Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Investors Meeting Presentation for Q2 FY2019 (April 1 to September 30, 2019)
Definitive Agreement for Strategic Alliance with Roivant Sciences

November 1, 2019

Hiroshi Nomura, President and CEO
Sumitomo Dainippon Pharma Co., Ltd.

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, 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, 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 (including compounds under development) contained herein is not intended as advertising or as medical advice.

Financial Results for Q2 FY2019

Financial Results for Q2 FY2019 (Core Basis)

Billions of yen

	Q2 FY2018 Results	Q2 FY2019 Results	Change			Q2 FY2019 (Apr.-Sep.)		FY2019	
			Value	FX impact	%	Forecasts	%	Forecasts	%
Revenue	226.2	230.6	4.4	(2.9)	2.0	228.5	100.9	475.0	48.5
Cost of sales *1	55.6	56.1	0.5	(0.8)	0.9	55.5	101.1	126.0	44.5
Gross profit	170.6	174.5	3.9	(2.2)	2.3	173.0	100.9	349.0	50.0
SG&A expenses *1	92.2	88.8	(3.4)	(1.1)	(3.7)	92.5	96.0	186.0	47.7
R&D expenses *1	41.3	41.0	(0.3)	(0.4)	(0.7)	41.0	100.0	86.0	47.7
Other operating income and expenses *2	0.1	0.1	(0.0)	–	(33.8)	0.0	–	0.0	–
Core operating profit	37.2	44.8	7.6	(0.7)	20.5	39.5	113.3	77.0	58.1
Changes in fair value of contingent consideration (negative number indicates loss)	(6.9)	① 41.8	48.6			17.0		12.0	
Other non-recurring items *3 (negative number indicates loss)	(0.7)	② (19.7)	(19.0)			(0.5)		(1.0)	
Operating profit	29.6	66.8	37.2		125.7	56.0	119.3	88.0	75.9
Profit before taxes	37.6	64.1	26.5		70.6	58.0	110.6	91.0	70.5
Income tax expenses	9.7	33.8	24.1			36.0		55.0	
Net profit attributable to owners of the parent	27.9	30.3	2.5		8.8	22.0	137.9	36.0	84.3

*1 Exclude non-recurring items (impairment losses, changes in fair value of contingent consideration, etc.)
*2 P/L on business transfer and Share of P/L of associates accounted for using equity method
*3 Non-recurring items (Other operating income and expenses except for *2 items, impairment losses, etc.)

FX rates: Q2FY2018 Results : 1US$ = ¥ 110.3, 1RMB = ¥16.7
Q2FY2019 Results : 1US$ = ¥ 108.6, 1RMB = ¥15.7

① Changes in fair value (cost reversal) due to:
・Discontinued P3 study for napabucasin pancreatic cancer (Q1)
・Revised business plans for alvocidib (Q2)
・Discontinued development for amcasertib (Q2)

② Non-recurring items recorded due to:
Impairment losses from
・Revised business plans for alvocidib (Q2)
・Discontinued development for amcasertib (Q2)

Financial Results for Q2 FY2019

Revenue of Major Products in Japan

Billions of yen

	Q2 FY2018 Results	Q2 FY2019 Results	Change Value	Change %	Q2 FY2019 (Apr.-Sep.) Forecasts	Q2 FY2019 (Apr.-Sep.) %
Trulicity® *	10.7	14.5	3.7	34.8	14.0	103.5
TRERIEF®	7.9	8.3	0.4	4.6	8.6	96.4
REPLAGAL®	6.3	7.0	0.7	11.1	6.1	115.5
METGLUCO®	5.1	4.9	(0.2)	(3.8)	4.7	104.6
SUREPOST®	3.0	3.4	0.5	15.8	3.1	111.3
AmBisome®	2.0	2.1	0.1	3.9	1.8	113.9
LONASEN® Tape	—	0.1	0.1	—	0.2	48.7
Promoted products Total	35.1	40.3	5.2	14.8	38.5	104.7
AMLODIN®	4.7	4.0	(0.7)	(15.1)	4.1	97.0
LONASEN® tablet/powder	6.3	3.9	(2.4)	(38.4)	4.0	96.9
AIMIX®	5.8	2.1	(3.7)	(63.3)	2.0	106.0
PRORENAL®	2.1	1.7	(0.4)	(19.3)	1.8	95.3
GASMOTIN®	2.0	1.6	(0.4)	(18.8)	1.6	100.4
AG products	2.3	3.8	1.4	61.3	3.4	111.0
Others	8.1	6.8	(1.3)	(16.2)	7.6	88.9
Total	66.4	64.2	(2.2)	(3.3)	63.0	101.9

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

Trulicity® continued to grow.

LONASEN® Tape was launched in September 2019.

GEs of LONASEN® tablet/powder were launched in June 2019.
Revenue of the AG products we sold are included in “AG products”

Revenue of Major Products in North America & China

	Q2 FY2018 Results	Q2 FY2019 Results	Change	Q2 FY2018 Results	Q2 FY2019 Results	Change			Q2 FY2019 (Apr.-Sep.)		
						Value	FX impact	%	Forecasts		Yen-basis %
North America	Million $			Billion yen					Million $	Billion yen	
LATUDA®	813	873	60	89.7	94.8	5.1	(1.4)	5.7	850	93.5	101.4
BROVANA®	152	152	(0)	16.7	16.5	(0.3)	(0.3)	(1.5)	151	16.6	99.2
APTIOM®	88	100	12	9.7	10.9	1.2	(0.2)	12.0	99	10.9	99.6
LONHALA® MAGNAIR®	4	13	9	0.4	1.4	1.0	(0.0)	241.9	12	1.3	106.4
XOPENEX®	19	18	(1)	2.1	2.0	(0.2)	(0.0)	(8.1)	20	2.2	88.9
Others	35	35	0	3.9	3.8	(0.1)	(0.1)	(1.3)	33	3.6	106.7
Total	1,111	1,191	80	122.5	129.3	6.8	(2.0)	5.6	1,165	128.1	101.0
China	Million RMB			Billion yen					Million RMB	Billion yen	
MEROPEN®	587	765	179	9.8	12.0	2.2	(0.8)	22.2	727	12.0	100.0
Others	94	130	36	1.6	2.0	0.5	(0.1)	29.4	103	1.7	120.2
Total	681	896	215	11.4	14.0	2.6	(0.9)	23.2	830	13.7	102.5

LATUDA® and APTIOM® sales showed growth.

MEROPEN® sales remained strong.

