



Kyowa Kirin Co., Ltd.

Financial Results Briefing for the Fiscal Year 2019

February 6, 2020

Revised on February 18, 2020

Event Summary

[Event Name]	Financial Results Briefing for the Fiscal Year 2019	
[Date]	February 6, 2020	
[Number of Speakers]	3	
	Masashi Miyamoto, PhD	Executive Director of the Board, President, and Chief Executive Officer
	Mitsuo Satoh, PhD	Vice President and Head of R&D Division
	Motohiko Kawaguchi	Director of Finance Department

Presentation

Moderator: Now, we will hold a briefing on Kyowa Kirin Co., Ltd.'s financial results for the fiscal year ended December 31, 2019, which was announced at 3:30 PM yesterday. Today's speakers are Masashi Miyamoto, Executive Director of the Board, President and Chief Executive Officer, Mitsuo Satoh, Vice President and Head of the R&D Division, and Motohiko Kawaguchi, Director of the Finance Department.

Today's financial results briefing is scheduled to take about 60 minutes. First, Miyamoto will explain our financial results, progress in the development pipeline, and business topics for around 20 minutes. We will then receive questions from you.

Please use our IR website for downloads of financial results, supplementary materials for financial results, and material for today's financial results briefing. Now, Miyamoto will explain the details of the financial results.

Summary of FY2019 Results



(Billion Yen / Rounded)

	2018 Results	2019 Results	Changes	2019 Plan	Progress
Revenue <i>[Overseas Ratio]</i>	271.5 <i>[32%]</i>	305.8 <i>[39%]</i>	+34.3 (+13%)	305.0 <i>[39%]</i>	100%
Gross Profit <i>[Gross Profit margin]</i>	198.1 <i>[73%]</i>	226.2 <i>[74%]</i>	+28.1 (+14%)	224.0 <i>[73%]</i>	101%
Core OP <i>[Core OP margin]</i>	50.3 <i>[19%]</i>	59.4 <i>[19%]</i>	+9.0 (+18%)	53.0 <i>[17%]</i>	112%
Profit from continued operation	49.2	37.7	-11.6 (-23%)	37.0	102%
Profit from discontinued operation	5.2	29.4	+24.2 (+467%)	31.0	95%
Profit	54.4	67.1	+12.7 (+23%)	68.0	99%

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5

Now, I would like to report on our financial results for FY2019.

This is a summary of the results.

Last year, we sold KYOWA HAKKO BIO CO., LTD. to Kirin Holdings Co., Ltd. in April. Therefore, from 1Q of last year, we record the pharmaceutical business as a continuing operation and the business of KYOWA HAKKO BIO CO., LTD. as a discontinued operation, as in the table.

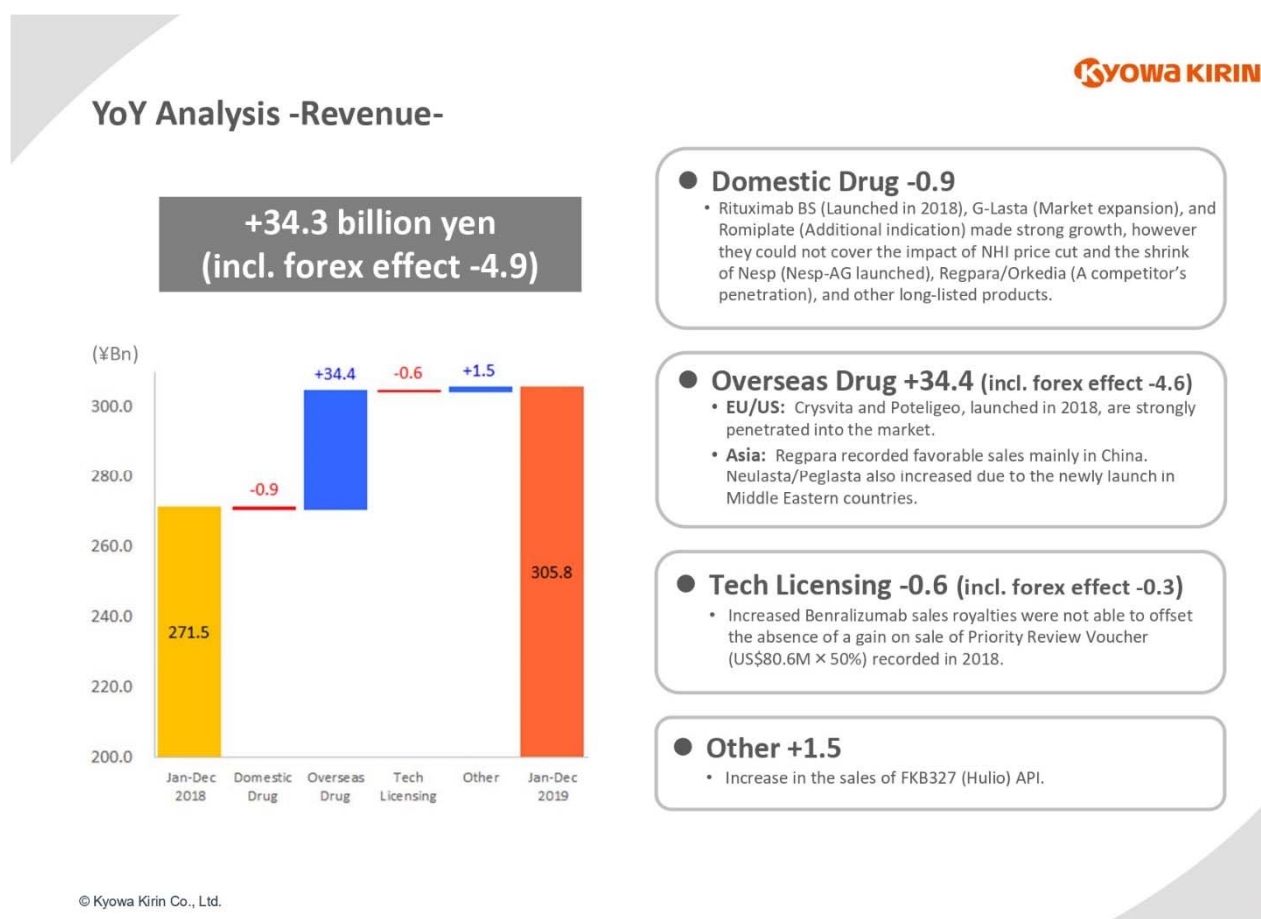
Looking at the results for 2019 compared to the previous year, in 2019, revenue was JPY305.8 billion, an increase of JPY34.3 billion compared to the previous year. Core operating profit was JPY59.4 billion, an increase of JPY9 billion, indicating that we have achieved increases in both sales and profits so far.

