Top Management Presentation
Results for Q2 FY2015 (April 1 – September 30, 2015)

DAIICHI SANKYO CO., LTD

Joji Nakayama
President and CEO

November 2, 2015
Today’s Topics

◆ FY2015 Q2 YTD Results

◆ FY2015 revised consolidated forecast

◆ Major management topics
  ● Edoxaban business update
  ● Trasformation of Daiichi Sankyo Inc.
  ● R&D update

◆ Luitpold business update
FY2015 Q2 YTD Results
## Overview of FY2015 Q2 YTD Results (JPY Bn)

<table>
<thead>
<tr>
<th></th>
<th>FY2014 Q2 YTD Results *1</th>
<th>FY2015 Q2 YTD Results</th>
<th>YoY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>429.6</td>
<td>478.8</td>
<td>+49.2</td>
</tr>
<tr>
<td>Cost of Sales</td>
<td>130.8</td>
<td>148.9</td>
<td>+18.1</td>
</tr>
<tr>
<td>SG&amp;A Expenses</td>
<td>153.7</td>
<td>144.5</td>
<td>-9.2</td>
</tr>
<tr>
<td>R&amp;D Expenses</td>
<td>84.9</td>
<td>88.4</td>
<td>+3.5</td>
</tr>
<tr>
<td>Operating Profit</td>
<td>60.2</td>
<td>97.0</td>
<td>+36.8</td>
</tr>
<tr>
<td>Profit before tax</td>
<td>62.2</td>
<td>90.8</td>
<td>+28.6</td>
</tr>
<tr>
<td>Profit attributable</td>
<td>36.7</td>
<td>70.7</td>
<td>+34.0</td>
</tr>
<tr>
<td>of the Company</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Currency Rate</th>
<th>USD/JPY</th>
<th>EUR/JPY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>103.05</td>
<td>138.91</td>
</tr>
<tr>
<td></td>
<td>121.80</td>
<td>135.07</td>
</tr>
<tr>
<td></td>
<td>+18.75</td>
<td>-3.84</td>
</tr>
</tbody>
</table>

*1 FY2014 Q2 Results have been restated and indicated as only the values for continuing operations excluding Ranbaxy.
Revenue

Increased by 49.2 JPY Bn
Decline in Daiichi Sankyo Europe
offsetted by growth of Japan, Luitpold and ASCA with Forex

Japan
Positive:
- Nexium: +6.6
- Memory: +3.7
- Teneria: +2.0
- Efient: +1.5
- Ranmark: +1.2

Negative:
- Cravit: -5.2
- Olmetec: -1.6
- Artist: -1.5
- Mevalotin: -1.3

Global (excl. Forex Impact)
Daiichi Sankyo Inc.:
- Olmesartan: +1.5
- Welchol: -1.3
- Effient: +0.5
- Movantic: +0.5

Luitpold:
- Venofer: -0.7
- Injectafer: +3.7

Daiichi Sankyo Europe:
- Olmesartan: -4.3
- Lixiana: +0.2

ASCA:
- Olmesartan: +1.9

FY2014 Results: 429.6
FY2015 Results: 478.8

Daiichi Sankyo, Inc. (US)
Luitpold (US)
Daiichi Sankyo Europe
Asia, South and Central America (ASCA)
Forex Impact

Positive Factors
Negative Factors
Increased by 36.8 JPY Bn due to increased revenue, decreased R&D and SG&A expenses and special items absorbing increased cost of sales and forex impact.
Profit attributable to owners of the Company

Increased by 34.0 JPY Bn
due to increased operating profit
Expenses relating to the sales of the Sun Pharma shares is booked as financial expenses

FY2014 Results: 36.7
Operating Profit: 36.8
Financial Income / Expenses: 8.6
Share of loss of investments: 0.5
Income Taxes etc.: 5.6
FY2015 Results: 70.7

Financial Income / Expenses +8.6
Expenses relating to sale of Sun Pharma shares etc.

