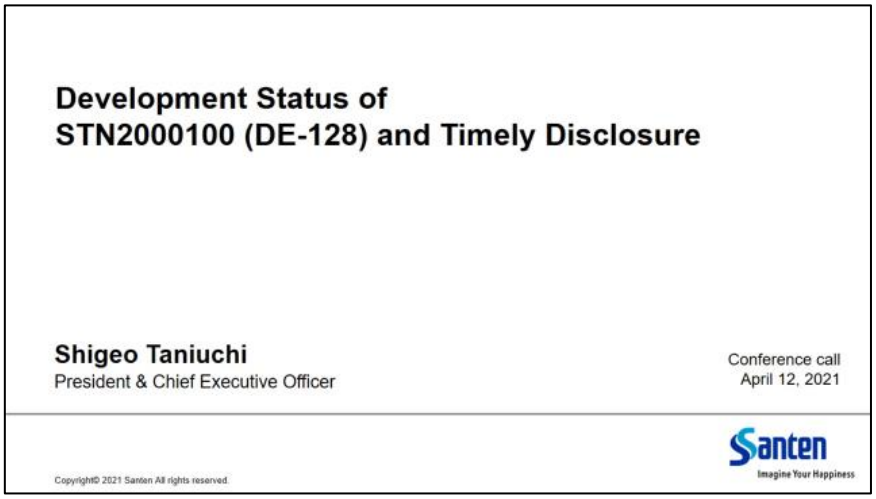
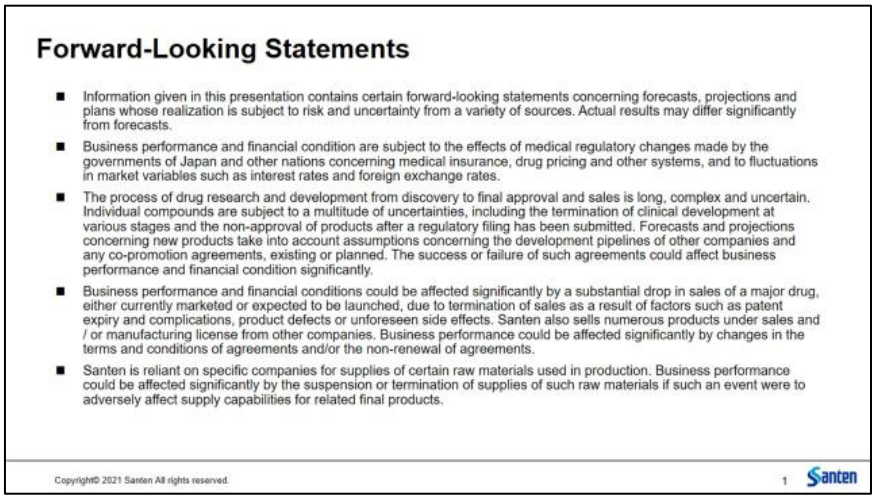
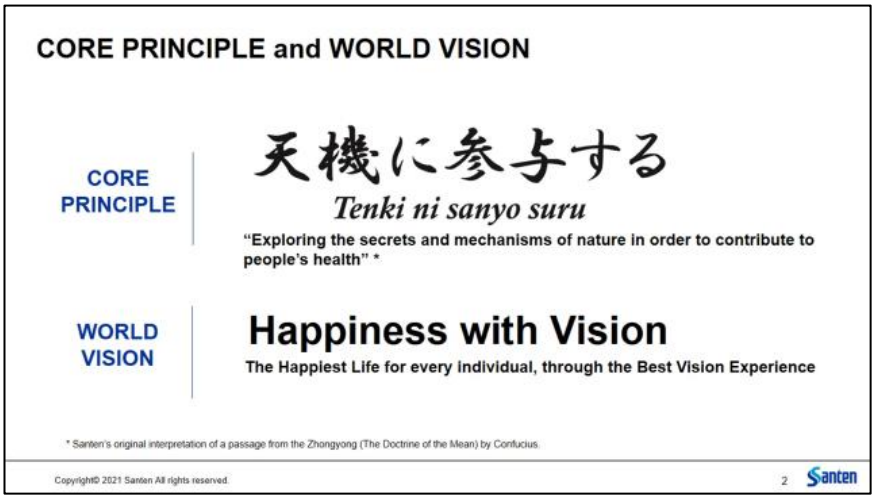
Development Status of STN2000100 (DE-128) and Timely Disclosure Apr 12, 2021 (Presentation)

