Passion for Innovation. Compassion for Patients.™



Top Management Presentation Financial Results for FY2016 Q3 (April 1 - December 31, 2016)

DAIICHI SANKYO CO., LTD

George Nakayama President and CEO

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Agenda



FY2016 Q3 Financial Results

FY2016 Revised Consolidated Forecast

Management Updates

- Grow Edoxaban
- Maximize Sales Potential of Injectafer

R&D Updates

- Strategic Partnership for Cellular Therapy Pipeline with Kite Pharma
- ADC Franchise Enhancement



FY2016 Q3 Financial Results

Overview of FY2016 Q3 Results



(JPY Bn)

	FY2015 Q3 YTD Results	FY2016 Q3 YTD Results	YoY
Revenue	758.6	734.4	-3.2% -24.2
Cost of Sales	237.7	241.7	+4.0
SG&A Expenses	232.3	220.5	-11.8
R&D Expenses	138.1	143.5	+5.4
Operating Profit	150.4	128.7	<u>-14.4%</u> -21.7
Profit before Tax	145.4	132.4	-13.0
Profit attributable to owners of the Company	110.7	88.2	-20.4%
Currency USD/JPY	121.70	106.68	-15.02
Rate EUR/JPY	134.37	118.09	-16.28

Revenue



Decreased by 24.2 Bn JPY (Increased by 16.6 Bn JPY excl. forex impact)



Positive Factors Negative Factors

* Increase 4.4 Bn JPY excluding negative impact of 7.0 Bn JPY in Venezuela **Forex impact USD: -25.8, EUR: -7.6, ASCA: -7.5

Operating Profit



Decreased by 21.7 Bn JPY

(Increased by 1.8 Bn JPY excl. forex impact and special items)



Special Items



(JPY Bn)

	FY2015 Q3 YTD Resu	lts	FY2016 Q3 YTD R	esults	YoY
Cost of Sales	Gain on sales of subsidiary Gain on sales of fixed assets	-2.4 -1.1		-	+3.5
SG&A Expenses	Restructuring costs in US Gain on sales of fixed assets	6.1 -8.2	Restructuring costs	10.6	+12.7
R&D Expenses	Restructuring costs in R&D	0.3		-	-0.3
Total		-5.3		10.6	+15.9

-: Cost decrease items

Profit Attributable to Owners of the Company





*Excl. increase and decrease of share of profit or loss of investments accounted for using the equity method and non-controlling interests

Major Business Units



(JPY Bn)

	FY2015 Q3 YTD Results	FY2016 Q3 YTD Results	ΥοΥ	vs. Forecast* (%)
Japan	377.5	390.2	+12.8	77.3%
Daiichi Sankyo Healthcare	39.9	51.9	+12.0	78.6%
Daiichi Sankyo Inc.	145.5	115.8	-29.7	80.4%
Olmesartan	88.4	60.9	-27.5	84.6%
Welchol	37.7	32.2	-5.5	78.5%
Effient	16.4	16.5	+0.1	-
Savaysa	0.3	1.4	+1.1	70.4%
Movantik	1.3	2.9	+1.6	-
Luitpold	69.0	64.3	-4.8	73.0%
Venofer	24.4	21.2	-3.1	75.9%
Injectafer	12.9	17.2	+4.3	71.7%
Daiichi Sankyo Europe	58.1	54.4	-3.7	77.7%
Olmesartan	44.4	34.6	-9.7	82.5%
Efient	3.3	6.1	+2.8	-
Lixiana	0.7	6.1	+5.5	68.2%
Asia, South and Central America (ASCA)	62.6	52.5	-10.1	73.9%

* Calculated based on new forecast updated in Jan.

Major Products in Japan



(JPY Bn)

		FY2015 Q3 YTD Results	FY2016 Q3 YTD Results	ΥοΥ	vs. Forecast* (%)
Nexium	ulcer treatment	62.0	67.4	+5.5	81.2%
Olmetec	antihypertensive agent	60.5	54.1	-6.4	78.4%
Memary	Alzheimer's disease treatment	32.7	36.3	+3.7	74.2%
Loxonin	anti-inflammatory analgesic	38.2	29.3	-8.9	79.2%
Tenelia	type 2 diabetes mellitus inhibitor	11.9	19.7	+7.8	75.7%
Lixiana	anticoagulant agent	9.6	17.9	+8.3	71.6%
Rezaltas	antihypertensive agent	14.1	13.6	-0.5	75.6%
Pralia	treatment for osteoporosis	9.0	13.3	+4.3	78.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	9.4	10.6	+1.3	81.6%
Inavir	anti-influenza treatment	2.5	7.9	+5.4	56.5%
Cravit	synthetic antibacterial agent	14.6	12.0	-2.6	85.8%
Omnipaque	contrast medium	13.2	11.1	-2.1	85.5%
Urief	treatment for dysuria	9.0	8.9	-0.2	80.8%
Artist	treatment for hypertension, angina pectoris and chronic heart failure	12.1	8.5	-3.6	77.3%
Mevalotin	antihyperlipidemic agent	10.8	8.3	-2.5	82.8%
Efient	antiplatelet agent	3.3	7.8	+4.6	71.2%

* Calculated based on new forecast updated in Jan.



FY2016 Revised Consolidated Forecast

FY2016 Revised Consolidated Forecast



			(JPY Bn)	
	FY2016 Forecast (as of Oct.)	FY2016 Forecast (as of Jan.)	vs. Forecast (as of Oct.)	Major factors -Forex impact +13.0 -Japan +6.0
Revenue	920.0	950.0	+30.0	-Overseas +9.0
Cost of Sales	307.0	318.0	+11.0	 Major factors Forex impact +3.0 Increase by increase in
SG&A Expenses	313.0	315.0	+2.0	revenue +8.0
R&D Expenses	200.0	207.0	+7.0	<u>Major factors</u> -Forex impact +5.0
Operating Profit	100.0	110.0	+10.0	-Efficient execution of expenses -3.0
Profit before Tax	100.0	110.0	+10.0	Major factors
Profit attributable to owners of the Company	65.0	70.0	+5.0	-Acceleration of RD +3.0
Currency Rate EUR/JPY	102.67 114.11	107.51 118.57	Assumption of curre USD/JPY : 110, EUI	ncy rate for Q4 R/JPY:120



Grow Edoxaban



Edoxaban: Japan



The DOAC market in Japan is expanding steadily. The sales market share of Lixiana has reached 14.3% (CY base).



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Edoxaban: Japan





Edoxaban: Germany and South Korea



Steady uptake of sales share after launch



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Maximize Sales Potential of Injectafer

Untapped Potential of Injectafer



Injectafer* has grown steadily in the US IV Iron market. However there is still potential for further growth.



*Injectafer is not indicated for patients who are dialysis dependent . Copyright © 2017 QuintilesIMS. Reprinted with permission Source: IMS National Sales Perspectives Nov. 2016 (includes all US IV Iron sales in all channels including dialysis chains)

Former Design



In IDA* treatment, market beyond Oncologist and Hem/Onc. has not been tapped since LPI focused its limited resources on the area of Oncologist and Hem/Onc.



New Design as of Jan. 2017



LPI sales team for Injectafer has become DSI employees. DSI/LPI formed a united sales team for Injectafer to accelerate growth.



Additional Effect on DS Group's US Business by United Sales Team for Injectafer



United sales team for Injectafer

To accelerate growth beyond oncologist and hem/onc

Leverage DSI's existing sales & marketing infrastructure for Injectafer

Establish a foundation for DSI's oncology business leveraging LPI sales team's experience with oncologists and hem/onc.

Maximize Daiichi Sankyo Group's US business



Strategic Partnership for Cellular Therapy Pipeline with Kite Pharma

Strategic Partnership for Cellular Therapy Pipeline with Kite Pharma



Kite Pharma, Inc. (Kite)

- Located in California, US, Established in 2009, NASDAQ IPO in 2014
- > One of the leading development companies for engineered T-cell* therapy in oncology
 - * Chimera Antigen Receptor T-cell: CAR-T T-cell Receptor T-cell: TCR-T
- Strong relationship with key academic research organizations such as the National Cancer Institute of US and venture companies

Scope of the collaboration

- Products
 - KTE-C19 (CD19 Chimera Antigen Receptor T cell) Exclusive license for clinical development, manufacturing and commercialization in Japan. Technology transfer to DS to take advantage of Kite's advanced T cell manufacturing technology
 - Kite's lead product candidate will be submitted for review in the United States and is currently in clinical development for future indications
 Optional licensing right for additional products over the next three years
- Territory : Japan

Advantage of collaboration

- > To enrich innovative oncology pipeline
- To take opportunity to enhance research and development capabilities and build up business infrastructure for the engineered T-cell therapy

Chimera Antigen Receptor T-cell: CAR-T





Production timeline of engineered T-cell



Employing refined and optimized process, therapeutic T-cell is available within 16-18 days with high probability of production success (97%)



	~1 day	14 ~ 16 days		~1 day	
Medical center		Cell engineering facility			Medical center
Selection of patients Collection of white blood cells	Transportation	Cell engineering	Quality Gontrol	Transportation	Preparation Infusion Observation

* A medical technology in which the blood of a person is passed through an apparatus that separates out one particular constituent and returns the remainder to the circulation.

KTE-C19



Development Status Several clinical studies including non-Hodgkin's lymphoma are on-going

- US: Breakthrough Therapy Designation (DLBCL¹/TFL²/PMBCL³) Rolling BLA submission for refractory aggressive non-Hodgkin lymophoma was initiated in Dec 2016 and will be completed in CY2017 Q1
- EU : PRIME (PRIority MEdicines) Designation (DLBCL)

Diffuse large B-cell lymphoma
 Transformed follicular lymphoma

3. Primary mediastinal B-cell lymphoma

Anticipate high probability of development success
 Potential to be a First-in-Class CAR-T product

(Reference) Major companies having CD19 CAR-T pipeline in clinic (Source:company web site) US/EU: Novartis phase 2 Juno/Celgene phase 2 Japan: Novartis phase 2

TAKARA-bio phase 1/2 IND submission

KTE-C19



ZUMA-1 Phase 2 Interim Analysis (ASH 2016)

- Chemorefractory patients with DLBCL, TFL, PMBCL
- 76 % of patients with DLBCL achieved objective response (p < 0.0001) and 47 % complete remissions (CR) at pre-specified interim analysis
- Adverse events in patients with a minimum one month follow up
 - ➢ Grade ≥3 Cytokine Release Syndrome 13%
 - ➢ Grade ≥3 Neurologic Events 29%

Generally reversible

Best Overall Response in patients with ≥3 month follow-up						
Subgroup	Ν	ORR*	CR			
DLBCL	51	76%	47%			
TFL/PMBCL	11	91%	73%			
Total 62 79% 52%						



ADC franchise enhancement

ADC franchise enhancement: U3-1402 HER3-ADC





ADC franchise enhancement: U3-1402 HER3-ADC

- 1. **HER3** overexpression is reported in breast cancer (BC) and correlated with poor prognosis* → Unmet Medical Needs for BC with HER3 overexpression
- 2. **Potential anti-tumor activity** in non-clinical study
 - U3-1402 showed tumor regression in BC xenograft models including hormone receptor positive and triple negative breast cancer which does not express HER2. (Right figures)

mean \pm SE ¹⁰⁰⁰ 500 U3-1402 U3-1402 0 10 20 7 21 14 Days after tumor inoculation

Patient-derived HER3-positive (HER2-

negative) Xenograft models



0

0

- TNBC model -



30

ADC franchise enhancement: U3-1402 HER3-ADC



- Initiated Phase 1/2 study in Japan
 - Research participants
 - HER3-positive advanced/unresectable metastatic breast cancer, treated with standard treatment, or no standard treatment is available
 - Study design (estimated enrollment: 80)
 - Dose escalation part: safety, tolerability, determination of maximum tolerated dose
 - Dose finding part: safety efficacy, determination of recommended dose for next phase
 - ✓ Phase 2 part: safety and efficacy at the recommended dose
 - Location : Japan (US, in preparation)
 - Top Line Results : FY2018 Q4 anticipated

NSCLC with EGFR mutation

Clinical study for second- or third-line treatment of is in preparation possibly to start in FY2017 Q1

Major R&D milestone events



Project	Indication/Study	Event	Target
CL-108	Pain/Opioid-induced nausea and vomiting (US)	Approval	PDUFA date Jan. 31, 2017
Denosumab	Rheumatoid arthritis (JP)	Approval	FY2017
CHS-0214 (etanercept BS)	Rheumatoid arthritis (JP)	NDA	FY2016
Tivantinib	METIV·HCC Hepatocellular carcinoma Phase 3 study (US/EU)	TLR	CY2017 H1
Mirogabalin	Fibromyalgia Phase 3 study (US/EU)	TLR	CY2017 H1
Quizartinib	QuANTUM-R AML 2 nd line treatment Phase 3 study (US/EU/Asia)	DMC interim analysis	CY2017 H1
Pexidartinib	Tenosynovial giant cell tumor (US/EU)	TLR	CY2017 H1
DS-8500	Type 2 Diabetes Phase 2b study (JP) (US)	TLR	FY2016 Q4 FY2017 H1

Red: new information

*TLR: Top Line Results

Reference



Major R&D Pipeline

As of January 2017



Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Oncology	 DS-3032 (US/JP) DS-8895 (JP) (MDM2 inhibitor) PLX7486 (US) (FMS / TRK inhibitor) PLX8394 (US) (BRF inhibitor) DS-5573 (JP) (Anti-B7-H3 antibody) DS-6051 (US/JP) DS-8201 (JP/US) (Anti-HER2 ADC) PLX9486 (US) (KIT inhibitor) DS-3201 (JP) (EZH1/2 inhibitor) DS-3201 (JP) (CSF-1R inhibitor) PLX73086 (US) (CSF-1R inhibitor) PLX51107 (US) (BRD4 inhibitor) 	 Patritumab (EU) (U3-1287 / Anti-HER3 antibody) Pexidartinib (US) (PLX3397 / CSF-1R/KIT/FLT3-ITD inhibitor) DS-1647 (JP) (Glioblastoma / G47Δ virus) 	 Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor) Denosumab (JP) (AMG 162 / Breast cancer adjuvant / Anti-RANKL antibody) Nimotuzumab (JP) (DE-766 / Gastric cancer / Anti-EGFR antibody) Vemurafenib (US/EU) (PLX4032 / Melanoma Adjuvant / BRAF inhibitor) Quizartinib (US/EU/Asia) (AC220 / AML-2nd / FLT3-ITD inhibitor) Quizartinib (US/EU/Asia) (AC220 / AML-1st / FLT3-ITD inhibitor) Pexidartinib (US/EU) (PLX3397 / TGCT / CSF-1R/KIT/FLT3-ITD inhibitor) 	
Cardiovascular- Metabolics	 DS-1040 (Acute ischemic stroke / TAFIa inhibitor) DS-2330 (Hyperphosphatemia) DS-9231/TS23 (Thrombosis / α2-PI inactivating antibody) DS-9001 (Dyslipidemia / Anti-PCSK9 Anticalin-Albumod) 	 Esaxerenone (JP) (CS-3150 / DM nephropathy / MR antagonist) DS-8500 (JP/US) (Diabetes / GPR119 agonist) 	 Edoxaban (JP) (DU-176b / AF / FXa inhibitor) Prasugrel (JP) (CS-747 / Ischemic stroke / Antiplatelet agent) Esaxerenone (JP) (CS-3150 / Hypertension / MR antagonist) 	 Edoxaban (ASCA etc.) (DU-176b / AF / FXa inhibitor) Edoxaban (ASCA etc.) (DU-176b / VTE / FXa inhibitor)
Others	 DS-1971 (Chronic pain) DS-1501 (Osteoporosis / Anti-Siglec-15 antibody) DS-7080 (US) (AMD / Angiogenesis inhibitor) DS-2969 (<i>Clostridium difficile</i> infection /GyrB inhibitor) DS-5141 (JP) (DMD / ENA oligonucleotide) VN-0102/JVC-001 (JP) (MMR vaccine) 	Laninamivir (US/EU) (CS-8958 / Anti-influenza / out-licensing with Biota)	 Mirogabalin (US/EU) (DS-5565 / Fibromyalgia / α2δ ligand) Mirogabalin (JP/Asia) (DS-5565 / DPNP/ α2δ ligand) Mirogabalin (JP/Asia) (DS-5565 / PHN / α2δ ligand) Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid μ- receptor regulator) <injection></injection> CHS-0214 (JP) (Etanercept BS / Rheumatoid arthritis / TNFα inhibitor) VN-0105 (JP) (DPT-IPV / Hib vaccine) Laninamivir (JP) (CS-8958 / Anti-influenza / nebulizer) 	 Hydromorphone (JP) (DS-7113 / Cancer pain / Opioid µ- receptor agonist)<oral></oral> CL-108 (US) (Acute pain / Opioid µ-receptor agonist) Intradermal Seasonal Influenza Vaccine (JP) (VN-00 / prefilled i.d. vaccine for seasonal flu) VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine) Denosumab (JP) (AMG 162 / Rheumatoid arthritis / Anti-RANKL antibody)

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