LATUDA® was launched in September 2019

FX rates: Q2FY2018 Results : 1US$ = ¥ 110.3, 1RMB = ¥16.7
Q2FY2019 Results : 1US$ = ¥ 108.6, 1RMB = ¥15.7

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
Q2 FY2019 Results	Revenue (Sales to customers)	64.2	129.3	14.0	4.3	211.9	18.7	230.6
	Cost of sales	26.3	11.4	2.3	1.5	41.6	14.5	56.1
	Gross profit	37.9	117.9	11.7	2.8	170.3	4.2	174.5
	SG&A expenses	24.6	55.9	4.2	1.6	86.2	2.6	88.8
	Core segment profit	13.3	62.1	7.5	1.2	84.2	1.6	85.7
	R&D expenses					40.6	0.4	41.0
	Other operating income/expenses					0.1	(0.0)	0.1
	Core operating profit					43.6	1.1	44.8
Q2 FY2018 Results	Revenue (Sales to customers)	66.4	122.5	11.4	7.0	207.3	18.8	226.2
	Cost of sales	25.9	9.7	1.9	3.5	41.0	14.6	55.6
	Gross profit	40.5	112.8	9.5	3.6	166.4	4.2	170.6
	SG&A expenses	25.1	58.1	4.4	1.9	89.4	2.7	92.2
	Core segment profit	15.4	54.8	5.1	1.7	76.9	1.5	78.4
	R&D expenses					40.8	0.5	41.3
	Other operating income/expenses					0.1	0.0	0.1
	Core operating profit					36.2	1.0	37.2
Change	Revenue (Sales to customers)	(2.2)	6.8	2.6	(2.7)	4.6	(0.2)	4.4
	SG&A expenses	(0.6)	(2.2)	(0.2)	(0.3)	(3.3)	(0.1)	(3.4)
	Core segment profit	(2.0)	7.3	2.4	(0.5)	7.2	0.1	7.3
	Core operating profit					7.4	0.2	7.6

In Japan segment, both revenue and profit decreased.

In North America and China segment, both revenue and profit increased.

Financial Forecasts for FY2019

Financial Forecasts for FY2019 (Core Basis)

Billions of yen

	FY2018 Results	FY2019 Previous forecasts	FY2019 Revised forecasts	Change from previous forecasts		Change from FY2018
				Value	%	Value
Revenue	459.3	475.0	**475.0**	15.7	3.4	—
Cost of sales	113.1	126.0	**125.0**	11.9	10.5	(1.0)
Gross profit	346.2	349.0	**350.0**	3.8	1.1	1.0
SG&A expenses	186.1	186.0	**187.0**	0.9	0.5	1.0
R&D expenses	82.9	86.0	**86.0**	3.1	3.8	—
Core operating profit	77.3	77.0	**77.0**	(0.3)	(0.4)	—
Changes in fair value of contingent consideration (negative number indicates loss)	9.1	12.0	**35.0**	25.9		23.0
Other non-recurring items (negative number indicates loss)	(28.5)	(1.0)	**(24.0)**	4.5		(23.0)
Operating profit	57.9	88.0	**88.0**	30.1	52.0	—
Income tax expense	16.4	55.0	**51.0**	34.6		(4.0)
Net profit attributable to owners of the parent	48.6	36.0	**36.0**	(12.6)	(26.0)	—
ROE (%)	10.2	7.1	**7.1**			
ROIC (%)	11.8	4.1	**4.8**			

Unchanged full-year forecasts for revenue and each profit item

Revised forecast of fair value of contingent consideration counts the change for Q2.

Revised forecast of other non-recurring items counts impairment losses and other items recorded in Q2.

FX rate assumption of RMB was updated.

FX rates: FY2018 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.5
FY2019 Previous forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5
FY2019 Revised forecasts : 1US$ = ¥ 110.0, 1RMB = ¥15.5

Financial Forecasts for FY2019

Segment Information (Core Basis)

Billions of yen

		Pharmaceuticals Business					Other Business	Total (Core basis)
		Japan	North America	China	Other Regions	Subtotal		
FY2019 Revised Forecasts	Revenue (Sales to customers)	136.0	260.0	27.3	13.7	437.0	38.0	475.0
	Cost of sales	63.0	22.7	5.0	4.9	95.6	29.4	125.0
	Gross profit	73.0	237.3	22.3	8.8	341.4	8.6	350.0
	SG&A expenses	53.3	116.0	9.0	3.2	181.5	5.5	187.0
	Core segment profit	19.7	121.3	13.3	5.6	159.9	3.1	163.0
	R&D expenses					85.0	1.0	86.0
	Core operating profit					74.9	2.1	77.0
FY2019 Previous Forecasts	Revenue (Sales to customers)	135.0	260.0	28.3	13.7	437.0	38.0	475.0
	Cost of sales	62.0	23.2	6.2	5.2	96.6	29.4	126.0
	Gross profit	73.0	236.8	22.1	8.5	340.4	8.6	349.0
	SG&A expenses	53.8	114.0	9.5	3.2	180.5	5.5	186.0
	Core segment profit	19.2	122.8	12.6	5.3	159.9	3.1	163.0
	R&D expenses					85.0	1.0	86.0
	Core operating profit					74.9	2.1	77.0
Change	Revenue (Sales to customers)	1.0	–	(1.0)	–	–	–	–
	SG&A expenses	(0.5)	2.0	(0.5)	–	1.0	–	1.0
	Core segment profit	0.5	(1.5)	0.7	0.3	–	–	–
	Core operating profit					–	–	–

Japan segment
- Incremental revenue of REPLAGAL®

North America segment
- Incremental expenses related to strategic alliance with Roivant Sciences

China segment
- Expected yen-based revenue decline due to update FX rate assumption despite strong sales trend

Research and Development

Research and Development

Main Event/Target for FY2019 (as of October 28, 2019)

Sumitomo Dainippon Pharma

✓ Done event / target Revisions since the announcement of July 2019 are shown in red.

Psychiatry & Neurology	☑ LONASEN® (New formulation : transdermal patch) : Obtain approval for schizophrenia in Japan ☑ Lurasidone : Submit NDA for schizophrenia and bipolar depression in Japan ☑ Dasotraline : NDA submission for BED in the U.S. ☐ Dasotraline : Determine development strategy for ADHD in the U.S. ☐ Apomorphine : Resubmit NDA for OFF episodes associated with Parkinson's disease in the U.S. ☐ SEP-363856* : Start next phase study (☑ Phase 3 study in the U.S., ☐ Phase 2 study in Japan)
Oncology	☐ Napabucasin : Promote global Phase 3 studies for colorectal cancer and pancreatic cancer (☑ Completed interim analysis in H1 FY2019, interim analysis results: Phase 3 study for colorectal cancer to be continued, Phase 3 study for pancreatic cancer discontinued)
Regenerative medicine / Cell therapy	☐ SB623 : Determine development policy for chronic stroke in the U.S. ☐ Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study
Other	☐ Imeglimin : Obtain two Phase 3 study results (☐ TIMES 2, ☑ TIMES 3) in Japan
Infectious Diseases	☐ Promote joint research with academia and others (antimicrobial resistance (AMR), universal influenza vaccines, malaria vaccines)
Frontier	☐ Promotion of the current themes (MELTIN, Aikomi), development of new themes

* Sunovion discovered SEP-363856 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform.