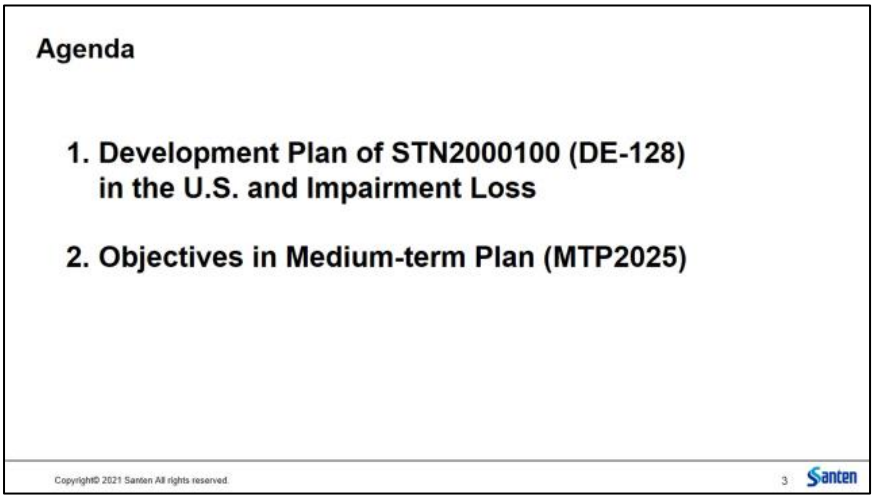


Good morning, everyone.

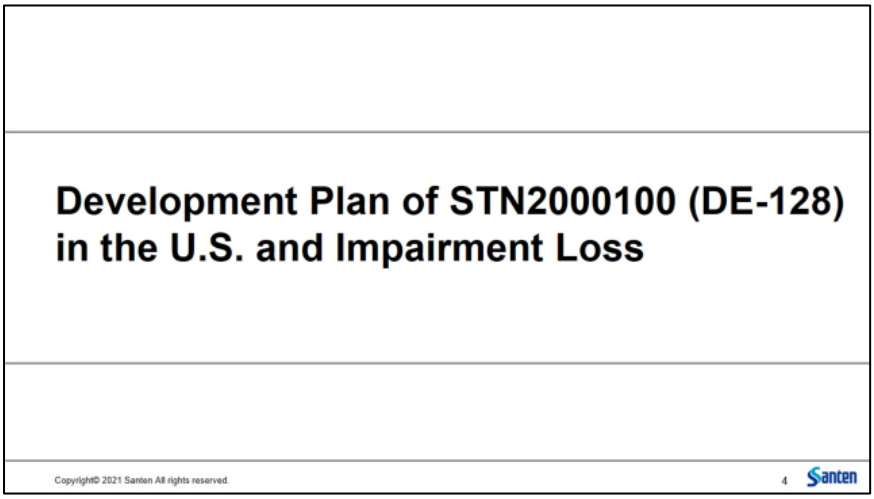
My name is Shigeo Taniuchi, President and CEO of Santen Pharmaceutical Co., Ltd.
I would like to start by thanking you all very much for taking the time to join today's session despite the short notice and the early start.