The profit for the continued operation was JPY37.7 billion, a decline of JPY11.6 billion. We will explain this in more detail below, but this is because the one-time positive figures in 2018 have disappeared and there were temporary negative figures in 2019.

The discontinued operation posted a gain of JPY30 billion from the sale of KYOWA HAKKO BIO CO., LTD.'s shares, which contributed significantly to a profit increase of JPY24.2 billion. Profit for the year increased by JPY12.7 billion to JPY67.1 billion.

Compared to the full-year forecast, both revenue and gross profit were achieved almost 100% but core operating profit has marked 112%. This is because there is a fairly large probability that revenue of Fujifilm Kyowa Kirin Biologics Co., Ltd. (FKB), which handles biosimilars, will be positive from this year, and FKB, therefore, applied the tax effect accounting. This led to an increase of JPY46 billion, resulting in the achievement rate of 112%.

Profit from the discontinued operation decreased slightly due to the unplanned additional business improvement costs for KYOWA HAKKO BIO CO., LTD. in 1Q, which made an impact on profit for the year.



Looking at this more closely, revenues increased by JPY34.3 billion, of which the impact of exchange rates was approximately minus JPY5 billion so, in real terms, I think it was an approximately JPY40 billion increase.

In Japan, the impact of NHI drug price revisions, the impact of long-listed drugs, and the expiration of Nesp's patents were offset by growth items, resulting in a YoY decline of JPY0.9 billion.

On the other hand, sales of overseas products have grown greatly, as shown here. Crysvita and POTELIGEO have made considerable contributions. In Asia, REGPARA, centered on China, and Neulasta/Peglasta in the Middle East (G-LASTA in Japan) have grown greatly, and this has become a positive factor.

As for technology licensing, as you know, there was revenue from the sale of the Priority Review Voucher for burosumab in 2018, which was not available in 2019. However, this was almost offset by increased royalties of benralizumab, resulting in a decrease of JPY600 million.

As for other revenue, increased sales of active pharmaceutical ingredients for Humira's biosimilars contributed to an increase of JPY1.5 billion.

Revenue of Major Items (Japan)



(Billion yen / Rounded)

Item	2018 Results	2019 Results	Changes	Reason	2020 Plan	Changes
Nesp + Nesp-AG*	53.7	47.6	-6.1 (-11%)		34.7	-27%
Nesp	53.7	33.6	-20.1 (-37%)	Nesp-AG launched in Aug 2019	4.0	-88%
Nesp-AG	—	14.0	+14.0		30.7	+119%
Regpara	13.3	6.5	-6.8 (-51%)	A competitor's penetration & switch to Orkedia	3.2	-51%
Orkedia	2.4	6.9	+4.5 (+190%)	Launched in May 2018	10.1	+45%
G-Lasta	20.7	24.6	+3.9 (+19%)	Market expansion & Steady market penetration	28.1	+14%
Rituximab BS	4.3	9.7	+5.4 (+125%)	Launched in Jan 2018	10.1	+5%
Allelock	12.6	10.8	-1.8 (-14%)	Generic drugs' market penetration	8.3	-23%
Patanol	13.4	13.6	+0.2 (+1%)		9.5	-30%
Nouriastr	9.4	9.7	+0.3 (+4%)		10.5	+8%
Crysvita	—	0.1	+0.1	Launched in Dec 2019	3.5	+5,138%
Technology licensing	2.7	4.6	+1.9 (+68%)		3.7	-20%

* AG stands for Authorized Generic. Official product name is Darbepoetin Alfa Injection Syringe [KKF].
Kyowa Kirin Frontier is a marketing authorization holder; Kyowa Kirin is a distributor.

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7

Let's look at the analysis by item in Japan. The revenue from Nesp and Nesp-AG totaled JPY47.6 billion, a decrease of JPY6.1 billion from 2018.

Sales by quarter are shown in the supplementary material of the financial summary on page four. In 4Q, Nesp posted revenue of JPY1.6 billion and Nesp-AG posted JPY8.4 billion. It is clear from the data that the original has been shifted to AG at a fair speed since the August launch. Based on the forecast that these trends will naturally continue, we are forecasting a total of JPY34.7 billion for this year.

With regard to REGPARA and ORKEDIA, due in part to the growth of competing products, the total decrease was JPY2.3 billion. We are currently switching from REGPARA to ORKEDIA, but when switching, dose and unit price decline slightly, which had a slightly negative impact.

This year, we will continue this switch, and the same impact will be seen. However, as ORKEDIA will grow slightly, we set such a forecast.

As in 2018, G-Lasta has grown very strongly in 2019, and we expect this trend to continue this year, reaching JPY28.1 billion.

Rituximab BS (biosimilar), which was launched in January 2018, grew steadily in 2019 and almost doubled. However, as you know, A competitive BS product has already been emerged. Therefore, we do not expect it to grow so much this year and set a forecast of JPY10.1 billion.

With regard to ALLELOCK and PATANOL, as you know, there have already been many generics of ALLELOCK, and this has had an impact. However, in 2019, the pollen dispersion was relatively high compared to 2018, resulting in this figure. This year, the figures are based on the assumption that the volume of pollen will not be so high. With regard to ALLELOCK, we expect that the impact of generics will continue to emerge.

Regarding NOURIAST, we have worked to aim at JPY10 billion in 2019, but we were not able to reach it. As you know, we launched istradefylline in the US last year, and we expect a slight increase, as it will be a favorable tailwind.

On December 6, last year, we launched Crysvita and sold JPY0.1 billion in Japan. This year, we expect to see a steady increase, with a forecast of JPY3.5 billion in 2020.

Revenue from technology licensing was JPY4.6 billion. FKB discontinued the development of the third drug candidate and then we withdrew its contractual liabilities at that time, resulting in revenue of about JPY1.4 billion. This made a substantial contribution, and the results exceeded the results of 2018. This year, we do not anticipate any special factors, so we are forecasting a total of JPY3.7 billion.

Revenue of Major Items (Overseas)

(Billion yen / Rounded)

Item	2018 Results	2019 Results	Changes	Reason	2020 Plan	Changes
Crysvita^{*1}	7.7	32.5	+24.8 (+321%)	Launched in Apr 2018	56.6	+74%
North America		25.1				
Europe & others		7.4				
Poteligeo	2.1	10.8	+8.7 (+416%)	Launched in Oct 2018	14.3	+32%
Nourianz	—	0.1	+0.1	Launched in Oct 2019	2.8	+3,962%
Abstral	12.8	11.2	-1.5 (-12%)	Preparation for Brexit	9.0	-20%
Technology licensing	15.8	13.3	-2.5 (-16%)	Crysvita PRV^{*3} in 2018	18.8	+41%
Benralizumab Royalty ^{*2}	3.3	8.9	+5.6 (+170%)	Launched in 2018		

*1 -In January, sales started in England at the list price of GBP2,992 per 10mg vial.