Income Taxes etc. -5.6
## Major business units

<table>
<thead>
<tr>
<th></th>
<th>FY2014 Q2 YTD Results</th>
<th>FY2015 Q2 YTD Results</th>
<th>YoY</th>
<th>vs. Revised Forecast (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Japan</strong></td>
<td>222.6</td>
<td>227.8</td>
<td>+5.2</td>
<td>46.4%</td>
</tr>
<tr>
<td>Daiichi Sankyo Healthcare</td>
<td>22.7</td>
<td>24.6</td>
<td>+2.0</td>
<td>50.3%</td>
</tr>
<tr>
<td>Daiichi Sankyo Inc.</td>
<td>78.1</td>
<td>93.4</td>
<td>+15.2</td>
<td>53.0%</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>47.2</td>
<td>57.1</td>
<td>+9.9</td>
<td>56.6%</td>
</tr>
<tr>
<td>Welchol</td>
<td>21.8</td>
<td>24.2</td>
<td>+2.4</td>
<td>51.5%</td>
</tr>
<tr>
<td>Efient</td>
<td>8.5</td>
<td>10.6</td>
<td>+2.1</td>
<td>-</td>
</tr>
<tr>
<td>Savaysa</td>
<td>-</td>
<td>-0.2</td>
<td>-0.2</td>
<td>-</td>
</tr>
<tr>
<td>Movantik</td>
<td>-</td>
<td>0.6</td>
<td>+0.6</td>
<td>-</td>
</tr>
<tr>
<td><strong>Luitpold</strong></td>
<td>26.8</td>
<td>46.4</td>
<td>+19.6</td>
<td>54.0%</td>
</tr>
<tr>
<td>Venofer</td>
<td>14.2</td>
<td>16.0</td>
<td>+1.8</td>
<td>53.4%</td>
</tr>
<tr>
<td>Injectafer</td>
<td>2.9</td>
<td>7.9</td>
<td>+5.0</td>
<td>46.4%</td>
</tr>
<tr>
<td><strong>Daiichi Sankyo Europe</strong></td>
<td>44.5</td>
<td>39.2</td>
<td>-5.3</td>
<td>51.6%</td>
</tr>
<tr>
<td>Olmesartan</td>
<td>35.4</td>
<td>30.2</td>
<td>-5.2</td>
<td>52.1%</td>
</tr>
<tr>
<td>Efient</td>
<td>2.3</td>
<td>2.2</td>
<td>-0.1</td>
<td>-</td>
</tr>
<tr>
<td>Lixiana</td>
<td>-</td>
<td>0.2</td>
<td>+0.2</td>
<td>9.4%</td>
</tr>
<tr>
<td><strong>Asia, South and Central America (ASCA)</strong></td>
<td>30.0</td>
<td>42.7</td>
<td>+12.8</td>
<td>48.5%</td>
</tr>
</tbody>
</table>
# Major products in Japan

<table>
<thead>
<tr>
<th>Product</th>
<th>Category</th>
<th>FY2014 Q2 YTD Results</th>
<th>FY2015 Q2 YTD Results</th>
<th>YoY</th>
<th>vs. Revised Forecast (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmetec</td>
<td>anti-hypertension</td>
<td>37.8</td>
<td>36.2</td>
<td>-1.6</td>
<td>45.8%</td>
</tr>
<tr>
<td>Nexium</td>
<td>anti-ulcer (Proton Pump Inhibitor)</td>
<td>32.1</td>
<td>38.7</td>
<td>+6.6</td>
<td>50.2%</td>
</tr>
<tr>
<td>Memary</td>
<td>treatment for Alzheimer</td>
<td>16.8</td>
<td>20.5</td>
<td>+3.7</td>
<td>43.6%</td>
</tr>
<tr>
<td>Loxonin</td>
<td>analgesic and anti-inflammatory</td>
<td>25.4</td>
<td>24.4</td>
<td>-1.0</td>
<td>55.4%</td>
</tr>
<tr>
<td>Cravit</td>
<td>antibacterial</td>
<td>14.2</td>
<td>9.0</td>
<td>-5.2</td>
<td>52.9%</td>
</tr>
<tr>
<td>Rezaltas</td>
<td>anti-hypertension</td>
<td>9.0</td>
<td>8.9</td>
<td>-0.1</td>
<td>46.9%</td>
</tr>
<tr>
<td>Artist</td>
<td>Treatment for hypertension, angina pectoris and chronic heart failure</td>
<td>9.4</td>
<td>7.9</td>
<td>-1.5</td>
<td>46.4%</td>
</tr>
<tr>
<td>Omnipaque</td>
<td>contrast medium</td>
<td>8.6</td>
<td>8.5</td>
<td>-0.1</td>
<td>49.7%</td>
</tr>
<tr>
<td>Mevalotin</td>
<td>anti-hyperlipidemia</td>
<td>8.3</td>
<td>7.0</td>
<td>-1.3</td>
<td>45.2%</td>
</tr>
<tr>
<td>Ranmark</td>
<td>treatment for bone metastasis</td>
<td>4.7</td>
<td>5.9</td>
<td>+1.2</td>
<td>51.8%</td>
</tr>
<tr>
<td>Urief</td>
<td>treatment for dysuria</td>
<td>5.6</td>
<td>5.7</td>
<td>+0.1</td>
<td>51.8%</td>
</tr>
<tr>
<td>Pralia</td>
<td>osteoporosis</td>
<td>3.0</td>
<td>5.4</td>
<td>+2.4</td>
<td>48.8%</td>
</tr>
<tr>
<td>Lixiana</td>
<td>anticoagulant</td>
<td>0.2</td>
<td>5.4</td>
<td>+5.2</td>
<td>45.2%</td>
</tr>
<tr>
<td>Efient</td>
<td>antiplatelet</td>
<td>0.3</td>
<td>1.8</td>
<td>+1.5</td>
<td>35.3%</td>
</tr>
<tr>
<td>Teneria</td>
<td>treatment for type 2 diabetes</td>
<td>3.3</td>
<td>5.3</td>
<td>+2.0</td>
<td>-</td>
</tr>
</tbody>
</table>
FY2015 revised consolidated forecast
# FY2015 revised consolidated forecast

