Q1 FY2023 Financial Transcript

Q1 FY2023 Financial Results

August 3, 2023

Santen Pharmaceutical Co., Ltd.

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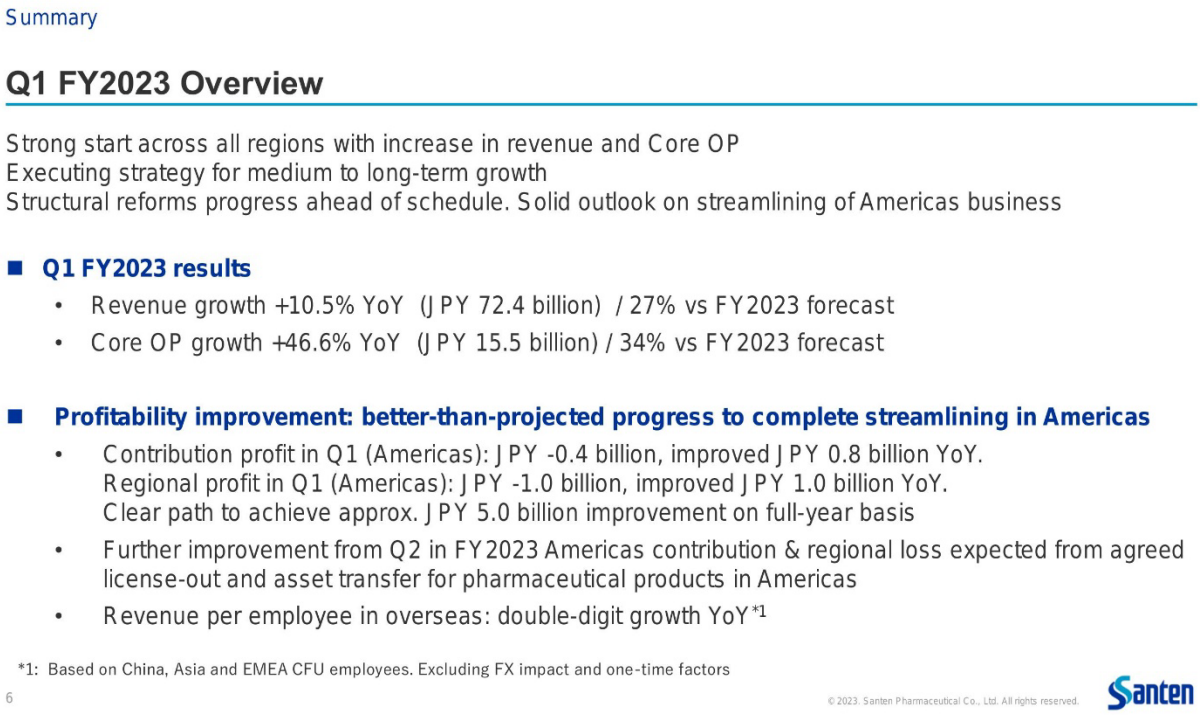
Financial Results

Kazuo Koshiji
Chief Financial Officer &
Chief Risk Officer



Koshiji: Please turn to page six.

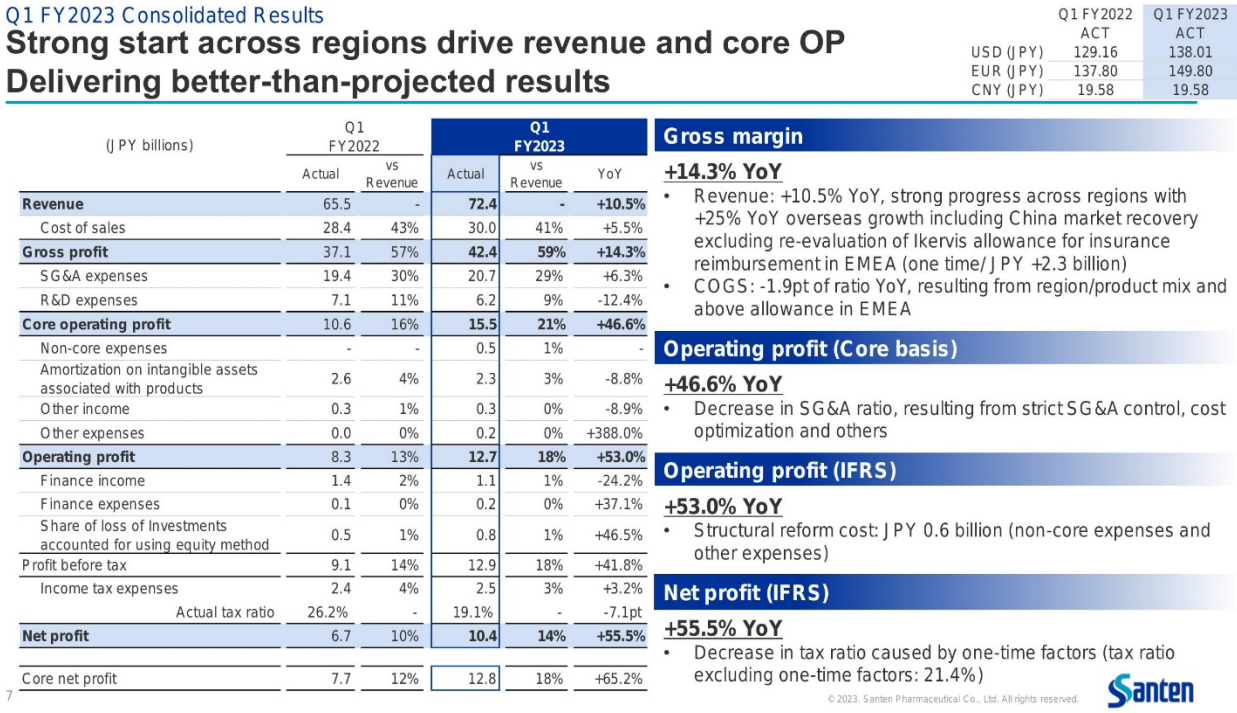
In Q1 of FY2023, all regions performed well, posting YoY increases in both sales and profit. Revenue increased 10.5% to JPY72.4 billion. Core operating profit increased 46.6% to JPY15.5 billion.

