Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

# 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)

Daiichi-Sankyo

| | FY2014 Q2 YTD Results *1 | FY2015 Q2 YTD Results | YoY |
|---|---|---|---|
| Revenue | 429.6 | 478.8 | +11.4% +49.2 |
| Cost of Sales | 130.8 | 148.9 | +18.1 |
| SG&A Expenses | 153.7 | 144.5 | -9.2 |
| R&D Expenses | 84.9 | 88.4 | +3.5 |
| Operating Profit | 60.2 | 97.0 | +61.0% +36.8 |
| Profit before tax | 62.2 | 90.8 | +28.6 |
| Profit attributable to owners of the Company | 36.7 | 70.7 | +92.8% +34.0 |
| Currency Rate USD/JPY | 103.05 | 121.80 | +18.75 |
| Currency Rate EUR/JPY | 138.91 | 135.07 | -3.84 |

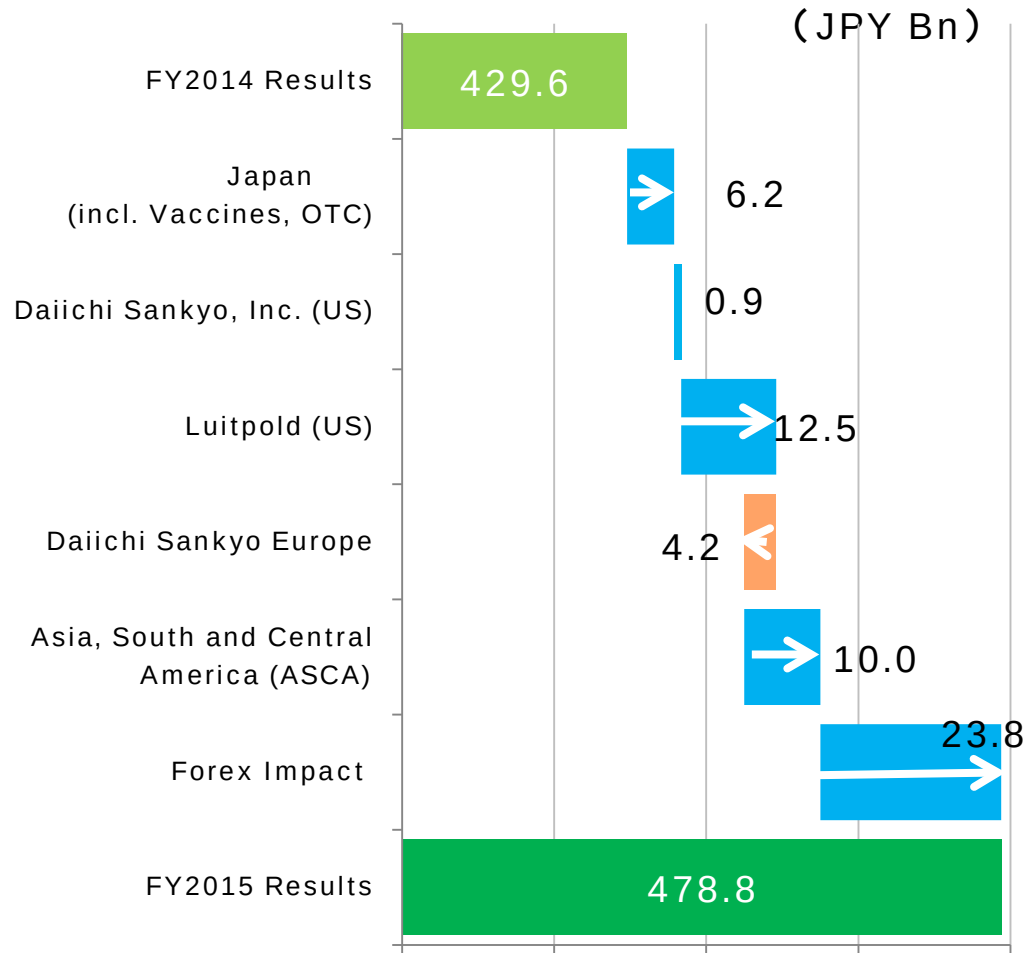
*1 FY2014 Q2 Results have been restated and indicated as only the values for continuing operations excluding Ranbaxy.

# Revenue

Positive Factors | Negative Factors

Daiichi-Sankyo

**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 | Lixana | +5.2 |
| | Memary | +3.7 | Pralia | +2.4 |
| | 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)

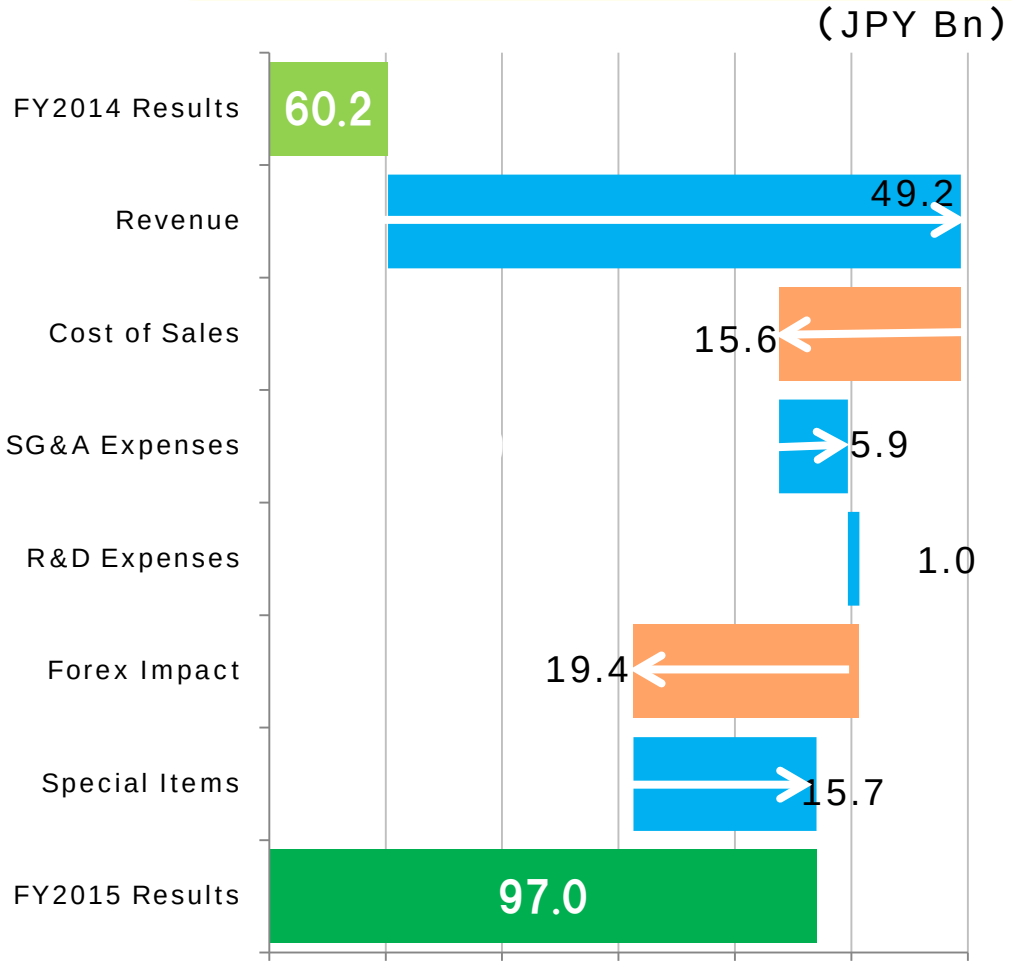
| | | |
|---|---|---|
| Daiichi Sankyo Inc. : | Olmesartan | +1.5 |
| | Welchol | -1.3 |
| | Effient | +0.5 |
| | Movantic | +0.5 |
| Luitpold : | Venofer | -0.7 |
| | Injectafer | +3.7 |
| Daiichi Sankyo Europe : | Olmesartan | -4.3 |
| | Lixiana | +0.2 |
| ASCA : | Olmesartan | +1.9 |

# Operating Profit

Positive Factors | Negative Factors

Daiichi-Sankyo

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




| | |
|---|---|
| Revenue | +49.2 |
| incl. forex impact | 23.8 |

| | |
|---|---|
| Forex impact | +19.4 |
| Cost of Sales | +6.0 |
| SG&A Expenses | +8.9 |
| R&D Expenses | +4.5 |

| | |
|---|---|
| Special Items | -15.7 |
| Gain on sales of subsidiary (->Cost of Sales) | -2.4 |
| Gain on sales of fixed assets (->Cost of Sales) | -1.1 |
| Gain on sales of fixed assets (->SG&A Expenses) | -8.2 |