<table>
<thead>
<tr>
<th></th>
<th>FY 2015 Forecast (as of Jul.)</th>
<th>FY 2015 Revised Forecast (as of Oct.)</th>
<th>vs. Forecast (as of Jul.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>950.0</td>
<td>980.0</td>
<td>+30.0</td>
</tr>
<tr>
<td>Cost of Sales</td>
<td>302.0</td>
<td>314.0</td>
<td>+12.0</td>
</tr>
<tr>
<td>SG&amp;A Expenses</td>
<td>338.0</td>
<td>354.0</td>
<td>+16.0</td>
</tr>
<tr>
<td>R&amp;D Expenses</td>
<td>190.0</td>
<td>192.0</td>
<td>+2.0</td>
</tr>
<tr>
<td>Operating Profit</td>
<td>120.0</td>
<td>120.0</td>
<td>0</td>
</tr>
<tr>
<td>Profit before tax</td>
<td>115.0</td>
<td>115.0</td>
<td>0</td>
</tr>
<tr>
<td>Profit attributable to owners of the Company</td>
<td>75.0</td>
<td>75.0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Major factors**
- Delay of entry of Welchol GEs
- Good performance of products of Luitpold and Nexium
- Increase of COGs by increase of revenue
- Expenses relating to DSI transformation and others

<table>
<thead>
<tr>
<th>Currency Rate</th>
<th>USD/JPY</th>
<th>EUR/JPY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>120.34</td>
<td>131.04</td>
</tr>
<tr>
<td></td>
<td>120.90</td>
<td>132.53</td>
</tr>
</tbody>
</table>

Forecast for Q3 and Q4: USD/JPY: 120  EUR/JPY: 130
Major management topics

- Edoxaban business update
- Transformation of Daiichi Sankyo, Inc.
- R&D update
Edoxaban business update: Japan (Lixiana)

◆ Sales growing steadily

- Approved and launched for DVT-OS in 2011
- Approved for AF and VTE in Sep 2014
- Sales growing steadily for FY 2015
  (5.4 JPY Bn for Q2 YTD due to in VTE especially)
- Revised sales forecast in Jul 2015: 5.0 → 11.0 JPY Bn

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Edoxaban business update: US (Savaysa)

- Approved (Jan), Launched (Feb)
  - AF: indicated only for patients with CrCL ≤95 mL/min
  - VTE: without limitation of use

- Negotiations with payers are on-going
  - Listed on the formularies of a few Medicare part D plans in 2016 in the non-preferred brand position. Negotiations for 2017 are ongoing.
  - Obtained broader access on commercial plans mostly on a non-preferred basis.
Edoxaban business update: EU (Lixiana)

◆ Making good start in each country
  ● Approved by EC with no limitation of use (Jun)
  ● Launched in Switzerland (May), UK (Jul), Germany (Aug) and Ireland (Sep)
  ● Recommendation for VTE (Aug) and AF (Sep) by NICE
  ● NOAC market is growing steadily in EU countries (About 30% in total patients, about 50% in new patients on DOT basis)
Edoxaban business update: other regions

