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「日本におけるケミカルバイオロジー研究新展開」 研究開発専門委員会第6回定例会 2013. 8. 5, ホテル京阪京都

#### Meiji Seika Pharma Co., Ltd.







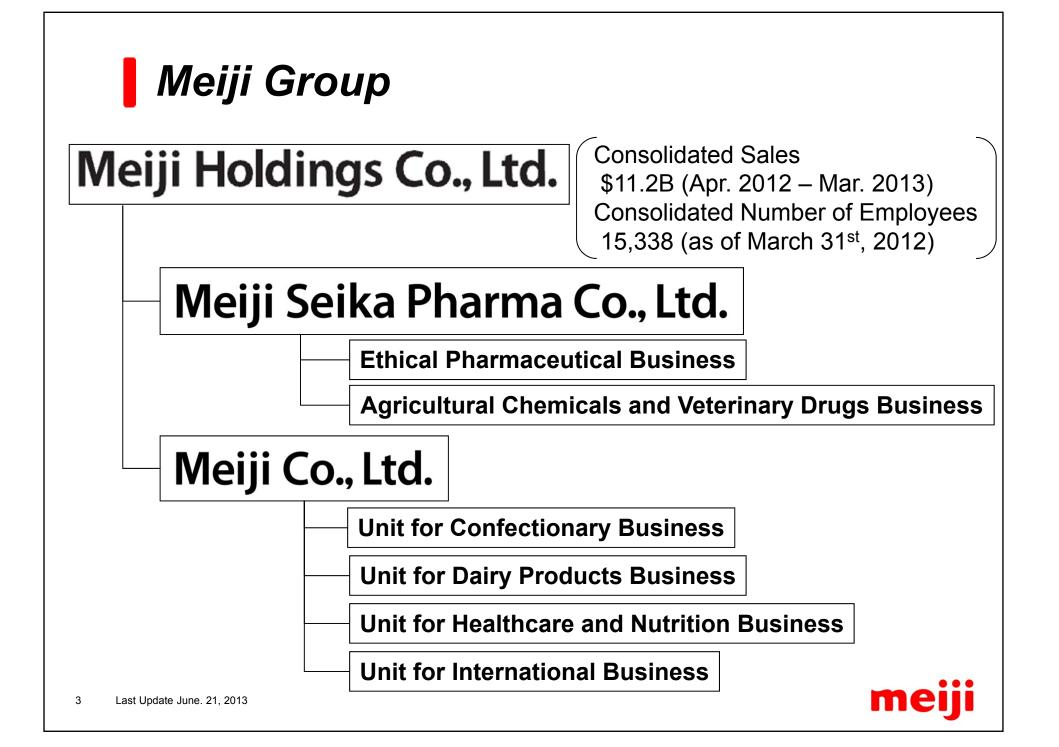


