

## Investors Meeting for FY2020 and Revision of Mid-term Business Plan 2022

Date/time: Thursday May 13, 2021; 10:45–12:15 (Q&A Session: 11:25 - approx. 50 minutes)

Attendees from Sumitomo Dainippon Pharma:

Hiroshi Nomura Representative Director, President and CEO

Toru Kimura Representative Director, Executive Vice President  
Chief Scientific Officer

### Presentation

Hi, this is Hiroshi Nomura, President and CEO of Sumitomo Dainippon Pharma. Thank you very much for your attendance at our Investors Meeting today. I appreciate your interest in and understanding of our business.

Financial Results for FY2020							Sumitomo Dainippon Pharma	
Financial Results for FY2020 (Core Basis)								
	FY2019 Results	FY2020 Results	Change			FY2020 Feb. 12 forecasts	(Ref.) Earnings related to Sumitovant	
			Value	FX impact	%		Billions of yen	
							FY19	FY20
<b>Revenue</b>	482.8	<b>516.0</b>	33.2	(6.8)	6.9	515.0	-	7.8
Cost of sales	128.3	<b>137.5</b>	9.1	(0.8)	7.1	138.5	6.5	46.5
Gross profit	354.4	<b>378.5</b>	24.0	(5.9)	6.8	376.5	9.0	24.6
SG&A expenses	190.0	<b>211.8</b>	21.8	(3.4)	11.5	212.5	(15.6)	(63.6)
R&D expenses	92.6	<b>97.1</b>	4.5	(1.7)	4.8	101.0	(15.5)	(63.6)
<b>Core operating profit</b>	72.0	<b>69.6</b>	(2.4)	(0.9)	(3.3)	63.0	(16.7)	(63.6)
Changes in fair value of contingent consideration (negative number indicates loss)	① 48.5	① <b>22.5</b>	(26.0)			26.0	(11.9)	(44.3)
Other non-recurring items (negative number indicates loss)	② (37.2)	② <b>(20.8)</b>	16.4			(40.0)		
<b>Operating profit</b>	83.2	<b>71.2</b>	(12.0)		(14.4)	49.0		
Profit before taxes	83.9	<b>77.9</b>	(6.1)		(7.3)	43.0		
Income tax expenses	48.0	<b>41.0</b>	(7.0)			34.0		
Net profit	35.9	<b>36.8</b>	0.9		2.5	9.0		
<b>Net profit attributable to owners of the parent</b>	40.8	<b>56.2</b>	15.5		38.0	27.0		

① Cost reversal due to:  
(FY19) Revised business plans for oncology pipelines and Lonhala® Magnair®  
(FY20) Revised business plans for oncology pipelines

② Non-recurring items due to:  
(FY19) Impairment losses on oncology pipelines, SB623, Lonhala® Magnair®  
(FY20) Gain on sale of former Ibaraki plant of the Company  
Impairment losses on oncology pipelines

FX rates:  
FY19 Results : 1US\$ = ¥108.7, 1RMB = ¥15.6  
FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7  
FY20 forecasts : 1US\$ = ¥106.0, 1RMB = ¥15.5

Allow me to begin by walking you through our financial results for FY2020.

In FY2020, we posted revenue of 516.0 billion yen, core operating profit of 69.6 billion yen, operating profit of 71.2 billion yen, and net profit attributable to owners of the parent of 56.2 billion yen. Revenue increased by 33.2 billion yen year-on-year. As stated in the Appendix, Equa® and EquMet® sales showed an increase to push up revenue in the Japan segment by 12.8 billion yen. Likewise, revenue in the North America segment grew by 19.2 billion yen due to strong sales of LATUDA®. As a result, gross profit showed an increase as well.

In regard to SG&A expenses, as stated in the small table to the right, an increase of around

40.0 billion yen was recorded on account of Sumitovant. This increase is attributable to their spending hikes on hiring and marketing to ensure smooth launches of relugolix and vibegron. That said, the net increase was around 21.8 billion yen because expenses earmarked for Sunovion and other existing businesses turned out to be lower than expected amid the COVID-19 pandemic. R&D expenses were almost flat and core operating profit decreased by 2.4 billion yen from the previous year.

The fair value of contingent consideration was 22.5 billion yen in FY2020. As we announced earlier, we posted a cost reversal of the fair value as we booked impairment loss on napabucasin and alvocidib. In the previous year, we had a lot more to impair and so significant cost to reverse. Compared to the rather unusual previous year, the cost reversal resulted in a lower level.

Other non-recurring items of 20.8 billion yen include impairment loss on napabucasin and alvocidib, on top of gains on the sale of fixed assets. As a result, operating profit amounted to 71.2 billion yen, down by 12.0 billion yen from the previous year. If we take into account taxes, profit and loss attributable to owners of non-controlling shareholders, and deficits, however, net profit increased year-on-year to 56.2 billion yen.

If you look to the right of the slide, you will find full-year forecasts for FY2020. Revenue looks almost as expected, but gross profit shows a small increase due to a slight difference in the mix. SG&A expenses are almost in line, but R&D expenses were slightly lower than we forecasted, which pushed up core operating profit by about 6.6 billion yen. You will also find a small difference in the fair value of contingent consideration and other non-recurring items. This is because we had calculated the reversal of the fair value of contingent consideration by assuming impairment loss on TP-0903. You might remember our explanation of this when we announced revisions to our financial forecasts. Partly because we had very good results from the Beat AML Study program, which we are working on for hematologic malignancies, however, we decided not to book impairment loss on TP-0903 for the full-year results, which caused the difference.

## Financial Results for FY2020 Segment Information (Core Basis)



Billions of yen

	Pharmaceuticals Business					Other Business	Total
	Japan	North America	China	Other Regions	Subtotal		
<b>FY2020 Results</b>							
Revenue (Sales to customers)	152.5	281.5	27.8	17.2	479.1	36.9	516.0
Cost of sales	77.5	20.8	5.4	5.7	109.4	28.1	137.5
Gross profit	75.1	260.7	22.5	11.5	369.8	8.7	378.5
SG&A expenses	50.8	143.8	9.2	2.8	206.7	5.1	211.8
Core segment profit	24.3	116.9	13.2	8.7	163.1	3.6	166.7
R&D expenses					96.2	0.9	97.1
Core operating profit					66.9	2.7	69.6
<b>FY2019 Results</b>							
Revenue (Sales to customers)	139.7	262.3	28.6	14.8	445.4	37.4	482.8
Cost of sales	65.0	24.0	5.4	5.0	99.5	28.9	128.3
Gross profit	74.7	238.3	23.2	9.8	346.0	8.4	354.4
SG&A expenses	51.8	120.8	8.8	3.4	184.8	5.2	190.0
Core segment profit	22.9	117.5	14.4	6.4	161.2	3.2	164.4
R&D expenses					91.7	0.9	92.6
Core operating profit					69.7	2.3	72.0
<b>Change</b>							
Revenue (Sales to customers)	12.8	19.2	(0.8)	2.4	33.7	(0.5)	33.2
SG&A expenses	(1.0)	23.0	0.5	(0.6)	21.9	(0.1)	21.8
Core segment profit	1.4	(0.6)	(1.2)	2.3	1.9	0.4	2.3
R&D expenses					4.5	(0.0)	4.5
Core operating profit					(2.8)	0.4	(2.4)

- **Japan:** Higher profit due to increased margin from sales growth and reduced costs
- **North America:** Lower profit mainly due to incremental costs of Sumitovant in spite of higher revenue and reduced costs at Sunovion
- **China:** Profit decreased mainly due to lower revenue

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The comparative table on Slide #4 sums up what I have just explained. Please use this for reference.

## Financial Forecasts for FY2021 Financial Forecasts for FY2021 (Core Basis)



Billions of yen

	FY2020 Results	FY2021 Forecasts	Change
Revenue	516.0	578.0	62.0
Cost of sales	137.5	156.0	18.5
Gross profit	378.5	422.0	43.5
SG&A expenses	211.8	263.0	51.2
R&D expenses	97.1	95.0	(2.1)
Core operating profit	69.6	64.0	(5.6)
Changes in fair value of contingent consideration (negative number indicates loss)	22.5	(1.0)	(23.5)
Other non-recurring item (negative number indicates loss)	(20.8)	(2.0)	18.8
Operating profit	71.2	61.0	(10.2)
Net profit attributable to owners of the parent	56.2	41.0	(15.2)
R O E (%)	10.1	6.9	
R O I C (%)	3.1	N/A	

### Expect revenue up, profit down for FY2021

- **Revenue:**
  - Increase mainly in North America by ¥68.2B
  - LATUDA® increase by ¥13.9B
  - Includes net product revenues from ORGOVYX™, GEMTESA®, relugolix combination tablet (pending FDA approval) as well as collaboration and licensing/milestone revenues from Pfizer (Forecasts are not disclosed)
  - Includes revenue from possible new alliance
- **SG&A and R&D expenses:** SG&A will increase mainly due to full sales activity of Sumitovant R&D includes cost reduction by possible new alliance

(Ref.) Expenses related to Sumitovant (¥B)

	2020	2021	Change
SG&A expenses *	46.5	96.0	49.5
R&D expenses	24.6	21.0	(3.6)

The figures are before intra-group elimination  
\* Include amortization of patent rights

**FX rates:**  
FY20 Results: 1US\$ = ¥106.1, 1RMB = ¥15.7  
FY21 Forecasts: 1US\$ = ¥110.0, 1RMB = ¥16.5

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Turning to Slide #6, you will find our financial forecasts for FY2021: revenue of 578.0 billion yen, core operating profit of 64.0 billion yen, operating profit of 61.0 billion yen, and net profit attributable to owners of the parent of 41.0 billion yen.

We used to show net profit here, but now that we have only one listed subsidiary, we may end up announcing their forecasts if we did, which is rather awkward. So, please forgive me

for limiting the scope of disclosure here.

We expect revenue to increase by 62.0 billion yen from FY2020, most of which is derived from the North America segment as indicated to the right. Contributing to this strong performance are sales growth of LATUDA<sup>®</sup>, as well as new offerings from Sumitovant, including ORGOVYX<sup>™</sup>, GEMTESA<sup>®</sup>, and—assuming approval for uterine fibroids—a relugolix combination tablet. We also expect to receive licensing/milestone revenues from collaboration with Pfizer. This is deferred revenue, which will be recognized over several years to come, including this fiscal year. We also expect milestone revenues from a possible new alliance project. In the revised Mid-term Business Plan, which I will go over later, we make it clear that we will aggressively seek alliances with third parties. The new alliance is expected to be finalized soon with a reasonably high probability, so we have factored that in our revenue.

