

## Q3 FY2020 Results Follow-up

### -Outlook for Chinese Business and Future Strategy-

## Q3 FY2020 Results Follow-up

### -Outlook for Chinese Business and Future Strategy-

Presentation / Q&A

**Shigeo Taniuchi**

President & Chief Executive Officer

Q&A

**Satoshi Suzuki**

Senior Corporate Officer, Head of Corporate Development Division

**Takayuki Yamada**

Corporate Officer, Head of China Business

**Kenji Morishima**

Corporate Officer, Head of China Product Development Department

February 5, 2021

Copyright© 2021 Santen All rights reserved.



#### Taniuchi:

Hello everyone. Thank you for attending today.

I touched on the material in today's briefing yesterday. I hope that in the future we can hold this type of separate event again, where we can talk about important matters in more detail outside the time limits of the standard financial results briefing.

First of all, I would like to talk about my views on the Chinese Business. As you may be aware, I was posted to China more than 10 years ago. I spent three years or so there starting in 2008. It was at that time that Santen switched from a distributor-led to an independent sales model, and launched the Suzhou factory.

At the time, we only had 30 MRs nationwide, and the number of employees was probably 100 or less. Our sales were around JPY3 billion per year at that time.

Since then, the ophthalmic medication market in China has grown significantly. However, even at that time, there was skepticism about the potential for the Chinese market to grow to that extent, both inside and outside the Company. In these circumstances, we have been working consistently with the Chinese ophthalmology community, working hand in hand with healthcare professionals to enhance ophthalmic medicine and increase its availability.

In addition to conducting regular promotional activities, we have worked to enhance education that will lead to the development in various areas of ophthalmology. This has included working to increase the number of doctors, as well as improving the network of hospital medical care linkages. As a result, sales have increased by an order of magnitude, ranging from JPY20 billion to JPY30 billion. In addition, our market share is increasing.

Over the past few years, we have put particular emphasis on the positioning of our Chinese Business. At the time when I was on my assignment, for example, we worked to create a market in which we

monetize products developed in Japan or in developed countries by deploying them regionally throughout their life cycles.

Therefore, we registered drugs developed in Japan, such as *Cravit* and *Hyalein*, in China, and when they are sold, they are either exported or locally produced. I think this was common among other companies also.

## China and Asia Business Strategy

### Leveraging Santen's Unique Strength



\*1:Key Opinion Leaders

Copyright© 2021 Santen All rights reserved.

On the other hand, in light of the development of the market and environment in China, as is the case for other companies, we too are making a major shift in our activities.

In other words, rather than being a market for the monetization of our products, how do we make the right upfront investments, in areas such as science or technology, or create markets together, thinking beyond terms like “developed country”. We are already making a shift to securing large profits.

In addition, we have been steadily raising our level of investment in this area over the past few years, in the form of investments at the Suzhou plant or R&D.

We anticipate questions on the current performance of *Cravit* and *Hyalein*. Today, I will also touch on those points at the outset. So what stance do we intend to take on ophthalmic healthcare in China? I hope that you will be keenly aware of the types of investments we are making, and the kinds of growth we are trying to achieve over the medium to long term. I hope that you will support our business in China. That's all from me.

Next, we will hear directly from Mr. Yamada, who has been assigned to China. Since before the coronavirus pandemic, Mr. Yamada has been placed in China, appraising the situation in China, including the changes resulting from the coronavirus pandemic, and taking the lead locally.

I hope he can share with us the voices and thoughts of the local people there.

**Yamada:**

Thank you. I would like to talk about the direction of China's future growth. Thank you in advance.

As a simple introduction, after taking a position in Santen's Corporate Development Division, I worked in Europe. I was responsible for the launch of operations in Italy and Benelux. Subsequently, after working at the European headquarters, I was assigned to China, and have been there for about two years.

As Mr. Taniuchi just mentioned, I have been working in China since before the coronavirus pandemic, working to change the direction of our Chinese Business in order to achieve continuous growth in the future. I would like to explain the future direction.

## Agenda

- 
- 1. Short-Term Impact from Value-Based Purchasing and Countermeasures**
  - 2. Growth Potential in China Market**
  - 3. Initiatives for Sustainable Growth**

Regarding the content of the presentation, I intend to talk about short-term impacts of Value-Based Purchasing (VBP), as well as mitigating measures. In addition, I would like to explain our measures for sustainable growth in light of the Company's perception of future growth potential in the Chinese market.

## VBP\*1 (Value-Based Purchasing)

Implemented for top compounds that account for the majority of medical costs. Starting with antibacterials, antihypertensives; the prices are reduced by about 70-80% on average. Generic products that pass the BE test\*2 can be bid

	"4+7" pilot	1 <sup>st</sup> round VBP	2 <sup>nd</sup> round VBP	3 <sup>rd</sup> round VBP	4 <sup>th</sup> round VBP
<u>Implementation</u>	Dec. 2018	Sep. 2019	Jan. 2020	Aug. 2020	Feb. 2021
<u>Target area</u>	11 cities	25 provinces	Nationwide	Nationwide	Nationwide
<u>Target molecule</u>	25	25	32	56	45
				<b>Cravit</b>	<b>Hyalein</b>

\*1: Value-Based Purchasing: Government assurances on purchase volume for the successful bidders. \*2: Bioequivalence test

Copyright© 2021 Santen All rights reserved.

6 

Let me start by touching on the short-term impact of VBP in China, as well as the measures we have taken to deal with it. This is a summary of the implementation of VBP and how our products have been included in this.

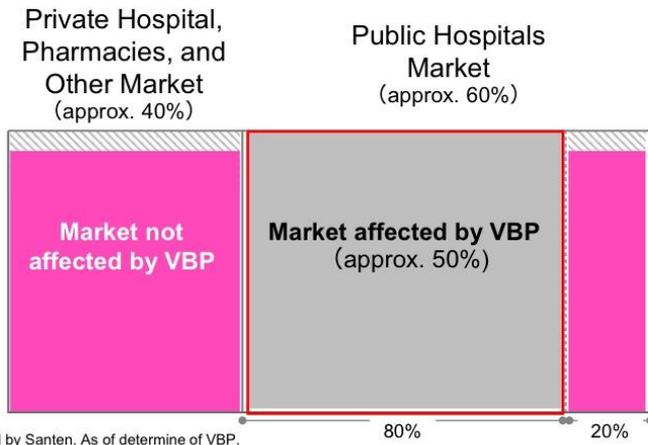
As you may be aware, VBP in China covers the drugs that account for the majority of medical expenses. The initial targets were antibacterial agents and antihypertensives. Prices reduced by an average of about 70% to 80%.