In May, I said that our full year forecast for the current fiscal year was conservative, taking into account possible risks, and that we would aim to exceed it. We recognize that we have kicked off a smooth start this first quarter towards surpassing our goals.

One of the basic policies of the new medium-term management plan is to improve profitability. One of the major milestones of this fiscal year is the completion of streamlining of the Americas business in H1. We acknowledge that there has been a prospect of achieving profitability improvement of approximately JPY 5.0 billion on annual basis.

The improvement in profitability in Q1 in the US has been more rapid than we had expected at the beginning of the period. As announced on July 19, we have completed the conclusion of the product license-out agreement and the asset transfer agreement for the Americas pharmaceuticals business. We are now in the process of transferring the business.

The profitability of our overseas business is an element of our medium-term management plan. We have achieved double-digit growth in sales per capita in China, Asia, and EMEA combined, even excluding transitory factors. The entire company is working with a high level of awareness to improve productivity.



Q1 FY2023 Consolidated Results

Strong start across regions drive revenue and core OP
Delivering better-than-projected results

	Q1 FY2022 ACT	Q1 FY2023 ACT
USD (JPY)	129.16	138.01
EUR (JPY)	137.80	149.80
CNY (JPY)	19.58	19.58

(JPY billions)	Q1 FY2022 Actual	Q1 FY2022 vs Revenue	Q1 FY2023 Actual	Q1 FY2023 vs Revenue	Q1 FY2023 YoY
Revenue	65.5	-	**72.4**	-	**+10.5%**
Cost of sales	28.4	43%	30.0	41%	+5.5%
Gross profit	37.1	57%	**42.4**	**59%**	**+14.3%**
SG&A expenses	19.4	30%	20.7	29%	+6.3%
R&D expenses	7.1	11%	6.2	9%	-12.4%
Core operating profit	10.6	16%	**15.5**	**21%**	**+46.6%**
Non-core expenses	-	-	0.5	1%	-
Amortization on intangible assets associated with products	2.6	4%	2.3	3%	-8.8%
Other income	0.3	1%	0.3	0%	-8.9%
Other expenses	0.0	0%	0.2	0%	+388.0%
Operating profit	8.3	13%	**12.7**	**18%**	**+53.0%**
Finance income	1.4	2%	1.1	1%	-24.2%
Finance expenses	0.1	0%	0.2	0%	+37.1%
Share of loss of Investments accounted for using equity method	0.5	1%	0.8	1%	+46.5%
Profit before tax	9.1	14%	12.9	18%	+41.8%
Income tax expenses	2.4	4%	2.5	3%	+3.2%
Actual tax ratio	26.2%	-	19.1%	-	-7.1pt
Net profit	6.7	10%	**10.4**	**14%**	**+55.5%**
Core net profit	7.7	12%	12.8	18%	+65.2%

Gross margin

+14.3% YoY

- Revenue: +10.5% YoY, strong progress across regions with +25% YoY overseas growth including China market recovery excluding re-evaluation of Ikervis allowance for insurance reimbursement in EMEA (one time/ JPY +2.3 billion)
- COGS: -1.9pt of ratio YoY, resulting from region/product mix and above allowance in EMEA

Operating profit (Core basis)

+46.6% YoY

- Decrease in SG&A ratio, resulting from strict SG&A control, cost optimization and others

Operating profit (IFRS)

+53.0% YoY

- Structural reform cost: JPY 0.6 billion (non-core expenses and other expenses)

Net profit (IFRS)

+55.5% YoY

- Decrease in tax ratio caused by one-time factors (tax ratio excluding one-time factors: 21.4%)