We expect SG&A expenses to increase by 51.2 billion yen. If you look at the numbers for Sumitovant-related expenses on the bottom right, you see a 49.5 billion yen increase in SG&A expenses. This is quite natural, as SG&A expenses automatically increase when their marketing activities begin to take off. Plus, we expect the amortization of intangible assets to increase by 21.6 billion yen from the previous year. Meanwhile, R&D expenses are almost flat, core operating profit is expected to decline by 5.6 billion yen year-on-year, and the numbers for the changes in fair value of contingent consideration and other non-recurring items are as you see them due to an absence of major factors. Towards the bottom of the table, you can see that both operating profit and net profit attributable to owners of the parent show a year-on-year decrease. All in all, we expect revenue growth but profit decline.

## Financial Forecasts for FY2021 Segment Information (Core Basis)



Billions of yen

	Pharmaceuticals Business					Other Business	Total	
	Japan	North America	China	Other Regions	Subtotal			
<b>FY2021 Forecasts</b>	Revenue (Sales to customers)	150.0	349.7	29.8	10.3	539.8	38.2	578.0
	Cost of sales	78.1	38.5	5.5	4.6	126.7	29.3	156.0
	Gross profit	71.9	311.2	24.3	5.7	413.1	8.9	422.0
	SG&A expenses	52.9	191.9	10.9	1.6	257.3	5.7	263.0
	Core segment profit	19.0	119.3	13.4	4.1	155.8	3.2	159.0
<b>FY2020 Results</b>	R&D expenses					94.0	1.0	95.0
	Core operating profit					61.8	2.2	64.0
	Revenue (Sales to customers)	152.5	281.5	27.8	17.2	479.1	36.9	516.0
	Cost of sales	77.5	20.8	5.4	5.7	109.4	28.1	137.5
<b>Change</b>	Gross profit	75.4	260.7	22.5	11.5	369.8	8.7	378.5
	SG&A expenses	50.8	143.8	9.2	2.8	206.7	5.1	211.8
	Core segment profit	24.3	116.9	13.2	8.7	163.1	3.6	166.7
	R&D expenses					96.2	0.9	97.1
<b>Change</b>	Core operating profit					66.9	2.7	69.6
	Revenue (Sales to customers)	(2.5)	68.2	2.0	(6.9)	60.7	1.3	62.0
	SG&A expenses	2.1	48.1	1.7	(1.2)	50.6	0.6	51.2
	Core segment profit	(5.3)	2.4	0.2	(4.6)	(7.3)	(0.4)	(7.7)
<b>Change</b>	R&D expenses					(2.2)	0.1	(2.1)
	Core operating profit					(5.1)	(0.5)	(5.6)

- **Japan segment:** Profit will decrease because revenue down mainly due to NHI price revision, and sales expenses up for imeglimin launch
- **North America segment:** LATUDA® will further increase  
Sumitovant related profit will decline due to increase in sales costs and amortization despite revenue growth of ORGOVYX™ and GEMTESA®  
Possible revenue from new alliance is included  
In the segment both revenue and profit will increase
- **China segment:** Revenue will increase due to growth of ALMARL® and LATUDA® but MEROPEN® sales will not change

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On Slide #7, there is a table showing the numbers I have just explained for comparison. If you look at the bottom rows for "Change," you will see revenue for the Japan segment showing a decrease. I will come back to this later, but this is mainly due to the NHI price revision. You may think expenses would increase, but this is because of a scheduled launch of imeglimin and the lower level of spending due to COVID-19 in FY2020. I have already explained the factors behind these numbers for the North America segment.

Sales for the Other Regions segment, too, show a slight decrease. This is because we had intensive shipments due to special circumstances in FY2020, and the decline is a reaction to that one-time event.

## Financial Forecasts for FY2021

### Revenue of Major Products in Japan



	FY2020 Results	FY2021 Forecasts	Change	
			Value	%
Equa®/EquMet®	40.1	37.4	(2.7)	(6.8)
Trulicity®*	33.9	38.2	4.3	12.8
TRERIEF®	16.2	17.9	1.7	10.5
REPLAGAL®	13.8	13.8	(0.0)	(0.0)
METGLUCO®	9.1	6.9	(2.2)	(24.6)
LATUDA®	2.4	6.7	4.3	180.7
LONASEN® Tape	1.3	2.5	1.2	96.2
AMLODIN®	6.5	5.0	(1.5)	(23.5)
AG products	8.0	10.1	2.1	26.3
Others	21.1	11.5	(9.6)	(45.6)
<b>Total</b>	<b>152.5</b>	<b>150.0</b>	<b>(2.5)</b>	<b>(1.6)</b>

Note: Sales of each product are shown by invoice price (\* Trulicity® is shown by NHI price)

- LATUDA®, Trulicity®, TRERIEF® will increase
- Expect launch of imeglimin but sales for FY2021 are not large number
- Expect impact of NHI price revision : (¥7.0B)

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I don't think I need to add any explanations to the numbers on Slide #8, which include the expected impact of the NHI price revision of 7.0 billion yen. You don't see numbers for imeglimin here because we do not expect its first-year number to be substantial. Rather, we will focus on promoting LATUDA® and LONASEN® Tape in FY2021. Meanwhile, we are hoping to achieve solid sales growth in our diabetes franchises.

## Financial Forecasts for FY2021

### Revenue of Major Products in North America & China



	FY2020 Results	FY2021 Forecasts	Change	FY2020 Results	FY2021 Forecasts	Change	
						Value	%
<b>North America</b>	Million \$			Billions of yen			
LATUDA®	1,946	2,004	58	206.5	220.4	13.9	6.7
APTIO M®	242	249	7	25.7	27.4	1.7	6.5
BROVANA®	274	106	(168)	29.1	11.7	(17.4)	(59.8)
KYNMOBI™	2	28	26	0.2	3.1	2.9	—
Others	188	792	604	20.0	87.1	67.1	335.9
<b>Total</b>	<b>2,653</b>	<b>3,179</b>	<b>526</b>	<b>281.5</b>	<b>349.7</b>	<b>68.2</b>	<b>24.2</b>
<b>China</b>	Million RMB			Billions of yen			
MEROPEN®	1,435	1,364	(71)	22.5	22.5	0.0	0.0
Others	340	442	102	5.3	7.3	2.0	36.9
<b>Total</b>	<b>1,775</b>	<b>1,806</b>	<b>31</b>	<b>27.8</b>	<b>29.8</b>	<b>2.0</b>	<b>7.1</b>

- **North America: Revenue up**
  - LATUDA® will increase
  - BROVANA® will decrease by GE erosion
  - Focus on market penetration of KYNMOBI™
  - Sumitovant sales are included in Others (forecast detail is not disclosed)
  - Others include revenue from possible new alliance
- **China: Revenue up**
  - On RMB basis, sales will be in almost same level

FX rates:  
 FY20 Results :1US\$ = ¥106.1, 1RMB = ¥15.7  
 FY21 Forecasts: 1US\$ = ¥110.0, 1RMB = ¥16.5

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On Slide #9 are the numbers for the North America and China segments. LATUDA® sales are expected to grow by 14.0 billion yen to 220.4 billion yen in FY2021. We also expect

APTIO<sup>®</sup> sales to see an increase.

On the other hand, we expect BROVANA<sup>®</sup> sales to drop, as we should see the market become crowded with generics following the expiration of its exclusive marketing period this coming June. Numbers for the Others sub-segment include sales of Myovant Sciences and Urovant Sciences, deferred revenue associated with the up-front payment by Pfizer, which will be recognized in coming years, and another up-front payment to be recognized in relation to a new alliance project with a different partner.

Research and Development					Sumitomo Dainippon Pharma
Development Pipeline (as of May 12, 2021)					
<span style="color:blue">■</span> : Psychiatry & Neurology <span style="color:orange">■</span> : Oncology <span style="color:green">■</span> : Regenerative medicine / Cell therapy <span style="color:yellow">■</span> : Others <span style="color:purple">■</span> : Frontier business            Revisions since the announcement of Jan. 2021 are shown in red					
Area	Phase 1		Phase 2	Phase 3	NDA/BLA submitted
Japan	EPI-589 (ALS)		SEP-4199 (Bipolar I depression)	SEP-363856 (Schizophrenia)	imeglimin (Type 2 diabetes)
	DSP-1181 (Obsessive compulsive disorder)		DSP-7888 (Glioblastoma)	SMC-01 (Mobile App for management of type 2 diabetic patient)	
U.S.	DSP-6745 (Parkinson's disease psychosis)	DSP-0509 (Solid tumors)	EPI-589 (Parkinson's disease/ALS)	SEP-363856 (Schizophrenia)	RVT-802 (Pediatric congenital athymia) BLA resubmitted
	SEP-378608 (Bipolar disorder)	TP-0184 (Hematologic malignancies)	SEP-363856 (Parkinson's disease psychosis)	DSP-7888 (Glioblastoma)	relugolix (Uterine fibroids)
	DSP-3905 (Neuropathic pain)	TP-1287 (Solid tumors)	SEP-4199 (Bipolar I depression)	relugolix (Endometriosis)	
	SEP-378614 (Treatment resistant depression)	TP-3654 (Hematologic malignancies)	TP-0903 (AML/Research group-initiated clinical study)	GEMTESA <sup>®</sup> (vibegron) (New indication: OAB in men with BPH)	
	SEP-380135 (Alzheimer's disease agitation)	TP-1454 (Solid tumors)	rodatristat ethyl (Pulmonary arterial hypertension)		
	DSP-0038 (Alzheimer's disease psychosis)	TP-0390 (Solid tumors)	URO-902 (Overactive bladder)		
China				LATUDA <sup>®</sup> (New indication: Bipolar I depression)	
				SEP-363856 (Schizophrenia)	
Europe					relugolix (Prostate cancer/Uterine fibroids)

Slide #11 shows our development pipeline. Please take a look at the project under Phase 1, the U.S. Here we have DSP-0038 in the light blue-colored Psychiatry & Neurology area, which is indicated for Alzheimer's disease psychosis. Developed with Exscientia by the AI drug discovery approach, this drug is now in the clinical study stage. In the Oncology area, we have DSP-0390. This anti-cancer drug kills cancer cells by controlling cholesterol and has entered the clinical study stage.


Under Phase 2, we have TP-0903 in the Oncology area. We have very high expectations for this, since, as I mentioned earlier, we have had good data so far in the Beat AML Study.

Under Phase 3, we have begun the development of SEP-363856 in Japan and China. Meanwhile, DSP-7888 for glioblastoma is in Phase 3 in the U.S.

As we announced before, we have resubmitted the application for RVT-802, whose approval should be obtained by the end of FY2021. In Europe, we have just submitted the application for relugolix for prostate cancer.

**Research and Development**

**Clinical Development Status (Major Changes since January 28, 2021)**



**Submission and Resubmission**

- relugolix Prostate cancer MAA submitted in March 2021 in Europe
- RVT-802 Pediatric congenital athymia BLA resubmitted in April 2021 in the U.S.

**Advanced**

- SEP-363856 Schizophrenia Started Phase 2/3 in Japan and China
- DSP-7888 Glioblastoma Changed from Phase 2 to Phase 3 in the U.S.