In addition to original products, generic products that have passed consistency tests are subject to bidding. From the pilot operation conducted in December 2018, *Cravit* was first included in last August's bid. The day before yesterday (Feb. 3, 2021), *Hyalein* was included in the fourth round of purchasing, and I believe you all know the results of that.

# VBP Impact on *Cravit*

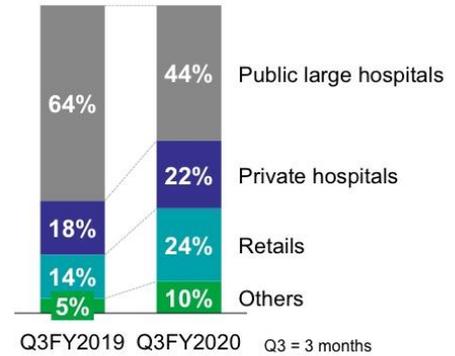
Markets targeted by VBP have seen a further shift to generics. In response, Santen are elevating our focus on expanding sales at private hospitals and pharmacies.

**Market structure of levofloxacin 0.5% (volume basis)<sup>\*1</sup>**



\*1: Estimated by Santen. As of determine of VBP.

***Cravit* sales by channel (volume basis)**



I will briefly touch on the current status of *Cravit*.

There is a switch to generics at large-scale public hospitals, which are the target market for VBP.

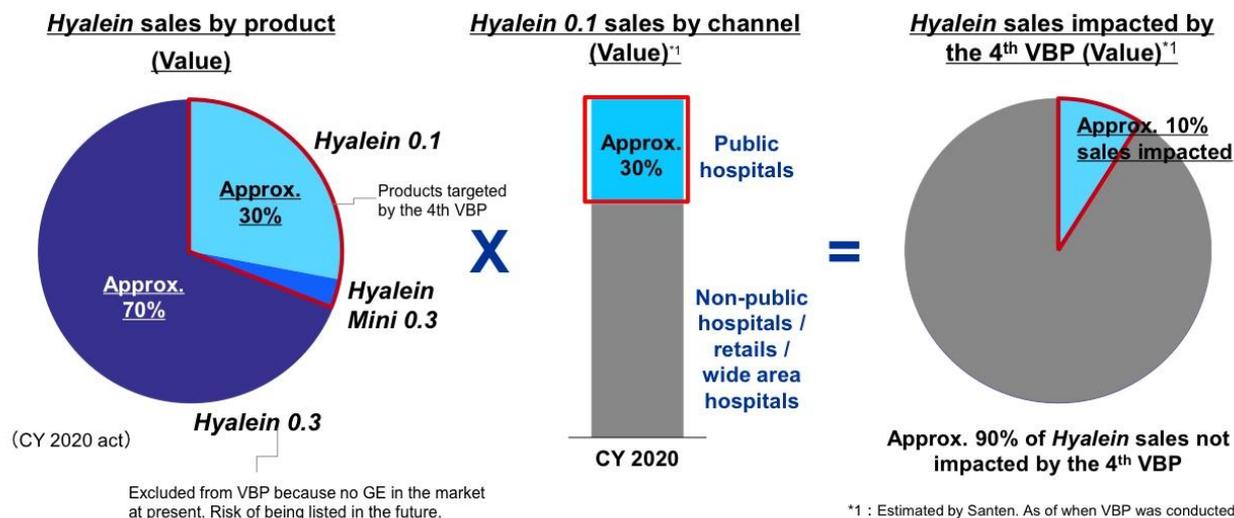
In other markets, such as private hospitals and pharmacies, Santen is expanding its business.

As the bar graph on the right shows, the ratio of national public hospitals has declined significantly, and accordingly, private hospitals, pharmacies, and other facilities are steadily expanding.

This graph just shows the ratio, but I think everyone is interested in the actual number. In reality, sales to private hospitals are increasing, and sales to pharmacies and other facilities are increasing dramatically. As I will discuss later, we can say that our current efforts to deal with the impact on *Cravit* and *Hyalein* have started to bear fruit.

# Hyalein Partially Subjects to the 4<sup>th</sup> VBP

Limited impact expected on financial results in FY2021 and beyond



These are the figures for *Hyalein*. Two days ago, the bid was made, however, *Hyalein 0.1%*, *Hyalein 0.3% Mini*, and *Hyalein 0.3% Multi-Dose* were not included in the bid. These were not included because there were no products that satisfied the consistency test this time. There is a possibility that this will change in the future.

On the other hand, I think that the position and composition ratio within the pharmaceutical industry as a whole is not large in monetary terms, so I think it is difficult to predict if and when they may become the subject of purchasing. However, we would like to take adequate steps to prepare for this.

I think it was also mentioned in yesterday's presentation, but *Hyalein 0.1%* was the main target this time. About 30% of our sales lie within the target of VBP, so the impact on sales of *Hyalein* as a whole will be around 10%. Overall, the impact on our business in China will be around 4%. We believe that this impact can be covered by future initiatives.

# Short-Term Growth Strategy

Minimize the VBP's impact by shifting to new products and launching new drugs

## 1. Focus on private hospitals

- Boost sales of *Cravit* and *Hyalein*
- Pitch *Diquas* in dry eye field

## 2. Accelerate on retail market initiatives

- Online / Offline pharmacies

## 3. Extend coverage of lower-tier hospitals



Therefore, as a short-term initiative, we are engaging in promotion activities with a focus on new products, *Tapros* and *Diquas*. In addition to aggressively shifting to this area, in the medium term, I think we will accelerate the launch of new drugs to minimize the impact of VBP.

In this context, activities with private hospitals will be strengthened in the short term. There are many patients who undergo surgery at their own expense. We will be able to continue to expand sales of *Cravit* and *Hyalein* in the area of private hospitals.