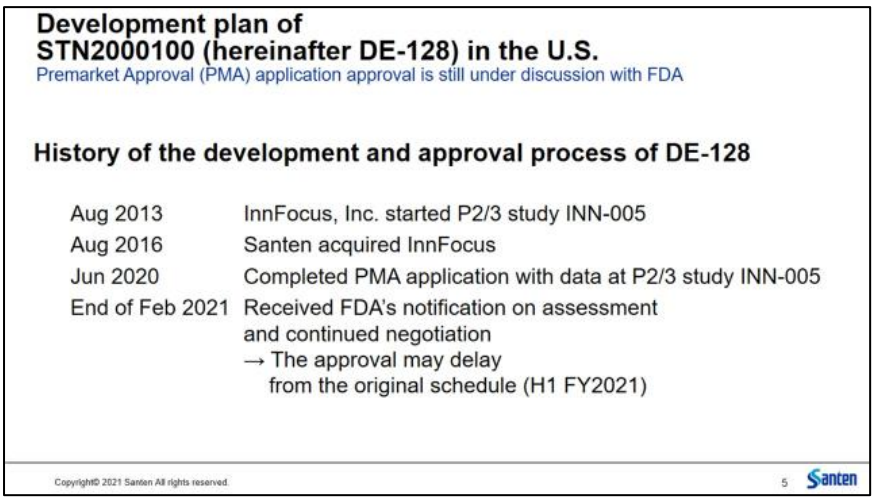






As you will see for today's agenda, I would like to begin with an explanation of the announcement made on the 9th of last week, which includes the development plan for STN2000100, hereinafter referred to as DE-128, in the U.S., as well as the recording of an associated impairment loss and our revised financial forecast. I would also like to touch on our approach to developing our next medium-term plan "MTP2025," which is scheduled to be announced on May 19.





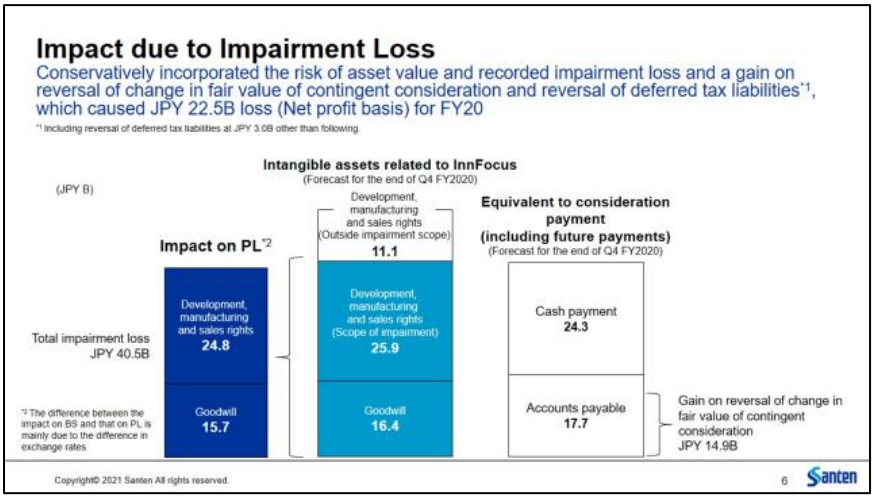
Firstly, I would like to explain the current status of DE-128 and the associated impairment loss.

In an effort to reinforce our glaucoma portfolio, Santen acquired InnFocus, Inc., the U.S.-based developer of minimally invasive glaucoma surgery device, DE-128, in August 2016, and subsequently commenced sales in Europe in addition to filing a premarket approval application for DE-128, also known as a PMA application, in the U.S..

However, we received feedback from the U.S. FDA at the end of February 2021 during the course of discussions with the agency, leading to the possibility that approval will be delayed from our initial assumption of the first half of FY2021.

Since Santen presented its stance to the FDA at the end of March with a view to obtaining PMA, at this time we are unable to provide a clear answer on the schedule and outlook for the future. However, we are committed to continuing to pursue the approval of this product. That being said, following discussions with our auditors in view of the situation we are in, we decided to conservatively factor in the risks associated with changes in the development schedule to the maximum extent possible and reevaluate the value of our intangible assets. As a result, we expect to record an impairment loss in our financial results for fiscal 2020.

The implications and financial impact of this change in the development status of DE-128 have been repeatedly discussed in detail with corporate officers as well as members of the Board of Directors. In particular, since the intangible assets associated with DE-128 are the largest of all the company's intangible assets, and the financial impact is significant both in the short and long term, we have considered various scenarios and options, as this is honestly a very tough decision for us to have had to make. Since this is a major change in the company's important assets on the balance sheet, we felt that we should inform you as soon as possible, and with the agreement of the Board of Directors, we announced these changes on the 9th of last week. I will explain the background and management's thoughts on this matter in the next slide.