-Since May, the List price in Germany has been revised to €2,550 per 10mg vial (from €3,388).

-Launched countries as of December 31, 2019 (excluding South America):

USA, Canada, Germany, Netherland, Luxembourg, England, Wales, North Ireland, Slovakia, Sweden, Israel, UAE, Czech, Denmark, Italy, Japan, Norway, Bahrain

*2 Sales royalties of "Fasenra" marketed by AstraZeneca. Includes our own estimation.

*3 PRV = Priority Review Voucher

Overseas, revenue from Crysvita was JPY32.5 billion, a substantial increase from 2018. Revenue in North America was JPY25.1 billion and in Europe and others JPY7.4 billion. Countries where we already launched Crysvita are shown below in the table. Since October 1, Czech Republic, Denmark, Italy, Japan, Norway, and Bahrain have been added.

As I will touch on later, in Europe, the indication of adults is now being reviewed, and after we got approval of that, it will grow further. By continuing to bring this product to market in countries where it has not yet been launched, we intend to increase the number of countries and the number of patients. Our goal for this year is JPY56.6 billion.

As the plan in Japan is JPY3.5 billion, we have set a goal of exceeding JPY60 billion in Japan and the regions shown here.

POTELIGEO has also grown very favorably. Revenue increased by JPY8.7 billion to JPY10.8 billion, even in North America alone. This year, we expect that we will be able to launch it in Europe in the latter half of the year, so we expect a revenue of JPY14.3 billion.

Nourianz, which was just launched last year, posted a revenue of JPY1 billion in 2019, and we have set a forecast of JPY2.8 billion for 2020.

Regarding Abstral, a fentanyl product that we sell in Europe, due to the fact that patents are expiring and that we had to prepare to Brexit, revenue in 2019 saw a slight decline compared to that of 2018. As the patent has expired, we expect revenue to be JPY9 billion in 2020.

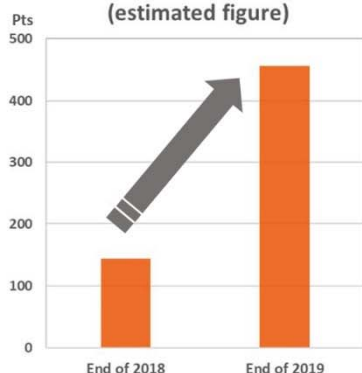
Regarding revenue from technology licensing, although royalties for benralizumab have steadily increased in 2019, there was no gain on the sale of the Priority Review Voucher of burosumab, which resulted in a decrease of JPY2.5 billion. However, in 2020, we expect royalties for benralizumab to grow steadily, and we set a target of JPY18.8 billion.

Crysvita (EMEA/RoW)

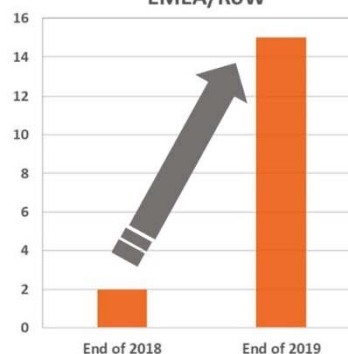


Successful Market Penetration in EMEA/RoW for the 2nd Year

Number of Pts in Active Treatment
(estimated figure)



Number of Countries
EMEA/RoW



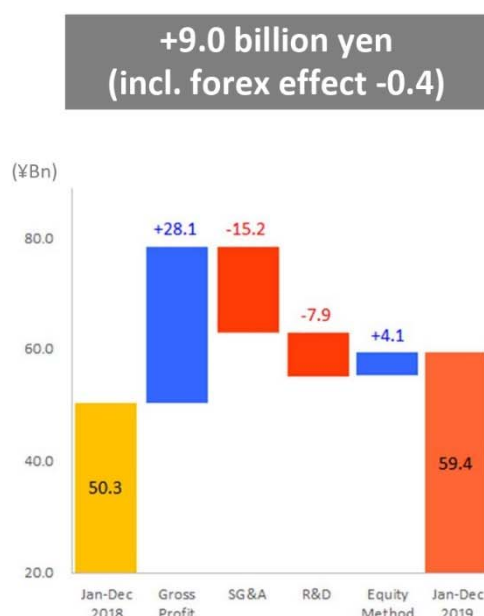
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9

As for Crysvita in the North American market, we have to wait for the financial results announcement by Ultragenyx.

In Europe and other areas, in 2019, the second year of the drug's launch, the number of countries in which we sell the drug has steadily increased to 15. The estimated number of (reimbursed) patients reached around 450 at the end of 2019, compared to the estimated 150 at the previous year end. Although this drug has a child indication only, it has grown steadily like this. This year, we would like to get an additional approval for an indication for adult patients, and make it grow as well as child patients.

YoY Analysis -Core OP-



● **Gross Profit +28.1 (incl. forex effect -3.4)**

- Increased in conjunction with the rise in the revenue. Gross profit margin up by 1 point, from 73% to 74%.

● **SG&A -15.2 (incl. forex effect +2.4)**

- Increased selling and launch readiness expenses in the EU/US, including Crysvita's profit sharing expenses in North America.

● **R&D -7.9 (incl. forex effect +0.5)**

- Negative: KHK4083 (P2 initiated in Oct 2018), RTA402 (P3 initiated in May 2018), KW-6356 (P2 initiated in Nov 2018), KHK7791 (P2 initiated in Mar 2019), etc.

● **Gain/Loss on Equity Method +4.1**

- Newly recognized deferred tax asset based on the future taxable income (\$4.6Bn).

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10

Next is the analysis of core operating profit. Core operating profit increased by JPY9 billion YoY. Gross profit increased by JPY28.1 billion. As revenue increased by JPY34.3 billion, about 80% was left. The gross profit margin also improved 1%.