Clinical Development Status (Major Changes since July 29, 2019)

Sumitomo Dainippon Pharma

Lurasidone

Japan: NDA for schizophrenia and bipolar depression submitted in July 2019

- ✓ Launch target: FY2020

Revised development strategy of alvocidib

U.S.: ：Revised policy to prioritize Phase 1/2 study for myelodysplastic syndromes (MDS) which is highly MCL-1 dependent

Study design: Combination with decitabine in 1st line MDS patients, plan to add combination product azacitidine

- ✓ Plan to launch in FY2023

DSP-0509

U.S.: Started Phase 1/2 study for solid tumors (combination therapy)

TP-3654

U.S.: Started Phase 1 study for myelofibrosis (monotherapy/combination therapy)

Discontinuation

Amcasertib: solid tumors, hematologic malignancies (Japan and U.S.: Phase 2 study)

Obeticholic acid (DSP-1747): development in China (nonalcoholic steatohepatitis, Primary Biliary Cholangitis)

Update on progress of proposal to acquire Cynata Therapeutics Limited (announced on July 19, 2019)

Withdrawn after unable to reach the mutually agreed terms

Research and Development

Product Launch Target (as of October 28, 2019)

Sumitomo Dainippon Pharma

Revisions since the announcement of July 2019 are shown in red.

Area	FY2019	FY2020	FY2021	FY2022	FY2023
Japan	**LONASEN®** (Schizophrenia/ Transdermal patch) Launched in September 2019	**lurasidone** (Schizophrenia/ Bipolar depression)	**imeglimin** (Type 2 diabetes)	**napabucasin** (Colorectal cancer)	
	RETHIO® (Conditioning treatment prior to autologous HSCT for malignant lymphoma)			**Allo iPS cell-derived products** *2 (AMD)	
				Allo iPS cell-derived products *2 (Parkinson's disease)	
U.S.	**dasotraline** (ADHD) Launch target under consideration	**Apomorphine** (OFF episodes associated with Parkinson's disease)	**napabucasin** (Colorectal cancer)	**SB623** *2 (Chronic stroke) Launch target under consideration	**SEP-363856** (Schizophrenia)
		dasotraline (BED)			**alvocidib** *1 (MDS)
					dubermatinib (TP-0903) (Solid tumors/ Hematologic malignancies) *1
					TP-0184 (Solid tumors) *1

: Psychiatry & Neurology : Oncology

: Regenerative medicine / cell therapy : Others

Expect peak annual sales to be 50 billion yen or more (described in the first launch)

*1 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

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

Overview of the Strategic Alliance

Aims of the Strategic Alliance

Sumitomo Dainippon Pharma

Acquire candidates for post-LATUDA®, early-stage pipeline, healthcare technology platforms, and talent for sustained growth and transformation of Sumitomo Dainippon Pharma Group

Key Challenges in MTBP 2022

- Expand post-LATUDA® assets
- Expand pipeline by continued creation of innovative new drugs
- Meet needs for preventive medical care and for digital technologies
- Reinforce profitability of North America and Japan business
  Expand presence in China and Asia
- Enhance organizational capabilities to address changes in external environment

Significant Reforms for Achieving Sustained Growth

- Obtain potential near-term blockbuster products: relugolix and vibegron

- Gain access to multiple innovative clinical programs, including in gene therapy
- Improve R&D productivity and future pipeline expansion by leveraging the DrugOme platform

- Expand pipeline in Japan with multiple early-stage assets

- Introduce a framework and talent programs to accelerate the digital transformation of the group
- Cultivate a dynamic organizational culture

Overview of the Strategic Alliance

■ Details of the definitive agreement (executed in October 2019)

Acquisition of Shares in Roivant Subsidiaries	• Acquires Roivant's ownership interests in 5 of its subsidiaries
Granting of Options for Roivant Subsidiaries	• Obtains options to acquire Roivant's interests in 6 of its subsidiaries (exercisable until 2024)
Partnership and Acquisition of Technology Platforms	• Acquires Roivant's technology platform and talent, Digital Innovation and DrugOme • Enters into client relationships with Roivant's independent technology subsidiaries, Datavant and Alyvant
Subscription for Shares in Roivant	• Acquires over 10% of Roivant shares

■ Plan

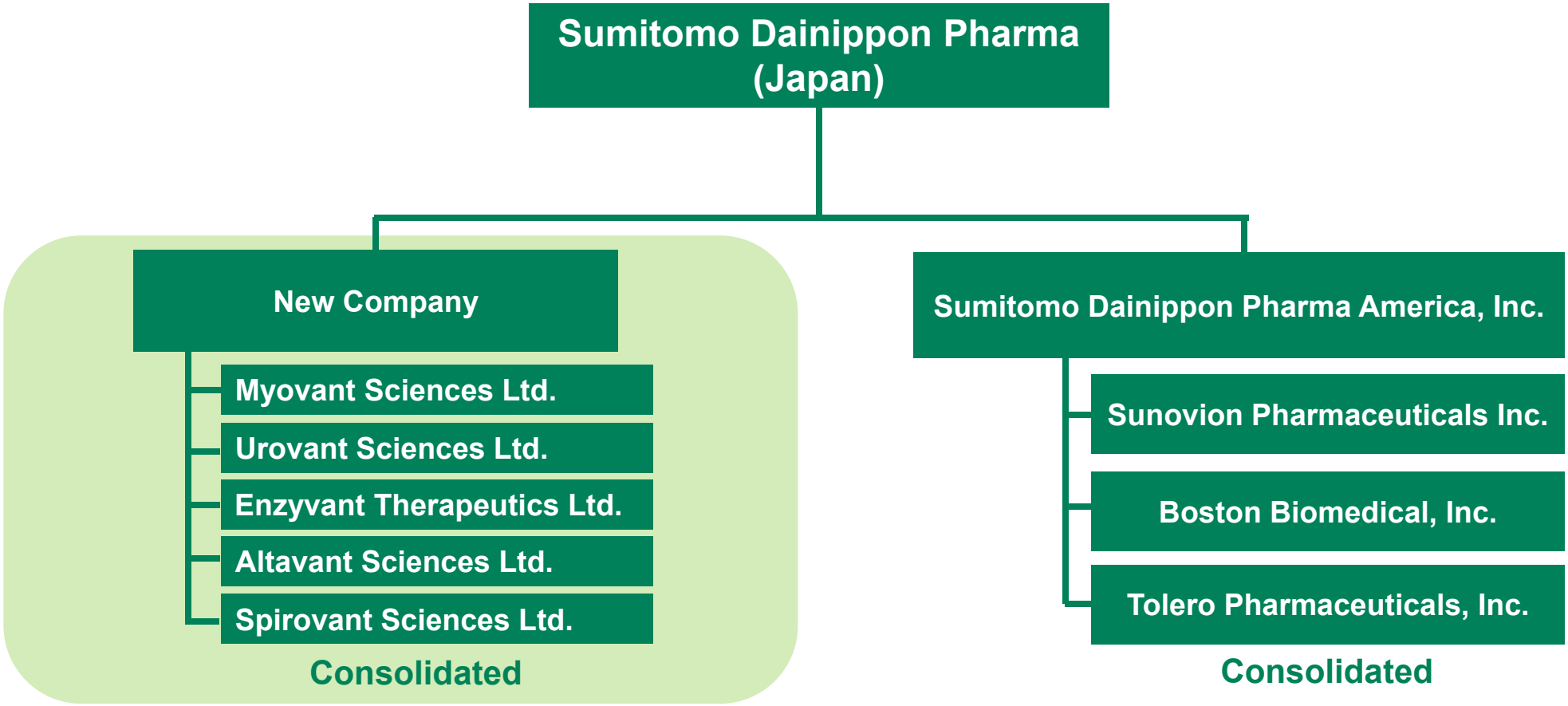
- Roivant will transfer the interests in 5 of its subsidiaries and talent related to healthcare platforms to a new, fully owned company ("New company") established for this strategic alliance
- Sumitomo Dainippon Pharma will acquire all shares of the new company and assets related DrugOme and Digital Innovation