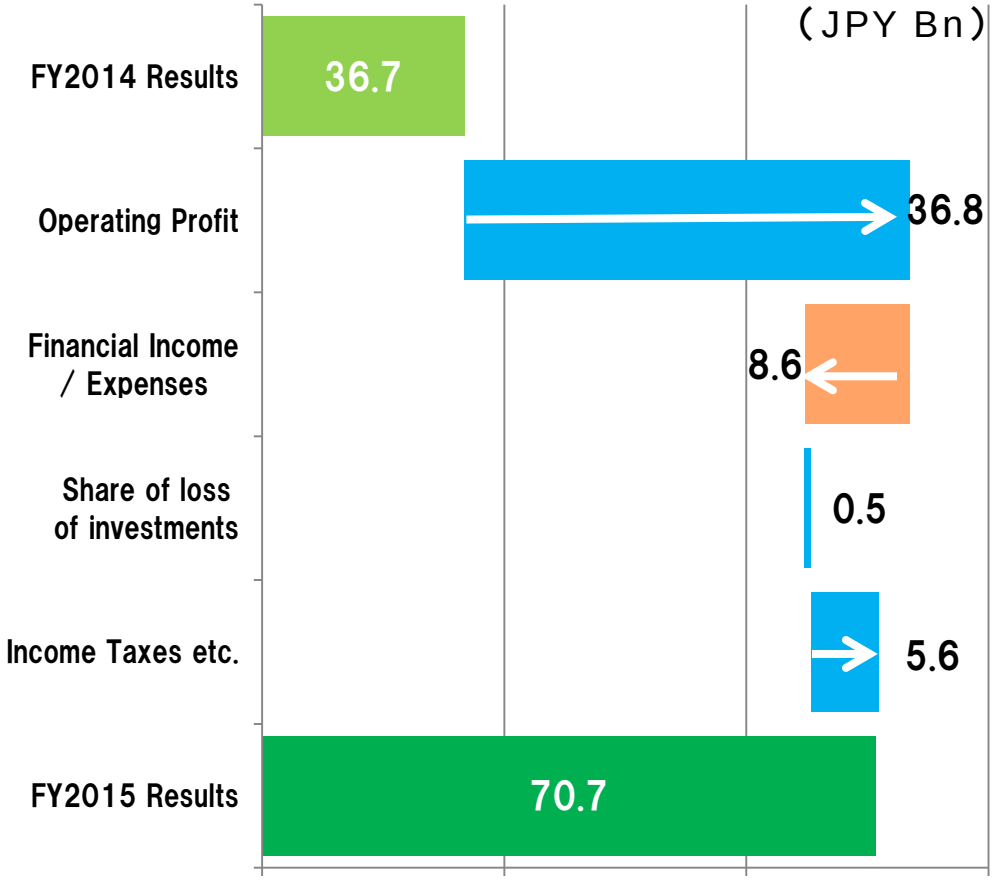
(FY2014: Settlement expenses with US Department of Justice +4.0)

# Profit attributable to owners of the Company

Positive Factors | Negative Factors

Daiichi-Sankyo

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




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

Income Taxes etc. -5.6

# Major business units

(JPY Bn)

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

# Major products in Japan

(JPY Bn)

| | | FY2014 Q2 YTD Results | FY2015 Q2 YTD Results | YoY | vs. Revised Forecast (%) |
|---|---|---|---|---|---|
| Olmetec | anti-hypertension | 37.8 | 36.2 | -1.6 | 45.8% |
| Nexium | anti-ulcer (Proton Pump Inhibitor) | 32.1 | 38.7 | +6.6 | 50.2% |
| Memary | treatment for Alzheimer | 16.8 | 20.5 | +3.7 | 43.6% |
| Loxonin | analgesic and anti-inflammatory | 25.4 | 24.4 | -1.0 | 55.4% |
| Cravit | antibacterial | 14.2 | 9.0 | -5.2 | 52.9% |
| Rezaltas | anti-hypertension | 9.0 | 8.9 | -0.1 | 46.9% |
| Artist | Treatment for hypertension, angina pectoris and chronic heart failure | 9.4 | 7.9 | -1.5 | 46.4% |
| Omnipaque | contrast medium | 8.6 | 8.5 | -0.1 | 52.8% |
| Mevalotin | anti-hyperlipidemia | 8.3 | 7.0 | -1.3 | 49.7% |
| Ranmark | treatment for bone metastasis | 4.7 | 5.9 | +1.2 | 45.2% |
| Urief | treatment for dysuria | 5.6 | 5.7 | +0.1 | 51.8% |
| Pralia | osteoporosis | 3.0 | 5.4 | +2.4 | 53.5% |
| Lixiana | anticoagulant | 0.2 | 5.4 | +5.2 | 48.8% |
| Efient | antiplatelet | 0.3 | 1.8 | +1.5 | 35.3% |
| Teneria | treatment for type 2 diabetes | 3.3 | 5.3 | +2.0 | - |

# FY2015 revised consolidated forecast

# FY2015 revised consolidated forecast

(JPY Bn)

| | FY 2015 Forecast (as of Jul.) | FY 2015 Revised Forecast (as of Oct.) | vs. Forecast (as of Jul.) |
|---|---|---|---|
| Revenue | 950.0 | 980.0 | +30.0 |
| Cost of Sales | 302.0 | 314.0 | +12.0 |
| SG&A Expenses | 338.0 | 354.0 | +16.0 |
| R&D Expenses | 190.0 | 192.0 | +2.0 |
| Operating Profit | 120.0 | 120.0 | 0 |
| Profit before tax | 115.0 | 115.0 | 0 |
| Profit attributable to owners of the Company | 75.0 | 75.0 | 0 |

**Major factors**
- Delay of entry of Welchol GEs
- Good performance of products of Luitpold and Nexium

**Major factors**
Increase of COGs by increase of revenue

**Major factors**
Expenses relating to DSI transformation and others

| | | | |
|---|---|---|---|
| Currency Rate | USD/JPY | 120.34 | 120.90 |
| | EUR/JPY | 131.04 | 132.53 |