- Approved in Korea (Aug)
- Filed NDA in China, Hong Kong, Taiwan, Thailand, Australia, Canada and Brazil
Edoxaban business update: LCM others

◆ LCM & others

● ENSURE AF (Cardioversion) - - NVAF undergoing electrical cardioversion, initiated in Mar 2014

● The Hokusai-VTE Cancer - - VTE associated with cancer, initiated in Jun 2015

● ETNA - - To collect real-world’s safety and efficacy date in the EU, Japan and certain ASCA countries

● Reversal agents - - Developing with the below companies
  - CSL Behring: 4F-PCC, Beriplex® / Kcentra™
  - Portola : andexanet alfa(PRT4445; biologics)
  - Perosphere: ciraparantag(PER977; small molecule)
Major management topics

- Edoxaban business update
- Transformation of Daiichi Sankyo, Inc.
- R&D update
DSI: Shift in product portfolio

With the LOE of Benicar and Welchol etc., DSI will transition from a maturing primary care product portfolio to a differentiated specialty portfolio centering on Pain and Oncology.

New Product Launches

- FY18: CL-108
- FY18: Mirogabalin
- FY18: Quizartinib
- FY18: Tivantinib
- FY18: Patritumab
- FY18: Pexidartinib

DSI: Shift in product portfolio

With the LOE of Benicar and Welchol etc., DSI will transition from a maturing primary care product portfolio to a differentiated specialty portfolio centering on Pain and Oncology.

New products

- CL-108
- Mirogabalin
- Quizartinib
- Tivantinib
- Patritumab
- Pexidartinib

Current products

- Benicar (olmesartan medoxomil)
- Welchol (colestipol HCl)
- Effient (prasugrel tablets)
- Zelboraf (vemurafenib)
Transform DSI (U.S.) to a specialist-driven company

◆ Transform DSI to a company with;
  ● Differentiated specialty portfolio
  ● Long-term opportunities in cardiovascular, pain, and oncology markets
  ● Agile, efficient, customer-centric operating model

◆ To prepare for these opportunities, DSI will streamline SG&A structure to be even more lean.
  ● Expect to complete transformation which includes headcount reductions of 1,000 to 1,200 positions (Sales force, head office etc.) by the end of FY15
Major management topics

• Edoxaban business update
• Transform of Daiichi Sankyo, Inc.
• R&D update
Progress of Major R&D pipeline
Change after FY2015 Q1 financial announcement

◆ Consistent progress of projects in late phase development

● Pexidartinib (PLX3397)
  Treatment of tenosynovial giant cell tumor (TGCT)
  ✓ Breakthrough Therapy Designation * by the FDA

Tenosynovial Giant Cell Tumor (TGCT)
A painful and motion limiting joint disease characterized by inflammation and overgrowth of the joint lining. Other than surgeries to remove tumor, no systemic therapies available.

*: Breakthrough Therapy Designation is designed to expedite the development and review of medicines that may demonstrate substantial benefit over currently available treatments in order to ensure that patients with serious diseases have access to new treatments as soon as possible.
Consistent progress of projects in late phase development

CL-108: opioid-containing formulation

- Third Phase 3 clinical trial of CL-108 met its primary endpoints
- Results from the study with patients who experienced moderate to severe pain after bunionectomy surgery demonstrated significant pain relief and prevention of OINV by CL-108 (both p<0.001).
- NDA and approval/launch in the US: targeted for FY2015 and FY2016, respectively, as scheduled
Enrichment of innovative pipeline

- The first clinical entry of DS-originated ADC* and challenge for unmet medical needs: new phase 1 entry
  - DS-8201: Antineoplastic drug (Anti-HER2** ADC)
  - DS-2330: Hyperphosphatemia treatment
  - DS-7080: Neovascular age-related macular degeneration (AMD) treatment (angiogenesis inhibitor)

- Enhancement of portfolio in antithrombotic franchise
  - DS-9231/TS23: α2-PI*** inactivating antibody, phase 1

- Consistent progress of vaccine projects
  - FluMist® Quadrivalent (US brand name), phase 3: In-licensed

*ADC: Antibody Drug Conjugate
**HER2: Human Epidermal growth factor Receptor 2
***α2-PI: α2-Plasmin Inhibitor
DS-originated ADC clinical entering