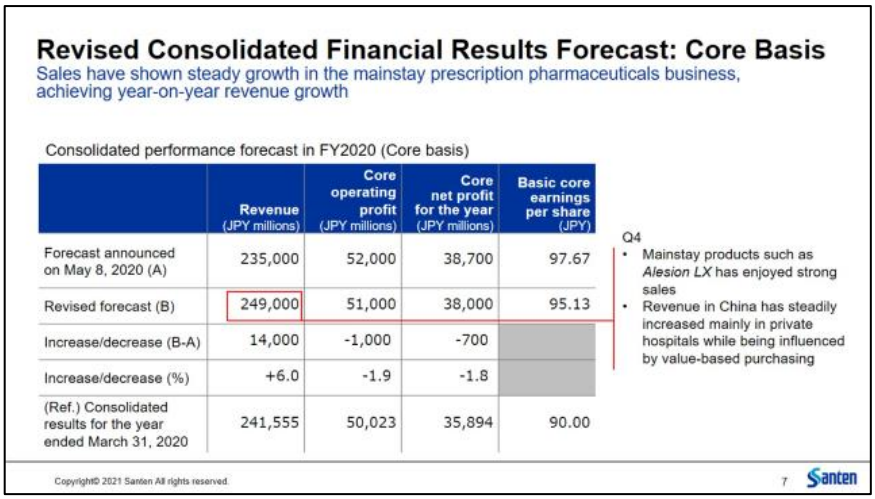
I would now like to outline the impact of this impairment on our balance sheet and profit & loss statements.

Currently, Santen has recorded 53.4 billion yen as intangible assets, comprising goodwill and development, manufacturing and sales rights related to InnFocus, which is developing DE-128.

As a result of reviewing the value of these assets, we expect to record an impairment loss of 40.5 billion yen, consisting of 15.7 billion yen for the entire amount of goodwill and 24.8 billion yen for development, manufacturing and marketing rights. On the other hand, a gain of 14.9 billion yen on reversal of change in fair value of contingent compensation and a reversal of deferred tax liabilities of 3.0 billion yen are expected to be recorded. While the impact on net profit for the period is projected to be 22.5 billion yen, as I will talk about in more detail later in the session, the overall net loss for the period is expected to be approximately 16 billion yen, taking into account other items that will affect net profit for the same timeframe.

Many of you may be surprised by the rather drastic scale of this impairment. For example, some of you may have the impression that "this is based on the premise that DE-128 will not be approved in the US." However, this is not the case at all. As mentioned earlier, the reason for this impairment is that we have factored in the maximum possible risk of "delay in the development schedule" in our reevaluation of asset value. One of the reasons why we decided to zero out our assets, which account for almost the entire business value of our U.S. operations, is that from a financial strategy perspective, we wanted to launch our next medium-term plan with a lighter intangible asset base and a higher return on invested capital. In addition, as management, we also wanted to eliminate the risk of additional impairment as a result of our presumed optimistic outlook, or the risk of a long-term slump in ROE.

Furthermore, some of you may also be surprised at the size of the impairment. This is due to factors related to IFRS balance sheet processing. In other words, although we paid 24.3 billion yen in acquisition costs, the amount of impairment is larger than the "existing cash out" because the future conditional compensation payment is also recorded on the balance sheet. Accordingly, while the scale of the impairment is large, it is offset by conditional compensation.



I would like to explain the revision of the consolidated financial results forecast, including the impact of this impairment loss.

The impairment will not have any impact on a core basis. We expect to achieve a year-on-year increase in net sales revenue due to steady growth, especially in our core prescription pharmaceuticals business

Firstly, in Japan, our mainstay products such as *Alesion LX* are performing well, and although the China business was affected by value-based purchasing, business is growing mainly in sales channels such as private hospitals. Specific figures are currently being compiled, so unfortunately, I am unable to provide a detailed explanation today. However, despite the challenging external environment, including Covid-19, local drug price revisions and value-based purchasing in China, our market share is increasing, and our current performance is solid. I hope you can rest assured that we are doing well in this regard.