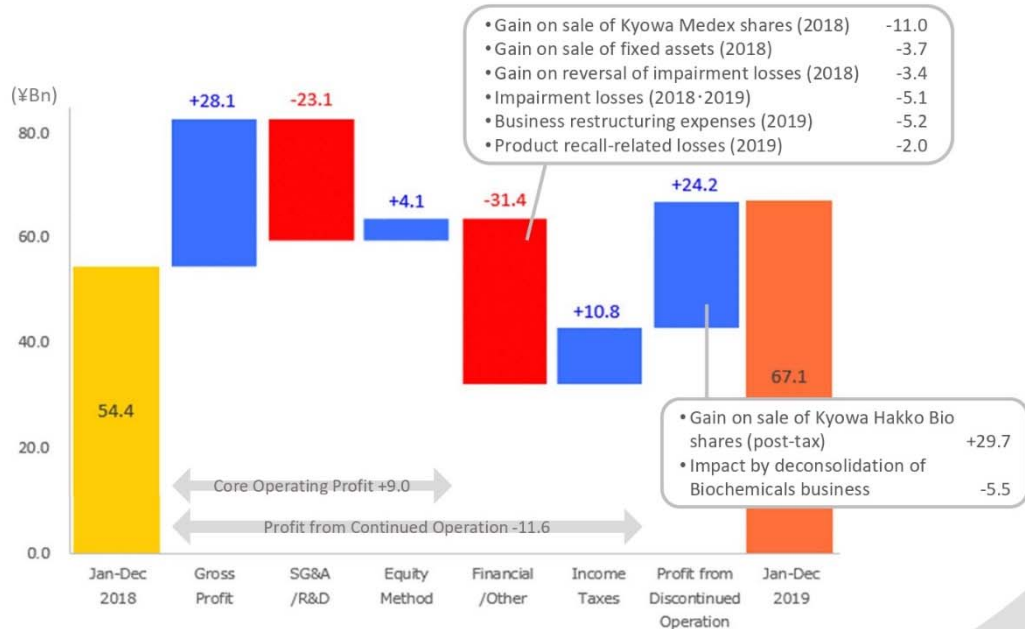
The SG&A expenses increased for sale and preparing for the launch in Europe and the United States. As I explain every time, since Crysvita's profit sharing expenses in North America are included in this figure, if Crysvita grows in North America, this figure also increases. As a result, SG&A expenses increased by JPY15.2 billion.

R&D expenditures, as shown, have increased substantially by JPY7.9 billion, partly because of steady progress in such items as KHK4083, RTA 402, KW-6356, and KHK7791.

Regarding gain/loss on equity method, as I explained earlier, FKB has begun sales of Humira's biosimilars in Europe, and we expect that it will turn a profit in 2020. As a result, the likelihood of future taxable income emerging has increased, and the Company posted deferred tax assets of JPY4.6 billion as a result of the adoption of tax effects accounting.

YoY Analysis -Profit-

Profit (Jan-Dec) +12.7 billion yen



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11

Let's look at the analysis of profit. Profit from the discontinued operation increased by JPY24.2 billion, partly due to the gain on the sale of shares of Kyowa Hakko Bio CO., LTD. As explained earlier, there were gains such as the sale of Kyowa Medex, the sale of fixed assets, and the reversal of impairment losses in 2018. However, these gains disappeared, and impairment losses were incurred in 2019. In addition, in relation to the voluntary retirement plan, the premium for the retirement allowance was added to this figure, and the product recall-related losses were JPY2 billion.

On January 31, we issued a press release about the Hofu Plant of Kyowa Hakko Bio CO., LTD. For many years there has been a manufacturing activity that deviated from the SOP. The Hofu Plant has already received administrative disposition from Yamaguchi Prefecture.

We are also a manufacturer of mitomycin C. In addition, the Company and Kyowa Hakko Bio CO., LTD. were originally the same company, and after that, we were the parent company of Kyowa Hakko Bio CO., LTD. And now, we are group companies. It has also been pointed out that, despite this position, we have not fulfilled its supervisory responsibilities sufficiently.

We regret this very deeply, and I am determined to take the initiative in rebuilding the Company in the future, and that all of our employees will take the initiative in tackling it.

In terms of mitomycin C, we would like to once more apologize for the shortage of product that is occurring at this time and that it is really causing great nuisance to patients and medical professionals.

P/L Impact from the Quality Control Issue (Recall of Mitomycin)

	Amount	Notes
Cost of Goods Sold	¥2.0 Bn	Mainly stock disposal
Impact to Core OP	-¥2.0 Bn	
Other Expenses (Provision for Product Recall-related Losses)	¥2.0 Bn	Including losses not yet determined
Impact to Pre-tax Profit	-¥4.0 Bn	

Recognized as Losses in FY2019

The impact of this matter on the Company's business results is as shown. Disposed inventories were included in cost of sales, resulting in a negative impact of JPY2 billion on core operating profit.

In addition, the estimated amount of other expenses is JPY2 billion, including some undetermined expenses, such as expenses related to the collection. Total effect is JPY4 billion.

The impact on this year is not expected to be significant so far. However, as we resume production and resume supply of mainly mitomycin in the future, the possibility of new expenses emerging is not zero. In such a case, we will promptly inform you.

Summary of FY2020 Forecasts

(Billion Yen / Rounded)

	2019 Results	2020 Forecasts	Changes
Revenue <i>[Overseas Ratio]</i>	305.8 <i>[39%]</i>	327.0 <i>[47%]</i>	+21.2 (+7%)
Gross Profit <i>[Gross Profit margin]</i>	226.2 <i>[74%]</i>	250.0 <i>[76%]</i>	+23.8 (+11%)
Core OP <i>[Core OP margin]</i>	59.4 <i>[19%]</i>	65.0 <i>[20%]</i>	+5.6 (+10%)
Profit from continued operation	37.7	49.0	+11.3 (+30%)
Profit from discontinued operation	29.4	—	-29.4 (-100%)
Profit	67.1	49.0	-18.1 (-27%)

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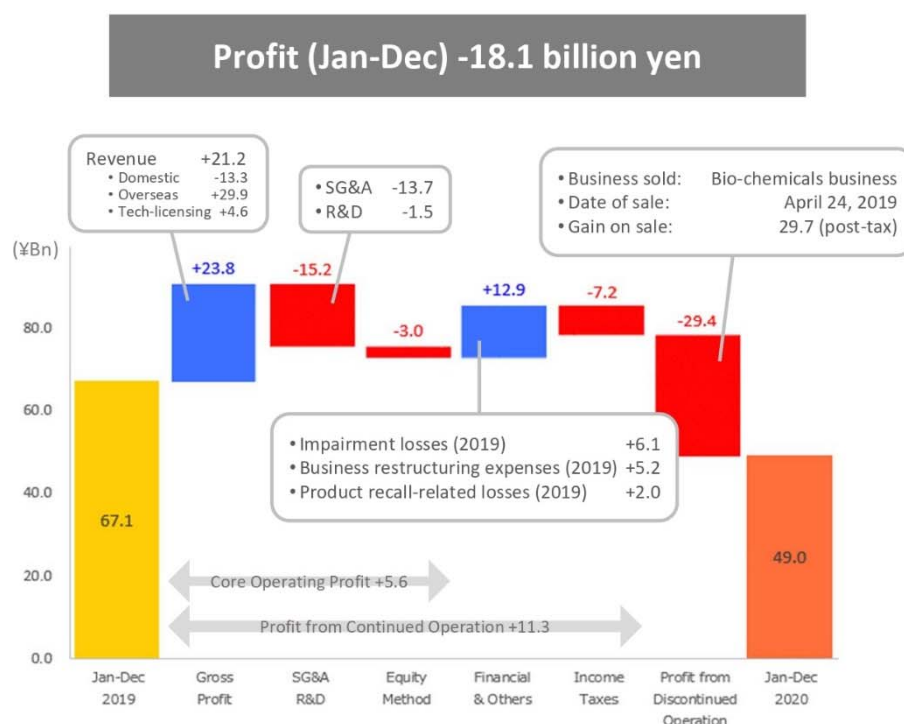
14

Forecast for the current year.