◆ DS-8201: treatment for malignant tumor

● The first antibody-drug conjugate utilizing DS-originated ADC technology entered into clinical phase
  ✓ Topoisomerase I inhibitor is connected to anti-HER2 antibody through a linker

● Characteristics: DS-8201 carries large amount of drugs per antibody and can deliver the drugs to targeted cell efficiently

Potent anti-tumor activity as compared to conventional therapies is expected, including treatment for HER2 low expressing tumor

● Current status:
  ✓ Phase 1 study for solid tumor in Japan is on going
Portfolio enhancement in thrombosis franchise

*a2-PI* inactivating antibody

- Licensor: Translational Sciences Inc. (Memphis, Tennessee, US)
- Global right for exclusive development and commercialization
- Currently in Phase 1
- To meet unmet medical needs for safe thrombus dissolution

- tPA* value limited by short treatment window and bleeding complications
- Limited innovation in therapeutic drugs until now

Provides innovative options for dissolving thrombi in acute cardiovascular disease and stroke

* tPA: Tissue Plasminogen Activator
In-licensing flu vaccine of new value-added formulation

◆ VN-0107/MEDI3250
  Nasal spray live attenuated influenza vaccine, quadrivalent
  (US brand name: FluMist® Quadrivalent)
  ● Licensor: US MedImmune (global biologics research and
development arm of AstraZeneca)
  ● Current development stage: J-NDA preparation
  ● NDA approval and Launch target: FY2017
  ● Character: A live attenuated influenza vaccine which is administered
    as a nasalspray and contains four protective strains.
    ✓ Less demanding vaccination compared
      with the injection formulation
    ✓ Evidence of higher efficacy and effectiveness
      for protection of Flu infection

Efficacy for prevention of seasonal Flu infection
Total of 8,475 subjects randomized in 16 countries
Source: Belshe et al., NEJM 2007
## Major R&D pipeline

### As of October 2015

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular-Metabolics</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>- DS-1040 (Acute ischemic stroke / TAFIa inhibitor)</td>
<td>- CS-3150 (JP) (Hypertension / DM nephropathy / MR antagonist)</td>
<td>- Prasugrel (JP) (CS-747 / ischemic stroke / anti-platelet agent)</td>
<td>- Edoxaban (ASCA etc.) (DU-176b / AF / oral factor Xa inhibitor)</td>
<td></td>
</tr>
<tr>
<td>- DS-8312 (Hypertriglyceridemia)</td>
<td>- DS-8500 (JP) (Diabetes / GPR119 agonist)</td>
<td>- Prasugrel (US) (CS-747 / sickle cell disease / anti-platelet agent)</td>
<td>- Edoxaban (ASCA etc.) (DU-176b / VTE / oral factor Xa inhibitor)</td>
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</tr>
<tr>
<td>- DS-2330 (Hyperphosphatemia)</td>
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<td></td>
</tr>
<tr>
<td>- DS-9231/TS23 (Thrombosis / α2-PI inactivating antibody)</td>
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</tr>
<tr>
<td><strong>Oncology</strong></td>
<td>- U3-1565 (US/JP) (Anti-HB-EGF antibody)</td>
<td>- Patritinab (US/EU) (U3-1287 / anti-HER3 antibody)</td>
<td>- Tivantinib (US/EU) (ARQ 197 / HCC / MET inhibitor)</td>
<td></td>
</tr>
<tr>
<td>- PLX7486 (US) (FMS / TRK inhibitor)</td>
<td>- DS-8273 (US) (Anti-DR5 antibody)</td>
<td>- Nimotuzumab (JP) (DE-766 / gastric cancer / anti-EGFR antibody)</td>
<td>- Vemurafenib (US/EU) (PLX4032 / melanoma adjuvant / BRAF inhibitor)</td>
<td></td>
</tr>
<tr>
<td>- DS-6051 (US) (NTRK/ROS1 inhibitor)</td>
<td></td>
<td></td>
<td>- Pexidartinib (US/EU) (PLX3397/TGCT / FMS/KIT/FLT3-ITD inhibitor)</td>
<td></td>
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<tr>
<td>- PLX9486 (US) (KIT inhibitor)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td>- SUN13837 (US/EU) (Spinal cord injury / modulator of bFGF signaling system)</td>
<td>- Mirogabalin (US/EU) (DS-5565 / fibromyalgia / α2δ ligand)</td>
<td>- Intradermal Seasonal Influenza Vaccine (JP) (VN-101 / prefilled i.d. vaccine for seasonal flu)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Laninamivir (US/EU) (CS-8958 / anti-influenza / out-licensing with Biota)</td>
<td>- Mirogabalin (JP/Asia) (DS-5565 / DPNP / α2δ ligand)</td>
<td>- VN-101 (JP) (Cell-culture H5N1 Influenza vaccine)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- DS-1093 (Anemia of chronic kidney disease / HIF-PH inhibitor)</td>
<td>- Mirogabalin (JP/Asia) (DS-5565 / PHN / α2δ ligand)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- DS-3801 (Chronic obstruction / GPR38 agonist)</td>
<td>- Denosumab (JP) (AMG 162 / rheumatoid arthritis / anti-RANKL antibody)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- DS-1971 (Chronic pain)</td>
<td>- Hydromorphone (JP) (DS-7113 / cancer pain / opioid μ-receptor regulator)</td>
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</tr>
<tr>
<td></td>
<td>- DS-1501 (Osteoporosis / Anti-Siglec-15 antibody)</td>
<td>- CHS-0214 (JP) (Etanercept BS / rheumatoid arthritis / TNFα inhibitor)</td>
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<tr>
<td></td>
<td>- DS-7080 (AMD / Angiogenesis inhibitor)</td>
<td>- CL-108 (US) (Acute pain / opioid μ-receptor regulator)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- VN-0201/JVC-001 (JP) (MMR vaccine)</td>
<td>- VN-0105 (JP) (DPT-IPV/Hib vaccine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- VN-0107/MEDI3250 (JP) (Nasal spray flu vaccine vaccine)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Red: Change after FY2015Q1 financial announcement  □: products mentioned in the presentation
DS R&D Day 2015