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

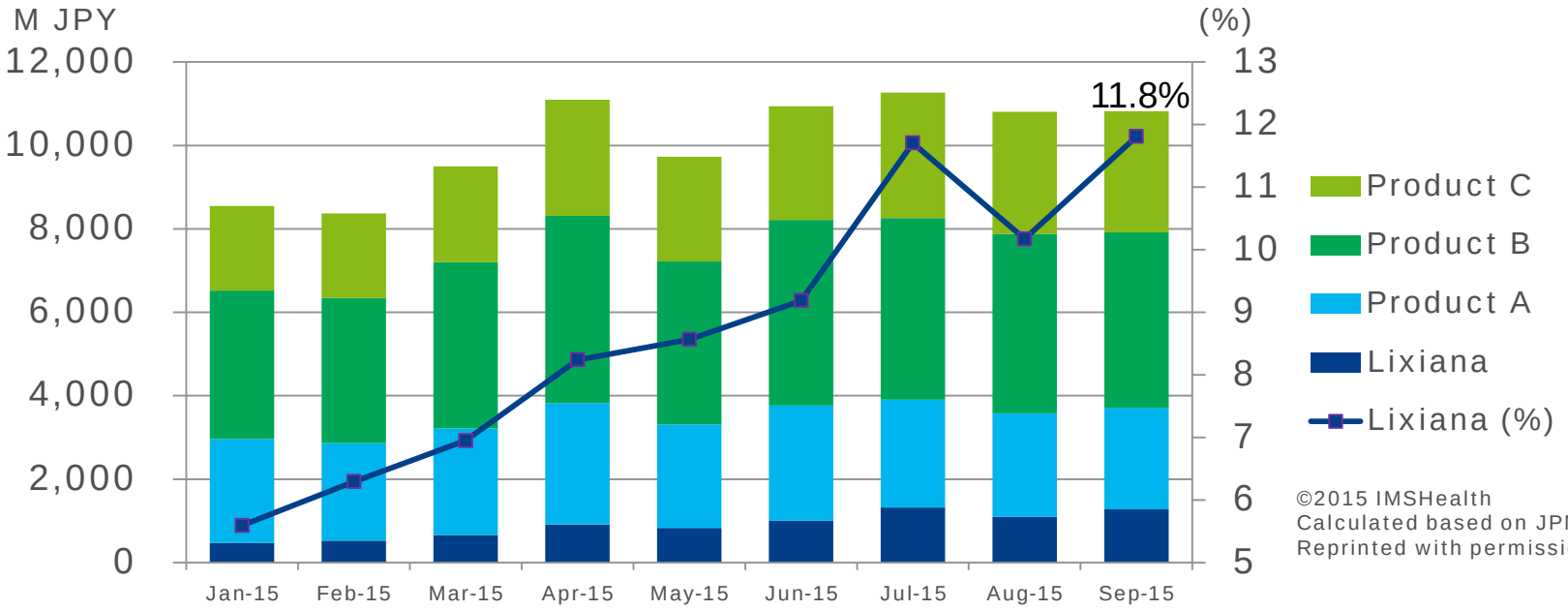
# Major management topics

- 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



# Edoxaban business update: US (Savaysa)

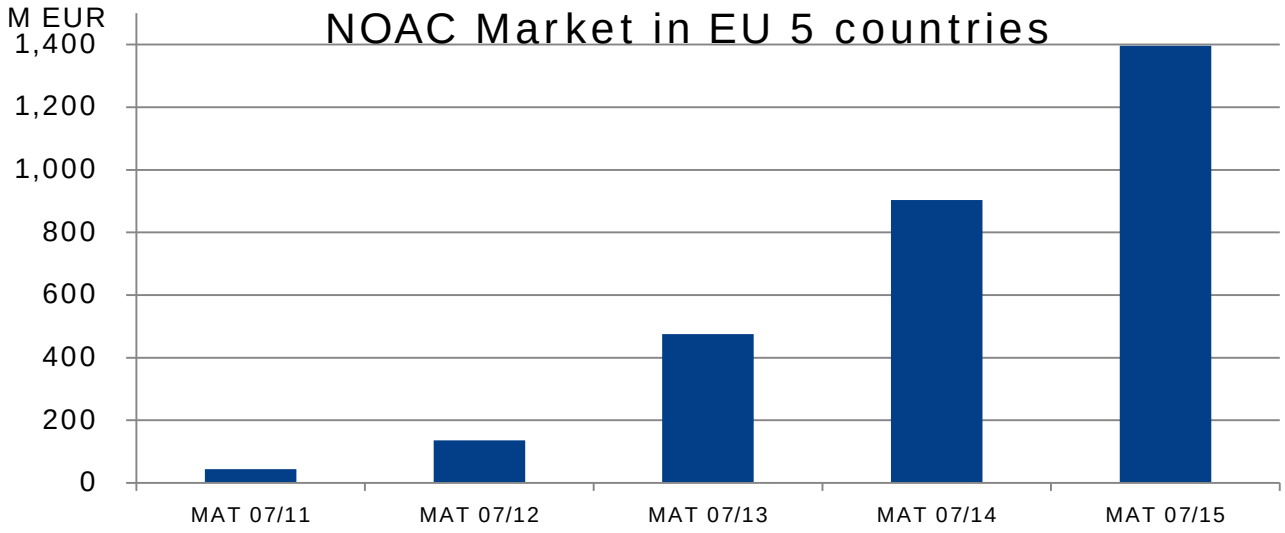
- Approved(Jan), Launched(Feb)
  - AF: indicated only for patients with CrCL **≤95 mL/min**
  - VTE: without limitation of use

- 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

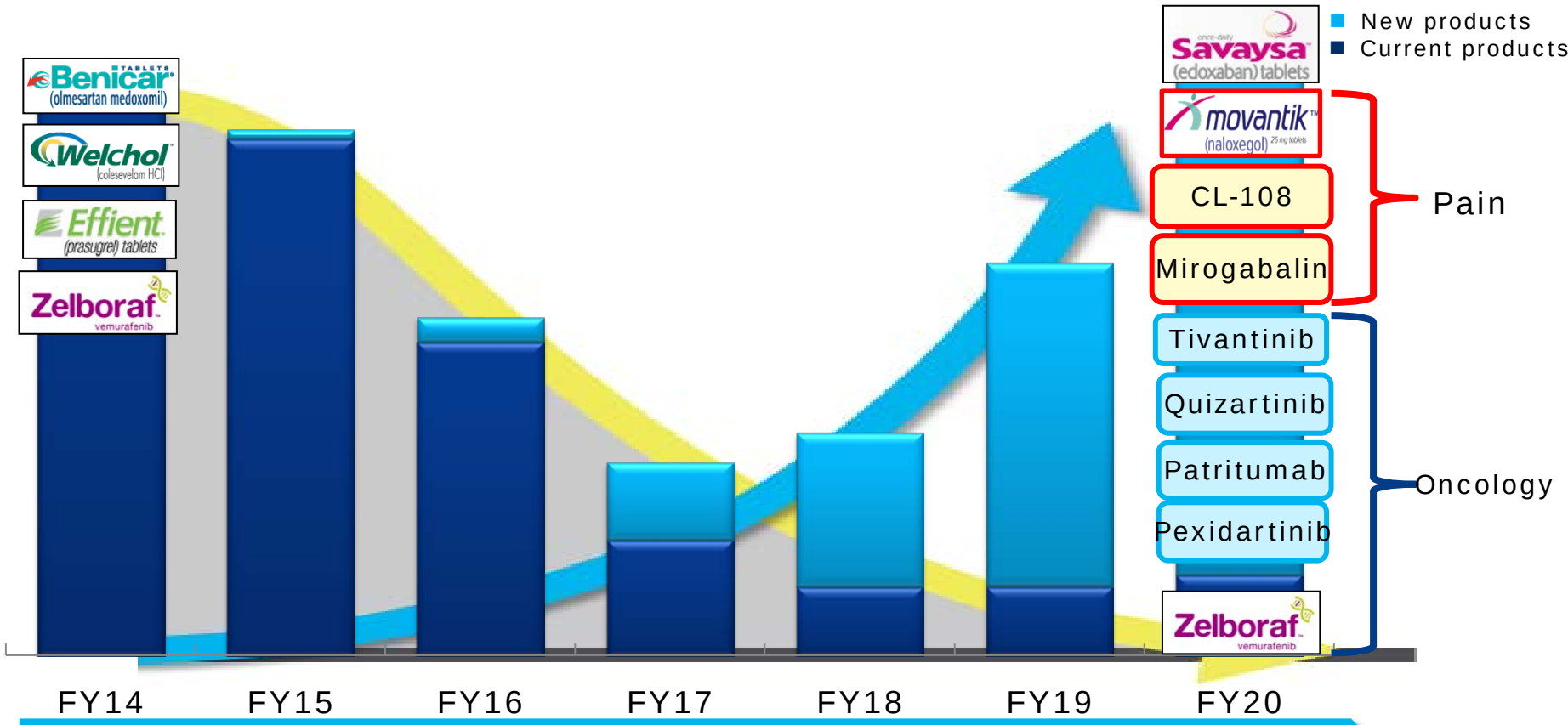
- ENSURE AF (Cardioversion) - - NVAF undergoing electrical cardioversion, initiated in Mar 2014
- The Hokusai-VTE Cancer - - VTE associated with cancer, initiated in Jun 2015
- ETNA - - To collect real-world's safety and efficacy date in the EU, Japan and certain ASCA countries
- Reversal agents - - 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**

Savaysa (edoxaban) tablets | movantik (naloxegol)

***CL-108***

**FY18~**

***Mirogabalin***
***Quizartinib***
***Tivantinib***
***Pexidartinib***
***Patritumab***

# 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

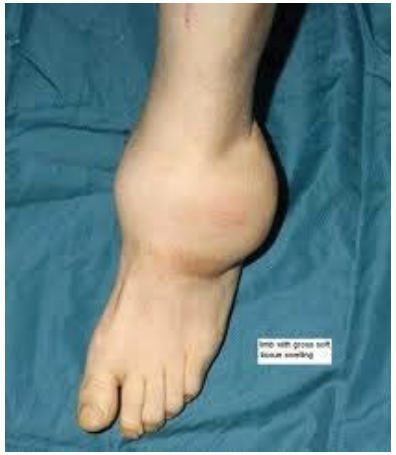
- Edoxaban business update
- Transform of Daiichi Sankyo, Inc.
- R&D update

# 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.

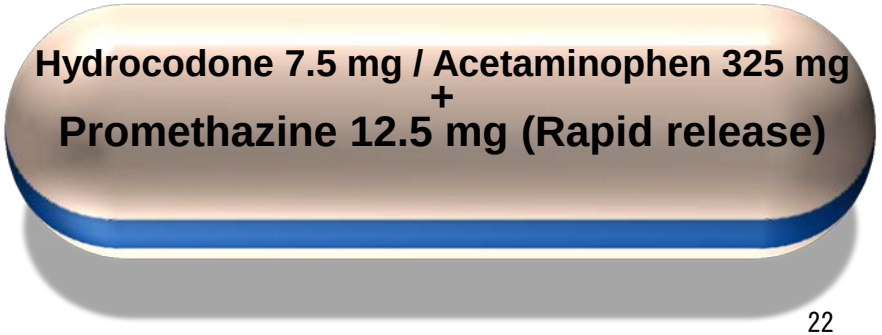
# Progress of Major R&D pipeline
## Change after FY2015 Q1 financial announcement

Daiichi-Sankyo

- 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

CL-108

In-licensed from Charleston Laboratories, Inc.
Novel, fixed-dose, bi-layered tablet comprising of hydrocodone, acetaminophen, and promethazine provides anti-emetic activity prior to hydrocodone effect.