**Newly added**

- DSP-0038 Alzheimer's disease psychosis Started Phase 1 in the U.S.
- DSP-0390 Solid tumors Started Phase 1 in the U.S.
- TP-0903 (dubermatinib) \* Acute myeloid leukemia (AML) Ongoing Phase 1/2 in the U.S.

\*A study in AML is underway as a research group-initiated clinical study. Deleted due to completed Phase 1 study in the U.S. and Japan for solid tumors

**Discontinuation**

- BBI608 (napabucasin) Colorectal cancer Phase 3 (the U.S. and Japan) , other solid tumors
- EPI-743 (vatiquinone) Leigh syndrome Phase 2/3 (Japan)

**Discontinuation in-house, under activity for out-license**


- DSP-2033 (alvocidib) AML (Phase 2 in the U.S.), MDS (Phase 1/2 in the U.S.)
- DSP-0337 Solid tumors (Phase 1 in the U.S.)

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Let me skip Slide #12, as I have already explained this.

**Research and Development**

**Main Event / Target for FY2021**

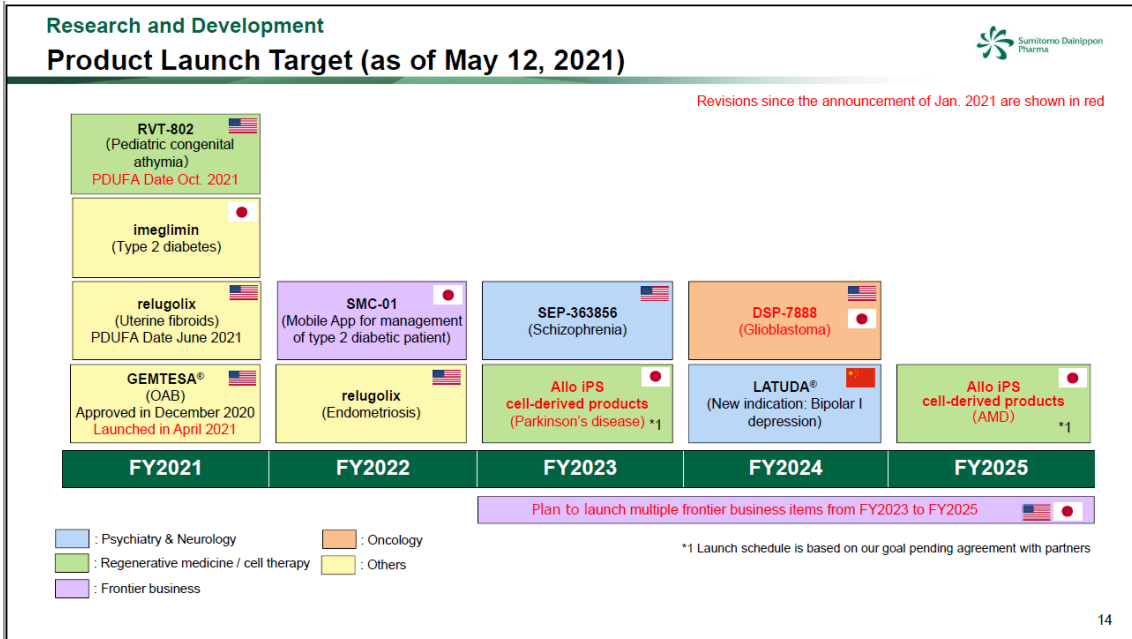


<b>Psychiatry &amp; Neurology</b>	<ul style="list-style-type: none"> <li>□ SEP-363856 : □ Start clinical program for the development (global study) of new indication</li> <li style="padding-left: 20px;">□ Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia</li> <li>□ SEP-4199 : Start Phase 3 study for Bipolar I depression</li> </ul>
<b>Oncology</b>	<ul style="list-style-type: none"> <li>□ DSP-7888 : Advance global Phase 3 study for glioblastoma</li> </ul>
<b>Regenerative medicine / Cell therapy</b>	<ul style="list-style-type: none"> <li>□ RVT-802 : Obtain approval for pediatric congenital athymia in the U.S.</li> <li>□ Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study</li> <li>□ Allogeneic iPS cell-derived products (Parkinson's disease) : Complete transplant in investigator-initiated clinical study</li> </ul>
<b>Infectious Diseases</b>	<ul style="list-style-type: none"> <li>□ Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines : Promote joint research and development projects</li> </ul>
<b>Others</b>	<ul style="list-style-type: none"> <li>□ relugolix : (U.S.) □ Obtain approval for uterine fibroids □ Submit NDA for endometriosis (Europe) □ Obtain approval for uterine fibroids □ Submit MAA for endometriosis</li> <li>□ imeglimin : Obtain approval for type 2 diabetes in Japan</li> </ul>
<b>Frontier</b>	<ul style="list-style-type: none"> <li>□ Promote the current themes (MELTIN, Aikomi, Drawbridge, BehaVR, and internal themes), development of new themes</li> </ul>

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Shown on Slide #13 are the main events and targets for FY2021. We will use this list to reflect on how many of these we will have achieved at the end of this fiscal year.





Slide #14 shows our product launch targets. As I explained before, we expect RVT-802 to be launched in the U.S. in FY2021, followed by relugolix for endometriosis sometime in FY2022. In Japan, we are conducting the clinical study of the mobile app for the management of type 2 diabetic patients, which we hope to release in FY2022. Also in Japan, we have allogeneic iPS cell-derived products for Parkinson's disease, which are under the investigator-initiated clinical study and should launch in the Japanese market in FY2023. For FY2024, we should be able to launch DSP-7888 for glioblastoma, which, as I mentioned earlier, has entered Phase 3. And for FY2025, although it is taking a bit longer than we expected, we are hoping to launch allogeneic iPS cell-derived products indicated for age-related macular degeneration (AMD).

At the bottom of this Slide, we made a brief comment on our product launch schedule for the frontier business. We are working hard to launch devices for blood sampling and assisting recovery of motor functions, hopefully starting in FY 2023.

## Background of Revision of Mid-term Business Plan 2022

- April 2019: Publication of Mid-term Business Plan 2022
    - ✓ Reshape business foundation through the “establishment of a growth engine” and the “building of a flexible and efficient organization,” preparing for the “Time for Change” and post-LATUDA revenue replacement
- ▼
- We decided to form the Strategic Alliance with Roivant due to a significant change in the medium- to long-term business outlook after the events such as discontinuation of development of napabucasin for pancreatic cancer which was expected as a revenue driver in post-LATUDA
    - ✓ Acquired relugolix and vibegron, which are expected to be the immediate revenues base
- ▼

### Revision of Mid-term Business Plan 2022

- **Currently working on (1) maximizing the product value of relugolix and vibegron and products that are expected to contribute to latest revenues, (2) advancing R&D activities for medium- to long-term growth, (3) advancing the reinforcement of business infrastructure to strengthen the company**

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Let me spend some time conveying the revision of the Mid-term Business Plan 2022, which starts from Slide #16. This ongoing Mid-term Business Plan was published in April 2019. Actually, we put together this plan in April 2018 and have pursued it since then. We deliberately delayed its announcement because we thought we should wait until the patent litigation over LATUDA® was settled.

In anticipation of the expiration of the patent and exclusive marketing period of LATUDA® in February 2023, as well as numerous environmental changes both in and outside of the company, we compiled this Mid-term Business Plan to prepare for the "Time for Change" and have been working on it to establish growth engines and build a flexible and efficient organization in the post-LATUDA period. As you have been informed, we had expected napabucasin to be a growth engine and thus designed the plan with a focus on it. Since we decided to discontinue its development for pancreatic cancer based on interim analysis in July 2019, however, we could no longer expect napabucasin to lead growth, eliminating the driving force behind the plan.

In the original Mid-term Business Plan, we mentioned Psychiatry & Neurology as the main area for M&As. However, because we had more offers than we could count on our fingers, each involving a huge amount of money, it was not realistic to purchase several businesses. We were wondering what to do, when we had the fortune of gaining the opportunity to form a strategic alliance with Roivant Sciences. Close analysis of the company revealed that they had highly promising potential compounds in their late-stage pipeline, though they were not necessarily in our focus areas. So we changed course to get on with an offer.

The moment we concluded that napabucasin lost its potential to be a powerful growth engine,

it occurred to us that we should develop relugolix and vibegron as the next growth engines. So, you could say that our basic policy remains intact, but we changed our approach in seeking to achieve it.

Accordingly, we are trying to maximize the product value of our pipeline, which includes relugolix and vibegron. However, we cannot pin our hopes on these two promising drugs alone. Instead, we must consider how to go about developing drugs currently in the late-stage clinical studies or new programs whose clinical studies are due to start, to ensure business growth over the mid- and long-term. At the same time, we know that our profit and loss situation will be very difficult once we lose exclusivity for LATUDA®. With all this in mind, we must revamp our approaches for the revised Mid-term Business Plan 2022, so that we can advance the reinforcement of business infrastructure to bolster our resilience.

**Revision of Mid-term Business Plan 2022**  
**Corporate Mission and CSR-Based Management**

**Corporate Mission** To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide

- Define implementation of corporate mission as “CSR-based management” and set material issues of CSR-based management (Materiality)
- Address material issues, aimed at solving social challenges and enhancing corporate value through our core competencies

**Material issues linked to value creation**  
 - solving issues is important for our sustained growth

<ul style="list-style-type: none"> <li>Improvement of healthcare infrastructure in developing countries</li> <li>Measures to address counterfeit medicines</li> <li>Local community contribution</li> </ul>	<ul style="list-style-type: none"> <li>Contribution to global health</li> <li>Initiatives to improve access to medicines</li> <li>Patient support and advocacy</li> </ul>	<ul style="list-style-type: none"> <li>Development of innovative products and healthcare solutions</li> <li>Contributing to the advancement of science</li> <li>Work style innovation</li> <li>Diversity and inclusion</li> <li>Training and development of employees</li> </ul>
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Our strengths: Research & Development, Global platform, Human resources

**Material issues that forms the foundation for business continuity**  
 - solving issues is essential for our sustained growth

<ul style="list-style-type: none"> <li>Respecting human rights</li> <li>Corporate governance</li> <li>Compliance</li> </ul>	<ul style="list-style-type: none"> <li>Risk management</li> <li>Fair and transparent corporate activities</li> <li>Corporate regulatory compliance, quality assurance and stable supply</li> </ul>	<ul style="list-style-type: none"> <li>CSR procurement</li> <li>Health, safety, and welfare of employees</li> <li>Environmental initiatives</li> </ul>
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Contribute to improved quality of life (QoL) for patients and their families  
 improve and sustain corporate value

- Returns to shareholders (stable dividends, increases in dividends linked to improvements in performance)
- Strategic investment aimed at sustained growth (includes research and development investment)
- Also contributing to achieving the Sustainable Development Goals (SDGs)

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On Slide #17, we show what will most likely be unchanged, so it's safe to skip this.