In these hospitals, we will continue to expand the use of *Diquas* and *Tapros*, which remain popular products.

In particular, *Diquas* has had very rapid penetration in recent months and has the potential to fully make solid headway in private hospitals. This situation is in line with the expansion of our sales channels, and we expect business growth.

In addition, we believe that the retail market is an extremely important part of our business, both in the short term and in the long term. This applies not just to so-called "town" pharmacies offline, but also online pharmacies, where sales are increasing. In terms of general consumption behavior, we can see that online consumption is expanding rapidly, so we would like to actively take advantage of this opportunity also.

Our coverage has been centered on tier 3 hospitals, but this segment still includes many clinics, community district hospitals, and so on. In light of this, we intend to expand our coverage to these hospitals and seize market opportunities.

As a complement to these short-term initiatives, I would like to discuss where we feel there is potential for growth, what direction we will take, and what strategies we will introduce in the future.

# Three Keywords for Achieving Business Growth

Accessing markets with high potential in the ophthalmology field

## (1) Glaucoma



## (2) Myopia



## (3) Change of market structure (private hospital / retail)



Copyright© 2021 Santen All rights reserved.

11 

I would like to speak today focusing on three key points.

Santen sees opportunities to expand in China by focusing on glaucoma and myopia, and also by capitalizing on structural changes in the market, particularly private and retail markets.

## Medical System Reform

Looking toward 2030: Opportunities related to improvements in medical care quality

### 1. Basic health insurance coverage

- 3 current insurance systems\*<sup>1</sup> to be integrated into a *universal insurance system*

### 2. Price control

- Securing medical funding through price cuts on high volume drugs with long-listed drugs
- Through annual revisions to NRDL\*<sup>2</sup>, aim to achieve *the lowest drug prices in the world*

### 3. Promoting innovation

- Significant reduction in review period for new drug applications

### 4. Directing patients to lower-tier hospitals and private hospitals

### 5. Medical reform through use of digital tools

\*1: URBMI, the Urban Residents Basic Medical Insurance. UEBMI, the Urban Employee Basic Medical Insurance. NCMS, the New Rural Cooperative Medical Scheme.  
Note that as of the end of August 2018, 29 provinces had completed the merger of URBMI and NCMS. In future, URBMI and UEBMI are expected to be ultimately integrated as well.

\*2: National Reimbursement Drug List

Copyright© 2021 Santen All rights reserved.

12 

Particularly in China, major healthcare system reforms have been implemented over the past few years.

There has been the announcement of Health China 2030, a major policy by the Chinese Government. The Government is in the midst of transforming the healthcare structure to capture improvements in

the quality of healthcare. There are a few pertinent points to note here, and I have listed some of them here.

Reform of the medical insurance system is one aspect. Until now, there has been a significant difference between urban and rural areas in terms of the nature of medical care received, and the coverage ratio. Now, the Government is taking the initiative to unify this, and to grant the right to receive appropriate medical care to a wide range of citizens.

Of course, it is reasonable to assume that the cost of healthcare will increase. As part of this effort, VBP is being conducted. The reimbursement list, or NRDL, which up until now has been updated once every few years, will now be reviewed annually, and in conjunction with these revisions, demands for pricing are becoming extremely strict.

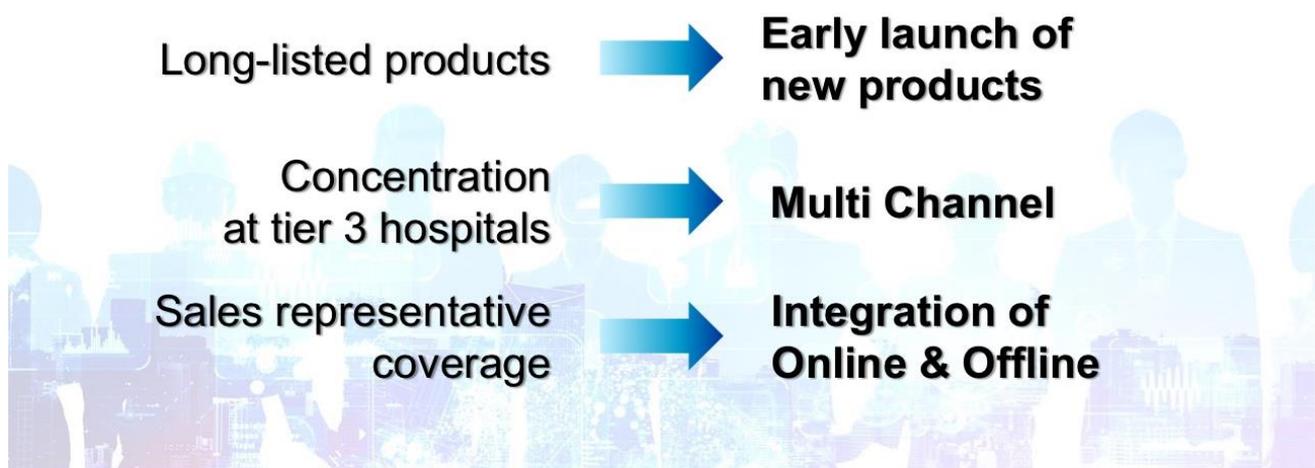
As work to broaden the coverage of basic insurance continues, we are also working to significantly reduce the lead time to new drug approval in order to further promote innovation. As I will explain later, we are also stepping up the process of applying for exemption from clinical trials in order to accelerate efforts to attract new innovations to China.

We have concentrated on tier 3 hospitals so far. In an effort to promote more of this type of medicine, we have been encouraging patients to visit lower-tier hospitals, private hospitals, pharmacies, and other institutions. I think the situation is such that our strategy, which I mentioned earlier, is in line with this market movement.

We are also advancing healthcare modalities using digital technologies that comprehensively support these efforts. I think the key point will be how we respond by capturing this situation.

## Responding to Medical System Reform

Need for business model reform that anticipates policy changes



As I mentioned earlier, we believe it is essential to reform our business model in a way that takes into account future policy changes.

I think it is extremely important to shift from our reliance on long-listed drugs, and to aggressively develop new products, and to launch new products quickly.