Revenue is forecast to increase by JPY21.2 billion YoY to JPY327 billion. Core operating profit is expected to be JPY65 billion, up JPY5.6 billion. Profit from continued operation is expected to be JPY49 billion, up JPY11.3 billion.

Since there is no longer any profit from discontinued operation, profit for the year, bottom-line, is also expected to be JPY49 billion.

2019 Results vs 2020 Forecasts



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15

I will explain the analysis for 2020 forecasts.

The revenue increase of JPY21.2 billion, and we expect the revision of the drug price and Nesp will have a negative impact. However, we expect this to be offset by an increase in overseas sales and technological revenues, resulting in an increase of gross profit by JPY23.8 billion.

SG&A expenses and R&D expenses will continue to grow. SG&A expenses, in particular, will increase as Crysvita in North America grows.

With regard to the equity method, the tax effect in 2019 will disappear, but in effect, we expect to achieve a surplus of approximately JPY1 billion.

As a result, we forecast a core operating profit of JPY5.6 billion and profit from continued operation of JPY11.3 billion.

Shareholder Returns Plan

- FY2019 dividends determined to be 42 yen (+7 yen)
- FY2020 dividends planned to be 44 yen (+2 yen)



Aiming continued escalation in dividends based on a payout ratio of 40%

[Basic policy for profit allocation]

Along with working to enhance retained earnings, such as preparing for future business developments, provide a stable dividend while comprehensively considering factors including the consolidated business results and dividend payout ratio.

- **Stock Repurchase** Flexibly acquire treasury stock based on the market environment and financial situation.
- **Retained Earnings** Allocate to investments that will lead to new growth, such as R&D, capital investments and development pipeline enhancements which will contribute to increased corporate value in the future.
- **Dividend** Based on the consolidated dividend payout ratio of 40% set forth in the Mid-term Business Plan, aim to stably and continually increase the dividend level in accordance with the growth in profits.

Based on this financial position, we have decided to pay an annual dividend of JPY42 per share for 2019, an increase of JPY7 per share from 2018. As the annual dividend for 2020 is currently planned to be JPY44, we intend to increase the dividend by JPY2.

In 2019, we recorded a temporary ROE of 10.1% due to the gain on the sale of shares of KYOWA HAKKO BIO CO., LTD., which we explained earlier. However, due to the absence of this portion, it will return to the 7% level in 2020. We will keep in mind that we strive to achieve the goal of more than 10%.

The Company has not changed its approach to profit distribution, and we would like to prioritize investments for the future business growth. In addition, we plan to steadily increase distributions during the medium-term plan, based on a payout ratio of 40%. Of course, we intend to acquire treasury stock in a flexible manner while taking into account our cash position and share price.

Key Development Updates in 19Q4

- **Acceptance of the application for the expanded use of KRN23 for adult XLH in Europe (November)**
- **Initiation of the phase 3 study of KW-3357 for the treatment of preeclampsia in Japan (November)**
- **Partial change approval of KHK7580 for hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism in Japan (December)**
- **Application for partial change approval of KHK4827 for axial spondyloarthritis in Japan (December)**
- **Submission of supplemental biologics license application of KRN23 for tumor-induced osteomalacia in the U.S. (December)**

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19

The following is a brief explanation of R&D. In 4Q of last year, an application for approval for KRN23 for adult XLH was accepted by the European authority in November.

We launched the phase three study of KW-3357 (ACOALAN) for preeclampsia in November.

Partial change of KHK7580 (ORKEDIA) for hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism was approved in Japan in December.

We also filed in December an additional application of KHK4827 (LUMICEF) for the treatment of axial spondylarthritis. LUMICEF is designated as an orphan drug for the treatment of systemic sclerosis at the same time.

In December, we filed an additional application of KRN23 for the treatment of tumor-induced osteomalacia in the US.

Key Development Updates after December

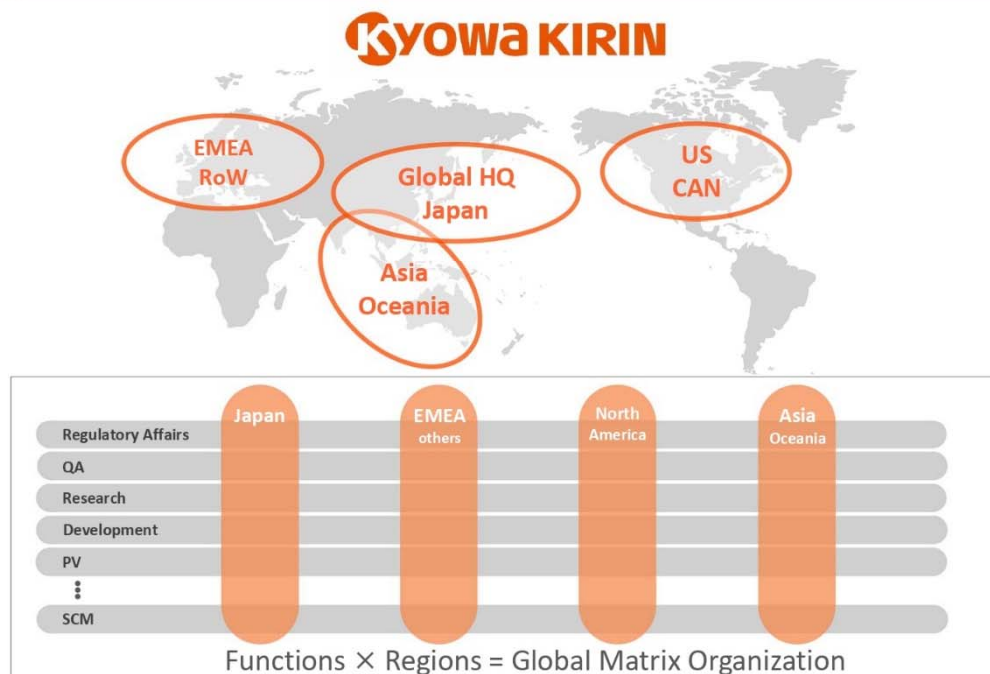
- Acceptance of the marketing authorization application for approval of KW-6002 for Parkinson's disease in Europe (January)

In 2020, an application for approval of istradefylline for the treatment of Parkinson's disease, which we filed in November last year, was officially accepted by the European authority in January, and we are now in the process of reviewing it.