Revision of Mid-term Business Plan 2022  
**Mid-term Business Plan 2022: Vision and Aim for 2033 (Updated October 2019)**



**Vision** For Longer and Healthier Lives  
 We unlock the future with cutting-edge technology and ideas

Aspire to establish a position as a “Global Specialized Player” with ability to meet increasingly diversified needs for healthcare in 2033

**Global Specialized Player**

<b>Pharmaceuticals + Solutions</b> Medicine / Cell Therapy + Healthcare Solutions (Frontier business)	<b>Global leader in 3 areas</b> Psychiatry & Neurology, Oncology, Re-generative / Cell	<b>Best-in-class focused on value</b>
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**in 2033**

**Mid-Term Business Plan 2022: Rebuild Business Foundation**

Establishment of growth engine + Building of flexible and efficient organization


**Acceleration of our growth by strategic alliance with Roivant**

Driver of sustained growth after LATUDA® LOE + Innovative change to new business model based on data technology of DrugOME and Digital Innovation

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Likewise, our vision and aim for 2033 on Slide #18 remain unchanged. We aspire to establish a position as a "Global Specialized Player."

Revision of Mid-term Business Plan 2022  
**Mid-term Business Plan 2022: Basic Strategies**



Reshape business foundation through the “establishment of a growth engine” and the “building of a flexible and efficient organization,” preparing for the “Time for Change” and post-LATUDA revenue replacement

**Global Specialized Player**

① Enhance innovation base with new approaches to drug discovery

② Deliver highest performance of clinical development	③ Pipeline expansion through strategic investment
④ Regional strategy targeting Japan, North America, and China	⑤ Launch frontier business

**I. Establishment of a growth engine**

“CHANTO”

Digital innovation

**II. Building of a flexible and efficient organization**

Flexible and efficient organizations/operations

Corporate culture and talent to drive innovation

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And no change to our basic strategies on Slide #19.

Significant changes in business outlook after LATUDA® LOE

	Positive events	Negative events
North America	<ul style="list-style-type: none"> <li>KYNMOBI™ (PD): Launched</li> <li>ORGOVYX™ (Prostate cancer): Launched</li> <li>GEMTESA® (Overactive bladder): Launched</li> <li>relugolix combination tablet (Uterine fibroids): NDA submitted</li> <li>SEP-363856 (Schizophrenia): POC obtained (BTD), phase 3 started</li> <li>SEP-4199 (Bipolar depression): Phase 3 in preparation</li> <li>RVT-802 (Pediatric congenital athymia): BLA resubmitted</li> </ul>	<ul style="list-style-type: none"> <li>LONHALA® MAGNAIR® (COPD): Downward revision of marketing plan</li> <li>KYNMOBI™ (PD): Delay of approval &amp; downward revision of marketing plan</li> <li>dasotraline (ADHD, BED): Withdrawal of application in U.S. / discontinuation of development</li> <li>SB623 (Chronic stroke): Discontinuation of development / return of rights</li> </ul>
North America, Japan	<ul style="list-style-type: none"> <li>DSP-7888 (Glioblastoma): Advanced to phase 3 (In process in Japan)</li> </ul>	<ul style="list-style-type: none"> <li>napabucasin (Pancreatic cancer/Colorectal cancer): Discontinuation of development</li> <li>alvociclib (Hematologic malignancies): Discontinuation of in-house development / working on out-licensing</li> <li>amcasertib (Solid tumors): Discontinuation of development</li> </ul>
Japan	<ul style="list-style-type: none"> <li>Equa®/EquMet® (Diabetes): Marketing alliance</li> <li>LONASEN® Tapes (Schizophrenia): Launched</li> <li>LATUDA® (Schizophrenia / Bipolar depression): Launched</li> <li>SEP-363856 (Schizophrenia): Phase 2/3 started</li> <li>imeglimin (Diabetes): NDA submitted</li> </ul>	<ul style="list-style-type: none"> <li>LONASEN® Tapes (Schizophrenia): Downward revision of marketing plan</li> <li>EPI-743 (Leigh syndrome): Discontinuation of development</li> </ul>
China	<ul style="list-style-type: none"> <li>LATUDA®: Launched (Schizophrenia), Phase 3 started (Bipolar depression)</li> <li>SEP-363856 (Schizophrenia): Phase 2/3 started</li> </ul>	

■ Psychiatry & Neurology ■ Oncology ■ Regenerative / Cell ■ Other

PD: Parkinson's disease; ADHD: attention-deficit hyperactivity disorder; BED: binge eating disorder; COPD: chronic obstructive pulmonary disease; POC: proof of concept; BTD: breakthrough therapy designation

Moving on to Slide #20, what you see here are key events, both positive and negative, that have occurred after the start of the current Mid-term Business Plan. As you can see, not all the products that we hoped would sustain business growth after LATUDA® LOE have been successful.

**A Decision on Strategic Alliance with Roivant**

**C Discontinued development of the pipelines**

**B Downward revision of marketing plans of the new products**

- LONHALA® MAGNAIR® [COPD]: Marketed in the U.S.
- KYNMOBI™ [PD]: Marketed in the U.S.
- LONASEN® Tape [Schizophrenia]: Marketed in Japan

**D Acceleration of drug cost reduction measures**

- Japan: Initiation of annual NHI drug price revision (FY2021)
- China: Expansion of centralized purchasing system or price bargaining system
- U.S.: Penetration of value-based pricing, possibility of introduction of international reference pricing

ADHD: attention-deficit hyperactivity disorder; BED: binge eating disorder; COPD: chronic obstructive pulmonary disease; PD: Parkinson's disease

On the left side of Slide #21 is a timeline from FY2019 to FY2021. Napabucasin's Phase 3 clinical study for pancreatic cancer was discontinued in July 2019. The strategic alliance with Roivant Sciences was signed in October of the same year. Then in FY2020, the development



of dasotraline was discontinued, and we made the tough decision to discontinue napabucasin's development overall following the failure to meet the primary endpoints at the Phase 3 clinical study for colorectal cancer. Meanwhile, we formed a strategic alliance with Roivant Sciences in October 2019, which gave us access to their late-stage pipelines. So far, we have been able to have those products approved for launch. In retrospect, it was very timely that we began speaking with Roivant Sciences about the alliance when napabucasin's Phase 3 clinical study for pancreatic cancer was not generating positive results.

We had to change the conditions for the Mid-term Business Plan because the new products listed at the top right did not grow as expected, and the operating environment changed. To be more specific, national governments in Japan, China, and the U.S. are accelerating measures to curb pharmaceutical expenses. More precisely, the U.S. looks set to start moving in this direction, so we have yet to see its impact on our business. Once such measures are taken, however, it will affect our business profoundly.

**Revision of Mid-term Business Plan 2022 (Effects of Strategic Alliance with Roivant)**

**Effects of Strategic Alliance with Roivant**

- ❑ Acquisition of revenue base in 2023 and beyond
  - ✓ relugolix (Myovant) and vibegron (Urovant)
- ❑ Expansion of pipelines
  - ✓ Acquisition of multiple assets with new modalities and unique characteristics
- ❑ Acquisition of digital technology platforms
  - ✓ DrugOME, Digital Innovation
- ❑ Expansion of global business alliances with acquisition of various talented human resources

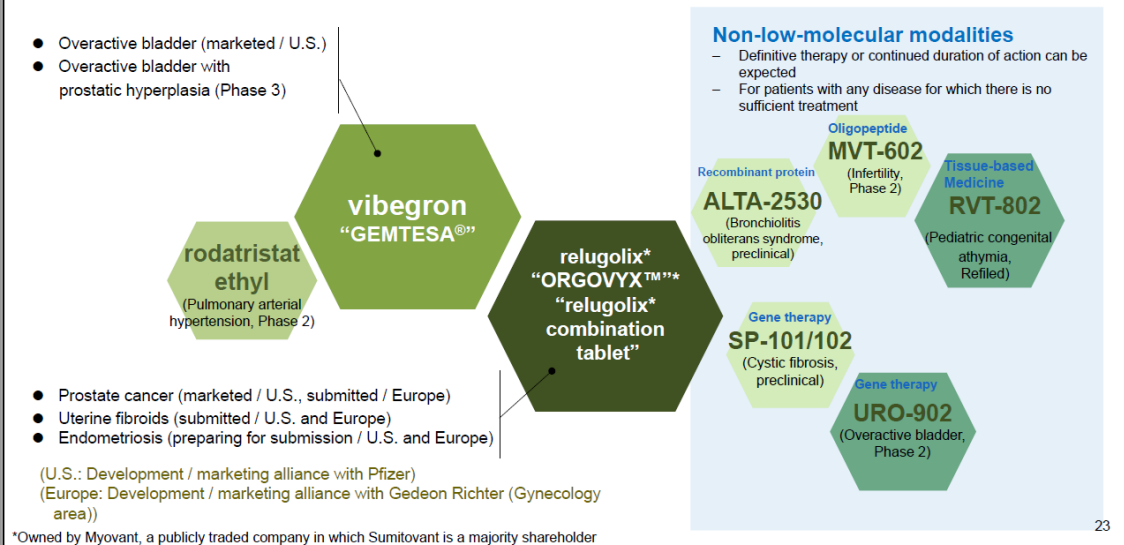

← Business alliance →


Acquired by share acquisition	Technology transfer	Business alliance
<b>Sumitovant Biopharma</b> <ul style="list-style-type: none"> <li>• Myovant Sciences</li> <li>• Urovant Sciences</li> <li>• Enzyvant Therapeutics</li> <li>• Altavant Sciences</li> <li>• Spirovant Sciences</li> </ul>	<b>DrugOME technology</b> Platform to accelerate pipeline acquisition /clinical development by using unique data analyses  <b>Digital Innovation technology</b> Platform to improve operational efficiency by utilizing healthcare-IT-related technology	<b>Datavant</b> Owns platform to promote use of healthcare-related data by connecting plural external healthcare-related data anonymized  <b>Alyvant</b> Owns platform to increase efficiency of sales operation of pharmaceutical products by using big data analyses

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On Slide #22, we itemize what we have gained from the alliance with Roivant Sciences. Allow me to omit my explanations as I believe I have spoken about this many times.

**Revision of Mid-term Business Plan 2022 (Effects of Strategic Alliance with Roivant)  
Acquisition of Pipelines that may Contribute to Early Revenue Generation and  
Development of Modalities**

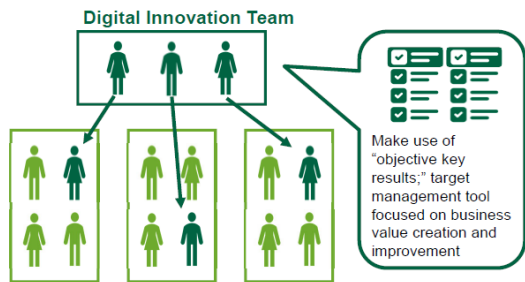


On Slide #23, you see the pipelines we have acquired recently. On the left side are low-molecular drugs, including relugolix, vibegron, and rodatristat ethyl. Of these, rodatristat ethyl is particularly promising, and we are making intensive efforts toward its development. If you turn your eyes to the right to the slightly sky blue-colored box, we have RVT-802, which is a tissue-based medicine, MVT-602, or oligopeptide, ALTA-2530, or recombinant protein, and SP-101/102 and URO-902 for gene therapy. As you can see, we have gained new techniques, technologies, and modalities for drugs other than low-molecular ones, which we believe will serve as fundamental technologies for future research seeds beyond our current programs.