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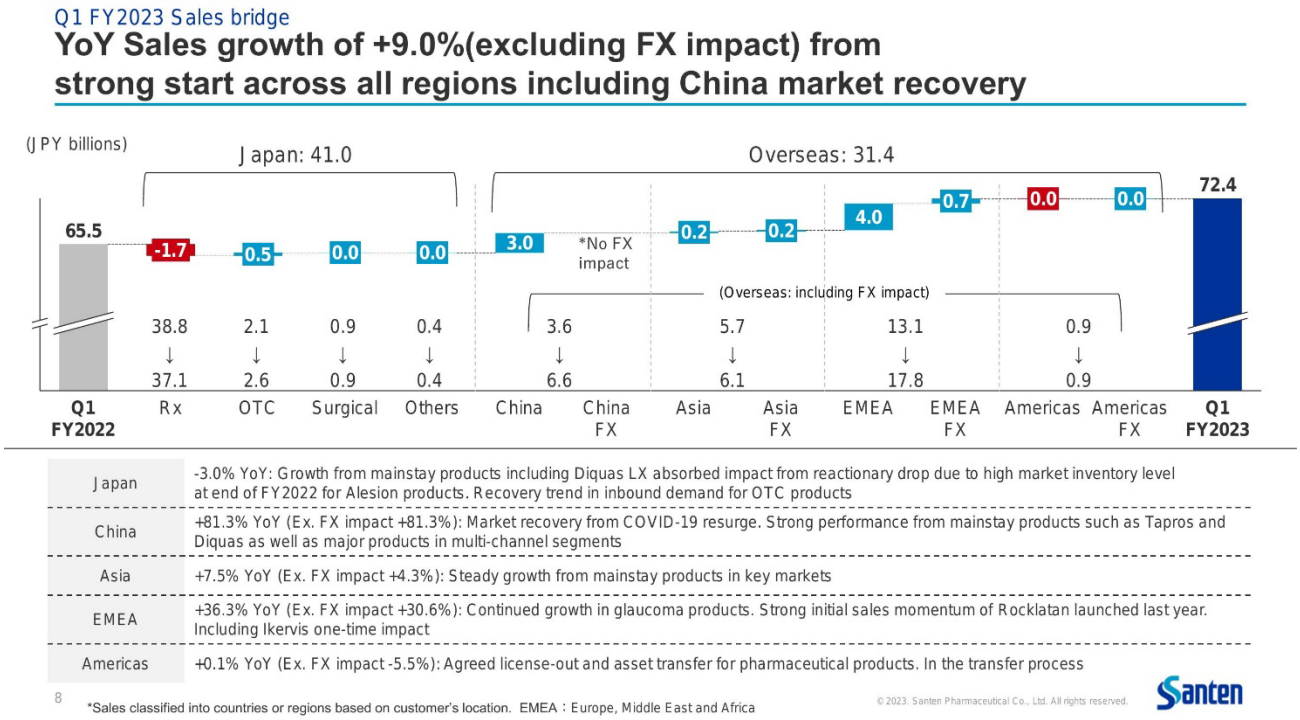
Koshiji: Please turn to page seven.

Here is the profit and loss situation for Q1. Sales were strong in all regions, mainly due to the market recovery in China. Foreign exchange rates also contributed. On a consolidated basis, the increase was 10.5%.

In EMEA, there was a onetime factor of JPY2.3 billion in return profit related to the reimbursement provision of *Ikervis*. Even excluding this factor, overseas sales revenue was up 25% YoY, a strong start.

Cost of sales to revenue ratio decreased YoY, partly due to changes in the product mix. Thanks to cost optimization activities and a decrease in the SG&A-to-revenue ratio, we brought about a 46.6% YoY increase in Q1 core operating profit.

Under the core heading, quarterly net profit was up 55.5% from the same period last year, or JPY10.4 billion, due in part to the posting of structural reform cost and a decrease in the tax rate due to onetime and other factors.



Japan	-3.0% YoY: Growth from mainstay products including Diquas LX absorbed impact from reactionary drop due to high market inventory level at end of FY2022 for Alesion products. Recovery trend in inbound demand for OTC products
China	+81.3% YoY (Ex. FX impact +81.3%): Market recovery from COVID-19 resurge. Strong performance from mainstay products such as Tapros and Diquas as well as major products in multi-channel segments
Asia	+7.5% YoY (Ex. FX impact +4.3%): Steady growth from mainstay products in key markets
EMEA	+36.3% YoY (Ex. FX impact +30.6%): Continued growth in glaucoma products. Strong initial sales momentum of Rocklatan launched last year. Including Ikervis one-time impact
Americas	+0.1% YoY (Ex. FX impact -5.5%): Agreed license-out and asset transfer for pharmaceutical products. In the transfer process

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*Sales classified into countries or regions based on customer's location. EMEA：Europe, Middle East and Africa

Koshiji: Next, page eight. This chart shows the factors that contributed to the change in sales.

