At a glance

Annual Topics for Fiscal 2018

- ESG
- Business
- R&D

2018

4

- Announcement of FY 2017 financial results

5

- Phase 2 started with *DS-8201* for Non-small-cell lung cancer

6

- Awarded first place in the WWF* ranking of corporate global warming countermeasures in 23 Japanese pharmaceutical companies
- Included in the MSCI Japan Empowering Women (WIN) Select Index, one of the GPIF indices
- 13th Ordinary General Meeting of Shareholders
- Data presentation (*DS-8201* Phase 1, *U3-1402* Phase 1, and *pexidartinib* Phase 3) at the American Society of Clinical Oncology (ASCO)

7

- Announced the transfer of 41 long-listed products in Japan
- Announcement of Q1 FY 2018 financial results

8

9

- Selected for the DJSI "World Index" in the pharmaceutical sector for two consecutive years
- Entered into an agreement regarding a combined study of *DS-8201* plus *Keytruda* (Merck in the U.S.)

10

- Reconstruction support following the Great East Japan Earthquake: Coastal Forest Restoration Project (held 4 times in total)
- Announcement of Q2 FY 2018 financial results

11

- Development alliance with the Roche Group for a HER2 low-expressing companion diagnostics
- Filed NDA for *Quizartinib* (Europe, U.S.)

12

- Data presentation (*DS-8201* Phase 1 and *U3-1402* Phase 1) at the San Antonio Breast Cancer Symposium in the U.S.
- R&D Day

2019

1

- Antihyperlipidemic agent introduced to Europe
- Acquired manufacturing and sales approval in Japan for the pain treatment *Tarlige* and the antihypertensive agent *MINNEBRO*
- Announced the transfer of the Takatsuki plant
- Announcement of Q3 FY 2018 financial results
- Initiated pivotal phase 3 trial of *DS-8201* targeting HER2 low expressing breast cancer patients

2

- The Daiichi Sankyo Group Value Report 2018 received a Prize of Excellence in the 21st Nikkei Annual Report Awards
- Filed NDA for *Pexidartinib* (U.S.)

3

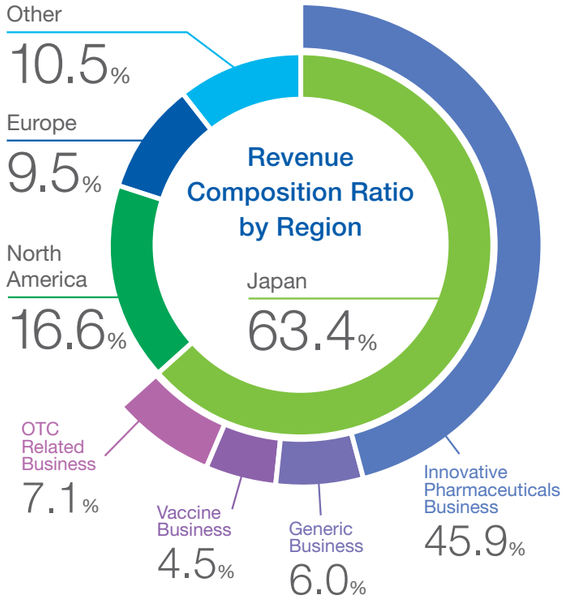
- Selected for the 2019 Certified Health and Productivity Management Organization Recognition Program (Large Enterprise Category)—White 500: for two consecutive years
- Global development and Commercialization Collaboration with AstraZeneca regarding *DS-8201*
- Accelerated BLA submission to U.S. FDA for *DS-8201* targeting breast cancer

* World Wide Fund for Nature

At a glance

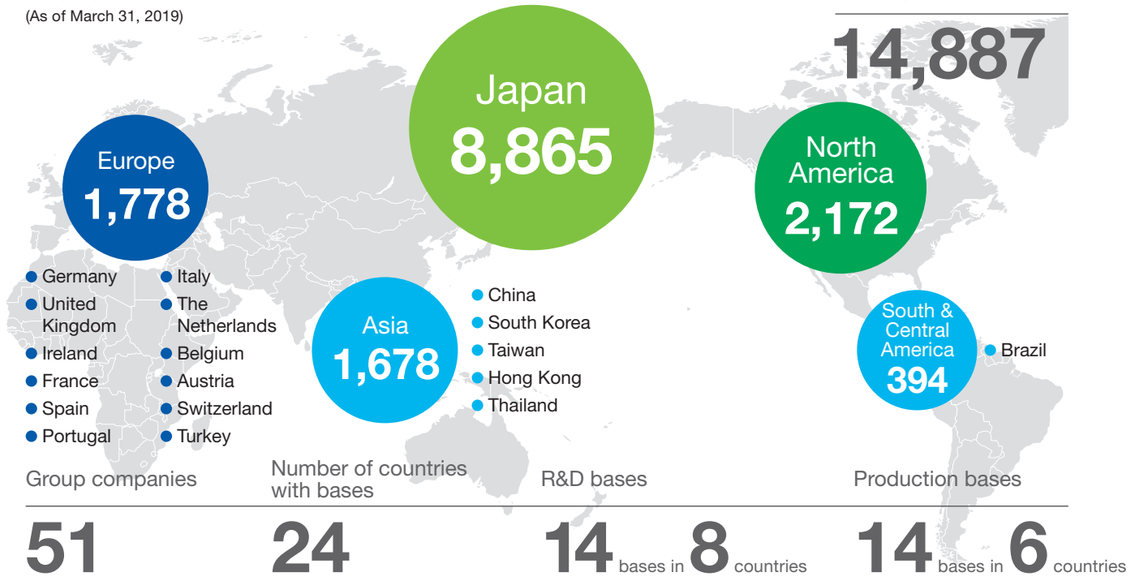
Summary of Financial Results in Fiscal 2018

		Ratio to revenue
Revenue	¥929.7 billion	—
Cost of sales	¥364.6 billion	39.2%
SG&A expenses	¥277.7 billion	29.9%
R&D expenses	¥203.7 billion	21.9%
Operating profit	¥83.7 billion	9.0%
Profit attributable to owners of the Company	¥93.4 billion	10.0%
ROE	7.8 %	
Liabilities	¥838.3 billion	
Total equity	¥1,249.7 billion	
Total assets	¥2,088.1 billion	
Equity ratio	59.8 %	



Employees and Bases

(As of March 31, 2019)



Key Products

Innovative Pharmaceuticals Business

Global

Anticoagulant
LIXIANA/SAVAYSA
Generic name *Edoxaban*

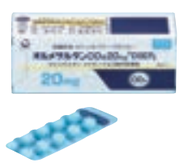
Global

Antihypertensive agent
Olmetec/Benicar
Generic name *Olmesartan*

Japan

Ulcer treatment
NEXIUM
Generic name *Esomeprazole*

Generic Business



Antihypertensive agent
Olmesartan (AG)

Vaccine Business

Seasonal influenza vaccine
Influenza HA Vaccine

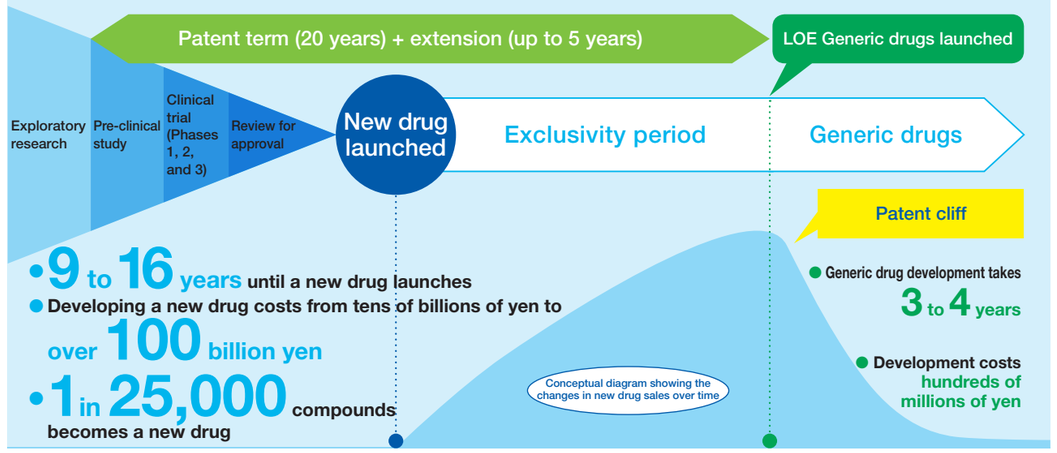
OTC Related Business

Antipyretic analgesics / Topical anti-inflammatory analgesics
Loxonin S

COLUMN: Pharmaceutical Company's Business Model

Launching a new drug requires an R&D period spanning some 9 to 16 years, as well as anything from tens of billions of yen to over 100 billion yen in costs. As such, it is said that the probability of creating a new drug is one in around 25 thousand compounds.

Once approved, new drugs enjoy an exclusivity period for as long as their patents are effective. After launch, sales of the new drug grow during the exclusivity period, but then fall dramatically once the exclusivity period ends and generic drugs are launched. This fall in sales at the loss of exclusivity (LOE) is called the "patent cliff." In order to overcome the patent cliff and achieve continuous growth, it is essential to continually develop and launch new drugs through R&D.



At a glance

At the Daiichi Sankyo Group, we build and expand pipelines while constantly placing focus on patients' unmet medical needs. The R&D Unit defines oncology as a priority area, and makes investments in a concentrated manner for three main pillars: the ADC (antibody drug conjugate) franchise, the AML (acute myeloid leukemia) franchise, and Breakthrough Science (creating first-in-class or best-in-class compounds with breakthrough mechanism of action or modality). In addition to this, we aim to create innovative medicines that change the SOC for rare diseases outside of the oncology field.

Major R&D Pipeline (In-House Development Projects, as of July 2019)

	Generic Name/Project Code Number/ MOA	Target Indication	Region	Stage	Partner
ADC Franchise	*[fam-] Trastuzumab deruxtecan/ DS-8201*/Anti-HER2-ADC	Breast cancer (HER2 positive post T-DM1)	JP/US/EU/ Asia	P2 P3	AstraZeneca
		Breast cancer (HER2 positive vs. T-DM1)	JP/US/EU/ Asia	P3	AstraZeneca
		Breast cancer (HER2 low expression)	JP/US/EU/ Asia	P3	AstraZeneca
		Gastric cancer (HER2 positive post trastuzumab)	JP/Asia	P2	AstraZeneca
		Colorectal cancer (HER2 expressing)	JP/US/EU	P2	AstraZeneca
		Non-small cell lung cancer (HER2 expressing/mutant)	JP/US/EU	P2	AstraZeneca
		Breast cancer, bladder cancer (combination with *nivolumab*)	US/EU	P1	BMS
	U3-1402/Anti-HER3-ADC	Breast cancer (HER3 expressing)	JP/US	P1	
		EGFR-mutant non-small cell lung cancer	JP/US	P1	
	DS-1062/Anti-TROP2-ADC	Non-small cell lung cancer	JP/US	P1	
AML Franchise	*Quizartinib*/FLT3 inhibitor	Acute myeloid leukemia (relapsed/refractory)	EU/Asia	Submitted	
		Acute myeloid leukemia (first-line)	JP/US/EU/ Asia	P3	
	Milademetan/DS-3032/MDM2 inhibitor	Solid tumor (lyposarcoma)	JP/US	P1	
		Acute myeloid leukemia	JP/US	P1	
	Valemetostat/DS-3201/EZH1/2 inhibitor	Peripheral T-cell lymphomas	JP/US	P1	
		Adult T-cell leukemia/lymphoma	JP	P1	
		Acute myeloid leukemia, acute lymphocytic leukemia	US	P1	
		Small cell lung cancer	US	P1	
	PLX2853/BET inhibitor	Acute myeloid leukemia	US	P1	
	Axicabtagene ciloleucel/ Axi-Cel®/Anti-CD19 CAR-T cells	B-cell lymphoma	JP	P2	Kite/Gilead
Breakthrough Science	*Pexidartinib*/CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	US/EU	Submitted	
	DS-1647(G47Δ)/Oncolytic HSV-1	Malignant glioma	JP	P2	
	DS-1001/ mutant IDH1 inhibitor	Glioma	JP	P1	
	DS-1205/AXL inhibitor	Non-small cell lung cancer (combination with *gefitinib*)	JP	P1	
		Non-small cell lung cancer (combination with *osimertinib*)	Asia	P1	
Specialty medicine	*Edoxaban*/Factor Xa inhibitor	Atrial fibrillation in very elderly patients	JP	P3/LCM*	
	Prasugrel/Anti-platelet agent	Ischemic stroke	JP	P3/LCM*	Ube Industries
	Esaxerenone/MR antagonist	Diabetic nephropathy	JP	P3/LCM*	Exelixis
	DS-1040/TAFIa inhibitor	Acute ischemic stroke, acute pulmonary thromboembolism	JP/US/EU	P1	
	Mirogabalin/α2δ ligand	Central neuropathic pain	JP/Asia	P3/LCM*	
	DS-5141/ENA oligonucleotide	Duchenne type muscular dystrophy	JP	P2	
	DS-1211/TNAP inhibitor	Prevention of ectopic calcification diseases	US	P1	Stanford Burnham Prebys Medical Discovery Insisute
Vaccines	*VN-0107/MEDI3250*/Nasal cavity spray live attenuated influenza vaccine	Prevention of seasonal influenza	JP	Submitted	AstraZeneca/ MedImmune
	VN-0105/DPT-IPV/Hib	Prevention of pertussis, diphtheria, tetanus, poliomyelitis and Hib infection	JP	P3	Sanofi
	VN-0102/JVC-001/ Measles-Mumps-Rubella vaccine	Prevention of Measles, Mumps and Rubella	JP	P2	

* Life Cycle Management

: Projects in the field of oncology which are planned for application based on the results of Phase 2 trials

: Projects that have been granted SAKIGAKE Designation (Japan), Breakthrough Therapy Designation (FDA), or Orphan Drug Designation

Clinical trial stages

P1: Phase 1	Conduct trials on a small group of healthy volunteers to assess safety and pharmacokinetics of drugs (patient volunteers may be included depending on the tests)
P2: Phase 2	Conduct trials on a small group of patient volunteers to assess safety, efficacy, dosage and administration regimen
P3: Phase 3	Conduct trials on a large number of patient volunteers to assess safety and efficacy in comparison with existing drugs