I provided an explanation regarding research and development.

“One Kyowa Kirin” Organization

Global Management System from April 2019



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22

We move on to business topics. 2019 was a year in which we worked on a number of major initiatives. We sold Kyowa Hakko Bio CO., LTD, and then, we solicited voluntary retirements. In July, the Company's name was changed, and the brand was unified globally to “Kyowa Kirin.”

With the willingness to become a global specialty pharma, since April, we have divided the commercial basis in four regions: Europe and the Rest of the World, Asia and Oceania, Japan, and North America.

In addition, we have changed the structure to a matrix system in which regulatory affairs, quality assurance, research, development, pharmacovigilance, supply chain management, et cetera are operated globally as a single organization. We have started this organizational matrix operation in April.

In fact, the action plan for 2020 and the budget for this year were created for the first time based on this new structure and are currently being implemented. In particular, under these global functions, we are working hard to recruit talented people for the respective functions. For example, in the case of regulatory affairs, quality assurance, and pharmacovigilance, overseas human resources are now at the top.

Although we have only just begun to do so, we are working to change our business structure.

All Products Kyowa Kirin Received MA in 2019 (incl. additional indication)



Making further leaps as a Global Pharmaceutical Company

For reference, here you see the products approved in 2019.

If you look at these things, you can feel that our business is expanding globally. By further enhancing these systems, we intend to expand our products globally and drive growth.

That is all.

Question & Answer

Yamaguchi: I'm Yamaguchi from Citi group securities. Thank you very much. The first question is about the sales forecast of Crysvita in Europe. Ultragenyx presented a rough range at the JP Morgan Conference. If back calculates, it would be about JPY19 billion, more than twice of JPY7 billion. Is this range correct?

This year, it has been relatively flat in Europe. What measures are you taking to achieve this figure, and whether the number of countries is expanding from the next fiscal year onward? Please let me know also if the certain amount of expected sales from the expanded use for adults are included in 2020 Europe forecast.

Miyamoto: Regarding Ultragenyx's forecast, we are not able to say anything about it.

As I explained earlier, it has not yet been launched in some of our main countries. In such countries, we are actively engaged in drug price negotiations and other activities. We have to resolve these negotiations as soon as possible, and after approval, we will launch it.

The indications for adults are being reviewed, so I think it is important to get approval for it, and perhaps, the labels are also important. As you know, we have to negotiate for drug prices in each country in Europe. By completing these negotiations, we will increase the number of countries in which we sell it.

In addition, Crysvita is also used for adolescent patients, people older than infants, in Europe, but when they become over 17, they should stop the treatment due to the current indication restriction. In this case, as their weight is comparatively heavy and the amount of dosage is weight dependent, so the unit price per person (adolescent, around 17 years old) is higher accordingly. This has stopped the sales growth. If we can get an approval for additional indication for adults, we will be able to expand its sales.

Yamaguchi: You cannot comment on Ultragenyx's figures. Okay, thank you.

The second question is about its domestic sales. It is supposed that there are about 6,000 patients (in Japan) in terms of the epidemiology, but this time (according to its estimated peak sales in the Central Social Insurance Medical Council's materials), JPY7.5 billion for 400 people. Although the drug price is high, I think that the number of patients targeted is smaller than expected. So, this year, you mentioned it will be applied to almost half of that. How many patients could you identify since the launch in December?

Miyamoto: There is certainly some data on the epidemiology, but we still don't have enough data to estimate accurate number of patients in Japan. Therefore, I believe that this may be the biggest risk to Crysvita in Japan.

In the case of patient identification, we naturally launch this drug for the first time. MRs who cover Japan are currently working on patient identification, and Medical Affairs team is trying to raise the awareness of the disease. I think that patients have been identified smoothly and then will be administered.

In fact, it has the broadest indication in the world in Japan, and it will be used for adult XLH patients of course, and for TIO patients. Japan is a market where sales doesn't rise at once, so we have made forecasts for this year based on such considerations.

Yamaguchi: Do you mean it will grow a bit more this year?

Miyamoto: No, the forecast was made as such.

Yamaguchi: Carefully?

Miyamoto: Conservatively.

Yamaguchi: Understood. Thank you very much.

Hashiguchi: Hashiguchi from Daiwa Securities. First, after receiving the (additional) approval of Crysvida for adult XLH patients in Europe, as for cost-effectiveness, there is a possibility that the price, the condition for reimbursement, et cetera will be a little more severe than for children.

How is the current situation of negotiation? And how much are you factoring it in the plan?

Miyamoto: Thanks. As you have said, I believe that it will be seen in Europe in a fairly severe manner. Therefore, in terms of the work for the application, we have collected a considerable amount of data and applied for it. We will negotiate with each country while emphasizing the clinical usefulness of the drug.

Hashiguchi: Your company responded in this way, but you see no reaction yet.

Miyamoto: Not yet.

Hashiguchi: I understand. Second, I would like to ask you about your medium-term (earnings) outlook. At the briefing a year ago, you revised the medium-term management plan slightly and aimed to achieve a core operating profit of more than JPY100 billion in the first half of the 2020s. However, if you were to increase by two digits from JPY65 billion in the current fiscal year, it would be in the mid-2020s, rather than in the first half, to reach JPY100 billion. How do you look at this?

Miyamoto: Thanks. We are not thinking about changing the plan for the first half of 2020. Because this year is the final year of the medium-term plan, we are now in the process of formulating the new medium-term plan. Within this framework, we have begun to scrutinize top-line growth and how much we will spend on R&D. Once we have decided on a new medium-term plan, we will announce it, although it may be around this time next year. Of course, if the assumptions change, target will change. At this point in time, however, I do not think that we will change the assumptions that I mentioned at this time last year.

Hashiguchi: Do you feel that there is a large discrepancy between the forecast and the current situation at this moment?

Miyamoto: There is not so much.

Hashiguchi: Thanks. That is all.

Wakao: Wakao from Mitsubishi UFJ Morgan Stanley Securities. First, I would like to ask you how you forecast Nourianz in the US in the current fiscal year. In terms of the number of possible US patients, I have an impression that your growth forecast is slightly slow. What are your assumptions? Please tell us if there is a reason why you need to be cautious in selling it.