As you can see, domestic sales were JPY41.0 billion and overseas sales were JPY31.4 billion. The overseas ratio is 43.3%.

For Japan, sales declined 3% YoY. This was mainly due to a reactionary drop due to temporary high market inventory level of *Alesion* from heavy pollen dispersion at the end of the last fiscal year. On the other hand, our mainstay products such as *Diquas LX* have been progressing as planned and the inbound demand for OTC, over-the-counter drugs, which is also a profitable business, is on a recovery trend.

Overseas, first of all, China has shown significant growth, reflecting the recovery of the market since the coronavirus pandemic. New products such as *Diquas*, as well as *Hyalein* sold through multiple channels, are performing well overall, in line with the market's recovery. In China, the exchange rate between the yen and the Chinese yuan was the same compared to the same period last year, so there was no effect of exchange rate fluctuations. The YoY increase in sales was 81%, or JPY3.0 billion.

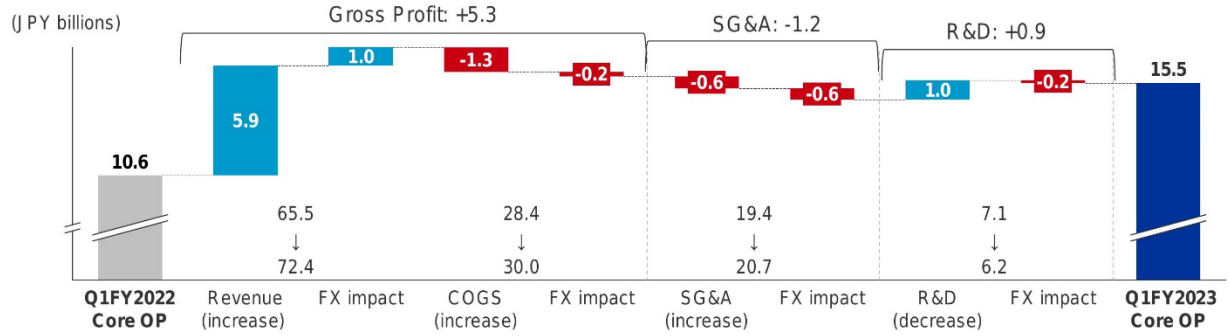
The circumstances were unusual last year, but compared to the same period the year before last, the level is almost the same and we are making progress toward a gradual recovery. This is our understanding.

In Asia and EMEA, sales were solid in major countries including foreign exchange rates. In EMEA, as I explained earlier, there was a onetime factor of JPY2.3 billion, which includes the profit return of the *Ikervis* provision.

In the Americas, we have already decided on the out-licensing and asset transfer of the pharmaceutical business. Since this is in the preliminary stage, the amount for Q1 is almost the same as the same period of the previous year, JPY900 million.

Q1 FY2023 Core OP bridge

Significant YoY Core OP improvement from strong sales and cost optimization



Gross profit	Net +5.3bil YoY. Increased revenue (incl. FX impact) and decrease in COGS ratio (-1.9pt YoY) from region/product mix and one-time factor
SG&A	Net -1.2bil YoY. SG&A ratio decreased from cost optimization, cost controls and others despite sales-linked-expense increases (SG&A ratio: -1.1pt YoY)
R&D	Net +0.9bil YoY. Mainly from fluctuations caused by development stage progress in each project and timing of expenses recording (R&D expenses ratio: -2.2pt YoY). No change for FY plan and policy to prioritize investment to R&D

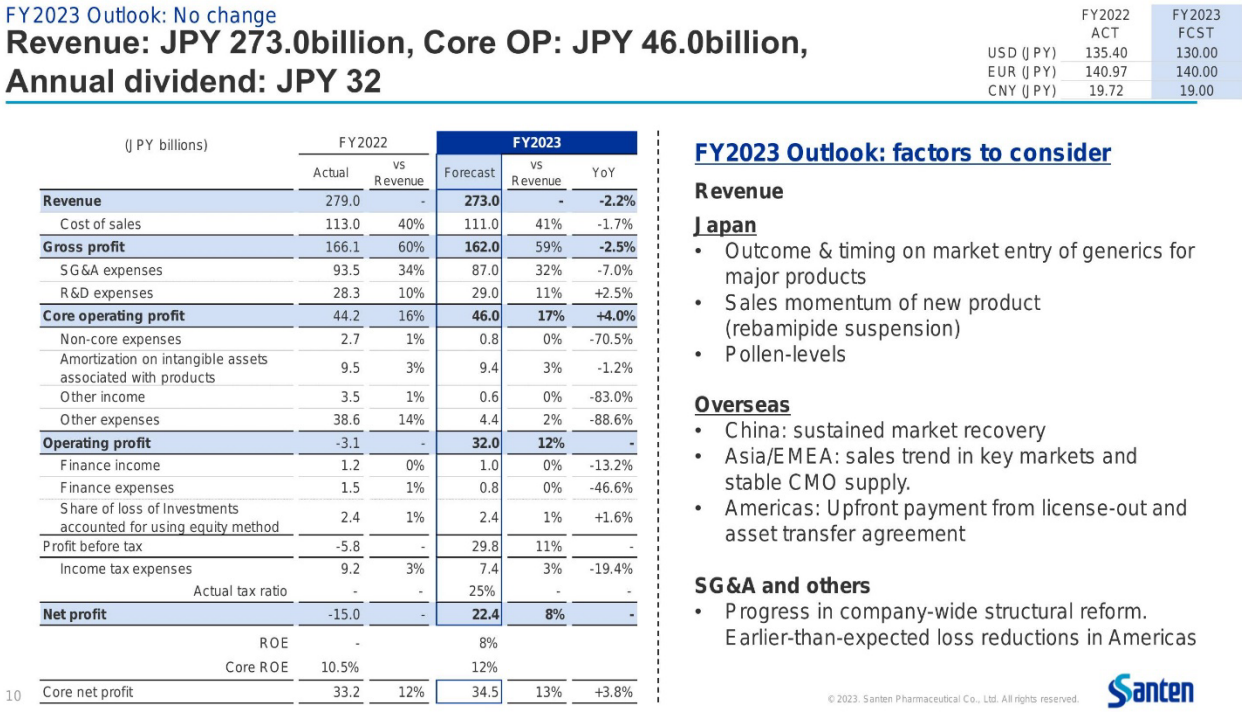
Koshiji: Page nine shows the factors affecting core operating profit. The YoY increase was JPY4.9 billion.

From left to right, the first is the gross profit factor. Revenue increased JPY6.9 billion due to strong sales in each region and the impact of foreign exchange rates. Overall gross profit was positive JPY5.3 billion YoY. This was due to onetime factor and a lower cost of revenue ratio due to a change in product mix.

Regarding SG&A expenses, there is an increase in costs associated with business activities, while on the other hand, we have undertaken activities to reduce costs. By optimizing these multiple factors, such as decrease in royalties, and controlling the increase in depreciation and amortization by reviewing investments, the SG&A-to-revenue ratio decreased by 1.1 point YoY. Although the absolute amount increased by JPY1.2 billion from the previous year, including the effect of exchange rates, we believe that we have been able to control the ratio to revenue appropriately.

Regarding R&D, there have been changes in the development stage of each project, resulting in changes in incurred expenses. For Q1 of the current fiscal year, there was a decrease of JPY900 million YoY. That is the current situation.

As a result, core operating profit amounted to JPY15.5 billion.



Koshiji: The next page, page 10, covers the earnings forecast.

As you can see, we have not changed our full year forecast, which we announced in May. We forecast revenue of JPY273.0 billion, core operating profit of JPY46.0 billion, and a dividend of JPY32 per share.

Although there have been transitory factors in Q1 and uncertainties in Q2 and beyond, we currently believe that we will be able to exceed our earnings forecast as a whole.

However, in order to make a specific upward revision, we need to determine the sales of individual products. We also need to consider the investment in R&D pipelines as upfront investments. We are currently examining the figures, but at present, the forecast remains unchanged. In any case, we believe that improvements can be made in terms of absolute amounts, expenses, and revenues.

As of today, as noted on the right side of the document, we have identified several factors that will affect our full year results. The situation of generic versions of our mainstay products in Japan and trends in pollen levels are among these factors. Another is the sustainability of market recovery in China, which we anticipate will improve even more than in Q1. We are also considering the effect of gross profit on overseas revenue, then there is our company-wide structural reform. What impact will these factors have on our profit? This is the situation we are considering, in conjunction with the upfront investment I mentioned earlier.

We recognize that the momentum is quite strong at this point, but since we are only a quarter of the way through the year, we will closely monitor the market and our own company over the next few months and provide timely and appropriate updates on our earnings outlook. This concludes my presentation.

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R&D Update

Peter Sallstig
Chief Medical Officer

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Santen

Q1 FY2023 R&D update

Progress in glaucoma and refractive error

Existing area	STN10**11**101 TAPCOM / TAPTIQOM	Glaucoma	Achieved **primary endpoint** in P3 trial in China (Filed by utilizing oversea data in December 2022)
New area	STN10**13**400 AFDX0250BS	Myopia	Achieved **FPI**[1] in P2a trial in Japan
	STN10**13**600 Ursodeoxycholic acid	Presbyopia	Achieved **LPO**[2] in P2a trial in US

1. FPI; First Patient In. 2. LPO; Last Patient Out.

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Santen

Sallstig: See page 12.

In the last quarter, R&D has had some developments in glaucoma and the refractive error therapeutic area.