## Development of “Digital Innovation” in Our Whole Company Group

□ Expect improved probability of success in operations across whole group companies and R&D as well as impact on the return on investment goal

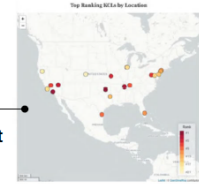
- Deploy digital innovators to each department/group
- Make efforts to solve problems on site and cooperate with each other cross-functionally



### Each subsidiary/department

- Create a position of Chief Digital Officer responsible for our whole company group
- Foster citizen data scientists

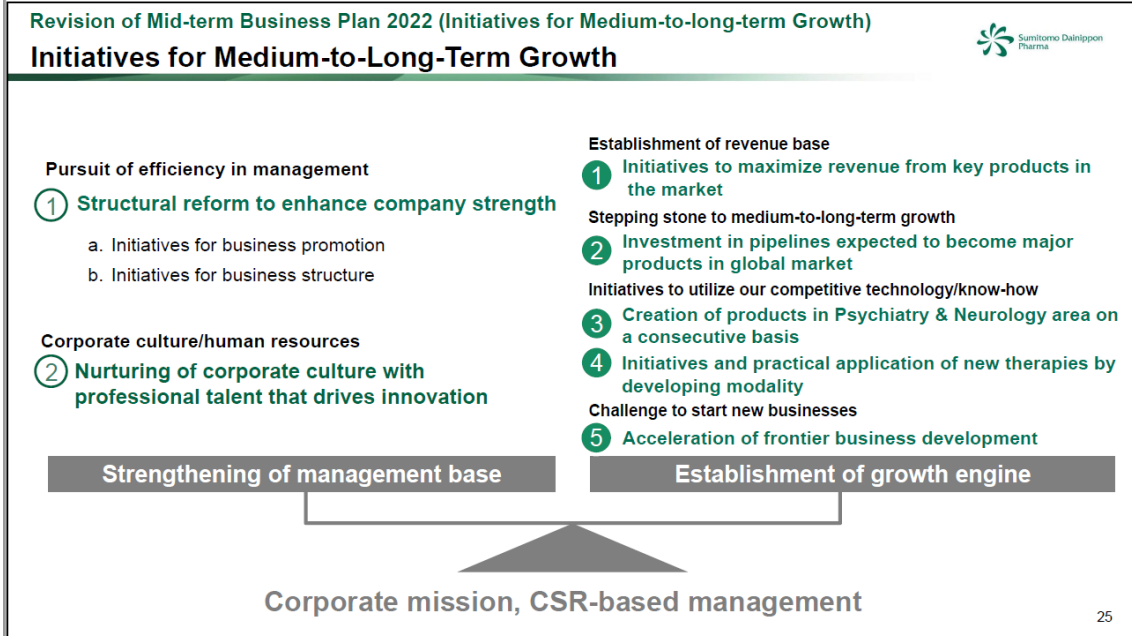
- Research for drug discovery
  - Identifying targets of research for new drug discovery based on information analyses utilizing a unique AI algorithm (DrugOME)
- Non-clinical study
  - Automated data acquisition utilizing image recognition
- Clinical study
  - Optimization of development strategy based on real world data analyses (DrugOME)
- Marketing operation
  - Productivity enhancement by effective and timely KOL mapping



Reference: Sumitovant Meeting (March 23, 2021) 24

We discuss how we are developing Digital Innovation on Slide #24. The need for "digital transformation" was mentioned in the original Mid-term Business Plan, and the alliance with Roivant Sciences significantly accelerated its pace. After the signing in 2019, we began examining how we could take advantage of Digital Innovation and DrugOME within our Group. We are now ready to apply these healthcare technology platforms on a full scale to research, development, and marketing where they will be most efficient, thus increasing the velocity of our business approaches, operational efficiency, and the probability of success in research and development.





Turning to Slide #25, our initiatives for mid-to-long-term growth are explained. We have re-configured what we set out to do when we kicked off the original Mid-term Business Plan, that is, establish growth engines and strengthen the management base.

Revision of Mid-term Business Plan 2022 (Initiatives for Medium-to-long-term Growth)

Sumitomo Dainippon Pharma

## Initiatives for Strengthening of Management Base: Pursuit of Efficiency in Management

① **Structural reform to enhance company strength**

**Launching initiatives to deal with environmental changes in the pharmaceutical industry and uncertainty after LATUDA® LOE**

- a. Initiatives for business promotion
  - Consideration/promotion of partnering on global basis to maximize revenue and cost reduction
  - Optimization of investment to R&D pipelines, sales and administrative costs suited to business scale
  - Consideration/promotion of selling products that have reached loss of exclusivity (LOE) and R&D assets
- b. Initiatives for business structure

North America	Japan
<ul style="list-style-type: none"> <li>□ Continued initiatives for optimization of infrastructure in North America</li> <li>□ Initiatives for creation of cost synergy by strengthening alliance among subsidiaries <ul style="list-style-type: none"> <li>• Utilization of marketing platform of Sunovion (distribution or marketing functions, etc.)</li> <li>• Strengthening of shared service operations in North America by SDPA*</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>□ Initiatives to optimize the structure to maintain sustainable revenue for business operations in Japan <ul style="list-style-type: none"> <li>• Business operation based on the assumption of shrinkage of the size of pharmaceutical market in Japan</li> <li>• Review global head office functions for optimization</li> <li>• Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction</li> </ul> </li> </ul>
Europe	China / Asia
<ul style="list-style-type: none"> <li>□ Initiatives to optimize the structure to maintain sustainable revenue for business operations in Europe</li> </ul>	<ul style="list-style-type: none"> <li>□ Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction</li> <li>□ Business expansion to geographical areas likely to contribute to our profits</li> </ul>

\*Sumitomo Dainippon Pharma America, Inc.

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On Slide #26, we describe how we will go about strengthening our management base. We have begun working on structural reform designed to enhance our corporate resilience. In the background to this are LATUDA® LOE and environmental changes that lie ahead, with consideration given to the previously-mentioned government programs to curb

pharmaceutical expenses, which should become more and more tangible in the fields we operate in.

With regard to the initiatives for business promotion, we believe it is important to expand the pie by promoting partnering on a global basis. Take Myovant Sciences' relugolix, as an example. By partnering with Pfizer, we have been able to make the pie bigger than we could have by promoting the product with a stand-alone approach, and this larger pie can now be shared amongst ourselves. I believe that we could do the same in other therapeutic areas of ours.

If an alliance program includes development, we should be able to lower the risk and cost of development projects. Suppose we have a certain development project. If we undertake it alone, we might be able to develop one indication only. But if we have partners, we should be able to develop the same product for two indications simultaneously.

By FY2023, LATUDA®'s exclusivity will have ended, and so we must expect a difficult profit and loss situation. Quite naturally, we have to reduce our R&D budget to some extent and thereby revise the way we allocate it. For products whose exclusivity has been lost, we might consider modifying marketing, back-office, or other systems.

Even when the exclusive marketing period has expired, some of the applicable products will still have well-recognized brand names, which should prevent their sales from drying up overnight; they will still have economic value, so selling the rights to them should be a possibility. We might also consider licensing or selling the R&D assets on which the company does not place a high priority.

Let me then speak about our initiatives in each geographical region. In North America, we have Sunovion and Sumitomo Dainippon Pharma Oncology under Sumitomo Dainippon Pharma America. We also have Sumitovant Biopharma and five companies under its umbrella. So, we have what we could call two separate holding company structures. The key point here is how we can create synergies going forward. In Japan, on the other hand, how we can survive the annual NHI price revisions and boost revenue will be the overriding imperative. In China and other Asian countries, too, we need to build a solid revenue base, and the same holds for Europe.

## ② Nurturing of corporate culture with professional talent that drives innovation

- Penetration/practice of “CHANTO”
  - Deliver highest performance (“CHANTO”) to achieve the goals, while responding to environmental changes
  - The Conduct Guidelines are to be observed by each of our employees to establish our position as a global specialized player by 2033
  - Promote a company-wide project, aiming at understanding/penetration and practice/habituation of the Guidelines at each workplace, which was verbalized by our executive officers
- Foster an organizational culture characterized by agility (quick and flexible) and unrelenting efforts instead of satisfaction with the status-quo
- Develop next-generation leaders by strategic personnel distribution and education/training program for selected employees

### “CHANTO” concept and key visual

**CHANTO**

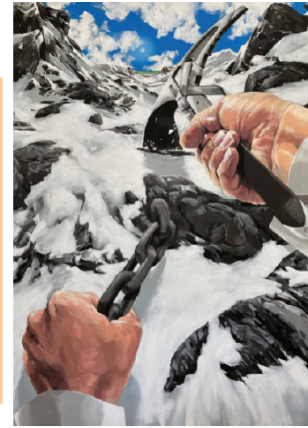
The era in which we cannot survive without each person's challenge

Drive in an anchor  
Pave the way for ourselves

Supporting and encouraging each other,  
Aim for the summit together

All leading roles, all supporting roles

Climb with our own strength  
to realize the future we envision



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Slide #27 is about corporate culture and talent development. In the original Mid-term Business Plan, we described about "accomplish with CHANTO spirit" (CHANTO means capability to deliver highest performance) and it has since been abbreviated to "CHANTO." We have started a project for the penetration of this concept in our company as well as in associated companies in Japan, and its penetration will be expanded to overseas group companies. One meaning in Japan of CHANTO is "properly" but we do not use it in the sense an adult would when telling a child to "do things properly." For us, it means each employee having challenging goals, thinking deeply about how to achieve them, the methods to use and the kind of team that will achieve them, and then steadfastly putting this into action to obtain good results.

There is no inconsistency between "Agility" below and CHANTO. To deliver highest performance it will be necessary to make a firm response to changes in the business environment, making efforts to achieve goals no matter what happens. On the right, there is a picture that looks like someone climbing a mountain. When we climb a mountain, the weather may not be good all the time and may change over time. We have to be properly prepared for any change in the weather. This means that we must be fully prepared for changes in the business environment too and continue making concerted efforts towards achieving our goals.

To do this, obviously, if the environment in our company is such that people cannot work happily, they will certainly not produce good work. We will continue to make concerted efforts in talent development and this will include nurturing the next generation of leaders.