Miyamoto: Thanks. As you have said, since there are about 1 million patients with Parkinson's disease in the US, it gives an impression that the number of possible patients for Nourianz is about three times more than that of Japan. The selection of the number of patients who can use Nourianz and of course, the fact that reimbursement systems are different from that of Japan should be considered. Many patients will be covered under Medicare because they are older patients. In addition, there are few new drugs in this market, but we have developed such a plan based on a model of the growth of new drugs that have recently emerged, while conducting a variety of simulations and taking into account the situation when we launch it in Japan.

Wakao: Given that sales have not risen so much in the last quarter, you did not expect that it would greatly exceed the plan?

Miyamoto: That's right. As it has been about a month since it was launched, we do not yet know how it will proceed.

Wakao: Thanks. Second, I would like to talk about the idea of M&A. It is already apparent that you will grow with the three global products of Crysvita, Nourianz, and Poteligeo. Since we have seen such growth potential, I believe that longer-term pipelines will be the focus. I think that KHK4083 will become a promising new drug. On the other hand, you mentioned at the time of last year's full-year financial results that the Company was considering incorporating external growth. What do you think about this point? I do not think there has been any particular movement in the past year.

Miyamoto: Our stance remains unchanged from what I mentioned last year. We use cash for growth investment, and the enhancement of the future pipeline is of considerable priority. In addition, we have decided to invest firmly in new modalities that we don't have yet, and we are working hard to explore external opportunities.

Wakao: Understood. Then, as you just mentioned, you're going to get modalities and platforms, but you are simply conducting due diligence and time is not yet ripe.

Miyamoto: It has not produced results, but we have been engaged in a considerable amount of activities.

Wakao: Understood. That is all.

Tanaka: I am Tanaka from Mizuho Securities. First of all, regarding Kyowa Hakko Bio CO., LTD., you have written in the recent press release that you need sufficient resources for quality function assurance regarding your company's efforts to prevent a recurrence. You have already taken in human resources from outside the company, but it is written that it is not yet sufficient. How long will it take for the Company to become sufficiently organized? Even in "One Kyowa Kirin", the four-region structure, you mentioned about the global quality assurance system. What do you think about such a system?

Miyamoto: Thanks. In fact, before this matter became apparent, with the recognition that we had to provide quality assurance globally before we get out of the international market, we had already begun to take various measures.

In February of last year, we were able to recruit a top global quality management executive in the United States, and led by him, we created a roadmap for 2023. In accordance with this, we are moving forward with the foot on the accelerator.

So, after this incident, we are working to secure human resources by accelerating particularly in Japan. In terms of the number of the staff, probably there will be considerable improvement this year in Japan.

However, as you know, quality assurance is not secured by only having a solid quality assurance department but is a company-wide story. We need to secure quality assurance not only by establishing strong quality assurance department and the production department, but by the entire Company, and I believe that it will take time.

As I mentioned earlier, we are formulating a road map for the next four to five years. Where we need to do it urgently, we are doing our utmost to deal with it in an urgent manner.

Tanaka: Understood. Thank you very much. Second, you have successfully tested RTA402 for Alport Syndrome, but as your company has the rights in Japan and Asia, will you file an application for this?

Reata says that the number of patients is about 1,200 in Japan and 30,000 in the United States. I think you are well aware of Japan's kidney patients, so please tell us how you see the figure of 1,200.

Satoh: First, regarding the application for the Alport, we are also participating in the global trial conducted by Reata in Japan. So, I think the FDA and Reata are in negotiations. If they agree in application in the US, we will naturally start consultations with the PMDA (Japanese authorities) on the application including the data of Japanese participants of the global study.

In terms of the number of patients (epidemiology data in Japan), this is the same situation as that of XLH. In collaborating with doctors, we need to identify the true number of eligible patients.

If it is possible to file an application, we will conduct accurate investigations together with the MA (Medical Affairs) department via activities to improve disease awareness and inform you when we roughly figure it out.

Tanaka: Thanks.

Muraoka: I am Muraoka from Morgan Stanley. Thank you very much. First, with regard to KHK4083, I think you mentioned that you were able to lead out data around mid-2020. I would like to know the timing of KHK4083's lead-out and the possibility that it may accelerate if the scenario works well.

Satoh: Thanks for your question. We are doing this for patients with atopic dermatitis, and we plan to conduct an interim analysis by 2Q of this year. This is the first evaluation item among primary endpoints, and I think it will be possible to get a sense of whether or not we can go further. However, for drugs for such as atopic dermatitis, the whole trials, including long-term safety evaluation, will continue, so if the results of the overall trials are to be reported accurately, I believe that it will be the first half of 2021.

Muraoka: If the results of the interim analysis are extremely good, is there any possibility of submitting an application as an anticancer drug, for example?

Satoh: I think it's a little different from anti-cancer drugs. It is necessary to carefully examine what happens during long-term administration, including safety issues and I think all trials will be carefully examined for longer period.

Nevertheless, I think that if we have a good feeling from the interim analysis, next activities for the pivotal test of phase three will continue to emerge.

Muraoka: I understand. In the same way, the next generation of istradefylline, KW-6356, is scheduled to release the data within 2020, as stated on slide 28. Is this correct?

Satoh: We are currently conducting dose-finding phase 2b trials, and the enrollment of patients has now been completed. I would like to take a look at the outcomes in the beginning of summer this year. If the results are good, we need to move forward to consider KW-6356 development strategies as a successor of istradefylline.

Muraoka: Can we hear something updated at the end of July?

Satoh: I'm not able to say exactly. We would like to report on the appropriate timing, including the overall development strategy.

Muraoka: Thanks. I would like to ask Mr. Miyamoto one more question. Stock prices have been rising for a long time, and there have been many discussions about parent-subsidary listings in the last few months. Could you tell us about your current stance on parent-subsidary listings?

Miyamoto: The stance has not changed at all. There are a lot of topics on this issue, and there are a variety of codes that need to be adhered to, and management should be fully aware of the importance of doing so.

For example, in last April, we sold KYOWA HAKKO BIO CO., LTD. to our parent company, Kirin Holdings Co., Ltd. We recognize that this process had been highly transparent. We will take a firm look at those issues. The relationship between Kirin Holdings Co., Ltd. and Kyowa Kirin Co., Ltd. itself, I believe, is not a point of view for us to answer. Our stance has not changed. It is a matter of thing that the holding company makes decisions.

Muraoka: From the perspective of Kyowa Kirin Co., Ltd.'s management, do you think that it is possible for Kyowa Kirin Co., Ltd. to increase its corporate value by listing on the stock exchange and acting independently?

Miyamoto: I don't think the current direction is wrong. Of course, if the decisions of the parent company change, that will change. At present, it is our mission to maximize value and to do our best to that end.

Muraoka: Thanks.