◆ Date : December 14, 2015, Monday at 3 pm

◆ Location : Daiichi Sankyo Co. Ltd
Nihonbashi HQ

◆ Contents : Oncology Strategy,
Update on Phase 3 projects etc.

◆ Speaker : Dr. Glenn Gormley
(Sr. Executive Corporate Office, Global R&D head)
Luitpold Business Update

Mary Jane Helenek
President & CEO, Luitpold Pharmaceuticals, Inc.
Luitpold Pharmaceuticals, Inc. (LPI)

- US-based specialty pharma
- Headquarters located in Shirley, NY
- Five locations in US
- Total employees: 880

Shirley, NY
HQ and Plant

Norristown, PA
Clin. Dev. and MA

New Albany, OH
R&D and Plant

Hilliard, OH
Plant

Columbus, OH
QC/QA (for Ohio)
LPI successfully competes in high value specialty branded & generic injectable market segments.

**Business Domains**
- IRON FRANCHISE (> 50% share of non HD segment)
- GENERIC INJECTABLE FRANCHISE

**Strategic Imperatives**
- Build Injectafer into our flagship product & market leader
- Maximize / expand existing portfolio
LPI successfully competes in high value specialty branded & generic injectable market segments.
What Is Iron Deficiency Anemia (IDA)?

- Iron is an integral component for hemoglobin in red blood cell (RBC), which is essential for oxygen transportation from lungs to the rest of the body.
- When demand for iron exceeds supply, iron depletion can occur, affecting RBC’s function and causing anemia.

### Signs and Symptoms of Iron Deficiency

**Mild to Moderate IDA:**
- Fatigue
- Pallor
- Decreased exercise capacity
- Cold hands and feet
- Tachycardia
- Lightheadedness

**Severe IDA:**
- Mouth Soreness
- Difficulty swallowing
- Spooning nails
- Pica
- Ice cravings

Patients at the earliest state of iron deficiency may fail to exhibit any physiologic impairment.
# Cause of IDA*

<table>
<thead>
<tr>
<th><strong>Inadequate Dietary Intake</strong></th>
<th><strong>Inadequate GI Absorption</strong></th>
<th><strong>Blood Loss</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Restricted diet</td>
<td>- Malabsorption syndromes / dysfunctional GI conditions</td>
<td>- Surgery</td>
</tr>
<tr>
<td></td>
<td>✓ e.g. IBD, bariatric surgery</td>
<td>- GI bleeding</td>
</tr>
<tr>
<td>- Chronic alcoholism</td>
<td>- Drug/food interactions</td>
<td>- Bleeding by cancer</td>
</tr>
<tr>
<td></td>
<td>- Upper gastrointestinal tract resection by cancer</td>
<td>- Menstruation</td>
</tr>
<tr>
<td></td>
<td>- Disease induced inflammatory conditions</td>
<td>- Fibroids / cysts</td>
</tr>
<tr>
<td></td>
<td>- Conditions that increase hepcidin</td>
<td>- Birth</td>
</tr>
<tr>
<td><strong>Increased Iron Demand</strong></td>
<td></td>
<td>- Dialysis</td>
</tr>
<tr>
<td>- Pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ESA** usage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** Erythropoiesis-Stimulating Agent
US IDA Population from Associated Etiologies