**Establishment of Growth Engine: Establishment of Revenue Base**

**1 Initiatives to maximize revenue from key products in the market**

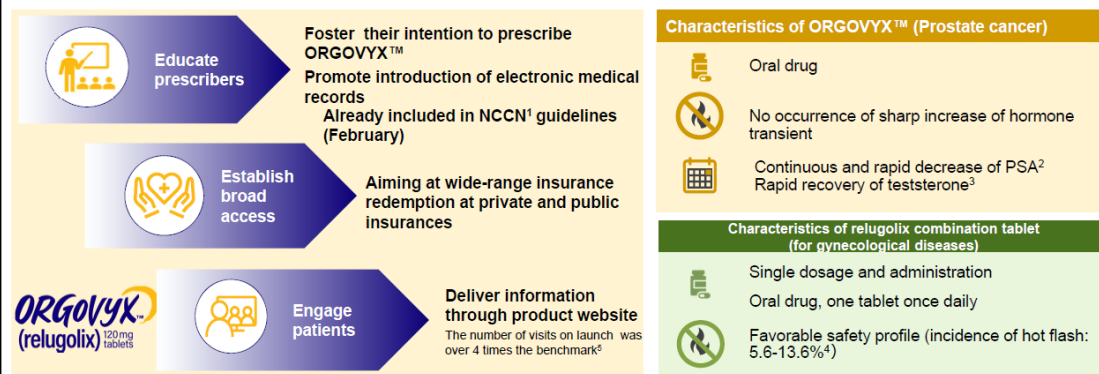
- **ORGOVYX™\***  
**relugolix\* combination tablet** (to be launched in 2021)
  - ▣ Maximize sales through alliance with Pfizer
  - ▣ Pursue synergies in costs by utilizing Sunovion's commercial capabilities (distribution)
- **GEMTESA®**
  - ▣ Pursue synergies in costs by utilizing Sunovion's commercial capabilities (marketing, distribution)
  - ▣ Maximize revenue outside of North America: partnership with external parties
- **LATUDA®**
  - ▣ North America: Leverage digital transformation for effective marketing operations that impact earnings
  - ▣ Maximize sales by expanding to Japan, China, and Asia
- **KYNMOBI™**
  - ▣ Concentrate on start-up in the U.S.
  - ▣ Maximize revenue outside of North America: partnership with external parties
- **Antidiabetics in Japan**
  - ▣ Maximize launched products and imeglimin by utilizing the infrastructure of the top sales company in the Japanese antidiabetic market

\*Owned by Myovant, a publicly traded company in which Sumitovant is a majority shareholder

Slide #28 is about establishing growth engines. For the time being, our efforts in formulating growth strategies will continue to center on relugolix and GEMTESA®. We will continue to expand LATUDA® in the remaining period and then in Japan, China and the rest of Asia. As there has been a little delay with KYNMOBI™, we will return it firmly to the original growth line. Diabetes is a major franchise area for us in Japan so we will fully leverage the in-licensing of imeglimin.

**Realization of Product Value Maximization of Relugolix (North America)**


**□ Achieve smooth market penetration and maximize product value by utilizing infrastructure and expertise of Pfizer under co-promotion agreement**



(1) NCCN, National Comprehensive Cancer Network  
 (2) PSA levels were monitored in the clinical study. The levels declined throughout the treatment period of 48 weeks: 65% decline in average after 2 weeks from initiation of ORGOVYX™, 83% after 4 weeks, and 92% after 3 months.  
 (3) On day 90 after termination of ORGOVYX™ administration, 55% of patients attained a testosterone level of the lower limit (<260ng/dL) or over the baseline.  
 Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. *New England Journal of Medicine*. 2020 June 4. DOI: 10.1056/NEJMoa2004325  
 (4) SPIRIT1 1 TLR; 2020/6/23 Webcast, SPIRIT 2 TLR; 2020/4/22 Webcast, LIBERTY 1/2; *N Engl J Med* 2021; 384:630-42  
 (5) DTC benchmark of cancer therapeutic drugs=The product website is visited 175 times/day  
 ORGOVYX™ prescribing information is available from [www.myovant.com/orgovyx-prescribing-information.pdf](http://www.myovant.com/orgovyx-prescribing-information.pdf)

I will skip Slide #29 as it features relugolix.

Revision of Mid-term Business Plan 2022 (Initiatives for Medium-to-long-term Growth)  
**Realization of Product Value Maximization of GEMTESA® (North America)**




❑ Pursue group synergies between Urovant and Sunovion to optimize marketing structures for urology specialists, long-term care facilities, and primary care providers with high frequency of prescription to realize early maximization of the product value

**Brand Vision**

Establish GEMTESA® as the best in category treatment option for patients suffering from symptoms of overactive bladder (OAB)

- 1 Anchor launch performance through a focus in urology
- 2 Establish leadership for OAB in long-term care
- 3 Broaden uptake in primary care for OAB patients
- 4 Secure and maintain access and affordability for patients and healthcare professionals
- 5 Drive awareness, education and advocacy for OAB patients



**Characteristics of GEMTESA®**


- ✓ Single dose and administration, crushable tablets
- ✓ Dose adjustment not required<sup>1</sup>
- ✓ Data on frequency of urge to urinate are stated in the package insert
- ✓ No warning for blood pressure increased
- ✓ No warning for drug interactions related to CYP2D6

(1) Treatment with Jemtesa for patients is started with prescription of 75 mg as initial and effective dose. Source: GEMTESA® U.S. FDA label for the treatment of overactive bladder. GEMTESA® prescribing information is available from www.gemtesa.com.

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Let me skip Slide #30 as it features GEMTESA®.

Revision of Mid-term Business Plan 2022 (Initiatives for Medium-to-long-term Growth)  
**Establishment of Growth Engine: Stepping Stone to Medium-to-Long-Term Growth**



**2 Investment in pipelines expected to become major products in global market**

- **SEP-363856**
  - Advance Phase 3 study for schizophrenia
- **SEP-4199**
  - Initiate Phase 3 study for bipolar I disorder
- **rodatristat ethyl**
  - Advance Phase 2b study for pulmonary arterial hypertension

**SEP-363856**

**[Indications]** Schizophrenia, symptoms of other psychiatric disorders

**[Characteristics]** Psychotropic drug with new mechanism of action, which does not act on dopamine receptors  
Designated as breakthrough therapy for schizophrenia

**[Launch]** U.S.: Targeted for FY2023  
Japan/Asia : Targeted for latter half of the 2020s

**rodatristat ethyl**

**[Indications]** Pulmonary arterial hypertension

**[Characteristics]** Due to new mechanism, this drug can be concurrently used for pulmonary arterial hypertension (tryptophan hydroxylase inhibitor)  
Based on approach, expect to see **disease modifying effects** instead of symptomatic treatment

**[Launch]** U.S./Japan/Asia: Targeted for latter half of the 2020s

**Utilization of external resources for maximization of revenue**

- Collaboration with business partners to maximize operations is expected
- Out-licensing in geographies outside of North America, Japan and Asia

**Advance of global study**

- Advance of efficient clinical study and solution of time-lag

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Slide #31 is about products that will support us after relugolix and vibegron. The methodology described is "utilization of external resources for maximization of revenue" and "advance of global study." Specifically, we are considering SEP-363856, SEP-4199, and rodatristat ethyl as the pipeline to support our growth for the next generation.

### 3 Creation of products in Psychiatry & Neurology area on a consecutive basis

- **Enhance probability of success in clinical settings**

- Sumitomo Dainippon 15% (6-8% industry average\*)
  - Further improvement by utilization of biomarkers

- **Expand early pipeline**

- 12 candidates in the past 3 years
  - Psychiatry (Phase 1; underlined)  
SEP-380135, SEP-378614, DSP-1181,  
DSP-0038, DSP-2342, DSP-3456
  - Neurology  
DSP-0187, DSP-0378, DSP-0551,  
DSP-4240, DSP-7970

#### Extensive experience with clinical studies

- Launched 8 products since 1995

#### High-tech exploratory/development research aiming at improvement of efficacy in humans

- Utilization of AI
- Analysis of mechanism of action by optogenetics
- Utilization of high predictability biomarkers such as brain waves
- High-tech phenotype drug discovery
- Initiatives for new modalities

#### Organizational structure to support product creation on a consecutive basis

- Research project system integrated from idea generation to clinical levels
- Virtual one-team system to stimulate cross-sectional collaboration

\*Clinical Development Success Rates 2006-2015

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Slide #32 concerns research areas for the next products. Statistically, the average probability of clinical success for our pipeline has been 15%, which is higher than the industry average. Through the use of biomarkers we aim to further increase the probability of success. As shown on the right of the slide, research combining the use of cutting-edge technology and scientific expertise in the form of project system and the virtual one-team system produced 12 products in the last 3 years. As there is great activity in the Psychiatry & Neurology area, we can look forward to products going on to the clinical level and then up through the stages of clinical development.

#### 4 Initiatives and practical application of new therapies by developing modality

- Provide treatment options to patients with a disease that has no sufficient treatment, aiming at radical cure
  - Cellular / tissue / transplanted organ drugs
  - Gene therapy
  - Protein drugs

##### Utilizing world-leading capability for regenerative / cellular drugs

- Application of world-leading iPS technology in clinical setting
- Utilization of infrastructure/know-how/human resources of the core technology for practical use (manufacturing)
- Efforts to deregulate regulatory affairs

##### Utilization of human resources who have knowledge about respective modalities; building of technological base

##### Allogenic iPS cell-derived drugs (Parkinson's disease)

【Indications】 Parkinson's disease  
 【Characteristics】 Co-development of **iPS cell-derived drug** with Center for iPS Cell Research and Application, Kyoto University. The drug is expected to recover nerve function.  
 Designated as Sakigake drug in Japan  
 【Launch】 Japan: Targeted for FY2023  
 (Clinical study is to be started in the U.S. in FY2022)

##### RVT-802

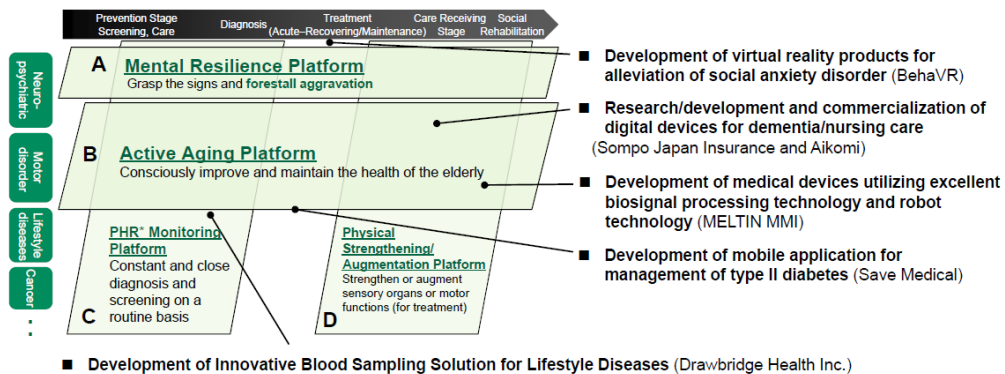
【Indications】 Pediatric congenital athymia  
 【Characteristics】 **The world's first drug of cultured thymus tissue** for fatal/congenital diseases  
 Designated as Regenerative Medicine Advanced Therapy designation in the U.S., etc.  
 【Launch】 U.S.: Targeted for FY2021

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Slide #33 shows initiatives and practical application of new therapies by developing modality. Here, a particular focus is the clinical application of iPS cells. It concerns products for cell therapy and gene therapy and protein drugs. Alternatively, we will make efforts to produce originality by pursuing research on small molecules, a focus of up till now, combining new knowledge, perhaps that concerning lipid nano particles or nucleic acids. The same is true for cancer and I will explain this a little later.

#### 5 Acceleration of frontier business development

Continue investment in potential technologies and businesses in the areas aiming to contribute through all stages from prevention to social rehabilitation



- Development of Innovative Blood Sampling Solution for Lifestyle Diseases (Drawbridge Health Inc.)

\*PHR: Personal Health Record

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Slide #34 is about frontier business. In such business, we work on developing products

that will be useful to patients and their families, in non-drug areas closely related to the diseases our drugs are designed to treat. I will not explain this in much detail but in the U.S. we are developing virtual reality products to mitigate social anxiety disorder. With a company called Aikomi, we are developing digital devices to alleviate BPSD. In addition, we are developing devices to augment motor function in patients with motor dysfunction together with MELTIN MMI and are currently testing mobile application for management of type 2 diabetes with a company called Save Medical. In other research, we are collaborating with Drawbridge Health to develop an innovative automated blood sampler for lifestyle diseases. These are projects that have been publicly announced. Apart from them, we are engaged in many other highly interesting projects. While we are engaged in many types of frontier business, we try to narrow down our focus.

Revision of Mid-term Business Plan 2022 (Policy of Approaching Oncology Area)

**Policy of Approaching Oncology Area**

Sumitomo Dainippon Pharma

□ **Revisit the R&D policy in oncology and undertake challenges on a continuous basis**

- Development: Initiatives focused on assessment of value of existing pipelines
- Discovery research: Work continuously on drug discovery in pursuit of our competitive edge
- Promote business collaboration/out-licensing operation

Meaning of continuation		Our approach	
Scientific challenge	High unmet needs & marketability	Development pipeline with distinctive features	Utilization of digital innovation, strengthening of modality development
Advancement of scientific & business levels	Expectation for buildup of revenue base for future	Feasibility assessment of the future commercialization	Establishment of competitiveness in drug discovery as a pharmaceutical company

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Slide #35 shows the policy for initiatives in the oncology area following the termination of the development of napabucasin. We are pressing ahead with 8 programs, of which the major one is for DSP-7888, that will be featured a little later. For the 7 programs other than that for DSP-7888, we will evaluate efficacy and safety in small-scale studies and go ahead with those that have possibilities in early programs to identify value as early as possible.

In regard to drug discovery research, we will work continuously on drug discovery in pursuit of our competitive edge using various modalities or new technologies. We are also thinking of alliances and out-licensing for R&D as part of the partnering policy that I mentioned earlier.



Revision of Mid-term Business Plan 2022 (Policy of Approaching Oncology Area)  
**Initiatives for Existing Development Pipeline**

Sumitomo Dainippon Pharma

□ Aim at early assessment of product value and commercialization

- Strengthen initiatives to identify the types of cancer/patients optimally through brief and small-scale tests
  - Actively utilize adaptive design
  - Strengthen connection between research and development
    - Translational research from research to clinical practice
    - Feedback between clinical data and research
  - Analyze clinical and research data obtained by our own digital technology

**Early assessment of product value**

**DSP-7888**

**[Indications]** Glioblastoma, other solid tumors (combined with immune checkpoint inhibitor)

**[Characteristics]** The world's first WT1 cancer peptide vaccine for immunotherapy, which activates both helper T cells/cytotoxic T cells

**[Launch]** U.S.: Targeted for FY2024 (indicated for glioblastoma)

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Slide #36 gives details of the 8 programs that I just mentioned. At Phase 3, DSP-7888 is furthest ahead and we will press on with it. For the other 7 programs, we will proceed with a little caution, confirming efficacy and safety as early as possible in small-scale studies.

Revision of Mid-term Business Plan 2022 (Policy of Approaching Oncology Area)  
**Realization of Pipeline with Competitive Edge**

Sumitomo Dainippon Pharma

**Establishment of competitiveness in drug discovery**

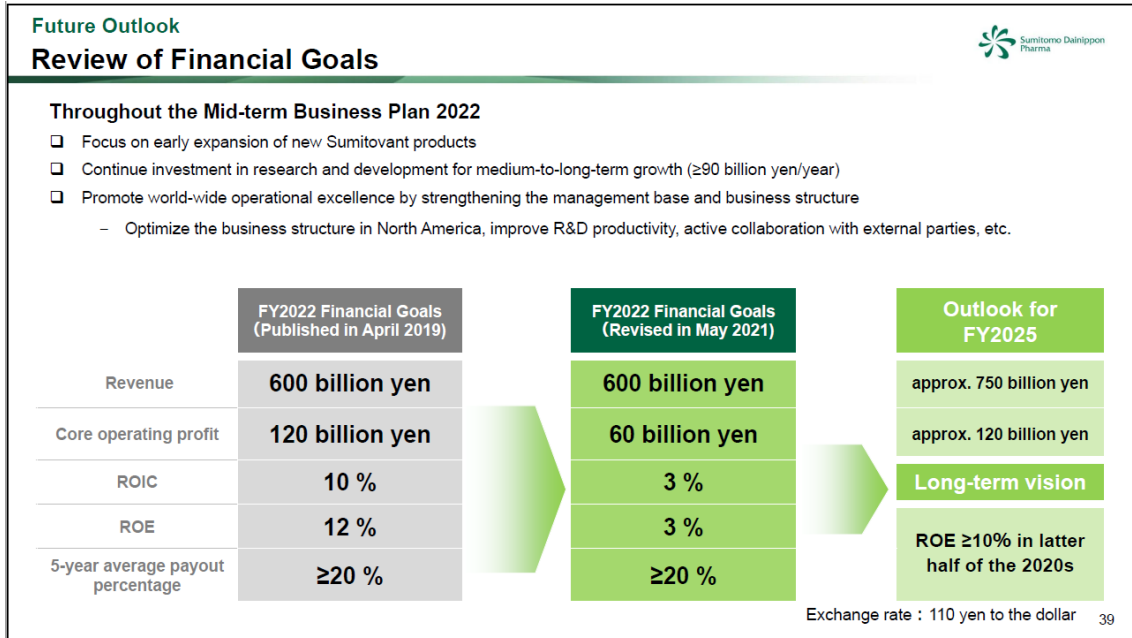
- Multiple new themes in progress specified by utilizing DrugOME**
  - Selection of target candidates for drug discovery based on literature with natural language processing technology used; exhaustive analyses of database information and trend forecasts
- Utilization of our new technology**
  - Drug discovery based on distinctive pharmacological concept
    - DSP-7888 (peptide vaccine that enables to activate both helper T cells and cytotoxic T cells)
  - Initiatives for technology aiming at higher levels of efficacy and safety:
    - New concept ADC: AiADC\* (Antitumor activity is expected only within the target tumor cells)
- Actively seeking of external input**
  - Participate in the planning of Beat AML Study led by LLS\*\*: TP-0903 (indicated for AML)
  - Searching for indicated type of cancer by joint research: TP-3654 (University of Virginia), TP-0184 (DFCI\*\*\*)

\*Antibody intracellular activated drug conjugate \*\*Leukemia & Lymphoma Society \*\*\*Dana-Farber Cancer Institute

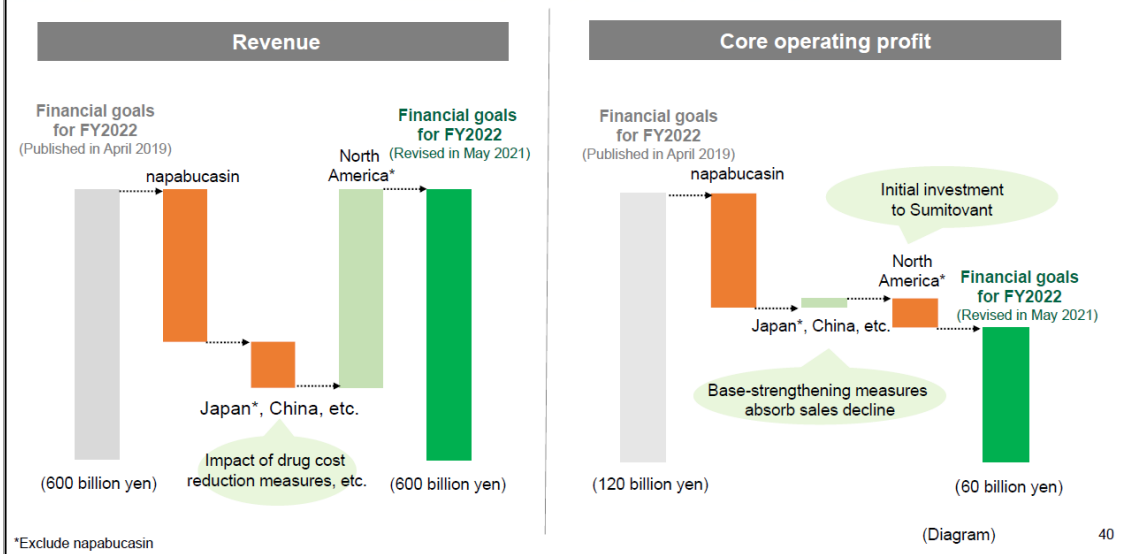
37

Slide #37 shows some of our research initiatives. We are applying DrugOME and AI in searches for targets and utilizing new in-house technologies. DSP-7888 is a peptide vaccine created through drug-discovery based on a distinctive pharmacology concept. Under the new concept of ADC we are researching AiADCs.

We have partnerships for research in the oncology area. An external research group is leading the Beat AML Study for TP-0903, and TP-3654 and TP-0184 are potential candidates resulting from joint research with academia.