Ueda: I am Ueda from Goldman Sachs Japan. First, I would like to ask about Nesp. Looking at the plan, I think you've already switched to AG, for example, in the dialysis and pre-dialysis phases, whether it has almost switched or whether the market share is being gained from other drugs. I think that oral EPA preparations will emerge in the future. How do you view the situation?

Miyamoto: I cannot talk about how much share we have gained. However, in general, I believe that it will change more quickly among the dialysis patients. Competition has become extremely intense, and while keeping an eye on this market condition, we have been planning a number of activities.

We have been working with GSK, so if daprodustat will be approved, I think that we will be able to strengthen our lineup by working with GSK to penetrate it. We launched erythropoietin in 1990, 30 years ago. On the basis of what we have built up in 30 years, we will steadily expand this area while firmly appealing our strengths to doctors and patients.

Ueda: When it comes to differentiate it from Nesp, do you think that the dialysis patients that had not been very effective with existing products will be the main target for the new oral product?

Miyamoto: Sorry, we do not comment on that because of the relationship with GSK.

Ueda: Understood. I would like to ask you about your development strategy. Please update the progress of your pipelines after the introduction of the category system in 2014. In terms of modalities, you are now working on nucleic acid and regenerative medicine. Previously, you said that you were taking a relatively cautious stance on regenerative medicine. Please tell us if you see the timing of clinical entry for nucleic acid drugs.

Sato: First, we have implemented the product category system since 2014, in the form of an overall development pipeline. We have not yet been able to explain all the details of our pipeline, but out of what we decided to conduct clinical development, the pipelines for pharmaceuticals, for which we accurately grasp the needs of the market and that will become an interesting positioning, has been listed up. It was very important in the sense of becoming GSP (Global Specialty Pharmaceutical company) to get the approval of the three global products. I was able to bring in the next three global product candidates

Regarding modality, this year is the final year of the current mid-term business plan, and we have been carrying it out under the slogan "four major modalities." Some have worked well, and some were, frankly stated, difficult.

Several new technologies are emerging for antibodies, and I would like to explain them at some stage.

The nucleic acid pharmaceutical business was difficult. We wanted to enter clinical trials with LNP, but we have learned that it was a difficult technology to have a wide margin of safety, and we have not successfully established the technology.

As Mr. Miyamoto mentioned, we would like to promote open innovation by actively introducing external technologies regarding modalities. At the end of this mid-term business plan and when we announce the next mid-term business plan, I think it will be possible to summarize and discuss our approach to modalities.

Ueda: In the past, there were some talks about regenerative medicine that could exceed your capacity. Do you have any changes to this?

Satoh: The business model of providing cell medicines differs from the business model of providing antibodies or small molecules in terms of the business infrastructure. In this sense, I felt that cell medicines are difficult.

Regarding regenerative medicine, we want to state our stance when we announce the next mid-term business plan.

Ueda: Thanks. That is all.

Akabane: Akabane from Tokai Tokyo Research Center. I have just one point. As for Nesp AG, the 4Q result is JPY8.4 billion, when quadruplicated, it becomes JPY33.6 billion, which is lower than your company's 2020 forecast. How did you formulate the budget? In addition, you mentioned original Nesp will remain about 10%, but how does it mean?

Miyamoto: First, Nesp AG does not have all of the indications as Nesp has. Nesp has an indication for MDS, myelodysplastic syndromes. Neither AG nor biosimilars have this yet. Therefore, Nesp will remain in that market.

We will not be able to unveil detailed simulations here, but within the Company, we have created this plan based on a variety of simulations, including past achievements.

Akabane: Do you estimate that the MDS portion is about 10%, not inventories or so?

Miyamoto: That's right.

Akabane: AG recorded JPY8.4 billion, very strong, in 4Q. Is this assumption that it will not grow in the same way this fiscal year?

Kawaguchi: I will answer that point. If you look at the figures of the results of Nesp for each quarter in 2018 on page four of the Appendix to the consolidated financial Summary, there is a seasonal tendency that 1Q is low, 4Q is high, so if you simply multiply 4Q, it looks too big.

Akabane: I understand well. Thank you very much.

Sakai: Sakai from Credit Suisse. First, regarding COGS, this fiscal year, you estimate it JPY77 billion and the cost sales ratio will be 24%. The absolute value of COGS will be down, so I can understand that the ratio will fall. However, why do you expect that there will be no big impact on cost sales ratio, despite Nesp AG, whose drug price is 30% lower than that of the Nesp brand, will increase so much. Is it because of Crysvita's growth that the impact of the costs is subsided? I guess that the COGS of Nourianz is probably virtually zero. Has this kind of product growth made it possible to cover these costs to some extent?

I think that Nesp AG will naturally decrease in the future when other BS or oral ESA drugs come in. Will the COGS ratio be stable at this level, or be improved further, depending on the product mix?

Kawaguchi: Thanks for your questions. First, the changes in product mix in Japan and overseas are the biggest. Overseas sales accounted for 39% of the total sales in the current fiscal year, up from 32% last year. And 47% next year. Going forward, it will continue to grow. The growing product in the global market is Crysvita. As the profitability of this product is high.

In addition, you are right about Japan. The effect of switching to AG is seen. However, the realignment of our production bases has eliminated some of the higher costs, and management efforts contribute to cover the margin decline due to Nesp AG in Japan.

Nevertheless, we recognize that the operating profit margin in Japan is gradually deteriorating. However, we intend to further improve the operating profit margin in the future by covering by overseas.

Sakai: Understood. Thank you very much. In addition, I'm afraid to hear every time, but I would like to ask you to update the FKB. I think FKB has much tax losses carried forward and those will be offset in the future, but please tell us how this JPY4 billion relates with that.

And, I understand the third product candidate was quitted and the fourth candidate is under consideration. Is the impact of the fourth candidate not included in the 2020 forecast? Please update them.

Kawaguchi: Regarding the impact of the tax effect, FKB has spent much money on development, and the amount of tax losses has become quite large. We can use this for a tax shield when income rises, but in accounting terms, it is not acceptable unless it is not highly probable that the income will rise.

Looking at the status up to the present time, 2018 was the year when Hulio (biosimilar of Humira) was just launched in Europe, so it was not certain with the future taxable income. But, in view of the progress made, there will be a surplus of JPY1 billion in 2020 on an equity method basis. This means that there is a certain possibility that future taxable income will be obtained from the accounting standpoint as well.

This is the first time that we have conservatively booked the tax shield for the portion that is expected to be almost certain, not all of the loss carryforward. If taxable income is more likely to emerge in FY2020, we would expect it to be added.

Since this was the first time, the amount was quite large. The tax effect for FY2020 is not included in this forecast at this stage.

Since the fourth candidate will incur a certain amount of development costs, this portion has been factored into the forecast for FY2020.

Moderator: This is the end of our briefing session. We are grateful for your participation today.

[END]