<table>
<thead>
<tr>
<th>Primary Disease</th>
<th>% IDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHF** Alone</td>
<td>17%</td>
</tr>
<tr>
<td>IBD**</td>
<td>36-76%</td>
</tr>
<tr>
<td>Celiac Disease</td>
<td>46%</td>
</tr>
<tr>
<td>Gastric Bypass</td>
<td>24%</td>
</tr>
<tr>
<td>Cancer</td>
<td>7-42%</td>
</tr>
<tr>
<td>HUB**/General IDA in Women</td>
<td>100%</td>
</tr>
<tr>
<td>Post Partum</td>
<td>15%</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>18%</td>
</tr>
<tr>
<td>CKD** Stage3</td>
<td>42%</td>
</tr>
<tr>
<td>CKD** Stage4</td>
<td>54%</td>
</tr>
<tr>
<td>Dialysis</td>
<td>92%</td>
</tr>
</tbody>
</table>

* IDA Statistics: American Regent Inc. and Vifor Pharma IDA prevalence data.

**Abbreviations - CKD: Chronic Kidney Disease, HUB: Heavy Uterine Bleeding, IBD: Inflammatory Bowel Disease, CHF: Chronic Heart Failure
Real Challenges in Current Iron Therapies

Intolerance / unsatisfactory response to oral iron
- Difficult-to-tolerate side effects
- Pill burden / Length of treatment
- Impaired absorption in a variety of circumstances

Safety concerns with IV irons
- Hypersensitivity and other reactions
- Black box warning (InFed® and Feraheme®)

Dosing and compliance issues with IV irons
- Limited indication (IDA associated with CKD)
- Long administration times or repeated office visits (for low, multiple-dose IV iron regimens)

LPI is providing practical solutions
Venofer®: The IV iron Market Share Leader

- “Lower-dose” IV iron
- Treatment of IDA in patients with CKD
  - Adult and pediatric
- Safety drives treatment choice:
  - In market research, HCPs often say that they choose Venofer because of its safety profile and tolerability
- Strong presence in non-HD segments (LPI)
- Growing in HD (Fresenius USA)
- >60 years of worldwide experience – trusted and established
Injectafer®: High-dose IV Iron with Broad Indication

- **Broader indication – Treatment of IDA in adult patients who have:**
  - ✔ Intolerance to oral iron or who have had unsatisfactory response to oral iron or;
  - ✔ Non-dialysis dependent chronic kidney disease

- **Convenient dosing & administration**
  - Up to 750 mg in a single dose*† + Up to 750 mg in a single dose*† = Total cumulative dose up to 1500 mg per course
  - At least 7 days apart
  - No premedication or test dose required
  - IV Infusion over at least 15 minutes
  - Slow IV push over at least 7.5 minutes
## Comparison between Injectafer® and Venofer®

<table>
<thead>
<tr>
<th>Molecule</th>
<th>Injectafer®</th>
<th>Venofer®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrate shell</td>
<td>Carboxymaltose</td>
<td>Sucrose</td>
</tr>
</tbody>
</table>

### Indications

<table>
<thead>
<tr>
<th></th>
<th>Injectafer®</th>
<th>Venofer®</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDA of various of non-CKD etiologies (e.g., cancer, GI disorders, HUB, postpartum)</td>
<td>Yes (for adult patients who have intolerance to oral iron or have had unsatisfactory response or oral iron)</td>
<td>Not FDA approved</td>
</tr>
<tr>
<td>IDA in patients with CKD</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Safety

<table>
<thead>
<tr>
<th></th>
<th>Injectafer®</th>
<th>Venofer®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black Box Warning</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Test Dose Required</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>MRI Interference</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