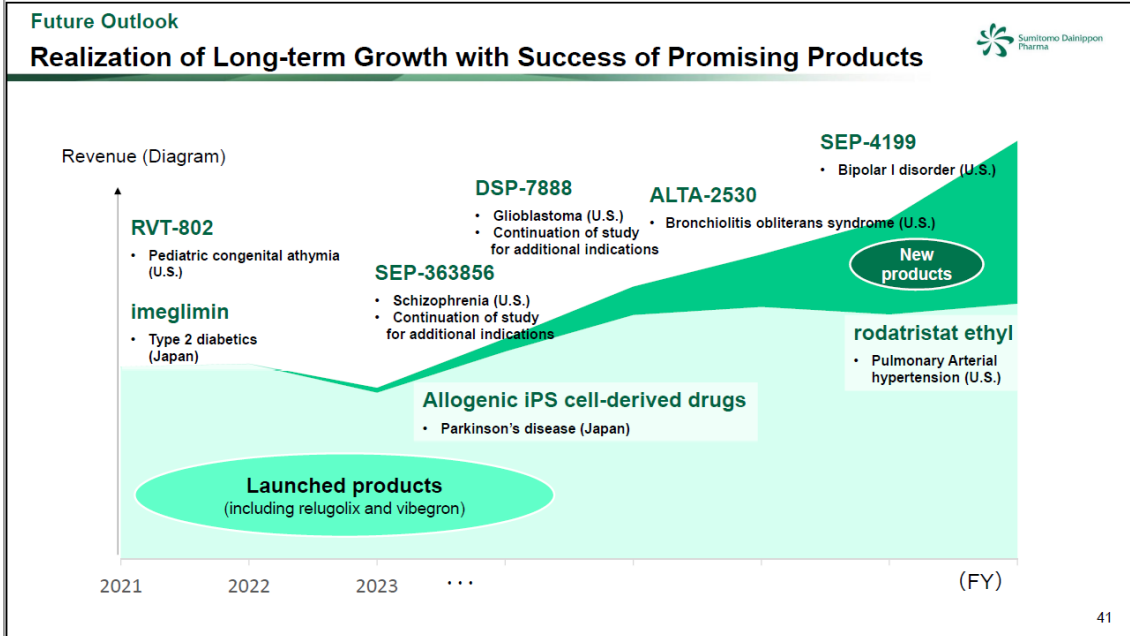
In the future outlook on Slide #39, on the left are the figures announced in the original Mid-term Business Plan, those in the middle are the figures in the current revised outlook and those on the right are the outlook for FY2025 for reference. While revenue in the current outlook is level with that in the original Mid-term Business Plan, core operating profit has dropped to half of what it was before.



In the diagram on Slide #40, the revenue originally seen for napabucasin of around 90 billion yen has been removed. Drug cost reduction measures in Japan and centralized purchasing in China have also had an impact. By growing relugolix, vibegron and other products in North America, we will bring the revenue level close to the original 600 billion yen.

Behind the halving of core operating profit are a drop of around 50 billion yen due to napabucasin and a decrease of around 10 billion yen in North America.

With the large burden of depreciation, it will be difficult for Sumitovant to be in the black in FY2022 and the current view is that the company will make a small loss or contribute a small amount of profit.



The probability of success has been applied to the figures we have seen up till now but it has not been applied in the diagram on Slide #41. This is a diagram giving an idea of how sales will increase if the products under the programs we are conducting now are launched according to this timeline. A key point will be how we deal with things in FY2023.

As we have already announced the change of trade name and the relocation of Tokyo Head Office, I will omit them here. Thank you for your attention.

**Q&A**

**Questioner 1**

Q: If you engage in business partnerships like the one you have with Pfizer for relugolix for your own products, what would the candidates be? What is the new alliance you will have in FY2021?

A: (President Nomura) We want to pursue partnering in the Psychiatry & Neurology and Oncology areas on a global level. Partnering also includes reductions in business risks through sharing development costs. The agreement for the new alliance in FY2021 is currently under negotiation and we should soon be able to make announcement concerning it. At present, I would like to refrain from giving details.

Q: On the negative side after announcement of the Mid-term Business Plan 2022, there were

downward revisions in the marketing plan, but on the positive side, there was no upward revision. What problems were there in the formulation of the marketing plans and how will this be addressed in future?

A: (President Nomura) Products whose marketing plans were revised downwards are LONHALA<sup>®</sup> MAGNAIR<sup>®</sup>, KYNMOBI<sup>™</sup> and LONASEN<sup>®</sup> Tape. Regarding KYNMOBI<sup>™</sup> and LONASEN<sup>®</sup> Tape, there was a problem in the marketing environment, which was difficulty in contacting doctors due to the impact of COVID-19, but we do not think that there was a major issue for our sales strategy. In FY2021, a key point will be raising doctors' awareness of KYNMOBI<sup>™</sup> and LONASEN<sup>®</sup> Tape and linking this to prescribing as far as possible. Owing to the short-lived durability of the inhalation device for LONHALA<sup>®</sup> MAGNAIR<sup>®</sup>, it lost competitiveness by being assigned to Medicare Part D, instead of Medicare Part B, as per the original plan. For future new products, assessing the market environment and competitor products, we will work by setting high level goals, not low goals. While it was unfortunate that we could not achieve the planned revenue targets, we will put all our energy into this, making use of what we have learned so far and new innovations to identify factors for improvement.

Q: Why are TP-0903 and SEP-4199 not in the launching schedule up to FY2025?

A: (Executive Vice President Kimura) TP-0903 is still at the stage of Phase 1/2 studies. Going forward, we aim to plan a launching schedule once we have looked into it in more detail. For SEP-4199, we are creating a development plan and making the preparations to start Phase 3 study. Time will be required to develop it for the target of psychiatric disorders, but we will make efforts to bring it to market as early as possible from FY2026 onwards.

#### Questioner 2

Q: In a rough percentage breakdown of revenue for Others in North America segment of the financial forecasts for FY2021, is at least half of the increase compared to the previous year due to the new alliance project?

A: (President Nomura) Yes, the amount for the new alliance project is quite large, roughly almost half.

Q: What image should we have for core operating profit that is expected to reach bottom in FY2023 or FY2024?

A: (President Nomura) You are already aware of the effect of patent expiry on revenue and core operating profit is expected to be under severe pressure.

Q: Regarding core operating profit of 120 billion yen in the outlook for FY2025, what are the

factors behind the increase compared with FY2022 financial goal?

A: (President Nomura) We plan to launch SEP-363856 in FY2023, and Sumitovant products will account for the largest share.

Q: Have the 2nd and 3rd indications for SEP-363856 been decided? Also, what is the state of progress in Phase 3 study for schizophrenia?

A: (Executive Vice President Kimura) The 2nd and 3rd indications for SEP-363856 have more or less been fixed internally and we expect to be able to announce them soon. Although Phase 3 study of SEP-363856 for schizophrenia is proceeding smoothly, due to the impact of COVID-19, there have been delays at some facilities and we are currently investigating this. However, we are unable to say how many months delay there will be.

### Questioner 3

Q: Will milestone revenue from the new alliance project contribute to sales and profits in FY2021?

A: (President Nomura) While the new alliance project milestone income may change depending on final agreement details, it will be necessary to consider whether it should be recognized as temporary revenue or deferred revenue, depending on milestone details regarding whether it is for past development or relates to future development. In FY2021, the amount recognized as temporary revenue recorded will be large but after that it will become smaller.

Q: Regarding the increase in revenue versus the previous year for Others in North America segment of the financial forecasts for FY2021, will you be able to achieve the targets for the ORGOVYX™, relugolix combination tablet and GEMTESA®?

A: (President Nomura) ORGOVYX™ competes with leuprorelin and based on the drug data, we believe ORGOVYX™ is superior. Revenue for January-March 2021 was approximately ¥400M and we think that the annual revenue target can be achieved. As far as we can see from local reports, GEMTESA® is on track.

Q: After the patent for LATUDA® expires, will you try to avoid making a loss in FY2023 through the sale of R&D assets? Or, do you think going into the red temporarily is unavoidable?

A: (President Nomura) We are responsible for managing capital on behalf of our shareholders, and a deficit would mean we hadn't been able to do this efficiently. We will make as much effort as possible to avoid a loss but core operating profit could be in deficit. Selling assets, whose period of exclusivity is over, may be a measure that we could take.

#### Questioner 4

Q: What about the breakdown of approximately 750 billion yen in revenue for FY2025? Sales of Sumitovant products are forecast at about 300 billion yen. Could you give details of the contributions of sales and milestone income for individual products and contribution by region?

A: (President Nomura) Regarding drivers of revenue in FY2025, among Sumitovant products, we think that relugolix will contribute much more than vibegron. By region, North America will be the main source of revenue.

Q: From FY2022 onwards, to what extent can SG&A expenses be kept down?

A: (President Nomura) Any increase in Sumitovant SG&A expenses will be absorbed by a decrease in LATUDA®-related SG&A expenses so we expect that they will hardly increase at all from FY2022 onwards. While depreciation of intangible assets will increase in FY2021, after that it will not increase. Since costs are assigned according to the scale of business, they will increase for Sumitovant and we want to create an efficient business structure that brings out the synergies of the 2 holding companies in North America.

Q: Will you consider major strategic investments in the future?

A: (President Nomura) For the strategic alliance with Roivant and after that, making Urovant into a wholly-owned subsidiary, we have invested nearly 400 billion yen. Since human resources will be required for developing Sumitovant products into growth drivers and we do not have staff capable of doing the integration required for major M&A in the future, we are not considering any at present. We may carry out small-scale M&A to acquire small size product candidates or infrastructure-related technologies, but we are not thinking of using the remaining 200 billion yen for strategic investment in one go.

#### Questioner 5

Q: What percentages of Roivant stock will Sumitomo Dainippon Pharma hold before and after the company's listing?

A: (President Nomura) 12% both before and after listing. We will also conduct private investment in public equity (PIPE) for Roivant, but our percentage holding of Roivant shares will not change.

Q: Will the valuation of Roivant stock change due to listing? Also, will there be an effect on PL?

A: (President Nomura) During the time that Roivant has been unlisted, we have conducted a valuation of the Roivant stock held by our company every fiscal year. However, the valuation will change once Roivant goes public because the stock will have a price. The valuation of Roivant stock after listing will be recorded as comprehensive income, but as the net profit attributable to owners of the parent will not be affected, there will be no effect on PL.

Q: When will the clinical study on the allogenic iPS cell-derived drug (age-related macular degeneration) begin? Why is it taking so long to get started?

A: (Executive Vice President Kimura) Our goal is to start the study by the end of FY2021. Although the non-clinical data necessary to start the study is sufficient, it is taking time to determine the types of patients it will be given to and how it will be administered.

#### Questioner 6

Q: How have you considered the probability of success in financial goals for development compounds?

A: (President Nomura) We have applied the probability of success to the revised financial goals for FY2022 as well as the financial goals in the outlook for FY2025. Since relugolix and vibegron are already approved, the probability of success has not been applied to them. In the diagram on Slide #41, as it would be difficult to visualize the contribution of new products, the probability of success has not been applied.

Q: To what extent are sales milestone payments from Pfizer included in the revenue of approximately 750 billion yen for FY2025? Also, how much is the annual amortization for relugolix and vibegron?

A: (President Nomura) We are unable to disclose specific details of milestone payments from Pfizer in FY2025. However, 500 million dollar of the money received from Pfizer will be recognized as profit over 6 years, and sales milestone income will arise at each milestone. While there will be a contribution from SEP-363856, the figures for FY2025 are higher mainly due to Sumitovant products. The amortization of intangible assets was planned to be 27 billion yen per year post approval of relugolix combination tablet, but since it will be approved during FY2021, this will be less than 27 billion yen in this period.