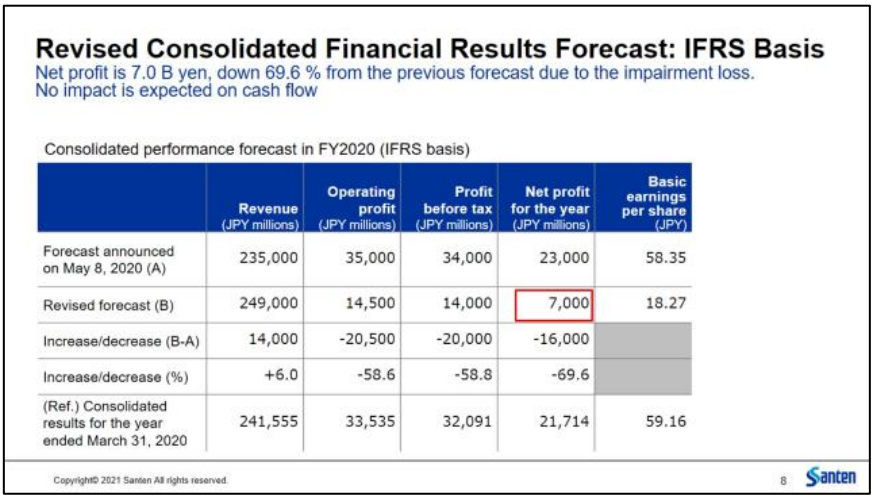
Forecasted core operating profit has been revised downward by one billion yen. I am sure many of you are wondering why we lowered our forecast even though sales revenue is higher than our initial forecast.

- First of all, as you may recall, the original budget for fiscal 2020 was very challenging in a sense, as it took into account the possibility of suspension of business activities and delays in clinical trials to the maximum extent possible, in order to reduce expenses and secure profit growth, amidst the extremely high uncertainty in the market due to the worldwide series of lockdowns last spring.
- However, as a result, while the world continues to move forward with COVID, we have increased expenses for responding to the New Normal and digital activities, in addition to the smooth resumption of our usual marketing activities and clinical trials, especially during the second half of the year. This led to growth in global market share and sales in the second half of the year, and as a result, we recognize that we are closer to the steady increased revenue and profit in FY20 that we had considered before COVID.
- On the other hand, co-promotion costs paid to Mitsubishi Tanabe Pharma have also increased due to the strong performance of *Alesion LX*.
- While we are strengthening marketing in China, we have not yet been able to fully offset the decrease in profit margin for this fiscal year due to value-based pricing, and there were also some effects from the Eyevance acquisition.

As a result of these series of adjustments, we expect to end up with a core operating profit margin similar to two years ago, fiscal 2019, and we have revised our financial forecast for both sales and profit.

We believe that the fact that we were able to continue our commitment to ophthalmology and increase our market share around the world in fiscal 2020, without falling into a contractionary equilibrium in the midst of a worldwide market downturn, puts us in a good position for the next mid-term plan.

In any case, we are still in the process of compiling the data, so I will provide further details when we announce our full-year financial results in May.

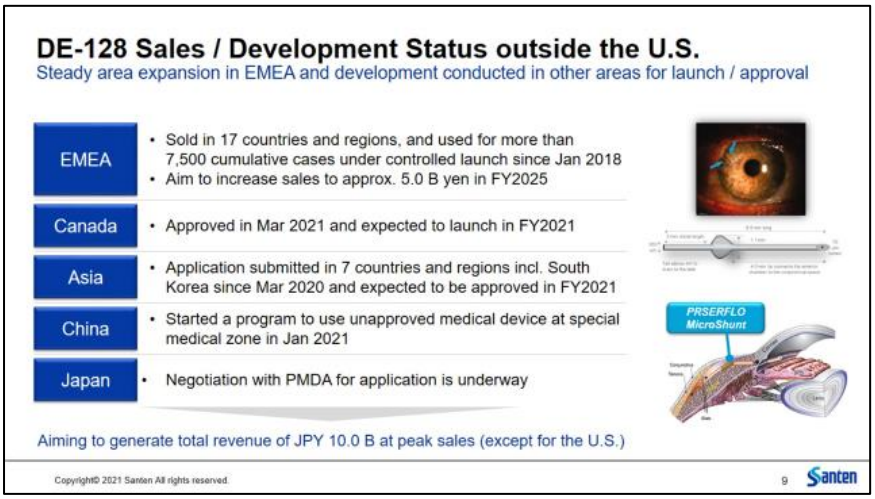


Our revised financial forecast on an IFRS basis is summarized here.