■ Purchase Price

- Consideration: US$3 billion (approx. 330 billion yen)
  - ✓ Shares of the new company
  - ✓ Shares of Roivant
- Closing: During FY2019 (scheduled)

Overview of the Strategic Alliance

Proposed Post-Acquisition Structure for New Company in North America (At the Closing)



Management Structure of the New Company

New Company CEO

Myrtle Potter

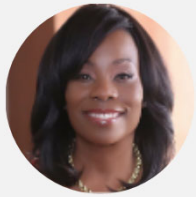
- Formulate and lead the execution of the business strategy and plan
- Ensure successful integration and operation of each New Company function

Vant Management	Scientific & Medical Development	Business & Commercial Development	Digital Innovation
• Governance of existing development programs at subsidiaries (“Vants”) • Review and support of ongoing development plans, trials, submissions, and launches • Portfolio management within and across Vants	• Serve as internal experts to support scientific functions at Vants • Explore enhanced scientific evaluation, development strategy, and trial planning through DrugOme	• Assess new business opportunities or Alliance partnerships • Apply DrugOme technology for asset identification and diligence and to craft commercial strategies • Various Alliance negotiations	• Deployment of digital innovation throughout Sumitomo Dainippon Pharma Group • Hire and train Digital Innovators • Support ongoing Digital Innovation projects
Myrtle Potter Chief Executive Officer	**Sam Azoulay, MD** Chief Medical Officer	**Adele Gulfo** Chief Business & Commercial Development Officer	**Dan Rothman** Chief Information Officer (and Chief Digital Officer for Sumitomo Dainippon Pharma Group)

Management Team of the New Company

Sumitomo Dainippon Pharma

Chief Executive Officer



Myrtle Potter

- Formerly President and Chief Operating Officer of Genentech; led the launch of numerous breakthrough products including AVASTIN and XOLAIR
- Former board roles at Amazon, Medco, Express Scripts, Rite Aid, etc.
- Vant Operating Chair at Roivant Pharma

Chief Medical Officer

Sam Azoulay, MD

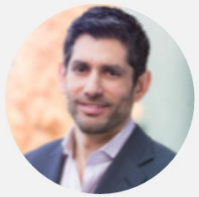
- Formerly SVP and Chief Medical Officer of Pfizer Essential Health, and various other senior leadership roles at Pfizer in Japan and Emerging Markets
- Chief Medical Officer at Roivant Pharma

Chief Business & Commercial Development Officer

Adele Gulfo

- Formerly President and General Manager of Pfizer's US Primary Care business; led the market preparation, launch, and commercialization of LIPITOR
- Former senior roles at AstraZeneca; responsible for launch of CRESTOR
- Chief of Commercial Development at Roivant Pharma

Chief Information Officer (and Chief Digital Officer for Sumitomo Dainippon Pharma Group)



Dan Rothman

- Formerly a Managing Director at Goldman Sachs; headed multiple departments and was responsible for internal and external technology platform development
- Chief Information Officer at Roivant

DrugOme Technology

Sumitomo Dainippon Pharma

Unique data analytics platform for accelerating clinical development and pipeline acquisition

Data source	Integrated database	Analysis	Output
Collect data	**Synthesize data**	**Conduct analysis**	**Improved decisions**

Structured data sources

- Pharmaceutical data
- Target molecule data
- Clinical trial registry
- FDA data
- Insurance claims data

Unstructured data sources

- FDA filings
- SEC filings
- Press releases
- Academic research

Analysis tools

- Applications to organize and analyze external trends (e.g. competitive landscapes, enrollment rates, indications of interest), etc.

Bespoke analyses

- Bolster investment and development strategy (e.g., estimated clinical trial costing, target patient population, etc.)

Support for clinical development

- Support for development strategy formulation
- Refined development period / cost estimates
- Optimize clinical trial design

Search for promising assets

- Efficiently analyze the business potential, development feasibility, clinical needs, etc. of programs of interest
- Identify and acquire promising assets to complement in-house development activities

Selection and incorporation of new data sources

Database maintenance and management

Application development and bespoke analyses

Computational Research team dedicated to DrugOme

Technology Platforms

Utilization of DrugOme in Sumitomo Dainippon Pharma Group

Our Approach

Mid-term Business Plan 2022
"Establishment of Growth Engine"

- Enhance Innovation Base with New Approaches to Drug Discovery
  Drug discovery research with big data and digital technologies
- Deliver Highest Performance of Clinical Development
  Improvement in probability of success and efficiency with big data

DrugOme Ecosystem

- Unique data analytics platform for accelerating clinical development and pipeline acquisition
- Computational Research team dedicated to DrugOme

Strategic Alliance with Roivant

- Client relationship with Datavant

Data-driven Pharmaceutical Company

Research

- Utilize real world data for *in silico* drug discovery (data-driven first in class drug discovery)

Development

- Optimize and improve clinical trials with big data analytics and integration
- Refine clinical development strategies
- Build evidence combining in-house (from clinical development to after launch) with real world data

Business Development

- Increase efficiency of in-licensing activities through unique data analysis (acquisition of promising assets)
- Refine valuation process with big data analytics and integration

Digital Innovation Technology

Optimizing business processes through technology

Overview of Digital Innovation

Digital Innovation system	Identifying issues and proposing solutions	Application implementation	Horizontal deployment of solutions
• Dedicated team of technologists (Digital Innovators) with strong coding and data analytics skills • Standardized system infrastructure (common development platform)	• Digital Innovators are embedded in business teams • They identify operational issues and propose solutions through close collaboration with business team	• Digital Innovators play a central role in quickly developing applications necessary for improving efficiency and solving issues in business teams	• Deploy know-how and problem-solving abilities horizontally across departments with similar operational issues

Example Digital Solutions

Digital Patient Recruitment Center

Problem: Low conversion rate of patient referrals
Solution: Creation of web survey to pre-screen patients and confirm visits
Result: Significantly increased monthly enrollment rate while materially decreasing monthly screen failure rate

Technology Platforms

Digital Innovation in Sumitomo Dainippon Pharma Group

Sumitomo Dainippon Pharma

Our Approach

Mid-term Business Plan 2022
"Digital Innovation"
Achieve both new value creation and operational reform through digital technology