In addition, we also want to shift from coverage concentrating on tier 3 hospitals to a multichannel model.

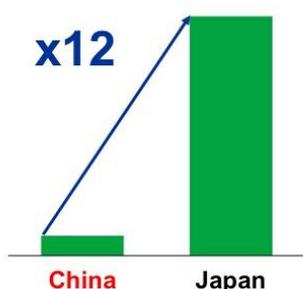
In the same way, our sales resources will continue to leverage our existing tier 3 hospital coverage while making use of online capabilities. This will encourage excellence among our MR staff.

## Sustainable Growth in the China Business: Glaucoma

Capture market potential through involvement in the development of an ecosystem

### Current

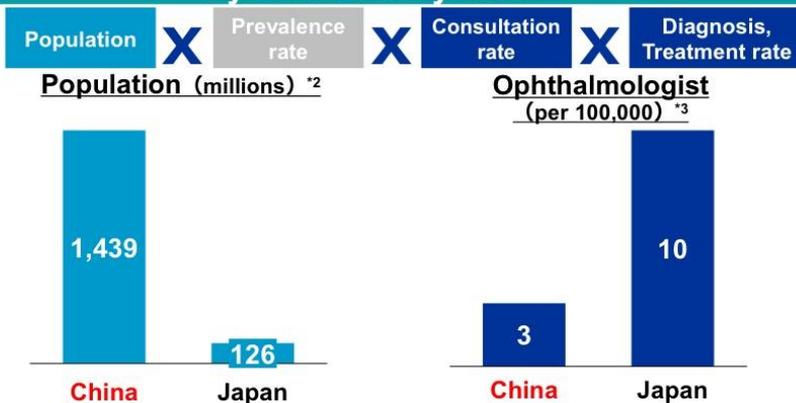
#### Glaucoma Market Size (value basis) <sup>\*1</sup>



<sup>\*1</sup> Source : Copyright © 2020 IQVIA. IQVIA MIDAS 2019.1Q-4Q; Santen analysis based on IQVIA data. Reprinted with permission.

<sup>\*2</sup> Source: UN World Population Prospects <sup>\*3</sup>:Santen estimation

### Growth Opportunities through Development of the Eye Care Ecosystem



Reprinted Q2 FY2020 Consolidated Performance material.

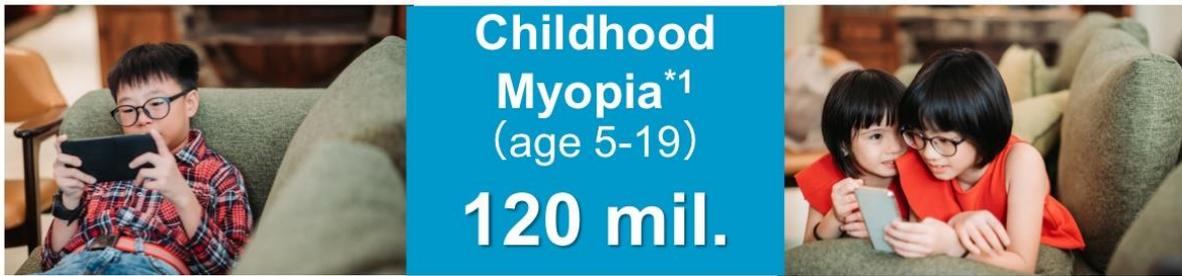
One example is glaucoma, which is one of our key points.

Comparing the glaucoma market in China and Japan, the difference is an order of magnitude of 12. As you all know, in terms of population, the situation is exactly the opposite, and I believe that the potential of the market in China is extremely large.

Simply increasing the number of doctors will take a long time to come to fruition. The Government itself has been working on how to develop this overall ecosystem, and we at Santen are looking at how, we too, can play a role. We believe that there are significant growth opportunities if we can engage in this area. Santen intends not just to sell products, but also to actively engage in the construction of new market ecosystems.

# Sustainable Growth in the China Business: Myopia

Chinese government recognizes childhood myopia as a major issue



## Chinese government: Measures to reduce myopia in children and adolescents

Goal to reduce child/adolescent myopia by more than 0.5% each year until 2023, relative to the nationwide percentage of child/adolescent myopia in 2018. Annual reduction target of more than 1% per year for those provinces with a high prevalence of myopia. Aim to achieve an Excellent rating of more than 25% under the National Survey on the Constitution and Health of Students by clearly reducing the incidence of child/adolescent myopia and significantly improving vision health by 2030. Goal to lower incidence of myopia to 3% in children 6 years or under, 38% or lower for elementary school-age children, 60% or lower for middle school-age adolescents and 70% or lower for high school-age adolescents.

\*1: 2020/Decision Resources, LLC. All right reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.

This slide covers the next key point, myopia.

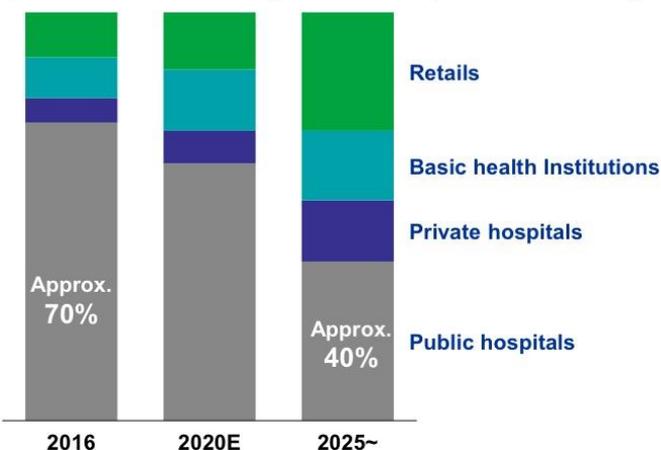
We see this as an extremely large market. Currently, it is said that there are 120 million short-sighted children in China, which the Chinese Government is regarding as a major social issue. The Government has announced measures to curb short-sightedness in children and young people, with guidelines to curb short-sightedness by 2030.

By simple calculation, if 100 million people spend JPY1 thousand per year, the market would be JPY100 billion per year. Finding a way to make the most of this opportunity is a major theme for us.