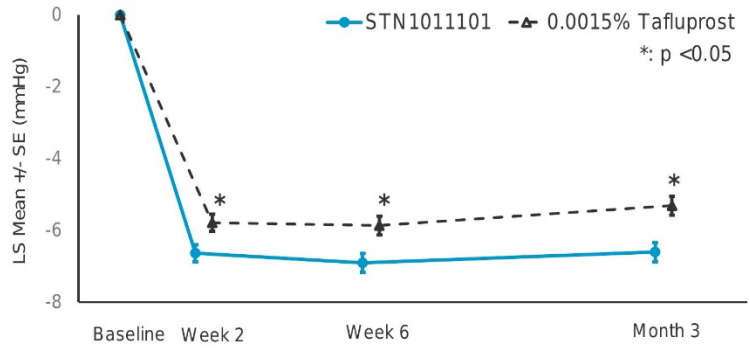
STN1011101 marketed as *Tapcom* for glaucoma in Japan and have been able to file in China ahead of time by utilizing overseas data. We obtained topline results of P3 in China and I will explain about this later.

In the refractive error area, we started the POC study of STN1013400 which is expected to become the next generation treatment for myopia and plan to complete it in FY2025. A POC study of STN1013600 for presbyopia in US has achieved last patient out and we plan to complete it this fiscal year.

STN10**111**01: Tafluprost / timolol maleate (combination)

Met primary endpoint in P3 trial in China. Confirmed safety and tolerance

Change from baseline of average diurnal IOP (ANCOVA analysis: Chinese information only)



- The superiority of STN10**111**01 IOP lowering effect compared to 0.015% tafluprost was confirmed (at Month 3 based on Bayesian method).
- Analysis only Chinese information showed statistically significant as well as the original EU study.
- STN10**111**01 was tolerated in Chinese population. No new safety issue was found.

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Sallstig: Next, I will introduce the P3 data of STN1011101 in China. This is on page 13. STN1011101 is a combination drug with tafluprost and timolol maleate for glaucoma. The IOP-lowering effect of STN1011101 was superior to that of tafluprost alone as well as in studies conducted outside of China. We also found no new problems with safety and confirmed its tolerability in Chinese patient population.

We have already filed by utilizing overseas data in China as previously informed. We expect that the data obtained in the Chinese population will further increase the probability of approval. This concludes my part. Thank you.

Question & Answer

Q1-1

My first question was about the one-off payment relating to the return of the *Ikervis* reimbursement provision. This figure of over JPY2.0 or 2.2-2.3 billion, was this just for Q1? Also, was this included in the forecasts or not? Please confirm those two points.

A1-1

Koshiji: The return on the *Ikervis* allowance is JPY2.3 billion, and this is only for Q1. It is included in the Company's forecast.

Q1-2-1

I have one more question.

I have heard about the basic cost reduction in the US. As of Q2, I think the figure of USD8 million will probably rise due to the impact of licensing and asset transfers that have occurred as a result of subsequent events. I think this will be in Q2, but I wonder if this is also in line with the Company's forecast or not. Is that USD8 million the only profitable impact that will appear in Q2? Could you please tell us a little bit about that?

A1-2-1

Koshiji: Regarding USD8 million, first of all, the item that is listed in Q2 may appear in either Q2 or Q3, depending on the timing. In our announcement on July 19, we announced that we had concluded contracts for three components, three projects, for two companies. The total amount to be recorded in revenue, which is the total here, will be USD9 million. These are to be recorded as revenue.

Of that amount, at least USD3 million will be recorded in Q2. The remaining USD6 million is in Q3 or Q4. In the contract, this depends on events as revenue recording trigger.

While I had mentioned *Cationorm* and *Verkazia* to Harrow Health for USD3 million and *Omlonti*'s transfer to Visiox for USD6 million, which is a licensing out, for the third component of the USD8 million, there is the transfer of assets of former Eyevance products to Harrow Health, for which the consideration is USD5 million. This figure was disclosed by Harrow Health. We plan to record this for other income, not revenue, under IFRS. This is very likely to be recorded in Q2. Does that answer your question?

Q1-2-2

Is all this in the Company forecast?

A1-2-2

Koshiji : That's not in there. It is not included because the amount is small.

Q1-2-3

I understand. The total is 9 plus 5, so USD14 million.

A1-2-3

Koshiji: Yes.

Q2-1-1

I have a question about Europe. I think I understand what you just explained about *Ikervis*, but other than that, for the outlook of *Ikervis*, that leaves JPY6.6 billion over the year and only JPY2.5 billion is left to go. There's just JPY2.5 billion left, and I'm not sure if that's enough. For Europe-related sales, like *Cosopt* and *Tapros*, it's a little bit better done vs the annual plan. Could you please explain the reason including whether there is onetime factor?

A2-1-1

Koshiji: The full year figure does not include the JPY2.3 billion onetime factor mentioned earlier. It is included in the figures on a consolidated basis, but not in the JPY6.6 billion figure.