As I mentioned earlier, we are ultimately forecasting 14.5 billion yen in operating profit for the full-fiscal year and 7.0 billion yen in net profit for the period, taking into account the impact of the impairment loss on forecasted financial performance.
However, this impairment loss is for accounting purposes only and will not affect cash flow at all.

So far, I have explained the accounting impact of this impairment loss.

Next, I would like to provide some supplementary information on our future business outlook.



As outlined earlier, we now face the possibility of changes to the approval schedule in the U.S. from our initial plan. However, here I would like to explain how things are progressing outside of the U.S. Sales and development of DE-128 are proceeding as planned, and are moving in a more positive direction than our expectations when the device was acquired.

Here, I would like to explain the situation in each region.

Firstly, in EMEA, which is most advanced in regards to DE-128, nearly 300 doctors in 17 countries and territories have currently completed training on the device since the start of controlled launch in January 2018. With a total of around 7,500 units being sold to date, sales are steady. In regards to reimbursement status

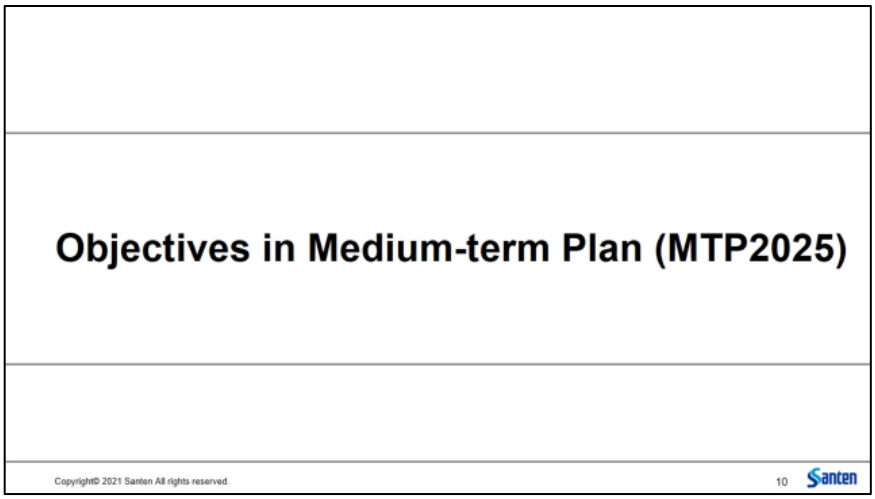
and unit price, things are trending upwards more so than at the time of acquisition, and in addition, the product has been well-received by medical professionals who have actually used the device. In light of this, we expect EMEA sales to be higher than previously forecasted when we re-evaluate development, manufacturing and marketing rights. Although the market unfortunately shrank significantly in fiscal 2020 due to the suspension of glaucoma surgeries in the wake of COVID and other factors, sales are expected to be around 800 million yen, but we are aiming for 1.5 billion yen in fiscal 2021 and 5 billion yen in fiscal 2025.

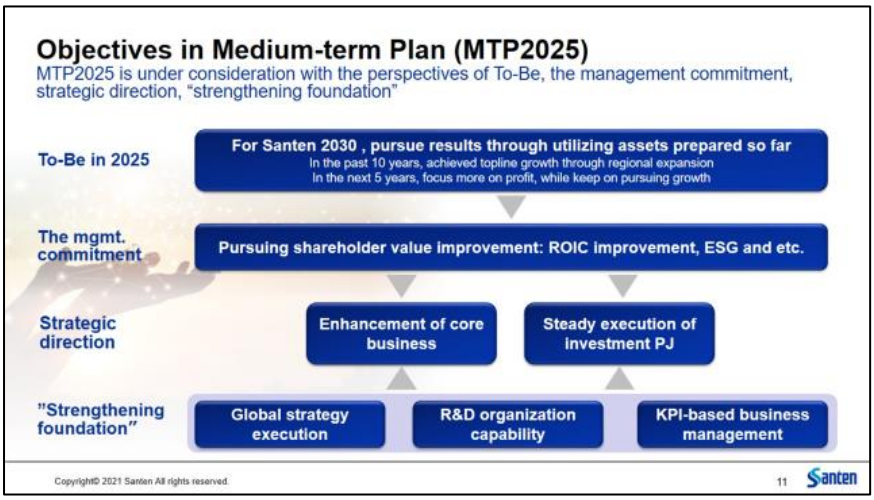
In Canada as well, the device was approved in March 2021, and we are working towards approval in other regions as well. And as we shared previously, a program in special medical zones in China is already underway.

As mentioned earlier, DE-128 will strengthen our glaucoma portfolio, and will play a vital role in promoting the provision of total solutions, that include both pharmaceuticals and devices, enhancing relationships with customers through the overall glaucoma-related product portfolio and increasing sales revenue.

Currently, the fruits of these efforts are already beginning to emerge in Europe and other regions, and we are aiming to achieve sales in the range of 10 billion yen on a global basis, excluding the U.S.

In addition, you may be wondering if we can do business in the critical U.S. market with the uncertainty of DE-128
As you may know, DE-128 was based on a sales alliance model with Glaukos, but apart from that, we acquired Evevance last year as a platform for marketing drugs, and we are proceeding with PMI despite the impact of COVID. Therefore, while monitoring the development status of DE-128, we will focus on growing the Evevance business in fiscal 2021 and monetizing it as soon as possible. The details and future direction of this U.S. business will be announced when the financial results and mid-term plan are announced.





Next I would like to touch upon our to-be management state over the medium to long term which is currently under discussion. In fact, we are scheduled to announce our medium-term plan on May 19, and I would like to share the key points of the review policy here today. .

First of all, we have set out our to-be state for 2025 as the overarching guiding principle of our medium-term management plan.
Over the past 10 years, we have raised our global presence and achieved top-line growth through regional expansion. Over the next five years, however, we will shift directions to steadily generate profits by thoroughly leveraging the assets we have acquired to date as well as our global market presence while at the same time continuing to grow.

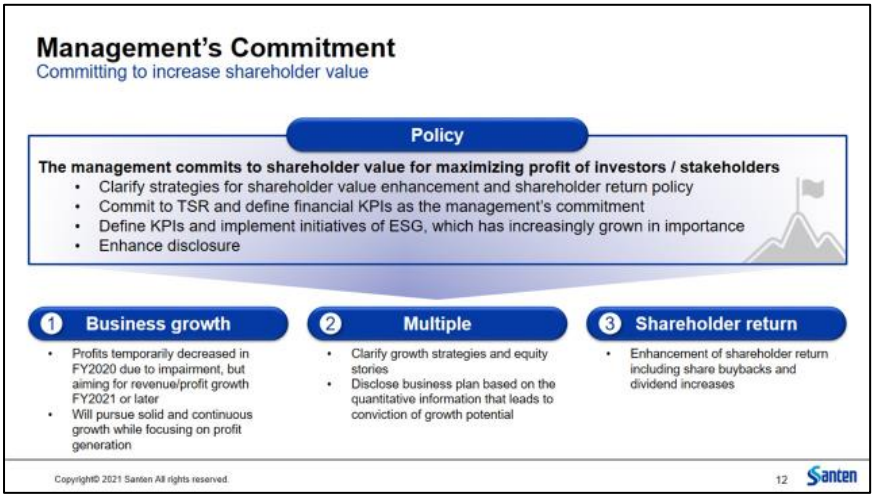
Secondly, based on our to-be state, and reflecting on the fact that we have not been able to adequately communicate our commitment to profit growth as a management team, we will prioritize strategies aimed at fundamentally improving Return on Invested Capital, ROIC, and strengthen our ESG initiatives. As a management team, we are committed to further pursuing increased shareholder value through these efforts.