## Changing Market Structure

Diversification of patient medical access led by changing roles of medical facilities

**Healthcare Market by Institution (Revenue basis)**



### Expected Changes

- Public hospitals (tier 3)**
  - Center of excellence
  - Focus on advanced medical practice
- Public hospitals (tier 2, tier 1, healthcare center etc.)**
  - Safety net / primary care
- Private hospitals**
  - Providing treatment to meet patient's needs
- Retails**
  - Self medication
  - Out-of-pocket treatment needs
  - Online medical treatment etc.

Copyright @ 2019 by Boston Consulting Group. All rights reserved. Reprinted with permission

We anticipate that the market is about to change dramatically. We expect that medical access for patients will also diversify.

As shown in the bar graph on the left, we expect the composition ratio of the market to change further in the future.

We anticipate that the main tier 3 hospitals, which until now have been the main destination for patients, will become core research centers as they turn into centers of excellence in the future.

Instead, lower-level facilities, healthcare centers, and other private hospitals and pharmacies will function as safety nets and provide primary care, and private hospitals will become facilities that can provide treatment tailored to patients' needs.

Pharmacies will respond to the need for medical treatment venues or in-house medical treatment as self-medication increases. And we believe that this will be a channel that can handle things like online medical treatment.

## **Growth Potential in China: Takeaway**

Growth opportunities led by significant change in market structure



**Qualitative change**  
Medical system reform, digitization

**Quantitative expansion**  
Economic development, medical infrastructure development

**3 keywords**  
Glaucoma, myopia, private / retail

This is a summary of growth potential. Qualitative changes associated with healthcare reform and digitization. Quantitative expansion accompanying economic development and the development of healthcare infrastructure. By working with the Government, we see opportunities for growth by creating even larger markets in the areas of glaucoma, myopia, and private-retail segments.

# Growth Strategy: Medium- to Long-Term

Transformation into a more robust business platform; sustainably enhancing market presence

## 1. Transform into scientific-driven & digitally enabled business model

- Diversify market approaches with broader coverage of the market
- Emphasize focus on scientific-driven approach
- Maximize product value through commercial excellence

## 2. Strengthen product development

- Expand local independent clinical trial capabilities
- Build product development research network with top hospital sites and reputable KOLs
- Tap into local product innovation to benefit global

## 3. Enhance supply capability to secure positioning

- Suzhou 2<sup>nd</sup> factory fulfills not only current demand but is also scalable. Able to accommodate growing market needs

Next, I would like to explain our policies on how we can translate such potential into growth. As a medium- to long-term initiative, we intend to further strengthen our business structure, which we believe will lead to the sustained maintenance and improvement of our presence in three major areas.

First of all, we intend to switch the focus of our promotional sales activities, focusing more on academic and online activities.

We aim to diversify our business activity. In expansion of our market coverage to include both online and offline, we intend to leverage our market presence advantage to date.

In addition, from the standpoint of differentiating ourselves from competitors, we intend to further enhance our ties with doctors and KOL by strengthening our academic approach in areas such as glaucoma.

Another area is commercial excellence. We believe that there are also significant opportunities for growth in terms of further improving the quality of our activities. We believe that there is still room to maximize product value, including new products and long-listed products. Therefore, I intend to address these points.

We will continue to strengthen product development. This is likely to become an extremely important factor over the medium to long term.

The issue of clinical development capabilities in China is becoming increasingly important.

We believe that it is essential to have development capabilities that will enable us to sufficiently conduct clinical development in China, considering regulatory affairs. This is currently under way for glaucoma products. As for myopia drugs, as I mentioned earlier, local clinical development is indispensable, and we have already begun such efforts.

Of course, in order to succeed in these areas, we believe it is necessary to further strengthen our product development network with leading facilities and KOL, and we intend to continue to do so.

In addition, demand will continue to grow as such demand is triggered and new products are introduced into the market. We believe that the supply of products that accompanies this will be an extremely important factor in enhancing our competitiveness.

As you know, we are currently starting construction of a new factory in Suzhou. Broadly speaking, the direction of design has been confirmed, and when we have reached the stage where we will begin construction, we will be in a situation to steadily advance our system for future growth.

## New Initiatives to Secure Medium- to Long-Term Growth

Transformation into scientific-driven & digitally-enabled business model



We have already begun to take various measures, and we are transforming our business in order to achieve growth over the medium to long term.

As I have said, we are expanding our sales channels and aggressively approaching channels other than the tier 3 hospitals that have been a focus to date. We have already assigned sales teams to this, and have already begun activities for each channel nationwide.

In addition, the Chinese digital transformation is a very rapid progress, and I believe that collaboration with online pharmacies will play an extremely important part. We have already begun a new business in areas such as online pharmacies and online medical care with Chinese providers. We intend to expand this system nationwide in the future.

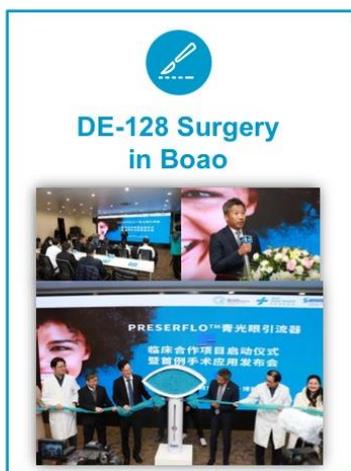
We are also collaborating on disease screening, and are working with local governments to achieve this. We recently held an event for a screening project in Shenyang City in the North-East of China, and also held a presentation in Shanghai to start screening for glaucoma, and conduct epidemiological surveys.

Through these efforts, we hope to uncover patients and educate them about glaucoma. We intend to further strengthen these activities in the future.

In addition, Santen has a deep-rooted connection with doctors, and has been conducting academic activities. As a result, there is a very high level of awareness of Santen among doctors. We plan to continue with this, and deepen our ties with academic societies for the further development of ophthalmology.

# New Initiatives to Secure Medium- to Long-Term Growth

Strengthen product development, enhance supply capability to secure market position



We are taking steady steps to strengthen our product development and product supply systems.

In January, two operations took place in the special medical district on Kainan Island, where DE-128 was used in the treatment of glaucoma. Further surgery is planned in February, and we will continue to take steps to build our track record and accelerate the speed of product approval through these new routes.

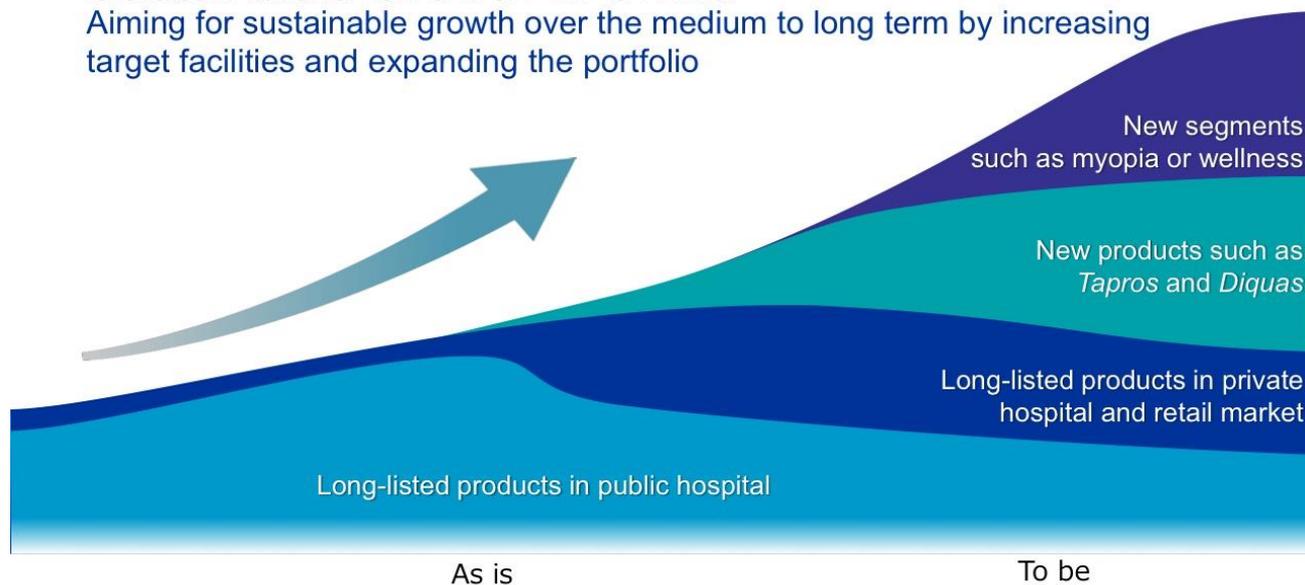
Verkazia, the drug for vernal keratoconjunctivitis, which has already been approved by the EMEA, will be added to the third list of new foreign drugs deemed urgently necessary in clinical practice.

As a result, we have made a formal announcement that the clinical development requirement will be waived. We are now preparing for production, regulatory registration, and so on, so that we would like to launch it to the market as soon as possible.

Regarding the new factory in Suzhou, as I mentioned earlier, we are making steady progress toward construction, and we intend to complete construction in the near future.

## Sustainable Growth in China

Aiming for sustainable growth over the medium to long term by increasing target facilities and expanding the portfolio



We aim to achieve sustainable growth in China based on these new measures.

From the current business structure, which is centered on long-listed products and national public hospitals, we will create new business areas. These will include myopia and wellness. We will focus more on multichannel growth and new products. In addition, we intend to continue to grow through the development of new ophthalmic medical care ecosystems.

That concludes my presentation. Thank you very much for your attention.

**Itagaki:** Thank you.

## Question & Answer

---

### Q1-1-1

Thank you very much. The first question relates to yesterday's financial results, and the second is about strategies.

First of all, regarding the *Hyalein 0.3% multi-dose*, I gathered from your explanation that it was not part of the purchasing this time, and the reason was that the consistency test was not met.

Is there any potential for VBP discussions to take place only with respect to this single *Hyalein* product in the future, at a time when it would meet the consistency criteria? I'm sorry to ask such a specific question, but it seems important given the 70% proportion of sales from this product.

### A1-1-1

**Taniuchi:** As Mr. Yamada mentioned earlier, the current situation is that there are no generics. Therefore, the purchasing procedures themselves do not hold, so this is not the case.

Regarding the question of whether or not generics will be registered in the future through consistency trials, in a word, I personally don't know. Even if it were done, there is a chance that they would not meet the consistency criteria. There is also the decision of the authorities about whether they would buy after something has been registered. There is a possibility that generics may come out, but not be listed separately.

So, we should keep in mind that we may lose about 30% of the public hospital sales if that occurs. As explained earlier by Mr. Yamada, we are working to further develop our business in other areas. I think we will keep doing what we're doing, and if it remains, it remains. If not, then it disappears.

### Q1-1-2

OK. I would like to ask you one more question. In that case, I think it's really up to the authorities to go ahead with intensive purchasing or not. On the other hand, it is possible to apply, and get an answer with respect to consistency. Although I can't read Chinese, my understanding is that if it passed, then local residents would understand this from state documents?

### A1-1-2

**Taniuchi:** Yes, that is of course true. If you don't mind, I will allow Mr. Morishima to explain further about this.

**Morishima:** The list authorized on the administrative website will be posted, so it will be clear and open whether you have passed or not.

### Q1-2

OK. Thank you very much.

Second, there was a lot of information about strategy, and I am well aware that the Chinese market is growing or becoming a modern market. I understand that local companies are not very competitive in the field of ophthalmology, including in their supply capabilities.

Local manufacturers are likely to grow in future, and also, other companies such as Novartis are likely to take a similar approach.

In that case, it seems that local manufacturers are likely to be competitive due to ability to respond to trends in their own country, and so on. How do you feel about the competitiveness of foreign-affiliated competitors, and to what degree do you feel they are focusing on the Chinese market?

#### A-1-2

**Taniuchi:** I would like to reply first, and then Mr. Yamada can jump in if necessary.

First of all, I think that it is natural that local companies, start-ups, and foreign companies work together, and that competition will intensify, or become more diverse.