In that respect, if we include this onetime factor, the full year figure is something like JPY8.9 billion, not JPY6.6 billion. The final level is expected to exceed JPY9.0 billion due to the effect of yen depreciation.

As for glaucoma-related products, we are not sure if this will continue to be the case in the future, but for now, we anticipate that sales will be in line with our full year forecast.

We were somewhat conservative about the impact of generics, but to some extent, we were still able to maintain our market share. Whether the same momentum can be maintained going forward remains to be seen. Thank you.

Q2-2

The other question is about the pipeline of presbyopia. You mentioned that the Last Patient Out will be achieved by the end of this fiscal year, but is it possible for you to show us something like top line data in Q2?

A2-2

Sallstig: For STN1013600, we plan to complete the trial within this fiscal year. As for the timing of data sharing, we will first conduct a detailed review of the data. Once that is completed, we will be able to share the data. Of course, the timing will depend on whether additional analytical analysis is necessary, but we expect the timing to be in Q3 or Q4.

Q3-1-1

I would like to start by asking you about the deviation from the Company plan.

In Mr. Koshiji's talk, he commented several times that there was a very strong upward movement, or that it was swinging upward. On the other hand, you mentioned that *Ikervis* and others are in the plan. Could you please explain about specific items, regions, costs, and other factors leading to the upward swing at this point?

A3-1-1

Koshiji: In this regard, if I may explain from the perspective of what is and is not included in the Company's initial earnings forecast, Japan is slightly down compared to the previous year as you can see. However, this is within our expectation, and the situation is slightly stronger than expected.

In China, the YoY growth rate is 81%, and here too, the momentum here is slightly stronger than originally planned. As for the full year forecast and China's progress against the regional sales profit, you may feel that we are down 25%. However, recovery from the coronavirus pandemic and other such factors will continue to drive the business in Q2 and beyond.

Asia is almost as expected. Regarding EMEA, overall, the situation is slightly stronger than expected, especially in the glaucoma segment. As a result, revenue are growing compared to the previous year, even excluding the transitory factors mentioned earlier.

In the US, the question is how much we can narrow the deficit. The results of the last fiscal year are shown on page 15 of the materials distributed today. Last fiscal year, the amount was minus JPY1.2 billion, and this fiscal year, it is minus JPY400 million. This figure is also due to the impact of the weak yen and other factors, but it is several hundred million yen lower than expected.

Therefore, the out-licensing or transfer on July 19, as I mentioned earlier, will reduce the deficit to minus JPY1.1 billion for the full year. We believe that the deficit could be reduced by controlling expenses in this area as well. Does this answer your question?

Q3-1-2

As you have just explained, revenues are generally favorable, and costs are in line with the plan at the beginning of the term, resulting in the overshooting of profit. Is my understanding correct?

A3-1-2

Koshiji: Yes, that's an accurate summary.

Q3-2

Secondly, I would like to ask you about the domestic trend for *Diquas LX*. Q1 also showed very strong growth YoY, but I am not sure if the growth here can basically be taken as a contribution from *LX*. If possible, could you tell us to what extent the current results are due to switching to *LX*?

A3-2

Koshiji: The growth in numbers here is due to *LX* growth. This is growth of LCM products. In quantitative terms, as of the end of June, the switch level was 50%. In terms of volume, we can see that the switch is taking place.

If we convert this to a monetary basis, the NHI price is different, so the switch level gets higher. (Santen post-amendment)

Q4-1

This is a bit of a housekeeping question, but I would like to ask about the tax burden. As for the tax burden being lowered this time around, I may have missed it, but can you tell us the reason for this? This is only a temporary situation, and we are wondering what will happen after Q2. As the forecast hasn't changed, I assume it will come back. First, regarding this area, that’s 25%, I am guessing. Can you tell me a little bit about what happens in this area?

A4-1

Koshiji: In the current fiscal year, the taxable income is slightly skewed because of the inclusion of the return profit from the *Ikervis* provision that I mentioned earlier. This has an impact. Nevertheless, the regional composition of profits and taxable income is gradually shifting to low-tax countries overseas. In reality, the nominal rate is 19.1%, but in real terms, we believe it is approximately 21%.

The main reasons for this are the changes in the composition by region, as I mentioned earlier, and also the relationship between the allowances.

The final full year, as you pointed out earlier, would be 25% of the final product. This may be slightly lower, but we are aware that such a level will be reached.

Q4-2

One more thing, you mentioned a little bit about the US deficit. When we look at a regional contribution profit, against a deficit of roughly JPY365 million for Q1, I think the full year projection is minus JPY1.1 billion.

I would like to ask you two questions on this point. As the US operation stops losing money, it may be too early to consider next steps, but the Company President's comment suggests that this does not mean you are leaving the US market. I believe there was something about business exploration, not new drug exploration. I'm wondering what you can tell me about movement in this area, and how costs will change, and the possibility of investment in the future. I appreciate that the forecast hasn't changed, but is it correct to say that there's no change in your view that the deficit will continue to shrink? I would like to confirm this, please.