New Value Creation
Operational Reform
through digital technology

Accelerating "Digital Innovation"

- Acquire Roivant's digital innovation platform
- Quickly solve operational issues using digital technology

Improve data utilization by business users

Improve operational efficiency by digitalization of business processes

- **Further focus on digital capability:**
  - Improve the decision-making process by leveraging data in addition to knowledge and experience
  - Improve the quality and speed of business processes with digital innovation
- **Company-wide efforts to identify opportunities leveraging digital technology and deliver best performance:**
  - Create new knowledge and results by using not only internal data in each department, but also data across multiple departments or external data
  - Create synergies through horizontal deployment of digital innovation

Promotion of Technology

- **Appoint a Chief Digital Officer for Sumitomo Dainippon Pharma Group**

Chief Digital Officer for Sumitomo Dainippon Pharma Group

Dan Rothman

Role: Deploy digital innovation throughout Sumitomo Dainippon Pharma group

- **Establish a dedicated office in Sumitomo Dainippon Pharma to promote new technology**

Utilize and expand new technology investments across entire Sumitomo Dainippon Pharma Group in cooperation with each business division

Overview of Roivant Subsidiaries Included in the Strategic Alliance

Sumitomo Dainippon Pharma

■ **Five subsidiaries: Upfront acquisition of Roivant's stakes**

* Number of employees as of the end of September 2019, except for the public companies which are as of last disclosed (end of March 2019)

Myovant Sciences

US Headquarters: Brisbane, California
Number of employees*: 167
Representative: Lynn Seely, President & CEO
Focus Area: Women's Health, Prostate Cancer
Pipeline: relugolix, MVT-602
Listed on the NYSE, ~46% ownership

Urovant Sciences

US Headquarters: Irvine, California
Number of employees*: 39
Representative: Keith Katkin, President & CEO
Focus Area: Urology
Pipeline: vibegron, URO-902
Listed on Nasdaq, ~75% ownership

Enzyvant Therapeutics

US Headquarters: Cambridge, Massachusetts
Number of employees*: 28
Representative: Rachelle Jacques, CEO
Focus Area: Pediatric Rare Diseases
Pipeline: RVT-802, RVT-801
Wholly owned

Altavant Sciences

US Headquarters: Cary, North Carolina
Number of employees*: 13
Representative: Bill Symonds, CEO
Focus Area: Respiratory Rare Diseases
Pipeline: rodatristat ethyl
Wholly owned

Spirovant Sciences

US Headquarters: Philadelphia, Pennsylvania
Number of employees*: 8
Representative: Joan Lau, CEO
Focus Area: Cystic Fibrosis Gene Therapy
Pipeline: SPIRO-2101, SPIRO-2102
Wholly owned

■ **Six subsidiaries: Options to acquire Roivant's stakes**

- Dermavant Sciences
- Genevant Sciences
- Sinovant Sciences
- Cytovant Sciences
- Metavant Sciences
- Lysovant Sciences

Roivant Subsidiaries Included in the Strategic Alliance

Leadership of Roivant Subsidiaries Included in the Strategic Alliance

Sumitomo Dainippon Pharma

President and CEO, Myovant

- Former Chief Medical Officer at Medivation
- Led development of XTANDI® for metastatic castration-resistant prostate cancer

Lynn Seely, MD

President and CEO, Urovant

- Former President and CEO at Avanir, which was acquired by Otsuka Pharma for $3.5 billion USD in 2014
- Responsible for developing and executing the corporate strategy that led to the approval and commercialization of NUEDEXTA®

Keith Katkin

Chief Executive Officer, Enzyvant

- Former Senior Vice President and Global Franchise Head of Complement at Alexion
- Launched multiple products, with broad experience in US and Global commercial leadership, including multiple high-profile product launches in rare diseases

Rachelle Jacques

Chief Executive Officer, Altavant

- Former Chief Development Officer at Roivant, held senior roles at Gilead and Pharmasset
- Led development of the top-selling cure for Hepatitis C viruses, SOVALDI® / HARVONI®

Bill Symonds, PharmD

Chief Executive Officer, Spirovant

- Former Managing Partner at Militia Hill Ventures, a venture capital firm that specializes in life sciences companies
- Has founded and served as CEO of several venture-backed biotechnology companies

Joan Lau, PhD

Pipeline Overview

Development Pipeline of Acquired Subsidiaries (as of October 31, 2019)

Product	Indication	Phase	Characteristics	Originator	Development	Expected peak revenue*
Relugolix	Uterine fibroids	Preparing to submit NDA (U.S.)	• Oral, once-a-day, small molecule GnRH (gonadotropin-releasing hormone) receptor antagonist	Takeda Pharmaceutical Company Ltd.	Myovant	Large
	Endometriosis	Phase 3				
	Prostate cancer	Phase 3				
Vibegron	Overactive bladder (OAB)	Preparing to submit NDA (U.S.)	• Oral, once-a-day, small molecule beta-3 adrenergic receptor agonist	Merck Sharp & Dohme Corp.	Urovant	Large
	OAB in men with BPH	Phase 3				
	IBS-associated pain	Phase 2a				
RVT-802	Pediatric congenital athymia	Applied (U.S.)	• Treatment of infants with congenital athymia by culturing thymus tissue obtained during cardiac surgery and implanting the cultured thymus tissue into quadriceps • Granted Breakthrough Therapy, Regenerative Medicine Advanced Therapy, Orphan Drug designations and Rare Pediatric Disease by FDA	Duke University	Enzyvant	Small
Rodatristat ethyl	Pulmonary arterial hypertension (PAH)	Phase 2a	• Prodrug of orally administered tryptophan hydroxylase (TPH) inhibitor	Karos Pharmaceuticals, Inc.	Altavant	

Phase 1 and Phase 2 assets

- MVT-602 (Development: Myovant, Phase 2 stage) Oligopeptide kisspeptin-1 receptor agonist for female infertility
- URO-902 (Development: Urovant, Phase 1 stage) Gene therapy for overactive bladder (OAB)

Preclinical assets

- SPIRO-2101 (Development: Spirovant) Adeno-associated virus (AAV)-based gene therapy for cystic fibrosis
- SPIRO-2102 (Development: Spirovant) Lentivirus vector (LVV)-based gene therapy for cystic fibrosis
- RVT-801 (Development: Enzyvant) Enzyme replacement therapy for Farber disease

* Large: Expect peak annual sales in global to be 50 billion yen or more; medium: 10-50 billion yen; small: less than 10 billion yen

Pipeline Overview

Relugolix (Development: Myovant Sciences)

Sumitomo Dainippon Pharma

■ **Characteristics**:

- Originator: Takeda Pharmaceutical Company Ltd.
- Oral, once-a-day, small molecule GnRH (gonadotropin-releasing hormone) receptor antagonist
- Reduces sex hormone levels by inhibiting pituitary GnRH receptors and suppresses estrogen and progesterone in women and testosterone in men
- Expected differentiation points from existing therapies
  - ✓ Combination with hormones (1) maintain bone health and mitigate hot flashes and (2) enable long-term use
  - ✓ Convenient once-a-day dosing with no titration required for uterine fibroids and endometriosis