The first thing we recognize as an advantage in this context is the credibility and brand Santen has been working on as a company for many years. Naturally, this is a little different from a network, but the sense of trust as a company is overwhelmingly high.

Compared to other foreign companies, Santen has worked hard to develop ophthalmic medicine in China over the past 30 years or so, and it is one thing that Santen has worked hard at.

Second, we already have production that is already operating locally, built about 15 years ago, and there we are conducting integrated manufacturing. GMP is also in place, including the European GMP.

There are no other manufacturers that can compete with our production capability: high-quality, large-scale commercial production working in three shifts. That's probably a considerable challenge for foreign and emerging manufacturers to catch up in the coming years. We have struggled considerably, so I think that there are some areas where we have already cleared that part of the learning curve.

In addition, we are strengthening our pipeline even more. I think that the breadth, quality, and quantity of the pipeline are extremely strong. Mr. Yamada, if there are any additions, please go ahead.

**Yamada:** Yes, we believe that one barrier to entry is our overwhelming existing presence. With this as a leverage point, I believe that the direction we should take is to further increase barriers to entry by expanding our presence in these broad markets.

In addition, there are a variety of startups at present, and it has been seen that the strengths of each company differ. One company is biased toward innovation, but how about the commercial, sales and marketing elements? Or a company is strong in sales and marketing, but weak R&D.

A variety of startups are emerging, so I think it will still take some time to become a company like ours that has comprehensive end-to-end capability. By the time such companies catch up, as I mentioned earlier, we intend to make steady progress in raising barriers to entry.

#### Q2-1

Thank you very much.

First, regarding *Hyalein*. I would like to confirm that the answer to previous question was that 30% of the sales of *Hyalein* were from national and public hospitals, so if *Hyalein* 0.3% were to targeted by VBP, there would be a possibility that about 30% of the sales of *Hyalein* would be lost. Is that correct?

## **A2-1**

**Taniuchi:** That's right, 30% would disappear, but as I mentioned earlier for *Cravit*, other sales channels, where, to date, our resources have not been so focused, can be utilized.

As we are doing with *Cravit*, we intend to increase (the sales volume), by strengthening other sales routes, such as retails, or by increasing the account at private hospitals, then means that it is not to be a straight 30% decrease.

We will strive to maintain the sales as much as possible by minimizing the decrease. I think there is still enough potential there. You could understand that we are not in a situation where the sales will suddenly drop.

## **Q2-2**

Yes, thank you.

Second, I have a question about the basics of VBP. In the past two years, it has been carried out twice a year. Am I correct in understanding that intensive purchasing is conducted at a pace of about twice a year, and the target will be decided based on a list by the Chinese Government?

## **A2-2**

**Taniuchi:** Yes, that is correct. Mr. Yamada, if there are any supplements, please go ahead.

**Yamada:** It is said that it will be held twice a year. Next, as last year, there will be bids around August and September, and it is said that the actual introduction will be around November. Products that have been subjected to consistency evaluation are listed, and the targets are decided under the initiative of the Government.

## **Q3-1**

I would also like to ask you two questions. The first is about this VBP, and mine is also quite a basic question.

In the case of your Company, for example, I think that the price of the *Cravit* has not fallen by much in bidding. If this is the case, is it correct to think that the price can be maintained in markets other than those under VBP because bidding has not lowered the price?

I also heard that in the event that the bidding company is unable to supply, there will be a penalty of not being able to participate in the bidding for a certain period of time. Could you first tell us if there is a possibility that your company's share can be restored?

## **A3-1**

**Taniuchi:** First of all, we are making efforts to win the bid, of course, and we have been disclosing the price, and I think the results will be later.

On the other hand, when we look at the actual prices that we won the bid with, it is a difficult price for us. Conversely, because we usually offer prices that we would never be able to produce at our level of quality, there is a point where it cannot reach.

Our stance is that we do not necessarily do what we do to protect prices, but rather offer appropriate prices.

As a result, the prevailing prices of both *Hyalein* and *Cravit* have not been significantly affected so far, of course. And then, there is a penalty if the product is not supplied. Now, when I watch *Cravit* at the moment, I heard that the company that won the bid seems to be working hard to supply the product. It does not seem as if there are back orders occurring.

As far as I know, there haven't been any such cases in the past, so I think it is a bit of a matter of seeing how the actual situation is. Mr. Yamada, do you have anything to add?

**Yamada:** Regarding the price, it's a little technical. There are other procedures for pricing in companies with unsuccessful bids. This is mainly the case in Shanghai, but there is such a procedure that uniform prices are applied across the country to the prices set by Shanghai. As a result, the price has not been lowered by a large margin for us so far.

### **Q3-2**

Thank you very much. Second, I would like to ask about your company's DE-127 treatment for myopia. In China, I think that Ocumension Therapeutics will probably develop OT-101 ahead of your company.

At the time of the IPO, I think that, certainly, in China, they were due to start Phase III in the middle of 2021. I think that your company announced the start of Phase I in FY2021. Could you tell us how you are thinking about this competitive environment?

Is it possible to close the gap by applying for exemption from clinical trials, manufacturing profile, or something like that? Could you tell us your thoughts on these points?

### **A3-2**

**Taniuchi:** To give a brief answer, there is not much in the way of product differentiation, as all are done with atropine. I think the key is creating a market after approval.

First of all, we recognize that they are starting clinical development, but we are now thinking in this way about how to leverage our presence, and also, how to accelerate and overtake at the clinical development phase. Therefore, it is not necessarily important that we started later, but we will focus on progressing as quickly as possible.

On top of that, it is not the case that when the product comes out, there is already a market there. As I mentioned earlier, there are 100 million eligible people. How do we involve doctors in this process, what kind of ecosystem do we create, and how do we approach children? The situation is that there is nothing there at the moment. That's where we leverage the size and presence of this company to work with academic societies and local communities to create treatment flows there. I think it is a challenge to create a situation where children are firmly engaged.

I would like to do focus on business methods that make the most of our presence.

### **Q4-1-1**

Regarding the current atropine point, are the protocols in China exactly the same as those in other Asian countries, including doses?

