

Investors Meeting Presentation for Q2 FY2022

(April 1 to September 30, 2022)

Hiroshi Nomura, President and CEO

Sumitomo Pharma Co., Ltd.

November 1, 2022

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties. Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein. Information concerning pharmaceuticals and medical devices (including compounds under development) contained herein is not intended as advertising or as medical advice.

Myovant Sciences Ltd. ("Myovant") is listed on the New York Stock Exchange, and the Group beneficially owns approximately 52% of the outstanding shares of Myovant. ORGOVYX® (relugolix), MYFEMBREE®/RYEQO® (relugolix combination tablet) are owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit <https://www.myovant.com>.

Additional Information and Where to Find It

This material may be deemed to be solicitation material in respect of the proposed acquisition of Myovant by Sumitovant and Sumitomo Pharma. In connection with the proposed acquisition, Sumitovant, Sumitomo Pharma and Myovant intend to file relevant materials with the SEC, including amended Schedule 13D filings and a transaction statement on Schedule 13E-3 with respect to Sumitovant and Sumitomo Pharma and a proxy statement on Schedule 14A with respect to Myovant. The definitive proxy statement and Schedule 13E-3 transaction statement will be sent to Myovant's shareholders and will contain important information about the proposed transaction and related matters. **SHAREHOLDERS OF MYOVANT ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH THE SEC, INCLUDING SUMITOVANT'S AND SUMITOMO PHARMA'S TRANSACTION STATEMENT, MYOVANT'S PROXY STATEMENT AND ANY AMENDMENTS OR SUPPLEMENTS THERETO, AND ANY OTHER RELEVANT DOCUMENTS FILED OR TO BE FILED WITH THE SEC, CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.** Investors and security holders will be able to obtain the documents free of charge at the SEC's web site, <http://www.sec.gov>, and Myovant shareholders will be able to obtain free copies of the proxy statement and Schedule 13E-3 through the Investor Relations page of Myovant's website, www.myovant.com.

Participants in the Solicitation

Sumitovant and its directors and executive officers, Sumitomo Pharma and its directors and executive officers, and Myovant and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the holders of Myovant common stock in respect of the proposed transaction. Information about the directors and executive officers of Myovant is set forth in the proxy statement for Myovant's 2022 Annual Meeting of Shareholders, which was filed with the SEC on July 28, 2022. Investors may obtain additional information regarding the interest of such participants by reading the proxy statement regarding the acquisition when it becomes available.



Financial Results for Q2 FY2022

Financial Results for Q2 FY2022

Financial Results for Q2 FY2022 (Core Basis)

	Q2YTD FY2021 Results	Q2YTD FY2022 Results	Change			Billions of yen FY2022	
			Value	FX impact	%	May 13 forecasts	%
Revenue	293.7	319.3	25.6	38.8	8.7	550.0	58.1
Cost of sales	76.9	92.8	16.0	11.6	20.8	164.5	56.4
Gross profit	216.9	226.4	9.6	27.2	4.4	385.5	58.7
SG&A expenses	124.4	152.3	27.8	21.1	22.3	283.5	53.7
R&D expenses	45.7	49.4	3.7	6.8	8.0	93.0	53.1
Other operating income/expenses	1.2	0.0	(1.2)	—	—	21.0	—
Core operating profit	47.9	24.8	(23.1)	(0.7)	(48.2)	30.0	82.8
Changes in fair value of contingent consideration (negative number indicates loss)	(0.1)	1.3	1.4			(0.5)	
Other non-recurring items (negative number indicates loss)	(0.2)	(55.0)	(54.8)			(5.5)	
Operating profit	47.6	(28.9)	(76.5)		—	24.0	—
Finance income/costs	1.7	49.9	48.3				
Profit before taxes	49.3	21.0	(28.2)		(57.3)		
Income tax expenses	19.3	36.3	17.0				
Net profit	30.0	(15.2)	(45.2)		—		
Net profit attributable to owners of the parent	36.5	(7.3)	(43.7)		—	22.0	—

Revised full-year forecasts (See P.12)

(Ref.) Earnings related to Sumitovant

	Billions of yen	
	Q2 FY21	Q2 FY22
Revenue	16.2	43.8
SG&A expenses *	41.4	62.3
R&D expenses	11.5	14.9
Core operating profit	(38.9)	(43.6)
Operating profit	(38.9)	(43.6)
Net profit	(39.5)	(50.0)
Net profit attributable to owners of the parent	(33.0)	(42.0)

The figures include intra-group transaction

* Include amortization of patent rights

Average rates:

Q2FY2021 Results : 1US\$ = ¥109.8, 1RMB = ¥17.0

Q2FY2022 Results : 1US\$ = ¥134.1, 1RMB = ¥19.9

FY2022 forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

Period end rates:

As of the end of March 2022 : 1US\$ = ¥122.4, 1RMB = ¥19.3

As of the end of September 2022 : 1US\$ = ¥144.8, 1RMB = ¥20.4

Financial Results for Q2 FY2022

■ Impairment loss on KYNMOBI®

■ Reason for impairment loss

Since market launch in September 2020, KYNMOBI® has not been performing to commercial expectations and as a result of reviewing forecast of the earnings, patent rights, etc. related to this product have been impaired, resulting in an impairment loss of approximately US\$406 million (approximately ¥54.4 billion)

➤ Background of Cynapsus acquisition

- ✓ Sunovion acquired KYNMOBI® from Cynapsus in October 2016. The total purchase price of the acquisition was approximately US\$635 million (approximately ¥65.9 billion)
- ✓ The apomorphine injection Apokyn was already launched in the market as a treatment for OFF episodes associated with Parkinson's disease, but an injection use was limited. It was decided to purchase KYNMOBI® to be able to help respond to the needs of patients suffering from OFF episodes

➤ Reasons for sluggish sales and reviewing forecast of the earnings

- ✓ Fewer Parkinson's patients in need of rescue medication than expected
- ✓ The safety profile of KYNMOBI® was different than expected., etc.