■ **Phase and Plan:**

Indication	Phase	Plan
Uterine fibroids	Preparing to submit NDA in the U.S.	NDA submission in FY2019 (U.S.)
Endometriosis	Phase 3	Phase 3 results in FY2019-2020
Prostate cancer	Phase 3	Phase 3 results in FY2019

Vibegron (Development: Urovant Sciences)

Sumitomo Dainippon Pharma

■ **Characteristics**:

- Originator: Merck Sharp & Dohme Corp.
- Oral, once-a-day, small molecule beta-3 adrenergic receptor agonist
- Selectively acts on beta-3 adrenergic receptor and increases urine accumulation function by relaxing the bladder, which potentially improves symptoms of urinary urgency, frequent urination and urge incontinence
- Expected differentiation points from existing therapies
  - ✓ High receptor selectivity and significantly lower risk of QT prolongation
  - ✓ Improvement of residual incontinence, etc. was also good, and early onset period in 2 weeks from the start to the period of administration

■ **Phase and Plan**:

Indication	Phase	Plan
Overactive bladder	Preparing to submit NDA in the U.S.	NDA submission in FY2019 (U.S.)
Overactive bladder in men with BPH	Phase 3	Phase 3 results in FY2020
IBS-associated pain	Phase 2a	Phase 2a results in FY2019-2020

Financial Impact and Funding

Financial Impact to FY2019

- Incorporated into the forecast for FY2019 are temporary costs related to acquisitions assuming the closing date at the end of March 2020

Impact to Financial Performance FY2020 onwards

- Positive impact to revenue in FY2022, while increases SG&A and R&D expenses
- Plan to review the business goals of Mid-term Business Plan 2022

Accounting

- Details such as purchase price allocation to be disclosed after closing

Funding Policy

- Cash proceeds to be raised with cash on hand and bridge loans
- To refinance through hybrid finance instrument to raise equity-like capital, in addition to bank borrowing, etc.

Deal Summary

Objectives to Achieve after Definitive Agreement with Roivant

- To acquire promising, future post-LATUDA® compounds
- To acquire platform technologies (DrugOme and Digital Innovation) and talent

Sumitomo Dainippon Pharma ⟷ **Alliance** ⟷ ROIVANT SCIENCES

Stock Acquisition	Pharma-Related Technology Platforms Transfer	Contract Agreements with Technology Vants
New Company • **Myovant Sciences** • **Urovant Sciences** • **Enzyvant Therapeutics** • **Altavant Sciences** • **Spirovant Sciences**	• **DrugOme Technology** (Unique data analytics platform for accelerating pipeline acquisition and clinical development) • **Digital Innovation Technology** (Platform for optimizing business processes through data analysis)	Healthcare IT Subsidiaries • **Datavant** (Platform with de-identification and linking technology of multiple external healthcare data to facilitate use) • **Alyvant** (Platform for increasing efficiency of sales and marketing activities for pharmaceutical products through big data analytics)

- Obtains options to acquire Roivant's interests in six additional companies, which will remain owned by Roivant until exercise
- Determine exercise of options by 2024

Operate businesses as strong partners

On Behalf of Roivant Sciences

Founder & CEO Vivek Ramaswamy

On Behalf of Roivant Sciences

Significance of Strategic Alliance for Roivant

- **Roivant's model is validated with commercial success of Alliance**
- **Option Vants have a well-respected potential partner and path to commercialization**
- **Shared technology solutions become more valuable with benefits of scale**
- **Large capital injection drives value creation at Roivant with strengthened ability to build new Vants**
- **Roivant gains strategic shareholder with deep commercial pharma expertise**
- **Roivant gains long-term partner with opportunities for expanded collaboration**

On Behalf of Roivant Sciences

Relugolix: Combination Therapy

Potentially Best-in-Class Profile

Dilemma in Treating Estrogen-Driven Diseases

Uterine fibroids and endometriosis are **estrogen-driven diseases**

Lowering estrogen levels is effective at reducing symptoms…

…however, **safety and tolerability issues arise** (e.g. bone mineral density loss) when estrogen levels are **too low**

Relugolix Combination Therapy Designed to Overcome Treatment Gap

One pill once a day designed for women

RELUGOLIX 40 MG + ESTRADIOL AND PROGESTIN = **DESIGNED TO OPTIMIZE ESTROGEN LEVELS**

Benefits of Relugolix Combination Seen in Phase 3:

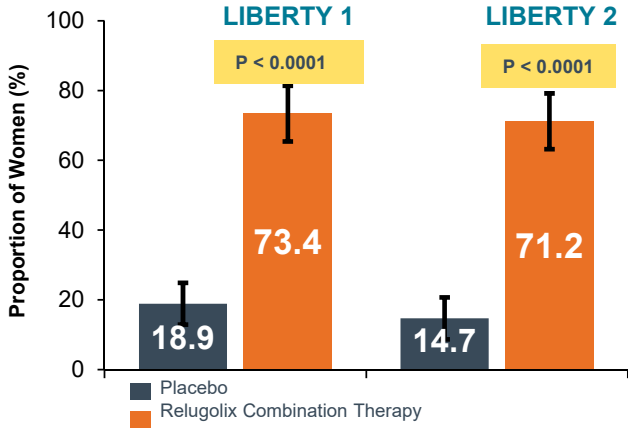
- **Convenient once-daily treatment** providing predictable efficacy for symptoms such as bleeding, pain, and anemia, **with no need to titrate**
- **Maintains bone health** and mitigates hot flush
- Potentially enables **long-term use**

Uterine Fibroids

U.S. prevalence: **~19M**, with **~5M** experiencing symptoms

Achieved primary endpoint of proportion of women with <80 mL uterine blood loss/cycle and ≥50% menstrual blood loss reduction in **Phase 3 trials**

Bone density maintained in lumbar spine observed in **Phase 3 LIBERTY1 and LIBERTY 2 trials**