### Dosing

<table>
<thead>
<tr>
<th></th>
<th>Injectafer®</th>
<th>Venofer®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum approved single dose</td>
<td>750mg</td>
<td>100mg – 400mg (depending upon indication)</td>
</tr>
<tr>
<td>Maximum approved cumulative dose</td>
<td>1500mg</td>
<td>1000mg</td>
</tr>
<tr>
<td>Number of administrations required to deliver cumulative dose</td>
<td>(for non-dialysis CKD IDA)</td>
<td></td>
</tr>
</tbody>
</table>

### Administration

<table>
<thead>
<tr>
<th></th>
<th>Injectafer®</th>
<th>Venofer®</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV Push</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>IV Infusion</td>
<td>Yes, over at least 15 minutes</td>
<td>Yes, over 15 minutes to 2.5 hours depending on dose</td>
</tr>
</tbody>
</table>
Injectafer: The Fastest Growing IV Iron in US

The IV Iron Market grew 15% in $ and 7% in mg volume from MAT August 2014 to MAT August 2015

**IV Iron $ sales**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales (M$)</th>
<th>Increase</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2013</td>
<td>509.1</td>
<td>15%</td>
<td>65%</td>
</tr>
<tr>
<td>Aug 2014</td>
<td>552.4</td>
<td>6%</td>
<td>60%</td>
</tr>
<tr>
<td>Aug 2015</td>
<td>635.6</td>
<td>16%</td>
<td>53%</td>
</tr>
</tbody>
</table>

**IV Iron mg sales**

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales (Mg)</th>
<th>Increase</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 2013</td>
<td>1,737</td>
<td>7%</td>
<td>68%</td>
</tr>
<tr>
<td>Aug 2014</td>
<td>1,853</td>
<td>8%</td>
<td>68%</td>
</tr>
<tr>
<td>Aug 2015</td>
<td>1,983</td>
<td>5%</td>
<td>67%</td>
</tr>
</tbody>
</table>

Source: IMS National Sales Perspectives Sept 2015
Hem-Onc Treats most Non-Dialysis IDA patients

65% of IV Iron is rendered in Hem/Onc offices or outpatient clinics.
Growth Strategy for Injectafer

- Build on Market share leadership in Hem-Onc
- Differentiate Injectafer from other treatment options
- Market expansion into new therapeutic areas
- Raise awareness of IDA among physicians & patients
- IDA is under-diagnosed & under-treated
LPI successfully competes in high value specialty branded & generic injectable market segments.

**Business Domains**

- **IRON FRANCHISE**
  (> 50% share of non HD segment)

- **GENERIC INJECTABLE FRANCHISE**

**Strategic Imperatives**

- Build Injectafer into our flagship product & market leader
- Maximize / expand existing portfolio
US Generic Injectable Business

- Market: $22.8 billion in sales (2.2 billion units) with consistent growth trends
- Dynamic market with much price / demand volatility
- Drug shortages still remain but are abating

Source: IMS NSP AUDIT MAT Sept 2015. Includes Generic and Branded Generic Injectables.
LPI’s Generic Injectable Business

- Focused on small volume vials and ampules
- Over 50 products in active production & lineup is increasing
  - Building inventory of key products to alleviate market shortages
- The business is growing rapidly
Growth Strategy for Generic Injectable Business

- High portfolio differentiation
  - Consistent supply of products with high quality
  - Responsive to rapid market changes
  - Strong relationships to quickly identify market opportunities

- Launch 5 new products in FY15
- ≈2 dozen products under active FDA review / pending approval
- >2 dozen products in active development
Investment to Expand Manufacturing Capacity

Intensive market needs
Consistent supply of products with high quality
LPI’s growing pipeline

Capacity Expansion

Shirley: Upgrade existing manufacturing infrastructure
New Albany: Consolidate operation & capacity expansion
Hilliard: Maximize space use & capacity expansion

To become a top 4 supplier of Generic Injectables in US Market
LPI is Positioned for Accelerated Growth

Double digit revenue and profit growth

($M)

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue (M)</th>
<th>Profit (M)</th>
<th>LE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>395</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>522</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>2015*</td>
<td>714</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>2016*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017*</td>
<td></td>
<td></td>
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</tbody>
</table>

* Based on the forecast

Venofer  Injectafer  Generics & Others
Financial forecasts, future projections and R&D information that Daiichi Sankyo discloses may include information that might be classified as “Forward Looking Statement”. These forward looking statements represent our current assumptions basis on information currently available. Please note that such are subject to a number of known and unknown risk and uncertainties and our future performance may differ from the expectations as expressed in such statements.