■ Future steps

- Promotion of KYNMOBI® in the U.S. is being discontinued and partnerships are under consideration
- Preparing to streamline resources and redirect efforts towards prioritized assets in the portfolio

■ Impact on consolidated financial results for FY2022

- Limited impact on core operating profit. Significant decline in profit at each profit level below operating profit
- There is no impact on cash flow

Financial Results for Q2 FY2022

Revenue of Major Products in Japan

Billions of yen

	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change		FY2022	
			Value	%	May 13 forecasts	%
Equa [®] /EquMet [®]	19.3	17.3	(2.0)	(10.3)	34.9	49.5
Trulicity [®] *	17.2	16.7	(0.5)	(3.1)	31.0	53.7
TRERIEF [®]	8.4	8.6	0.2	1.9	17.3	49.6
LATUDA [®]	3.0	4.6	1.6	54.3	9.9	46.9
METGLUCO [®]	4.1	4.0	(0.2)	(4.5)	7.8	50.7
LONASEN [®] Tape	1.0	1.4	0.4	45.6	2.7	51.5
TWYMEEG [®]	0.1	0.5	0.4	521.1	1.5	33.8
AG products	4.8	4.6	(0.2)	(3.9)	9.7	47.7
Others	18.7	8.9	(9.8)	(52.4)	15.2	58.6
合計	76.6	66.6	(10.0)	(13.1)	130.0	51.2

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

- Progress is almost as forecasted in the segment total
- LATUDA[®] showing steady growth
- Prescription days limit of TWYMEEG[®] was lifted in September 2022
- Sale of REPREGAL[®] included "Others" decreased (Q2 YTD FY2021: ¥7.1B)
- NHI price revision affected (¥6.2B) on Japan segment total

Financial Results for Q2 FY2022

Revenue of Major Products in North America & China

	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change			FY2022		
						Value	FX impact	%	May 13 forecasts		Yen-basis %
North America	Million \$			Billions of yen					Million \$	Billions of yen	
LATUDA®	920	952	32	101.0	127.6	26.6	23.1	26.3	1,726	215.8	59.1
APTIOM®	124	129	5	13.6	17.4	3.7	3.1	27.4	255	31.8	54.6
RETHYMIC®	—	19	19	—	2.6	2.6	0.5	—	48	6.0	42.7
BROVANA®	83	21	(62)	9.1	2.8	(6.3)	0.5	(69.0)	26	3.2	88.0
KYNMOBI®	3	2	(1)	0.3	0.2	(0.1)	0.0	(29.2)	18	2.3	10.4
ORGOVYX®	29	79	50	3.2	10.6	7.4	1.9	232.4	601	75.2	59.5
MYFEMBREE®	3	10	7	0.2	1.4	1.2	0.3	643.4			
GEMTESA®	19	71	51	2.1	9.5	7.3	1.7	344.9			
Others *	411	174	(237)	45.3	23.3	(22.0)	4.2	(48.6)			
Total	1,592	1,457	(135)	174.9	195.3	20.5	35.3	11.7	2,674	334.3	58.4
China	Million RMB			Billions of yen					Million RMB	Billions of yen	
MEROPEN®	850	942	92	14.4	18.7	4.3	2.7	29.8	863	16.8	111.6
Others	217	266	49	3.7	5.3	1.6	0.8	43.2	553	10.8	49.0
Total	1,067	1,208	141	18.1	24.0	5.9	3.5	32.5	1,416	27.6	87.1

North America segment

Revenue increased due to the impact of fluctuations in FX rates and products of Sumitovant

■ Sale of LATUDA® is in line with forecasts

■ BROVANA® decreased due to loss of exclusivity in June 2021

■ Revenue from license agreement decreased in “Others” (See the breakdown below the table)

China segment

MEROPEN® increased continuously

* Lump-sum revenue included in “Others”

Q2 YTD FY2021	Revenue from the alliance with Otsuka \$270M	Q2 YTD FY2022	Revenue from the license agreement for ORGOVIX® \$50M Milestone revenue from approval of endometriosis \$29M

FX rates:

Q2FY2021 Results : 1US\$ = ¥109.8, 1RMB = ¥17.0

Q2FY2022 Results : 1US\$ = ¥134.1, 1RMB = ¥19.9

FY2022 forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

Financial Results for Q2 FY2022

Segment Information (Core Basis)

Billions of yen

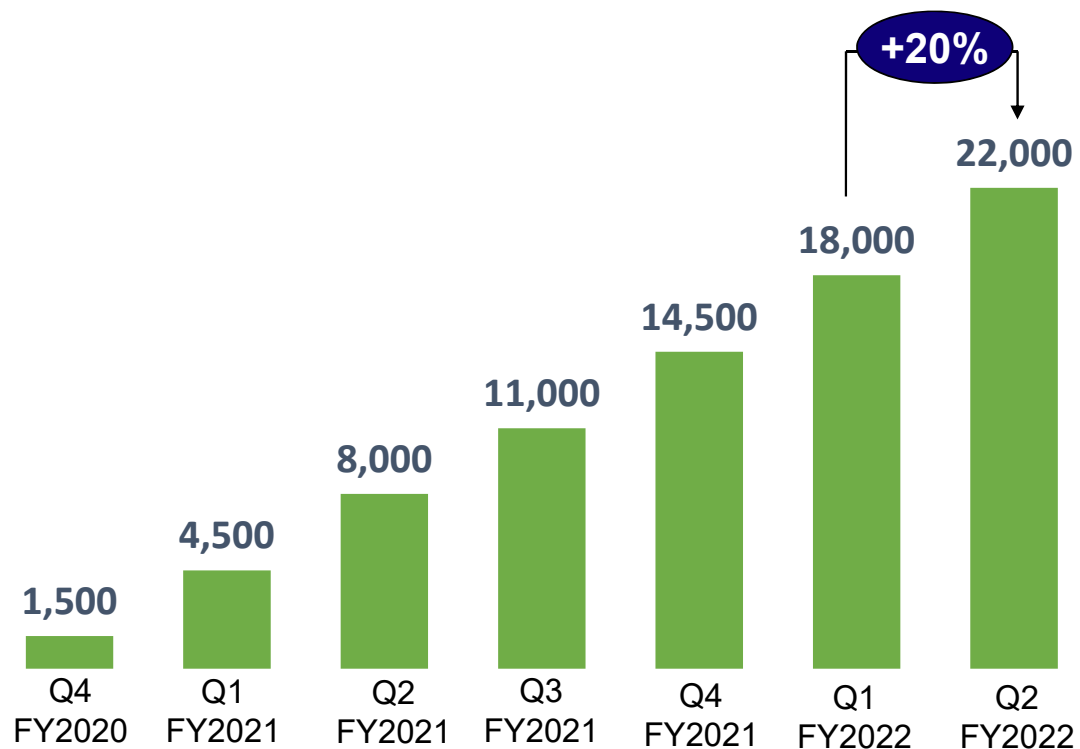
		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
Q2 YTD FY2022 Results	Revenue (Sales to customers)	66.6	195.3	24.0	11.3	297.2	22.1	319.3	
	Cost of sales	36.2	31.2	5.3	3.0	75.6	17.3	92.8	
	Gross profit	30.4	164.2	18.7	8.3	221.6	4.8	226.4	
	SG&A expenses	26.1	116.9	5.6	0.8	149.3	2.9	152.3	
	Core segment profit	4.4	47.3	13.2	7.5	72.3	1.9	74.2	
	R&D expenses						48.4	1.0	49.4
	Core operating profit						23.9	0.9	24.8
Q2 YTD FY2021 Results	Revenue (Sales to customers)	76.6	174.9	18.1	4.6	274.2	19.6	293.7	
	Cost of sales	41.3	15.2	3.1	2.2	61.8	15.1	76.9	
	Gross profit	35.3	159.6	15.0	2.4	212.4	4.5	216.9	
	SG&A expenses	25.5	89.4	5.4	1.5	121.9	2.6	124.4	
	Core segment profit	9.8	70.2	9.6	0.9	90.5	1.9	92.4	
	R&D expenses						45.3	0.4	45.7
	Core operating profit						46.4	1.5	47.9
Change	Revenue (Sales to customers)	(10.0)	20.5	5.9	6.7	23.1	2.5	25.6	
	SG&A expenses	0.5	27.5	0.1	(0.7)	27.5	0.3	27.8	
	Core segment profit	(5.4)	(23.0)	3.6	6.6	(18.2)	(0.0)	(18.2)	
	R&D expenses						3.0	0.6	3.7
	Core operating profit						(22.5)	(0.6)	(23.1)

- **Japan:** Lower profit due to declined sales by NHI price revision and increased expenses
- **North America:** Profit decreased since the impact of higher expenses exceeded increased revenue
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Profit includes the revenue of \$50M from the license agreement for DSP-0187

Financial Results for Q2 FY2022

Marketing Status of ORGOVYX®

- Obtained approx. 4,000 new patient starts in Q2 FY2022 (20% growth vs. Q1 FY2022)