# Progress of Major R&D pipeline
## Change after FY2015 Q1 financial announcement

Daiichi-Sankyo

- 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

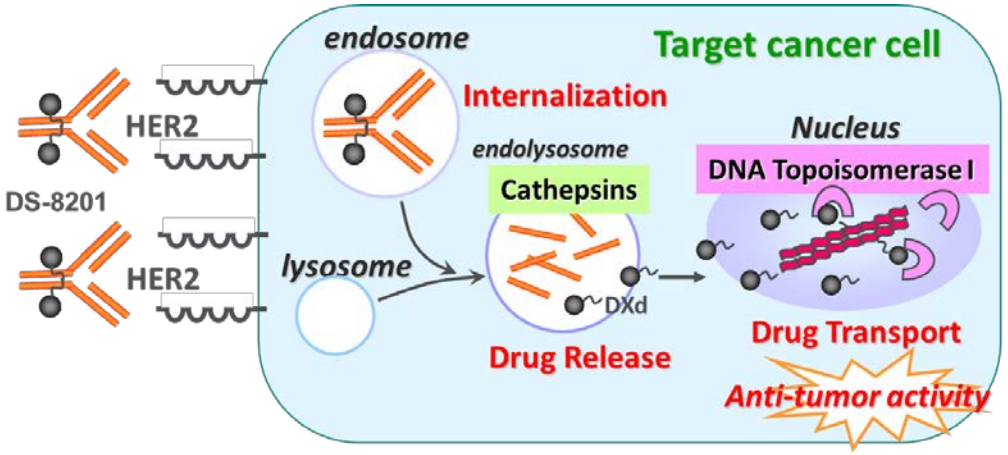
*ADC: Antibody Drug Conjugate
**HER2: Human Epidermal growth factor Receptor 2
***α2-PI: α2-Plasmin Inhibitor

# 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



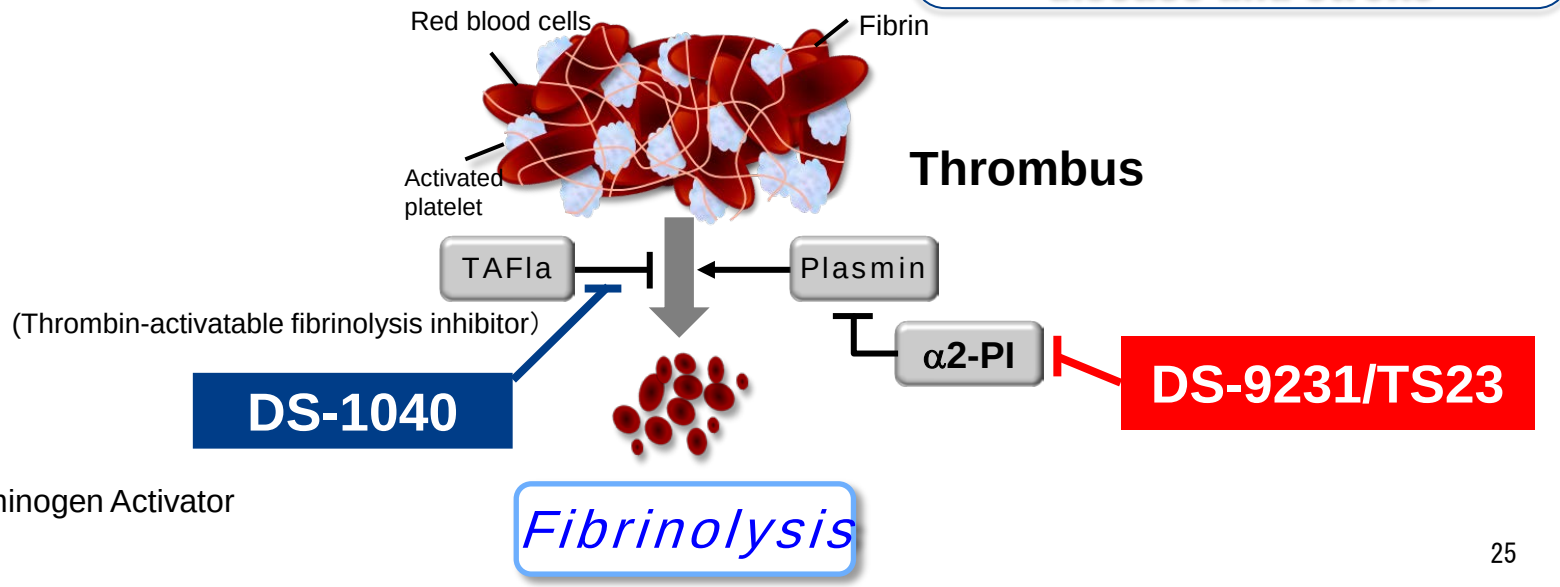

*(DS R&D Day 2014)*

# Portfolio enhancement in thrombosis franchise

## DS-9231 / TS23 α2-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



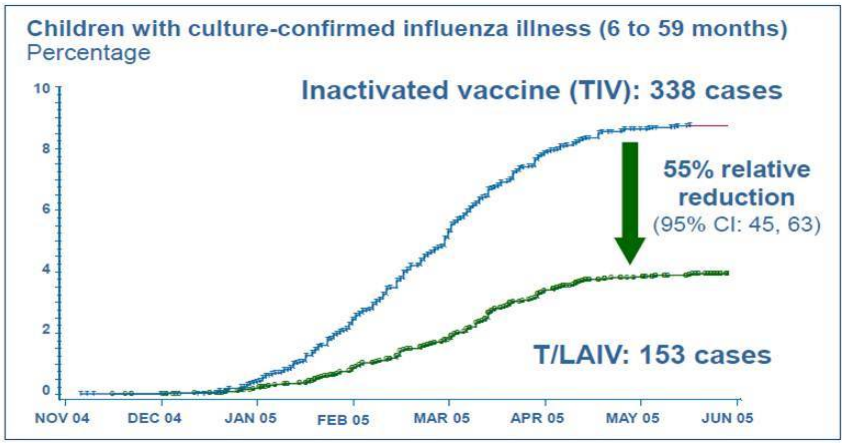

* tPA: Tissue Plasminogen Activator

# In-licensing flu vaccine of new value-added formulation

## VN-0107/MEDI3250

Nasal spray live attenuated influenza vaccine, quadrivalent (US brand name: FluMist® Quadrivalent)

- Licenser: 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

Daiichi-Sankyo

| Therapeutic area | Phase 1 | Phase 2 | Phase 3 | Application |
|---|---|---|---|---|
| Cardiovascular-Metabolics | ■ DS-1040<br>(Acute ischemic stroke / TAFIa inhibitor)<br>■ DS-8312<br>(Hypertriglyceridemia)<br>■ DS-2330<br>(Hyperphosphatemia)<br>■ DS-9231/TS23<br>(Thrombosis / **α2**-PI inactivating antibody) | ■ CS-3150 (JP)<br>(Hypertension • DM nephropathy / MR antagonist)<br>■ DS-8500 (JP)<br>(Diabetes / GPR119 agonist) | ■ Prasugrel (JP)<br>(CS-747 / ischemic stroke / anti-platelet agent)<br>■ Prasugrel (US)<br>(CS-747 / sickle cell disease / anti-platelet agent) | ■ Edoxaban (ASCA etc.)<br>(DU-176b / AF / oral factor Xa inhibitor)<br>■ Edoxaban (ASCA etc.)<br>(DU-176b / VTE / oral factor Xa inhibitor) |
| Oncology | ■ DS-3032 (US/JP)<br>(MDM2 inhibitor)<br>■ PLX7486 (US)<br>(FMS / TRK inhibitor)<br>■ PLX8394 (US)<br>(BRAF inhibitor)<br>■ DS-6051 (US)<br>(NTRK/ROS1 inhibitor)<br>■ PLX9486 (US)<br>(KIT inhibitor)<br>■ U3-1565 (US/JP)<br>(Anti-HB-EGF antibody)<br>■ DS-8895 (JP)<br>(Anti-EPHA2 antibody)<br>■ DS-8273 (US)<br>(Anti-DR5 antibody)<br>■ DS-5573 (JP)<br>(Anti-B7-H3 antibody)<br>■ DS-8201 (JP)<br>(Anti-HER2 ADC) | ■ Patritumab (US/EU)<br>(U3-1287 / anti-HER3 antibody)<br>■ Pexidartinib (US)<br>(PLX3397 / FMS/KIT/FLT3-ITD inhibitor) | ■ Tivantinib (US/EU)<br>(ARQ 197 / HCC / MET inhibitor)<br>■ Denosumab (JP)<br>(AMG 162 / breast cancer adjuvant / anti-RANKL antibody)<br>■ Nimotuzumab (JP)<br>(DE-766 / gastric cancer / anti-EGFR antibody)<br>■ Vemurafenib (US/EU)<br>(PLX4032 / melanoma adjuvant / BRAF inhibitor)<br>■ Quizartinib (US/EU)<br>(AC220 / AML / FLT3-ITD inhibitor)<br>■ Pexidartinib (US/EU)<br>(PLX3397/TGCT / FMS/KIT/FLT3-ITD inhibitor) | |
| Others | ■ DS-1093<br>(Anemia of chronic kidney disease / HIF-PH inhibitor)<br>■ DS-3801<br>(Chronic obstipation / GPR38 agonist)<br>■ DS-1971<br>(Chronic pain)<br>■ DS-1501<br>(Osteoporosis / Anti-Siglec-15 antibody)<br>■ DS-7080<br>(AMD / Angiogenesis inhibitor)<br>■ VN-0201/JVC-001 (JP)<br>(MMR vaccine) | ■ SUN13837 (US/EU)<br>(Spinal cord injury / modulator of bFGF signaling system)<br>■ Laninamivir (US/EU)<br>(CS-8958 / anti-influenza / out-licensing with Biota) | ■ Mirogabalin (US/EU)<br>(DS-5565 / fibromyalgia / **α2δ ligand**)<br>■ Mirogabalin (JP/Asia)<br>(DS-5565 / DPNP/ **α2δ ligand**)<br>■ Mirogabalin (JP/Asia)<br>(DS-5565 / PHN / **α2δ ligand**)<br>■ Denosumab (JP)<br>(AMG 162 / rheumatoid arthritis / anti-RANKL anti-body)<br>■ Hydromorphone (JP)<br>(DS-7113 / cancer pain / opioid **μ**-receptor regulator)<br>■ CHS-0214 (JP)<br>(Etanercept BS / rheumatoid arthritis / TNF**α** inhibitor)<br>■ CL-108 (US)<br>(Acute pain / opioid **μ**-receptor regulator)<br>■ VN-0105 (JP)<br>(DPT-IPV/Hib vaccine)<br>■ VN-0107/MEDI3250 (JP)<br>(Nasal spray flu vaccine vaccine) | ■ Intradermal Seasonal Influenza Vaccine (JP)<br>(VN-100 /prefilled i.d. vaccine for seasonal flu)<br>■ VN-101 (JP)<br>(Cell-culture H5N1 Influenza vaccine) |

Red：Change after FY2015Q1 financial announcement □：products mentioned in the presentation

# DS R&D Day 2015

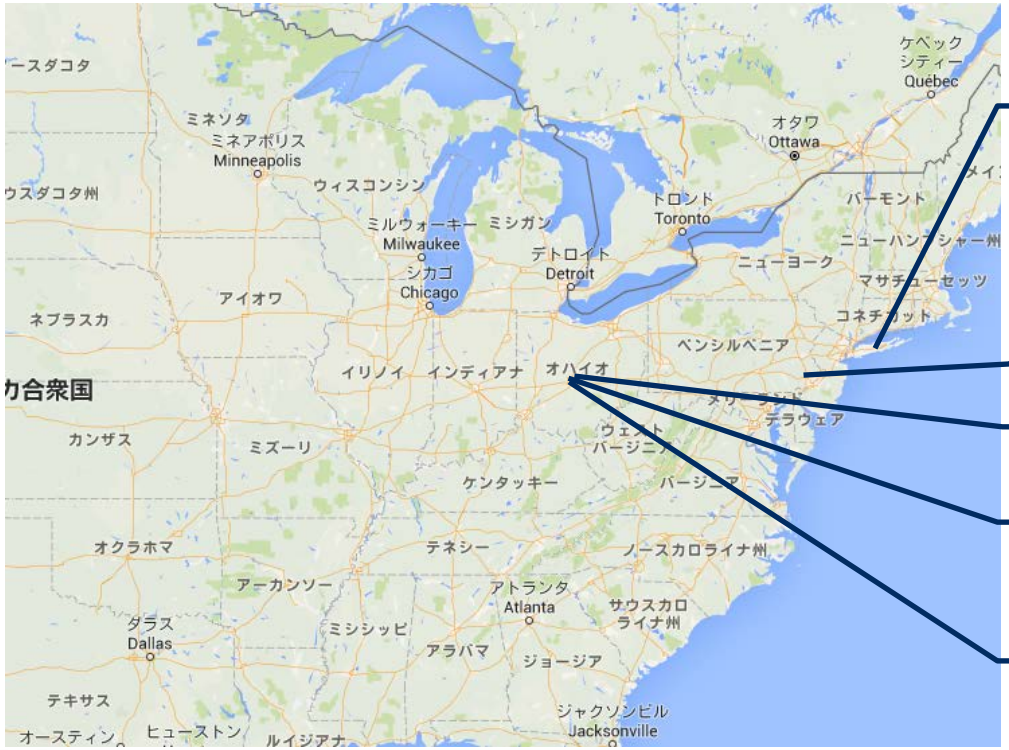
- Date : December 14, 2015, Monday at 3 pm
- Location : Daiichi Sankyo Co. Ltd
  Nihonbashi HQ
- Contents : Oncology Strategy,
  Update on Phase 3 projects etc.
- Speaker : Dr. Glenn Gormley
  (Sr. Executive Corporate Office, Global R&D head)

# 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 - A Diversified Specialty Company

**LPI successfully competes in high value specialty branded & generic injectable market segments.**

| Business Domains | *Strategic Imperatives* |
| --- | --- |
| **IRON FRANCHISE** (> 50% share of non HD segment) | ***Build Injectafer into our flagship product & market leader*** |
| **GENERIC INJECTABLE FRANCHISE** | ***Maximize / expand existing portfolio*** |

# LPI - A Diversified Specialty Company

Daiichi-Sankyo

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| --- | --- |
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| GENERIC INJECTABLE FRANCHISE | *Maximize / expand existing portfolio* |

LUITPOLD PHARMACEUTICALS, INC

# 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*

## Inadequate Dietary Intake

- Restricted diet
- Chronic alcoholism

## Increased Iron Demand

- Pregnancy
- ESA** usage

## Inadequate GI Absorption

- Malabsorption syndromes / dysfunctional GI conditions
  - ✓ e.g. IBD, bariatric surgery
- Drug/food interactions
- Upper gastrointestinal tract resection by cancer
- Disease induced inflammatory conditions
- Conditions that increase hepcidin

## Blood Loss

- Surgery
- GI bleeding
- Bleeding by cancer
- Menstruation
- Fibroids / cysts
- Birth
- Dialysis

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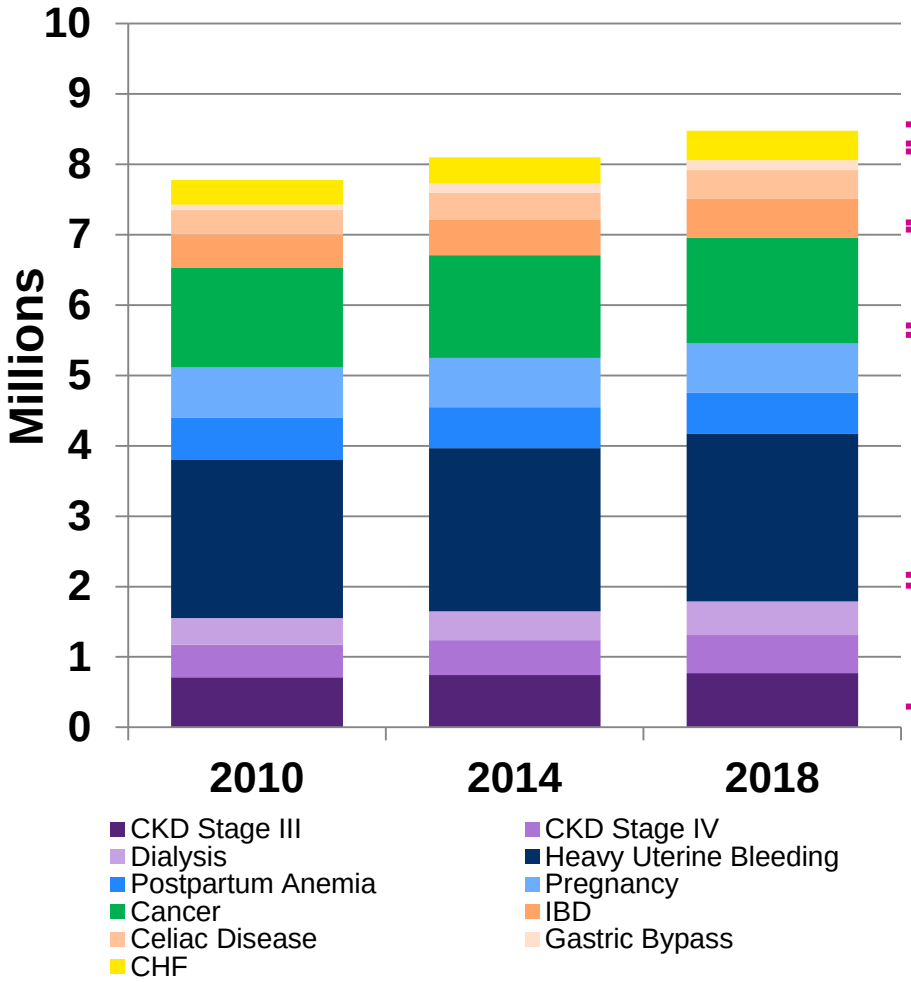
* Adapted from Jacinto MS, Madan S. Iron deficiency anemia. Pharmacist. April 2000;HS39-HS48.
** Erythropoiesis-Stimulating Agent

# IDA population & Treatment Options are Growing

Daiichi-Sankyo

## US IDA Population from Associated Etiologies




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

Injectafer
Oral Iron
Iron Dextran
Venofer
SFG & Feraheme

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* 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

Daiichi-Sankyo

| | |
|---|---|
| **Intolerance / unsatisfactory response to oral iron** | • **Difficult-to-tolerate side effects**<br>• **Pill burden / Length of treatment**<br>• **Impaired absorption in a variety of circumstances** |
| **Safety concerns with IV irons** | • **Hypersensitivity and other reactions**<br>• **Black box warning (InFed® and Feraheme ®)** |
| **Dosing and compliance issues with IV irons** | • **Limited indication (IDA associated with CKD)**<br>• **Long administration times or repeated office visits (for low, multiple-dose IV iron regimens)** |

**LPI is providing practical solutions**

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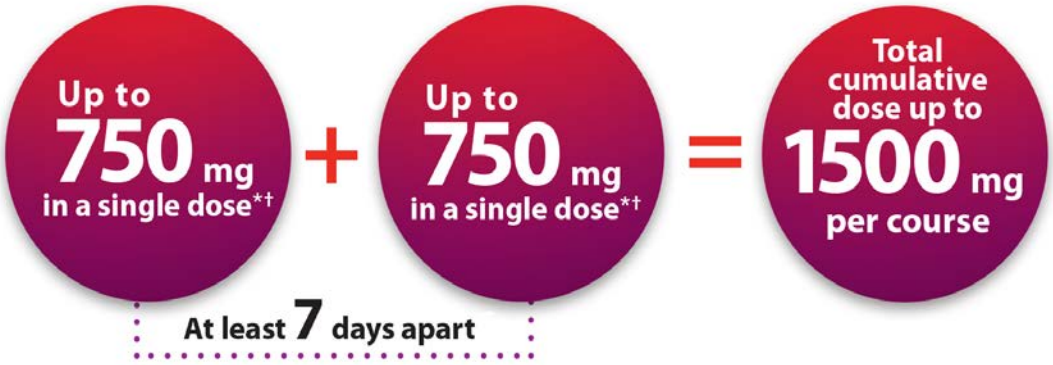
# Venofer®: The IV iron Market Share Leader


- **"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**


**IV Infusion over at least 15 minutes**

**Slow IV push over at least 7.5 minutes**

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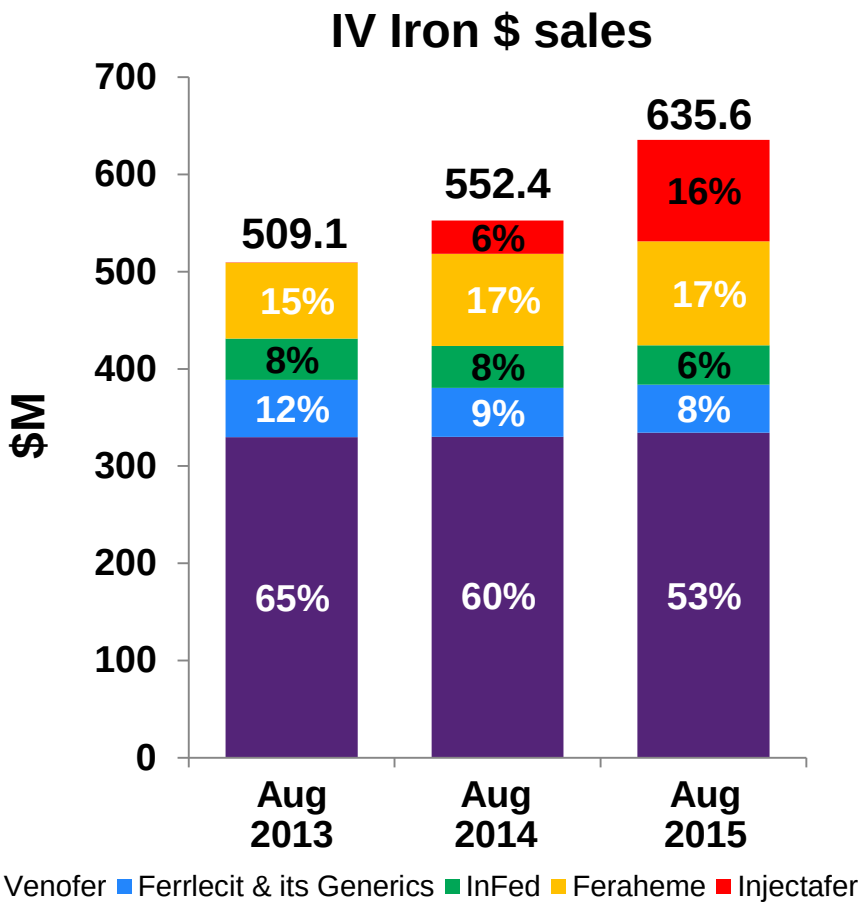
# Comparison between Injectafer® and Venofer ®

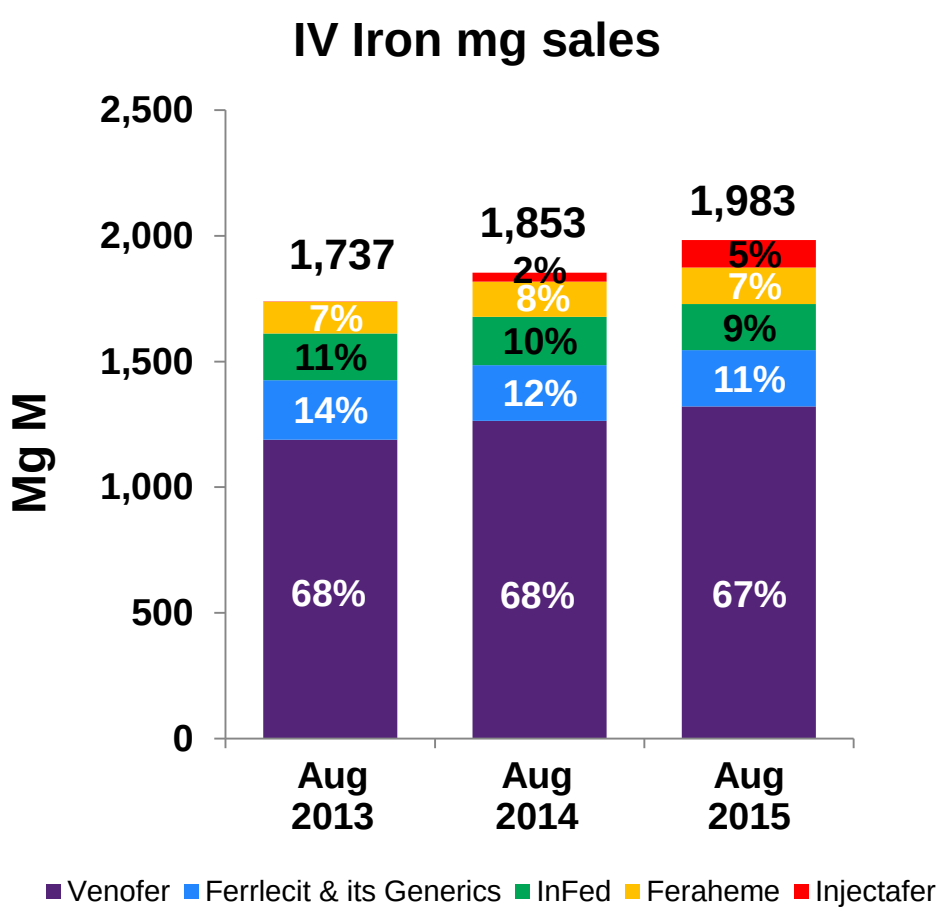
| | | Injectafer® | Venofer ® |
|---|---|---|---|
| Molecule | Carbohydrate shell | Carboxymaltose | Sucrose |
| Indications | IDA of various of non-CKD etiologies (e.g., cancer, GI disorders, HUB, postpartum) | Yes (for adult patients who have intolerance to oral iron or have had unsatisfactory response or oral iron) | Not FDA approved |
| | IDA in patients with CKD | Yes | Yes |
| Safety | Black Box Warning | No | No |
| | Test Dose Required | No | No |
| | MRI Interference | No | No |
| Dosing | Maximum approved single dose | 750mg | 100mg – 400mg (depending upon indication) |
| | Maximum approved cumulative dose | 1500mg | 1000mg |
| | Number of administrations required to deliver cumulative dose |  |  (for non-dialysis CKD IDA) |
| Administration | IV Push | Yes | Yes |
| | IV Infusion |  Yes, over at least 15 minutes |  Yes, over 15 minutes to 2.5 hours depending on dose |

# Injectafer: The Fastest Growing IV Iron in US

Daiichi-Sankyo

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

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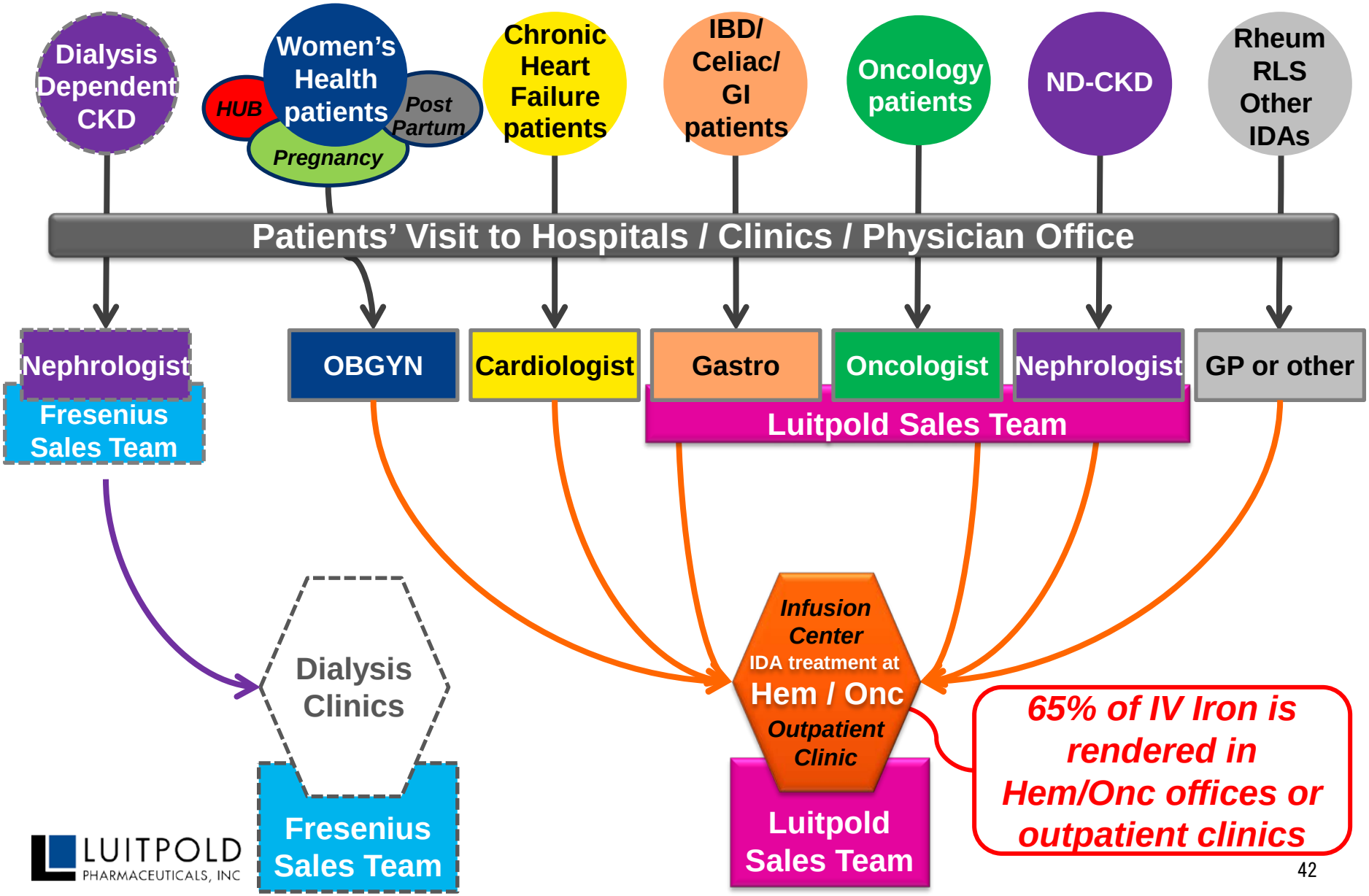
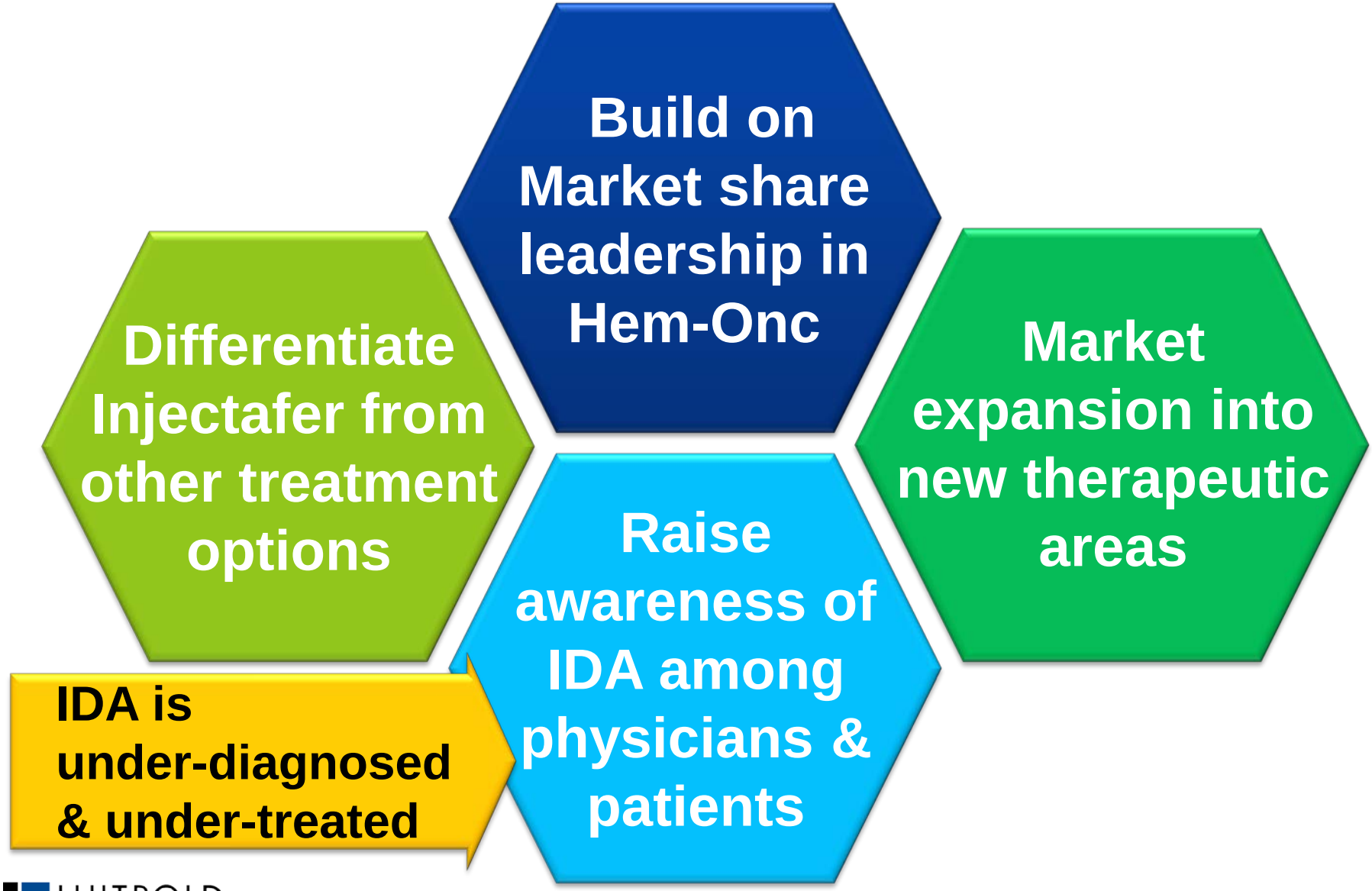
Source: IMS National Sales Perspectives Sept 2015

# Hem-Onc Treats most Non-Dialysis IDA patients



# Growth Strategy for Injectafer



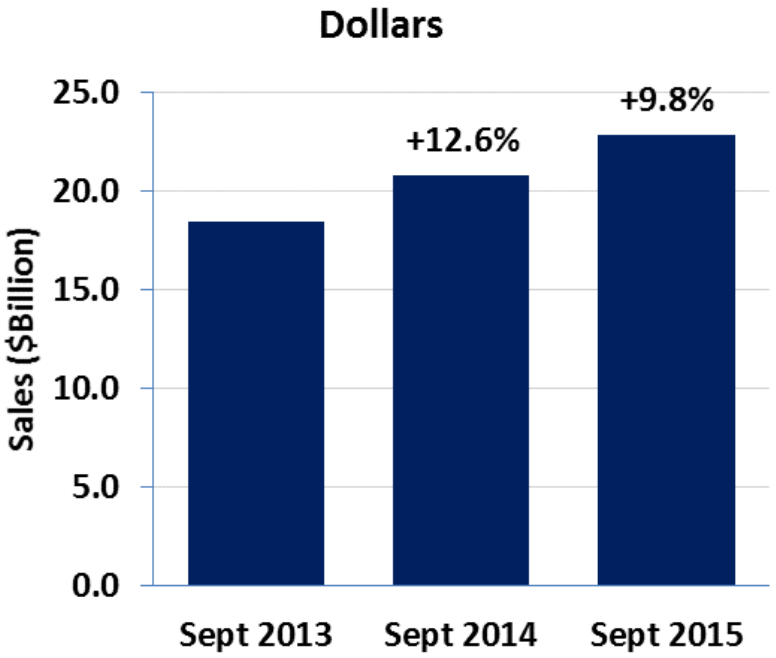
# LPI - A Diversified Specialty Company

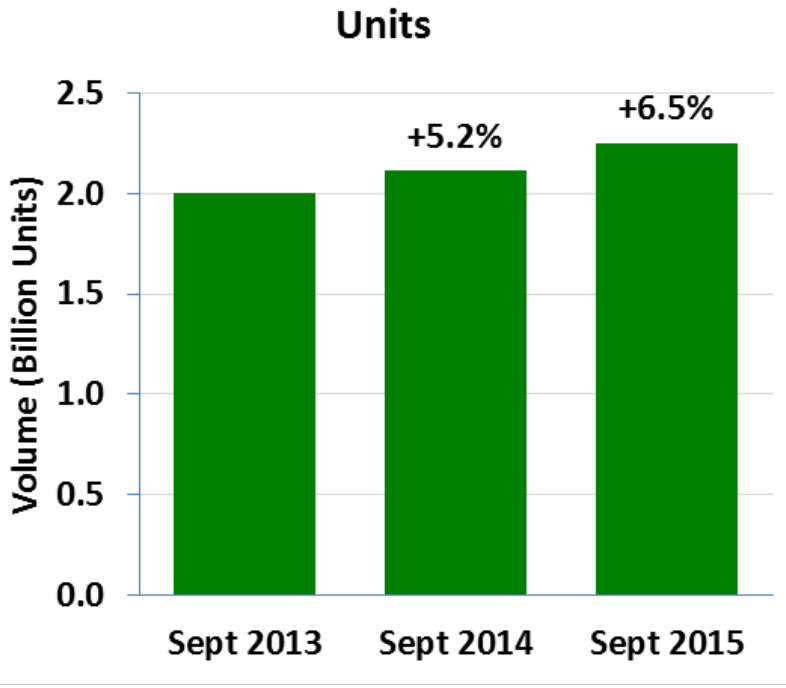
**LPI successfully competes in high value specialty branded & generic injectable market segments.**

| Business Domains | *Strategic Imperatives* |
| --- | --- |
| IRON FRANCHISE (> 50% share of non HD segment) | *Build Injectafer into our flagship product & market leader* |
| GENERIC INJECTABLE FRANCHISE | ***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**



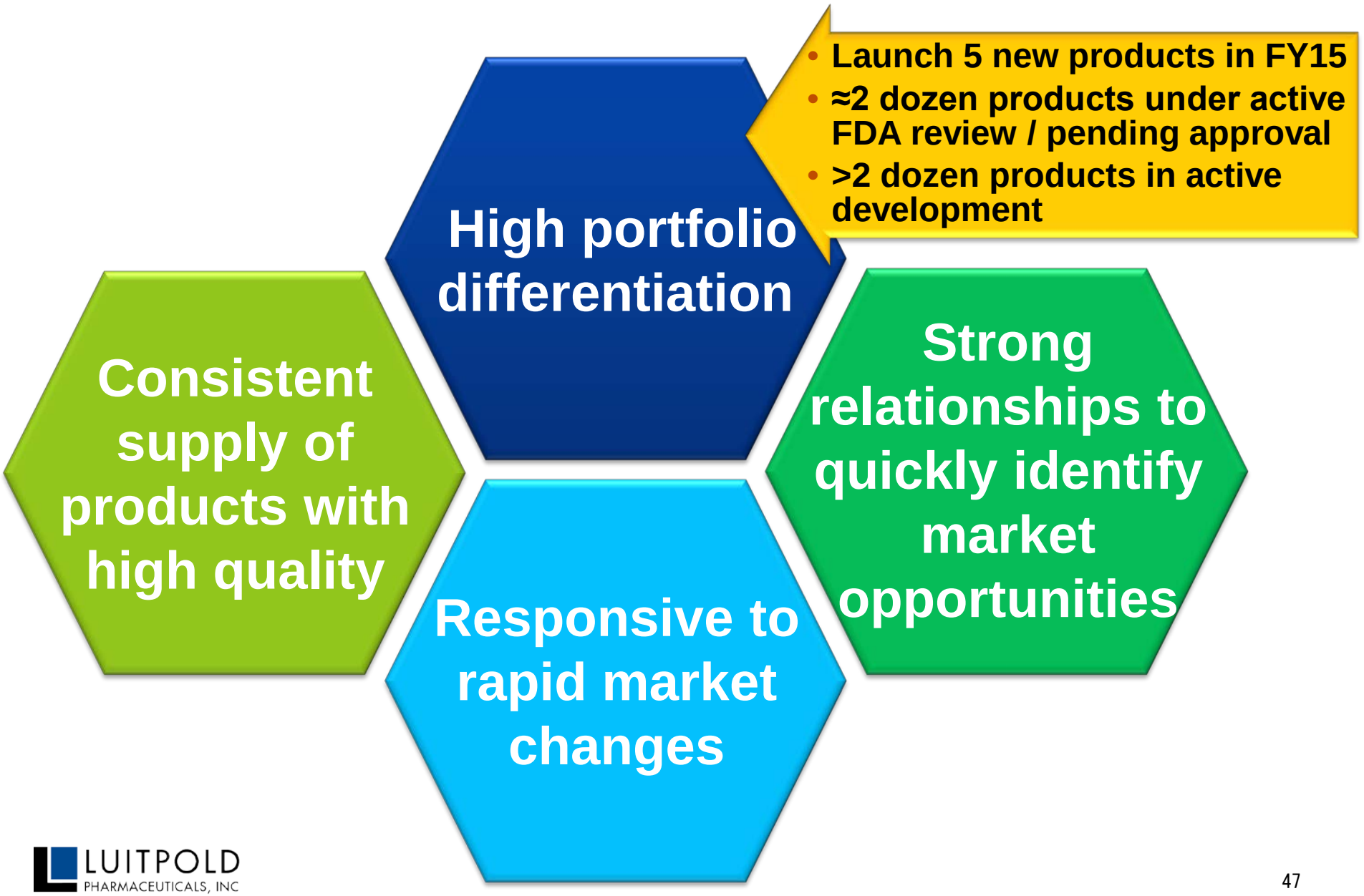




Source: IMS NSP AUDIT MAT Sept 2015. Includes Generic and Branded Generic Injectables.

# 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



# Investment to Expand Manufacturing Capacity

Daiichi-Sankyo

**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**

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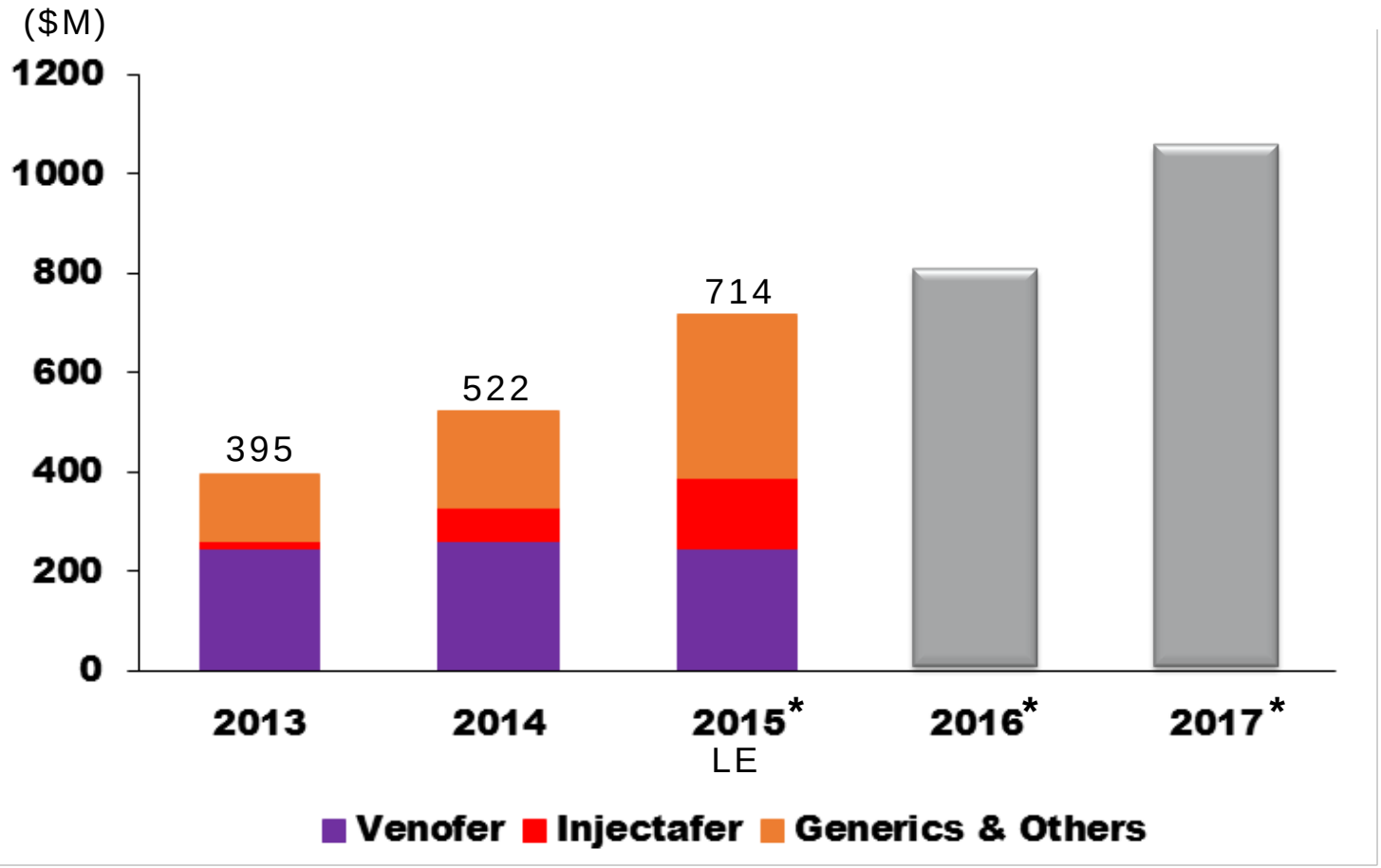
# LPI is Positioned for Accelerated Growth

## Double digit revenue and profit growth




* Based on the forecast

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