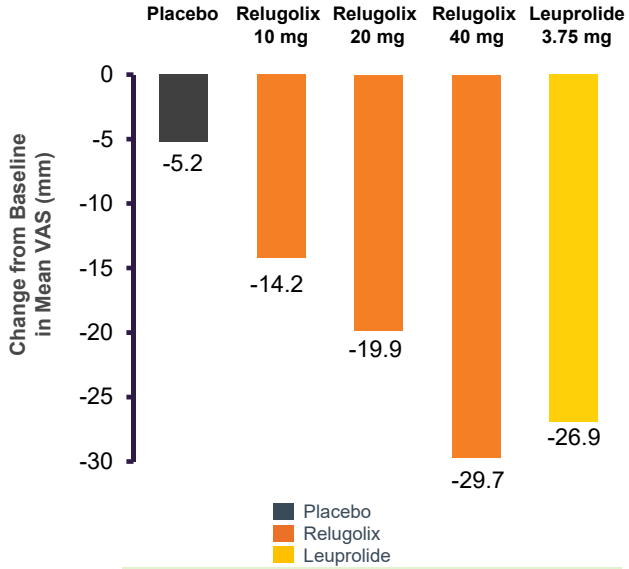
Two Positive Phase 3 Trials

Anticipated NDA Filing FY2019

Endometriosis

U.S. prevalence: **~8M**, with **~6M** experiencing symptoms

Dose-dependent reduction in dysmenorrhea observed in **Phase 2 trial**



Two Ongoing Phase 3 Trials

Results Expected FY2019-2020

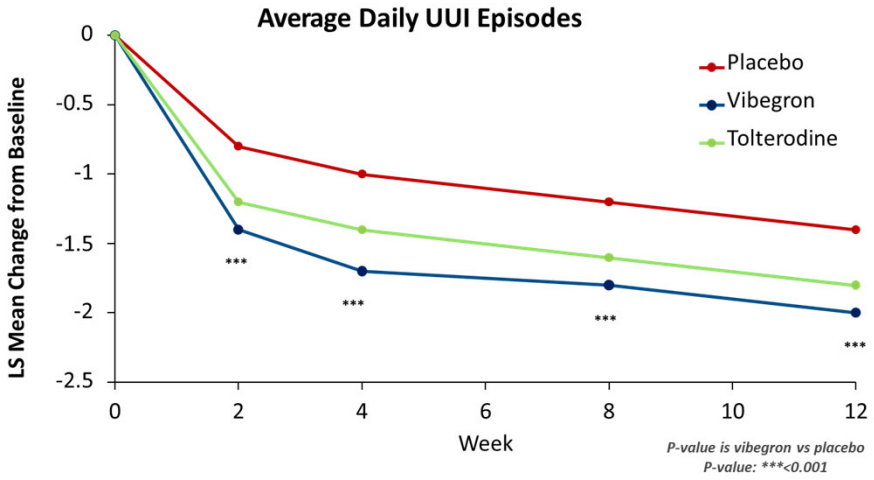
<Reference>
Myovant public disclosures

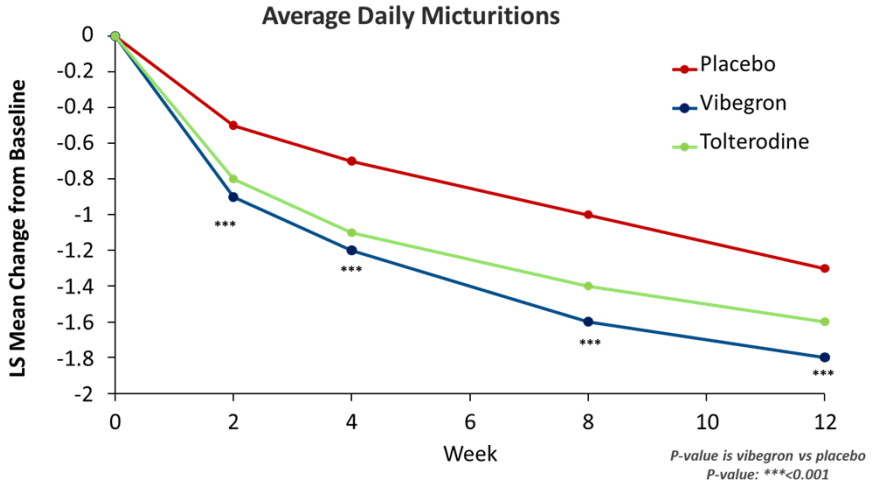
On Behalf of Roivant Sciences

Vibegron: A Potential Best-In-Class β3 Agonist

Positive Phase 3 Trial Results in OAB

Demonstrated reduction on both co-primary endpoints: Urge Urinary Incontinence (UUI) and Micturitions Over Time





Sizable Market Opportunity

*Over 18 million prescriptions written each year **in the US alone***

Differentiated Option

*Addresses need for treatments that **do not pose a risk for dementia or result in DDIs***

Positive Phase 3 Results

*Statistical significance on **both** co-primary endpoints with favorable safety and tolerability*

<Reference>
Urovant public disclosures

On Behalf of Roivant Sciences

Enzyvant, Altavant, Spirovant

Vant	Product	Characteristics	Indication	Phase
ENZYVANT	**RVT-802**	• Tissue-based regenerative therapy • Granted Breakthrough Therapy, Regenerative Medicine Advanced Therapy, Orphan Drug designations and Rare Pediatric Disease by FDA	Pediatric congenital athymia	Applied (U.S.)
	RVT-801	• Enzyme replacement therapy	Farber disease	Preclinical
ALTAVANT SCIENCES	**Rodatristat ethyl**	• Prodrug of orally administered tryptophan hydroxylase (TPH) inhibitor	Pulmonary arterial hypertension (PAH)	Phase 2a
spirovant	**SPIRO-2101** **SPIRO-2102**	• Portfolio of gene therapies	Cystic fibrosis	Preclinical

On Behalf of Roivant Sciences

Significance of Strategic Alliance for Roivant

- **Roivant's model is validated with commercial success of Alliance**
- **Option Vants have a well-respected potential partner and path to commercialization**
- **Shared technology solutions become more valuable with benefits of scale**
- **Large capital injection drives value creation at Roivant with strengthened ability to build new Vants**
- **Roivant gains strategic shareholder with deep commercial pharma expertise**
- **Roivant gains long-term partner with opportunities for expanded collaboration**

Appendix

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Financial Results for Q2 FY2019 (Full Basis)

Billions of yen

	Q2 FY2018 Results	Q2 FY2019 Results	Change	
			Value	%
Revenue	226.2	230.6	4.4	2.0
Cost of sales	55.6	56.3	0.7	1.2
Gross profit	170.6	174.3	3.8	2.2
SG&A expenses	99.0	47.0	(52.0)	(52.5)
R&D expenses	41.3	60.2	18.8	45.6
Other operating income and expenses	(0.6)	(0.3)	0.3	
Operating profit	29.6	66.8	37.2	125.7
Finance income and costs	8.0	(2.7)	(10.7)	
Net profit attributable to owners of the parent	27.9	30.3	2.5	8.8

Adjustments to Core Operating Profit

Q2 FY2019 Results

Billions of yen

IFRS Full Basis		Adjusted amount
Revenue	230.6	–
Cost of sales	56.3	(0.2)
Gross profit	174.3	0.2
SG&A expenses	47.0	41.8
R&D expenses	60.2	(19.1)
Other operating income and expenses	(0.3)	0.4
Operating profit	66.8	(22.1)

IFRS Core Basis		Adjusted items
Revenue	230.6	
Cost of sales	56.1	
Gross profit	174.5	
SG&A expenses	88.8	Changes in fair value of contingent consideration 41.8
R&D expenses	41.0	Impairment loss (19.1)
Other operating income and expenses *1 (profit/loss on business transfer, share of profit/loss of associates accounted for using equity method)	0.1	
Core operating profit	44.8	
Changes in fair value of contingent consideration (Positive number indicates profit)	41.8	From SG&A expenses 41.8
Other non-recurring items *2 (Negative number indicates loss)	(19.7)	Impairment loss (19.1)

IFRS Full Basis : Each item is shown by original financial value under IFRS

IFRS Core Basis : Each item is shown by value after adjustment for calculating core operating profit

*1 "P/L on business transfer" and "share of P/L of associates accounted for using equity method" included in "other operating income and expenses" are used for calculation for core operating profit.