### **A4-1-1**

**Taniuchi:** I'll pass this question to Mr. Morishima.

**Morishima:** Protocols conducted in Singapore have different doses and different concentrations. Last month, we made guidelines for myopia clinical trials, so we plan to proceed with clinical trials in accordance with Chinese guidelines.

**Q4-1-2**

Would you be able to tell us which dose is being used?

**A4-1-2**

**Morishima:** I'm afraid this has not yet been disclosed.

**Q4-2**

Understood. Also, I'm sorry for a basic question, but is it correct that the reimbursement list is once a year and VBP is once every two years? What are the relationships between these two systems, and are they correlated? I know that China is a big market.

I haven't fully grasped the system, or the terms used. This is also the case with your company's presentation, but there are so many qualitative parts, and it would be very helpful if you could include a few more numbers. Do you have any thoughts about that?

**A4-2**

**Taniuchi:** Thank you.

I appreciate your comment about figures. I would like to express some of these as ratios next time. First of all, since the NRDL determines if there is national healthcare reimbursement for a product, it is a reimbursement list for so-called basic, universal healthcare.

In this context, VBP is primarily to allocate the cheapest long-listed products. NRDL includes new drugs, indicating if they will or will not be reimbursed. As for long-listed drugs, their price is lowered further through VBP.

On the other hand, as we saw from Mr. Yamada's presentation, the overall national market will increasingly be limited to basic healthcare and very difficult-to-treat conditions, and the part in between will be shifted to private healthcare. We are shifting to private insurance and private clinics, and the whole picture now is that rather than all insurance, as in Japan, we are getting closer to the US form.

Next time, I would like to take the opportunity to present some more information about strategy, including some overall numbers.

**Q5-1**

First, in Japan, the drug price will be determined based on the NHI drug price survey. In the case of China, is the creation of the NRDL a transparent process? Or is it a top-down, opaque process?

**A5-1**

**Taniuchi:** Simply speaking, the central government creates the NRDL, and then uses it as a basis to create a list of reimbursements in each province. On the other hand, prices are negotiated separately from the reimbursement list and are determined either by the state or by each province.

I think it would be better to understand that there are not many countries like Japan where reimbursement and drug prices are combined, and that most countries have separate systems for reimbursement and price negotiation, such as in Europe.

#### **Q5-2**

Thank you very much. What is the current penetration rate of generics in the retail market and private hospitals, and what are the trends in the future?

#### **A5-2**

**Taniuchi:** Mr. Yamada, do you know about generics in this segment?

**Yamada:** I don't have any specific figures, but in general, many of the people who go to private hospitals are already going to pay their own money or to receive medical treatment at their own expense. Private hospitals are looking for a suitable surgery or drug, based on the patient base.

We recognize that use of branded products is relatively high, and we are aware of the value at that point.

**Taniuchi:** The national NRDL is becoming more like Medicare and Medicaid, and generics are becoming the priority there.

I hope that you will understand it structurally, as in the US style, in which brand products will come out in the form of private insurance.

#### **Q5-3**

Understood. As a company, do you have any plans to provide myopia treatment solutions through the medical device approach? And finally, is there another way to use the joint venture in Chongqing?

#### **A5-3**

**Taniuchi:** For short-sightedness, we have not yet announced any interventions using medical devices. The Company is considering several approaches to myopia treatment, including both drug and non-drug options, to provide treatment for short-sightedness in Asia.

Just a brief answer as we're short on time, but Chongqing is still in the process of construction as planned.

#### **Q6-1**

Thank you very much.

First, based on the strategy explained today, what is likely to happen to SG&A expenses in China for the time being? In terms of the balance with the top line, what will you see in the future in terms of profits and losses, and margins in the Chinese Business?

#### **A6-1**

**Taniuchi:** We intend to increase our sales channels, as mentioned, while keeping a close eye on the relationship between the top line and the bottom line.

As a whole, we have actually cut the costs and personnel involved in MR and marketing activities, so the impact on the bottom line is neutral. In fact, one effect of the coronavirus pandemic has been a gradual decrease in expenses. We would like to work to maintain this.

#### **Q6-2**

Thank you very much.

Please tell us about the market potential of DE-128. The current glaucoma market in China is 1/12 the size of the Japanese market, but how much potential is there for surgical treatment using these minimally invasive tubes?

In markets where there is an absolute shortage of doctors, it seems likely that eye drops will take the lead. Do you have any expectations of a major change in the future?

#### **A6-2**

**Taniuchi:** As you pointed out, the number of glaucoma specialists is still not sufficient. At the same time, glaucoma operations are still being conducted in the vein of “central excellence”, as mentioned earlier. In terms of the overall ratio to population, I think it will still increase over the long term.

On the other hand, there are enough trabeculectomy to do this, so we will begin to switch to DE-128. We will continue to work hard to train and increase the number of surgeons. As you have pointed out, there may not be a large Ultra C right now, but I think there is a tremendous potential to create this.

#### **Q7-1**

Thank you very much. I would like to ask about potential patient trends with respect to *Hyalein* and *Cravit* in private hospitals and retail in the future.

Does the emergence of cheap similar products in the national hospitals mean that the behaviors of private hospitals and retail, patients and doctors here will change as a result? Does it reduce the demand?

Perhaps there are a variety of reasons, whether price sensitivity or use is different, but if you have a view of the changes in demand here, I would like to ask about this.

#### **A7-1**

**Taniuchi:** Regarding private hospitals, first of all, the situation in China was similar to how it was in Japan in the past. There has been an almost religious belief in the large national hospitals. It was common in China to see people lining up to wait. Private hospitals were not so busy in the past.

That has changed dramatically, particularly during the coronavirus pandemic, where people are unhappy to queue to be seen at a crowded tier 3 hospital and be given generic medications as a result.

With economic development, people would like to receive preferential services at private hospitals, where they can have appointments over the Internet. They are willing to do this even if they have to pay out of their own pockets. Naturally, part of this is wanting good medications. The needs of middle-class people in China are becoming increasingly apparent under these circumstances.

The people who used to go to tier 3 hospitals noticed that they were different, so I think that the number of private hospitals is increasing quite rapidly.

Therefore, I believe that the private hospital market segment will be more active in the future, and I hope you will appreciate that we also see great opportunities there.