Estimated Cumulative Patients Treated with ORGOVYX®

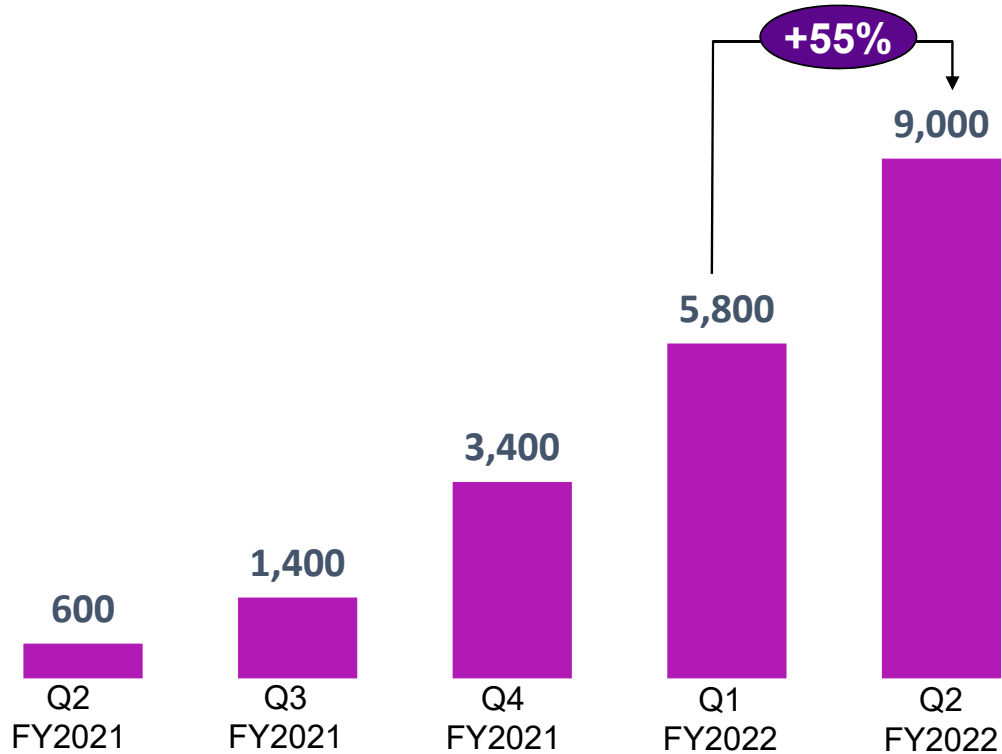
- Prescribed approx. 22,000 patients since launch
- Obtained the leading GnRH antagonist therapy for advanced prostate cancer with a 55% share based on months of therapy
- Since launching in January 2021, ORGOVYX® drove approx. 2.3 times increase of the GnRH antagonist market for products for the treatment of advanced prostate cancer

Source : Press release of Corporate Updates and Financial Results for Second Fiscal Quarter 2022 of Myovant Sciences Ltd.

Financial Results for Q2 FY2022

Marketing Status of MYFEMBREE®

- Obtained approx. 3,200 new patient starts in Q2 FY2022 (55% growth vs. Q1 FY2022)



Estimated Cumulative Patients Treated with MYFEMBREE®

- Prescribed approx. 9,000 patients since launch
- Obtained 54% total prescriptions (TRx) share and 67% new-to-brand prescription (NBRx) share among GnRH antagonists therapies for uterine fibroids in July 2022
- In August 2022, the FDA approved MYFEMBREE® for the endometriosis, establishing it as the first and only once-daily oral GnRH antagonist treatment in the U.S. approved for both uterine fibroids and endometriosis. MYFEMBREE® was launched in the U.S. for endometriosis as additional indication by Myovant and Pfizer in August 2022

Source : Press release of Corporate Updates and Financial Results for Second Fiscal Quarter 2022 of Myovant Sciences Ltd.

Financial Results for Q2 FY2022

Marketing Status of GEMTESA®

- Prescribed 47,492 TRx in Sep. 2022 and in line with FY2022 forecast

	GEMTESA®	
	June 2022	Sep. 2022
TRx Share in Beta 3	9.3%	11.3%
Monthly TRx numbers	38,100	47,492

- Coverage has not expanded since June 2022. Plan to secure most of peak coverage during FY2022 (Secured 13.6M lives of Medicare Part D, 28% of all of Medicare Part D, coverage starting in January 2023)

	GEMTESA®	
	June 2022	Sep. 2022
All of commercial lives (Approx. 180 million)	55%	55%
All of Medicare Part D lives (Approx. 48 million)	30%	30%

- From October 2022, increase the number of sales reps in charge of co-promotion partner Sunovion Pharmaceuticals Inc. approx. 30 (approx. 80 in total, not including managers), and engage in more activities for Primary Care Physicians (prescribe approx. 20% of beta-3 OAB treatments in the U.S.). Sales reps of Urovant Sciences Ltd. (approx. 150 in total, not including managers) will continue to focus on Urologist and Long-Term Care (prescribe approx. 45% of beta-3 OAB treatments in the U.S.)



Financial Forecasts for FY2022

Financial Forecasts for FY2022

Financial Forecasts for FY2022 (Core Basis)

Billions of yen

	FY2022 May 13 Forecasts	FY2022 Revised Forecasts	Change from Previous forecasts	
			Value	FX impact
Revenue	550.0	604.0	54.0	42.3
Cost of sales	164.5	182.0	17.5	15.5
Gross profit	385.5	422.0	36.5	26.8
SG&A expenses	283.5	312.0	28.5	25.2
R&D expenses	93.0	100.0	7.0	7.5
Other operating income and expenses (Core basis)	21.0	22.0	1.0	2.3
Core operating profit	30.0	32.0	2.0	(3.6)
Changes in fair value of contingent consideration (negative number indicates loss)	(0.5)	1.0	1.5	
Other non-recurring item (negative number indicates loss)	(5.5)	(63.0)	(57.5)	
Operating profit	24.0	(30.0)	(54.0)	
Net profit attributable to owners of the parent	22.0	(15.0)	(37.0)	
R O E (%)	3.6	(2.4)		
R O I C (%)	0.7	(1.0)		

FX rates:

FY2022 Previous forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

Revised forecasts : 1US\$ = ¥140.0, 1RMB = ¥20.0

- Revenue:** Revised up by ¥54.0B
(excluding exchange rate impact)
 Japan (¥4.2B)
 North America +¥7.0B
 China +¥8.7B
- SG&A expenses and R&D expenses:** Increase due to FX rate impact
- Other operating income and expenses (Core basis):** Plan to record consideration for priority review vouchers and the transfer of market rights for BROVANA® /XOPENEX HFA®, \$75M
- Other non-recurring item:** Impairment loss on patent rights and other assets for KYNMOBI®

Financial Forecasts for FY2022

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
FY2022 Revised Forecasts	Revenue (Sales to customers)	125.8	382.3	37.2	17.0	562.3	41.7	604.0	
	Cost of sales	66.1	69.9	7.9	5.6	149.5	32.5	182.0	
	Gross profit	59.7	312.4	29.3	11.4	412.8	9.2	422.0	
	SG&A expenses	53.0	239.0	11.9	1.9	305.8	6.2	312.0	
	Core segment profit	6.7	73.4	17.4	9.5	107.0	3.0	110.0	
	R&D expenses						97.4	2.6	100.0
	Core operating profit						31.6	0.4	32.0
May 13 Forecasts	Revenue (Sales to customers)	130.0	334.3	27.6	16.1	508.0	42.0	550.0	
	Cost of sales	67.6	53.6	5.6	5.2	132.0	32.5	164.5	
	Gross profit	62.4	280.7	22.0	10.9	376.0	9.5	385.5	
	SG&A expenses	53.0	211.0	11.6	1.6	277.2	6.3	283.5	
	Core segment profit	9.4	69.7	10.4	9.3	98.8	3.2	102.0	
	R&D expenses						90.5	2.5	93.0
	Core operating profit						29.3	0.7	30.0
Change	Revenue (Sales to customers)	(4.2)	48.0	9.6	0.9	54.3	(0.3)	54.0	
	SG&A expenses	0.0	28.0	0.3	0.3	28.6	(0.1)	28.5	
	Core segment profit	(2.7)	3.7	7.0	0.2	8.2	(0.2)	8.0	
	R&D expenses						6.9	0.1	7.0
	Core operating profit						2.3	(0.3)	2.0

- **Japan:** Revenue decrease due to termination of contract for Trulicity®
- **North America:** Increased revenue from lump-sum contract payments and milestone revenue exceed increased expenses
- **China:** Delay in starting VBP (volume-based procurement)

■ Acquisition of Consolidated Subsidiary Myovant as a Wholly Owned Subsidiary

- **Summary:** Entered into a definitive agreement with Myovant Sciences Ltd. to acquire all outstanding shares not already owned for \$27.00 per share

Total amount approx. \$1.7 B (approx. 250 billion yen), premium approx. 50% (compared to closing share price on Sep. 30)

- **Purpose:** Utilize cash flow generated by ORGOVYX[®] and MYFEMBREE[®], which are expected to become major products, for Sumitomo Pharma Group and accelerate implementation of management strategies
- **Schedule:** The transaction is anticipated to close in the fourth quarter of FY2022
- **Funding:** The transaction will be financed through a combination of cash on hand and bank borrowings. A financing commitment has been received
- **Accounting:** “Non-controlling interests” in equity is reduced, and the difference between the decreasing non-controlling interests and the consideration is treated as a decrease in capital surplus
- **Impact on consolidated financial results for FY2022:** The transaction is expected to have a negative impact on each profit level below core operating profit, but the amount of impact is yet to be determined because it depends on timing of the transaction closing. Not factored it into revisions to financial forecasts



Research and Development

Research and Development

Development Pipeline (as of October 31, 2022)

 : Psychiatry & Neurology
 : Oncology
 : Regenerative medicine / Cell therapy
 : Others
 : Frontier business
 Revisions since the announcement of July 2022 are shown in red

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	DSP-9632P (Levodopa-induced dyskinesia in Parkinson's disease)	DSP-0390 (Glioblastoma)	EPI-589 (ALS/Investigator-initiated study)	ulotaront (SEP-363856) (Schizophrenia)	
	DSP-0187 (Narcolepsy)	TP-3654 (Myelofibrosis)	Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated study)	SEP-4199 (Bipolar I depression)	
	DSP-0378 (Dravet syndrome, Lennox-Gastaut syndrome)	DSP-5336 (Acute leukemia)			
		guretolimod (DSP-0509) (Solid tumors)			
U.S.	SEP-378608 (Bipolar disorder)	guretolimod (DSP-0509) (Solid tumors)	EPI-589 (Parkinson's disease/ALS)	ulotaront (SEP-363856) (Schizophrenia)	
	DSP-3905 (Neuropathic pain)	TP-1287 (Solid tumors)	ulotaront (SEP-363856) (Parkinson's disease psychosis)	ulotaront (SEP-363856) (Adjunctive major depressive disorder)	
	SEP-378614 (To be determined)	TP-3654 (Myelofibrosis)	rodatristat ethyl (Pulmonary arterial hypertension)	SEP-4199 (Bipolar I depression)	
	SEP-380135 (To be determined)	TP-1454 (Solid tumors)	URO-902 (Overactive bladder)	GEMTESA® (vibegron) (New indication: OAB in men with BPH)	
	DSP-0038 (Alzheimer's disease psychosis)	DSP-0390 (Glioblastoma)			
	DSP-3456 (Treatment resistant depression)	DSP-5336 (Acute leukemia)			
		KSP-1007 (Complicated urinary tract infections, Complicated intra-abdominal infections)			
China				LATUDA® (New indication: Bipolar I depression)	lefamulin (Bacterial community-acquired pneumonia)
				ulotaront (SEP-363856) (Schizophrenia)	

Clinical Development Status (Major Changes since July 29, 2022)

■ ulotaront

U.S.: Started Phase 2/3 study for Adjunctive Major Depressive Disorder (aMDD)

■ DSP-0378

Japan: Started Phase 1 study for Dravet syndrome and Lennox–Gastaut syndrome

■ DSP-6745

U.S.: Discontinued development for Parkinson’s disease psychosis (Phase 1 study)

■ DSP-7888

U.S.: Discontinued Phase 1/2 study for solid tumors
Development strategy under consideration

■ TP-0903

U.S.: Discontinued Phase 1/2 study (Research group-initiated study) for acute myeloid leukemia (AML)
Development strategy under consideration

■ MYFEMBREE® (relugolix combination tablet)

U.S.: Approved additional indication for endometriosis in August 2022

■ METGLUCO® (metformin)

Japan: Approved additional indication for infertility treatment (“ovulation induction for patients with polycystic ovary syndrome” and “controlled ovarian stimulation in assisted reproductive technology for patients with polycystic ovary syndrome”) in September 2022

■ KSP-1007

U.S.: Obtained designation of Qualified Infectious Disease Product (QIDP) and Fast Track

Progress of ulotaront (Co-Development with Otsuka Pharmaceutical)

■ First indication: Schizophrenia

- Top-line results for pivotal studies in the U.S. expected CY2023

■ Second indication: Adjunctive Major Depressive Disorder (aMDD)

- Clinical program lead: Otsuka Pharmaceutical
- Started Phase 2/3 study in the U.S., and plan to dose the first patient by the end of CY2022
- Study design:

Patients	Adults between 18-65 years of age with major depressive disorder with inadequate response to antidepressant therapy (ADT)
Arms	<ul style="list-style-type: none">▪ ulotaront + ADT▪ Placebo + ADT
Primary endpoint	Change from the baseline to week 14 in MADRS total score

■ Third indication: Generalized Anxiety Disorder (GAD)

- Clinical program lead: Sunovion/Sumitomo Pharma
- Start Phase 2/3 study by the end of CY2022. More information to be forthcoming on study design

Research and Development

Main Events / Targets for FY2022 (as of October 31, 2022)

✓ Completed action / target Revisions since the announcement of July 2022 are shown in red

Psychiatry & Neurology	<ul style="list-style-type: none"> <input type="checkbox"/> ulotaront (SEP-363856) : <input type="checkbox"/> Start clinical studies for two new indications (<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Adjunctive major depressive disorder <input checked="" type="checkbox"/> Generalized anxiety disorder) <input type="checkbox"/> Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia <input type="checkbox"/> SEP-4199: Advance Phase 3 studies for Bipolar I depression
Oncology	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> relugolix : (Europe) Obtain approval for prostate cancer <input type="checkbox"/> Advance early Phase studies
Regenerative medicine / Cell therapy	<ul style="list-style-type: none"> <input type="checkbox"/> Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study <input type="checkbox"/> Allogeneic iPS cell-derived products (Parkinson's disease) : Start clinical study in the U.S. <input checked="" type="checkbox"/> Start construction of manufacturing plant in the U.S (for RETHYMIC® and allogeneic iPS cell-derived products)
Infectious Diseases	<ul style="list-style-type: none"> <input type="checkbox"/> KSP-1007 (Antimicrobial resistance) : Complete Phase 1 study in the U.S. <input type="checkbox"/> universal influenza vaccine, malaria vaccines : Promote joint research and development projects
Others	<ul style="list-style-type: none"> <input type="checkbox"/> relugolix : (U.S.) <input checked="" type="checkbox"/> Obtain approval for endometriosis <input type="checkbox"/> (Europe) <input type="checkbox"/> Submit MAA for endometriosis
Frontier	<ul style="list-style-type: none"> <input type="checkbox"/> Launch products: <input checked="" type="checkbox"/> (Japan) MELTz Neurorehabilitation device for hand/fingers <input type="checkbox"/> (U.S.) VR contents for mental health (brand name: First Resort, general wellness product) <input type="checkbox"/> Promoting the current themes and generating evidence data for maximizing the value of the launched products: Digital device for relieving BPSD, etc.

Appendix

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Appendix (Financial Results for Q2 FY2022)

Financial Results for Q2 FY2022 (Full Basis)

Billions of yen

	Q2 YTD FY2021 Results	Q2 YTD FY2022 Results	Change	
			Value	%
Revenue	293.7	319.3	25.6	8.7
Cost of sales	76.9	92.8	16.0	20.8
Gross profit	216.9	226.4	9.6	4.4
SG&A expenses	124.7	207.9	83.2	66.8
R&D expenses	45.7	50.0	4.3	9.4
Other operating income and expenses	1.1	2.5	1.5	
Operating profit	47.6	(28.9)	(76.5)	—
Finance income and costs	1.7	49.9	48.3	
Profit before taxes	49.3	21.0	(28.2)	(57.3)
Income tax expenses	19.3	36.3	17.0	
Net profit	30.0	(15.2)	(45.2)	—
Net profit attributable to owners of the parent	36.5	(7.3)	(43.7)	—

Appendix (Financial Results for Q2 FY2022)

Financial Position and Cash Flow

Billions of yen

B / S	As of March 2022	As of Sep. 2022	Change
Assets	1,308.0	1,408.0	99.9
Goodwill / Intangible assets	593.8	625.8	31.9
Other financial assets (Non-current)	115.8	104.9	(11.0)
Trade and other receivables	151.4	181.2	29.8
Cash and deposit / Short-term loan receivable	230.2	265.6	35.3
Liabilities	634.4	689.3	54.9
Bonds and borrowings	269.0	249.7	(19.3)
Fair value of contingent consideration (Other financial liabilities)	4.4	3.8	(0.6)
Provisions	119.1	149.8	30.6
Deferred revenue (Other liabilities)	58.9	72.6	13.7
Equity	673.6	718.6	45.0
Attributable to owners of the parent	607.9	646.1	38.3
Ratio of equity attributable to owners of the parent to total assets	46.5%	45.9%	

Goodwill increase due to FX rate impact
Intangible assets decrease due to
impairment loss

Decrease in changing securities valuation

Decrease due to repayment

Decrease in fair value mainly due to review
of development plan

C / F	Q2YTD FY2021	Q2YTD FY2022	Change
Operating CF	(28.2)	29.5	57.7
Investment CF	3.6	7.1	3.4
Financial CF	(13.2)	(26.7)	(13.4)
Cash and cash equivalents	156.5	250.6	94.1
(Operating funds)	168.6	271.3	102.7

Appendix (Financial Forecasts for FY2022)

Revenue of Major Products in Japan

Billions of yen

	FY2022 May 13 Forecasts	FY2022 Revised Forecasts	Change Value
	Equa [®] /EquMet [®]	34.9	34.9
Trulicity [®] *	31.0	23.8	(7.2)
TRERIEF [®]	17.3	17.0	(0.3)
LATUDA [®]	9.9	9.9	—
METGLUCO [®]	7.8	7.8	—
LONASEN [®] Tape	2.7	2.7	—
TWYMEEG [®]	1.5	1.5	—
AG products	9.7	9.7	—
Others	15.2	18.5	3.3
合計	130.0	125.8	(4.2)

- Decrease due to termination of contract for Trulicity[®]

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

Appendix (Financial Forecasts for FY2022)

Revenue of Major Products in North America & China

	FY2022 May 13 Forecasts	FY2022 Revised Forecasts	Change	FY2022 May 13 Forecasts	FY2022 Revised Forecasts	Change
North America	Million \$			Billions of yen		
LATUDA®	1,726	1,726	—	215.8	241.6	25.8
APTiom®	255	255	—	31.8	35.7	3.9
RETHYMIC®	48	46	(2)	6.0	6.4	0.4
BROVANA®	26	24	(2)	3.2	3.4	0.2
KYNMOBI®	18	3	(15)	2.3	0.4	(1.9)
ORGOVYX®	601	677	76	75.2	94.8	19.6
MYFEMBREE®						
GEMTESA®						
Others						
Total	2,674	2,731	57	334.3	382.3	48.0
China	Million RMB			Billions of yen		
MEROPEN®	863	1,290	427	16.8	25.8	9.0
Others	553	570	17	10.8	11.4	0.6
Total	1,416	1,860	444	27.6	37.2	9.6

North America segment

Increase due to the impact of foreign exchange, as well as lump-sum contract payments and milestone revenue

China segment

Increase due to delay in VBP of MEROPEN®

FX rates:

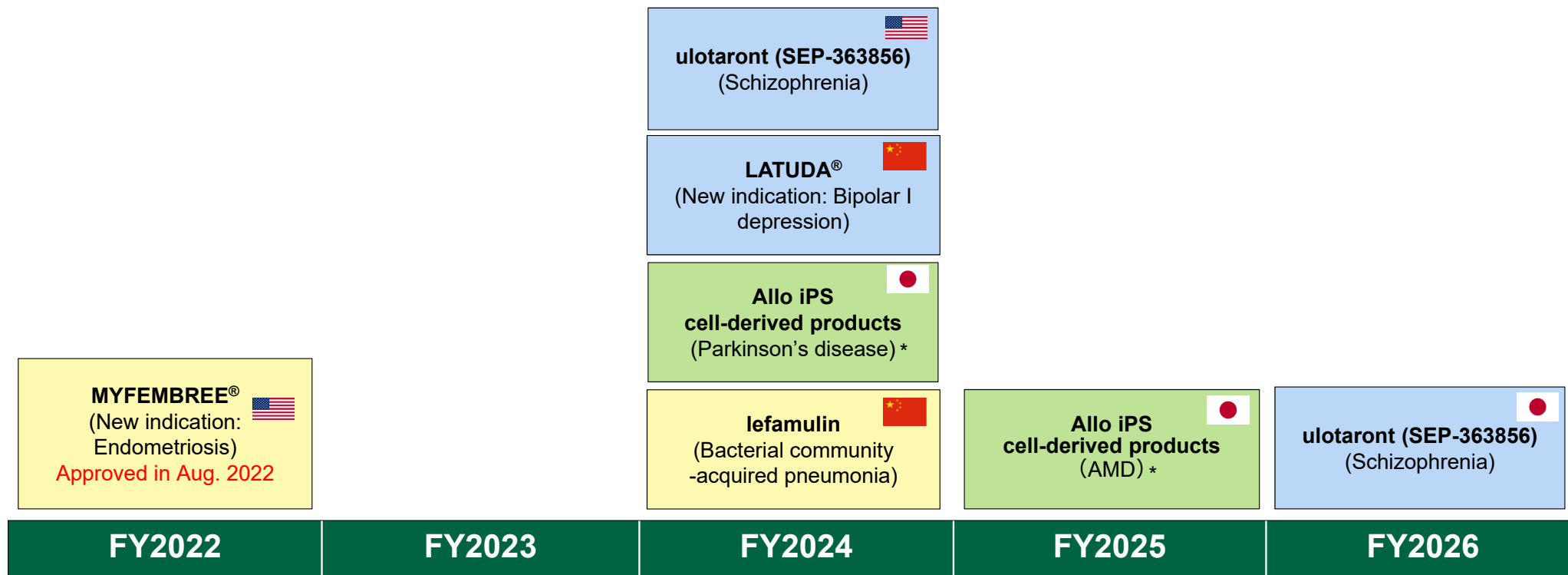
FY2022 Previous forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

Revised forecasts : 1US\$ = ¥140.0, 1RMB = ¥20.0

Appendix (Research and Development)

Product Launch Target (as of October 31, 2022)

Revisions since the announcement of July 2022 are shown in red



- : Psychiatry & Neurology
- : Oncology
- : Regenerative medicine / cell therapy
- : Others

* Launch schedule is based on our goal pending agreement with partners

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of October 31, 2022)

No revisions since the announcement of July 2022

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RETHYMIC®)	Duke University	Global	Cultured thymus tissue	Launched in March 2022 (U.S.)
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor cells	In progress: investigator-initiated study (Phase 1 / 2 study) (Japan) Preparing to start clinical study (U.S.)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	In progress: clinical research
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor cells	In progress: clinical research (Sub-Acute Phase) In progress: pre-clinical study (Chronic Phase)
Kidney failure	Jikei University Bios	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	In progress: pre-clinical study

Aim to start clinical study in FY2022

Aim to launch in FY2024 *

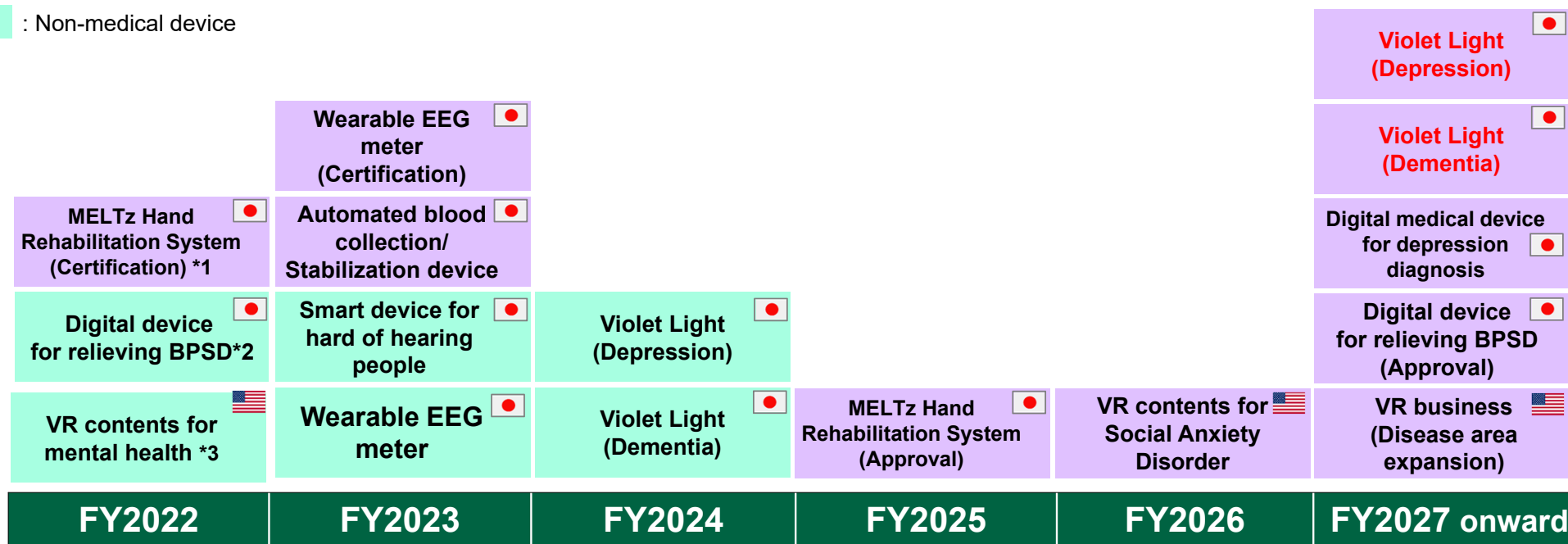
* Launch schedule is based on our goal pending agreement with partners

Appendix (Research and Development)

Product Launch Target (Frontier Business) (as of October 31, 2022)

Revisions since the announcement of July 2022 are shown in red

- : Medical device
- : Non-medical device



*1 Certified medical device named "Active extension / flexion / extension rotation exercise device" (Accepted name for medical devices), **launched in September 2022** by Sumitomo Pharma

*2 Full-scale sales primarily by partners (Aikomi : our associated company)

*3 Sales primarily by partners (BehaVR) (Profit share 50-50 with both companies)

The project description varies with the product (device sales, solution business, royalties, etc.)

New Chemical Entity: DSP-0378

- ✓ Target indication: Dravet syndrome* and Lennox-Gastaut syndrome* *Treatment-resistant epilepsy with onset in infancy or early childhood
- ✓ Origin: in-house
- ✓ Mechanism of action: gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator
Compound by itself does not activate the receptors, but potentiates the effect of GABA only when GABA binds to its receptors
- ✓ Stage: Phase 1 in Japan
- ✓ Expected profile:

- To exhibit a potent antiepileptic effect against broad epilepsies through inhibition of excessive neuronal firing via potentiation of various subtypes of GABA_A receptors expressed in synaptic and extrasynaptic regions
- Different mode of action from common GABA_A receptor potentiators such as benzodiazepines and neurosteroids