In order to achieve such growth, we have set two strategic directions and are currently examining the specifics of these directions: the first is to further strengthen our core business, i.e., our existing prescription ophthalmic drugs business in various regions around the world, and improve profitability. The second is to steadily execute the investment deals and development projects we have carried out so far to generate revenue for further growth over the medium to long term.

Lastly, simply formulating a strategy does not necessarily ensure that the strategy will be realized, so we will simultaneously work on strengthening the foundation of the company to ensure the implementation of the strategy, taking the review of the development schedule as a lesson learned.

I will explain the details in the medium-term plan, but broadly speaking we seek to strengthen three major areas as the foundation for realizing the strategy:
"Global strategy execution"
"R&D organizational capabilities," and
"KPI-based business management."

Next, I would like to talk in more specific terms about management's commitment to increasing shareholder value, including some supplementary information.



As management, we recognize that it is extremely important to make efforts to enhance shareholder value. We need to change the mindset of the management team itself, in addition to setting out our to-be state.

As a prerequisite for this change, we will commit to TSR, in order to place greater emphasis on increasing shareholder value. In addition to setting financial and non-financial KPIs, we will develop shareholder return policies and define ESG initiatives, and incorporate them into our medium-term management plan,

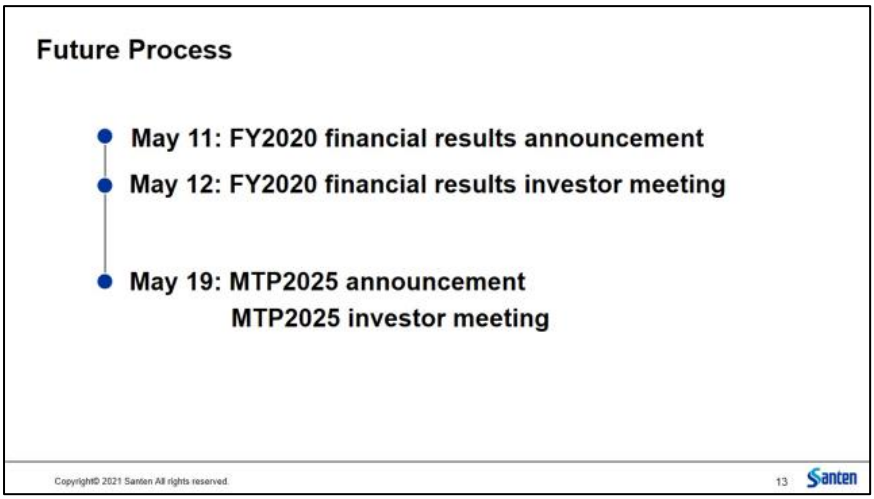
As part of these efforts, we will change management through the following three approaches.

The first approach relates to business growth. Although profit temporarily declined in the current fiscal year due to the impairment loss, we will continue to pursue continuous growth going forward on an IFRS basis in mind. The details will be explained in the medium-term plan.

The second approach related to multiples. Recognizing the fact that the information we have disclosed to date has been insufficient in terms of content, from a qualitative and quantitative perspective, and in terms of messaging, we will make efforts to fundamentally review our stance on IR disclosure and will strive to disclose more appropriate information to investors at the right time. We will also improve our mean of disclosure so that investors better understand our future growth strategy and story by formulating and announcing business plans based on quantitative information.

Thirdly, with regard to shareholder return, we will strengthen shareholder return, including through the buyback of shares and by increasing dividends. These points will be explained in detail when we announce financial results and in the medium-term plan.

Going forward, we will work to increase shareholder value while keeping global standards in mind.



Lastly, I would like to briefly explain our next steps outlined.

First of all, we are planning to announce our financial results on May 11 and hold an investor meeting to explain financial results on May 12, where we will report on our financial results for fiscal 2020, including this impairment loss.

The following week, we plan to announce our medium-term plan and hold an investor meeting on May 19. At this meeting, we will also explain our new commitment to increasing shareholder value, including the points that I was not able to fully explain today.

I would like to thank you all for joining us here today despite the short notice.
As a management team, we also take the changes in our stock price since last November very seriously. Myself, as well as the entire Santen management team, are committed to making improvements and achieving maximum results so that you can have renewed confidence in us. I hope that you will continue to support us.

Thank you very much for your kind attention.