*2 Non-recurring items including "other operating income and expenses" except for *1 items, and impairment losses, etc.

Financial Position / Cash Flows

Billions of yen

Financial Position	As of March 31, 2019	As of Sep. 30, 2019	Change
Assets	834.7	805.0	(29.7)
Non-current assets	461.4	422.4	(39.1)
Current assets	373.3	382.7	9.4
Liabilities	336.6	293.4	(43.2)
Non-current liabilities	138.4	100.2	(38.2)
Current liabilities	198.2	193.2	(5.0)
Equity	498.1	511.7	13.5
Shareholders' equity ratio	59.7%	63.6%	

Cash Flows	Q2FY2018	Q2FY2019	Change
Operating CF	7.0	31.8	24.8
Investment CF	(0.6)	10.8	11.5
Financial CF	(23.1)	(11.2)	11.9
Cash / Cash equivalents	137.6	(164.7)	27.1
Operating funds	152.4	186.3	33.9

【Assets】

Non-current

- PP&E 9.5
- Intangible assets (23.7)
- Deferred tax assets (16.8)

Current

- Other financial assets (20.0)
- Cash and cash equivalents 27.4

【Liabilities】

Non-current

- Other financial liabilities (34.5)

Current

- Provisions (5.9)

【Operating CF】

- Change in trade and other payables 16.1

【Investment CF】

- Change in short-term loan receivable 13.1

【Finance CF】

- Repayment of loan and redemption of bonds 13.5

Appendix (Financial Forecasts for FY2019)

Revenue of Major Products in Japan

Billions of yen

	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts
Trulicity® *	23.1	28.2	28.2	—
TRERIEF®	15.7	17.1	17.1	—
Equa®/EquMet®	—	16.0	16.0	—
REPLAGAL®	12.5	11.8	12.6	0.8
METGLUCO®	10.1	9.3	9.3	—
SUREPOST®	6.1	6.2	6.2	—
AmBisome®	4.0	3.9	3.9	—
LONASEN® Tape	—	1.8	1.8	—
Promoted products Total	71.5	94.3	95.1	0.8
AMLODIN®	9.1	7.5	7.5	—
LONASEN® tablet/powder	12.2	5.2	5.2	—
AIMIX®	8.2	3.7	3.7	—
PRORENAL®	4.0	3.3	3.3	—
GASMOTIN®	3.8	3.1	3.1	—
AG products	5.5	6.9	6.9	—
Others	15.0	11.0	11.2	0.2
Total	129.3	135.0	136.0	1.0

Revised forecast of REPLAGAL® based on its 1st half progress

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

Appendix (Financial Forecasts for FY2019)

Revenue of Major Products in North America & China

	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts	FY2018	FY2019 Previous Forecasts	FY2019 Revised Forecasts	Change from Previous Forecasts
North America	Million $				Billion yen			
LATUDA®	166.3	172.1	172.1	–	184.5	189.3	189.3	–
BROVANA®	30.4	30.0	30.0	–	33.7	33.0	33.0	–
APTIOM®	18.5	20.5	20.5	–	20.5	22.5	22.5	–
LONHALA® MAGNAIR®	1.3	3.8	3.8	–	1.4	4.2	4.2	–
XOPENEX®	4.2	3.7	3.7	–	4.6	4.1	4.1	–
Others	7.1	6.3	6.3	–	7.8	6.9	6.9	–
Total	227.7	236.4	236.4	–	252.5	260.0	260.0	–
China	Million RMB				Billion yen			
MEROPEN®	128.4	145.5	148.8	3.3	21.2	24.0	23.1	(0.9)
Others	21.2	26.6	27.3	0.7	3.5	4.3	4.2	(0.1)
Total	149.6	171.5	176.1	4.6	24.7	28.3	27.3	(1.0)

Unchanged in North America forecast

Revised downward in China due to FX impact though sales remained strong

FX rates: FY2018 Results : 1US$ = ¥ 110.9, 1RMB = ¥16.5
FY2019 Previous forecasts : 1US$ = ¥ 110.0, 1RMB = ¥16.5
FY2019 Revised forecasts : 1US$ = ¥ 110.0, 1RMB = ¥15.5

Appendix (Research and Development)

Development Pipeline (as of October 28, 2019)

Sumitomo Dainippon Pharma

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

Revisions since the announcement of July 2019 are shown in red.

Area	Phase 1		Phase 2	Phase 3	NDA submitted
Japan	**dasotraline** (ADHD) **SEP-363856** (Schizophrenia) **EPI-589** (ALS)	**alvocidib** (AML) **dubermatinib (TP-0903)** (Solid tumors)	**SEP-4199** (Bipolar I depression) **DSP-7888** (Solid tumors/ Hematologic malignancies) **Allo iPS cell-derived products** (Parkinson's disease) Investigator-initiated clinical study	**EPI-743** (Leigh syndrome) **napabucasin** (Colorectal cancer) **imeglimin** (Type 2 diabetes)	**lurasidone** (Schizophrenia/ Bipolar depression) **RETHIO®** (Conditioning treatment prior to autologous HSCT for malignant lymphoma)
U.S.	**DSP-6745** (Parkinson's disease psychosis) **SEP-378608** (Bipolar disorder) **DSP-3905** (Neuropathic pain) **SEP-378614** (Treatment resistant depression) **SEP-380135** (Agitation in Alzheimer's disease)	**alvocidib** (AML/MDS) **dubermatinib (TP-0903)** (Solid tumors/ Hematologic malignancies) **DSP-0509** (Solid tumors) **TP-0184** (Solid tumors) **DSP-0337** (Solid tumors) **TP-1287** (Solid tumors) **TP-3654** (Solid tumors/ Hematologic malignancies)	**EPI-589** (Parkinson's disease/ALS) **SEP-363856** (Parkinson's disease psychosis) **SEP-4199** (Bipolar I depression) **alvocidib** (r/r AML) **DSP-7888** (Solid tumors) **SB623** (Chronic stroke)	**SEP-363856** (Schizophrenia) **napabucasin** (Colorectal cancer)	**dasotraline** (BED) **dasotraline** (ADHD) Development strategy under consideration **apomorphine** (OFF episodes associated with Parkinson's disease) Received Complete Response Letter

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of October 28, 2019)

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status	
Chronic stroke (SB623)	SanBio	North America	Allo mesenchymal stem cell	**Completed Phase 2b study Development strategy and launch target under consideration**	
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	**In progress: clinical research Preparing to start clinical study (Japan)**	**Aim to launch in FY2022 ***
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	**In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)**	
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	**Preparing to start clinical research**	
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	**In progress: clinical research**	
Kidney failure	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	**In progress: pre-clinical study**	

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

Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows