set out a certain direction forward. It depends on the actual tariff being imposed and also manufacturing cost compared to the cost we have right now, the labor cost, personnel, the property costs. We need to confirm if it were outside of the US, what happens, so we also need to factor in all these elements to make a decision. So at this point of time, it's quite difficult for us to give you a clear answer to your question.

Sogi [Q]: And next question, SAIL66, I think, trispecific T cell engager product. You decided to discontinue this product. So this T cell engager, trispecific T cell engager modality itself had a challenge. Is that the right understanding? What is the reason for your decision to discontinue this? And this trispecific T cell engager, what is your thinking going forward for this?

Kusano [A]: SAIL66 was your question. So regarding SAIL66, Claudin-6 was the target in a tumor. Also on T cell, CD3 and CD137, triple-specific antibody to be bonded to both of them. And this is Dual-Ig technology is utilized. The Claudin-6 which is present in tumor antigens and CD3 on T cell went through to results in effect.

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By also binding to CD137 on T cells, it promotes sustained activation of exhausted T cells, leading to expectations for a stronger anti-tumor effect. As I mentioned, the results will be presented in a paper, upcoming paper, also in academic conference. And regarding triple-specific antibody Dual-Ig technology, we have ALPS12, which targets DLL3 that is frequently expressed in small cell lung cancer and neuroendocrine carcinoma. The testing for these are underway, still right now so Dual-Ig technology will be further pursued.

Sogi [M]: Understood. Thank you very much.

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46

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