A4-2

Koshiji: In that respect, this trend of reducing the deficit is as we mentioned at the beginning of the term. Also, as the Company President has stated in past briefings, the minimum prerequisite for further introduction of products into the US market is the development of large, well-differentiated, competitive products. We do not anticipate any upfront investment activities that will result in high costs in the current or next fiscal year. Depending on the status of the development, I think the time frame would be at least H2 of FY2024, FY2025, or later.

However, I would like to point something out, as shown on page seven of this document, relating to loss of investments accounted for using equity method, which are mainly losses of affiliated companies in the US. These are from Verily, which is a joint venture with Alphabet Group, healthcare company of Google. From these activities, we are consolidating 49% under the equity method of accounting. This is an affiliated company that develops medical equipment, so in terms of activities in the US, this is the only part that is in the red.

Q5-1-1

I'm looking at pages seven and eight. As you mentioned, the Company is doing very well, with double-digit growth in revenue and a 50% increase in both core and full. The China results on page seven and eight are very positive. They show an 81% increase.

However, when I look at the breakdown, I notice about *Diquas* and *Tapros*. *Diquas* is 95% up from last year's Q4, and *Tapros* is 23% up. On the other hand, given that *Cravit* is down 20% and OTC drugs are falling, I don't think the results are entirely attributable to recovery from the coronavirus pandemic. Could you tell me where I'm going wrong here?

A5-1-1

Koshiji: You mention that the ones that have not grown are *Cravit* and OTC drug. The reason why *Cravit* is not growing is that we recognize that the market is on the road to recovery, but the surgical market, including the refractive surgery market, has not yet returned to the pre-pandemic level.

In this respect, *Cravit* is prescribed for the prevention of secondary infections in the postoperative phase of surgery, which is why it is not being used as much as it should be. In our full year forecast, we had assumed that the number of surgeries would not return to the pre-pandemic level. In that respect, the results for *Cravit* in China are essentially within our expectation. I hope that answers your question.

Also, OTC drugs are still not that high on the priority list. In terms of money, we are devoting more resources to *Diquas*, or glaucoma area, which is expected to grow in the future. The result is shown here in Q1 results for OTC drugs, which are less than JPY100 million. I hope that makes sense.

Q5-1-2

In Q1, sales of *Tapros* and *Diquas* grew, but in H2, if there is a surgical recovery, *Cravit* sales will increase, so the Chinese market is strong, as you explained earlier.

A5-1-2

Koshiji: Yes.

Q5-1-3

Of course, there is the impact of the pandemic, but should we not take the impact of volume based purchasing too seriously anymore?

A5-1-3

Koshiji: No, we cannot rule out risks associated with volume based purchasing. Page 15 shows revenue by region, and we have factored in the risk of volume based purchasing into our full year sales forecast and the figure is JPY28.0 billion. Thank you.

Q5-2

Last question. When you look at it as a whole, as you explained earlier, there is a spot factor of JPY2.3 billion from *Ikervis*, but even if you exclude this, the progress rate is 27% in terms of revenue so it seems to me that even excluding spot factor, things were as good for Q1. I think that's a pretty good estimate.

A5-2

Koshiji: Yes, we are aware of that.

Q6-1-1

On page 10, you describe various factors that contributed to the full year results. Let me go over one more time the assumptions that your company is currently looking at and what is actually happening now regarding generics products in Japan and Europe.

A6-1-1

Koshiji: In this respect, first of all, in Japan, there are several in the area of our mainstay products, including for *Tapros*, where a new generic product was launched in July. However, given the current situation and considering our forecast for the full year, I would say that it does not appear to be having a significant impact on sales. That is how we consider it.

Q6-1-2

How many companies launched generic products?

A6-1-2

Koshiji: One company.

For *Alesion* and *Eylea*, I think in the case of *Alesion*, it is the middle of August. As for *Eylea*, I think the direction will be finalized by the end of August, so I can't comment at this stage. We will consider the outlook for the full year in light of these factors. I think that is the way it will unfold. That is the status in Japan.

Also, EMEA. In Europe, the situation differs from country to country, so it is difficult to say. We expect that a certain percentage of our mainstay products will be affected by the erosion of generics, but as of Q1, we have not made any major changes to our full year forecasts. Q1 was good, but it is still too early to make any upward revisions.

Q6-1-3

For *Tapros* and *Tapcom*, are generics products already available in some countries in EMEA?

A6-1-3

Koshiji: We are expecting the generics products to be launched this year for *Tapros* only. (Santen post-amendment)

Q6-2

Tapros only, yes, I understand. Thank you very much. Second question, regarding STN1012700 for myopia, the Phase III trial is scheduled to be completed in December, right? Please let me know if this schedule will remain the same.

A6-2

Sallstig: I think you are probably talking about Japan, but there is no change to the timeline. We hope to be able to share the results by the end of this fiscal year.