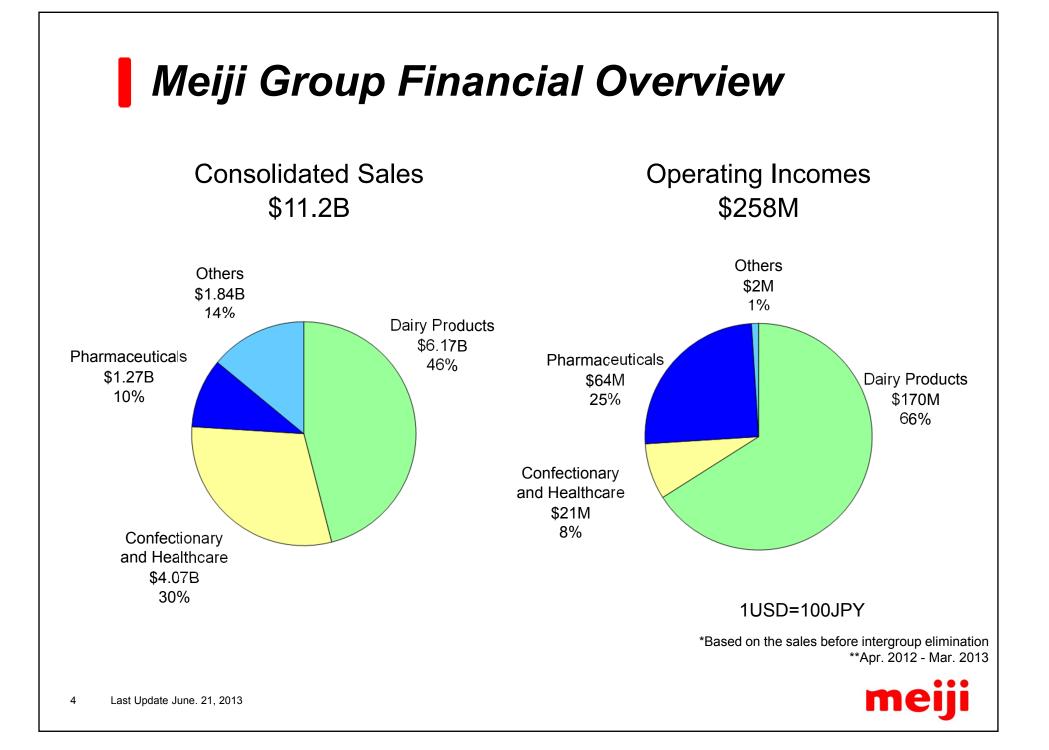
1 Last Update June. 21, 2013

# Meiji Group Overview



2 Last Update June. 21, 2013





# Meiji Seika Pharma Co., Ltd.

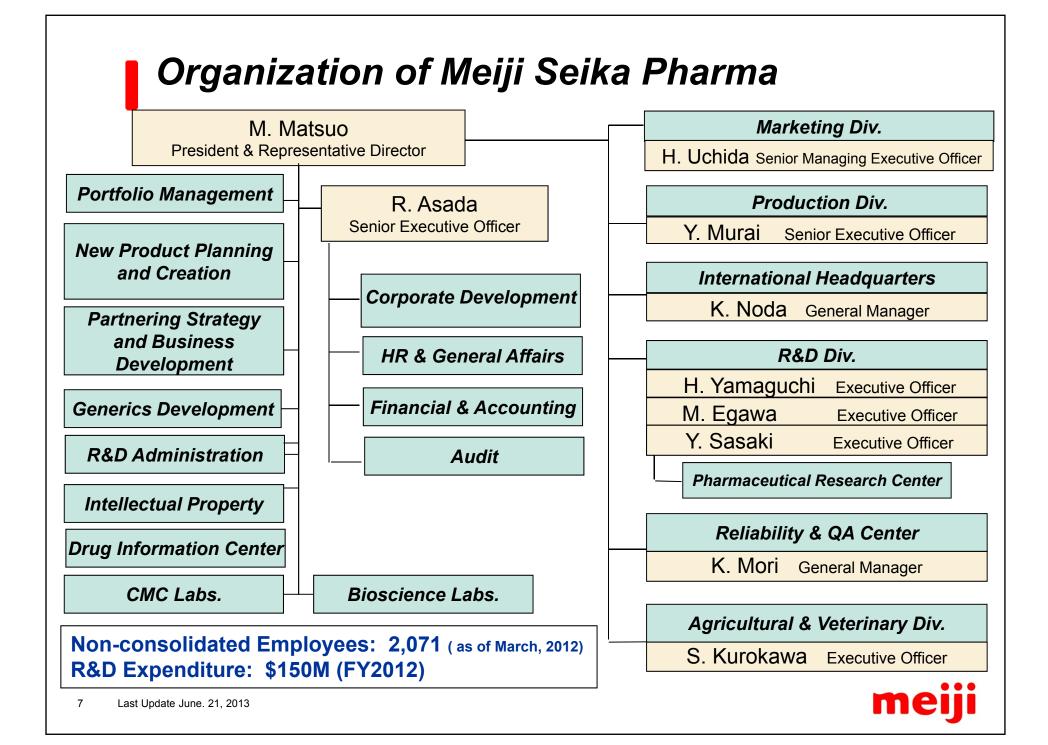


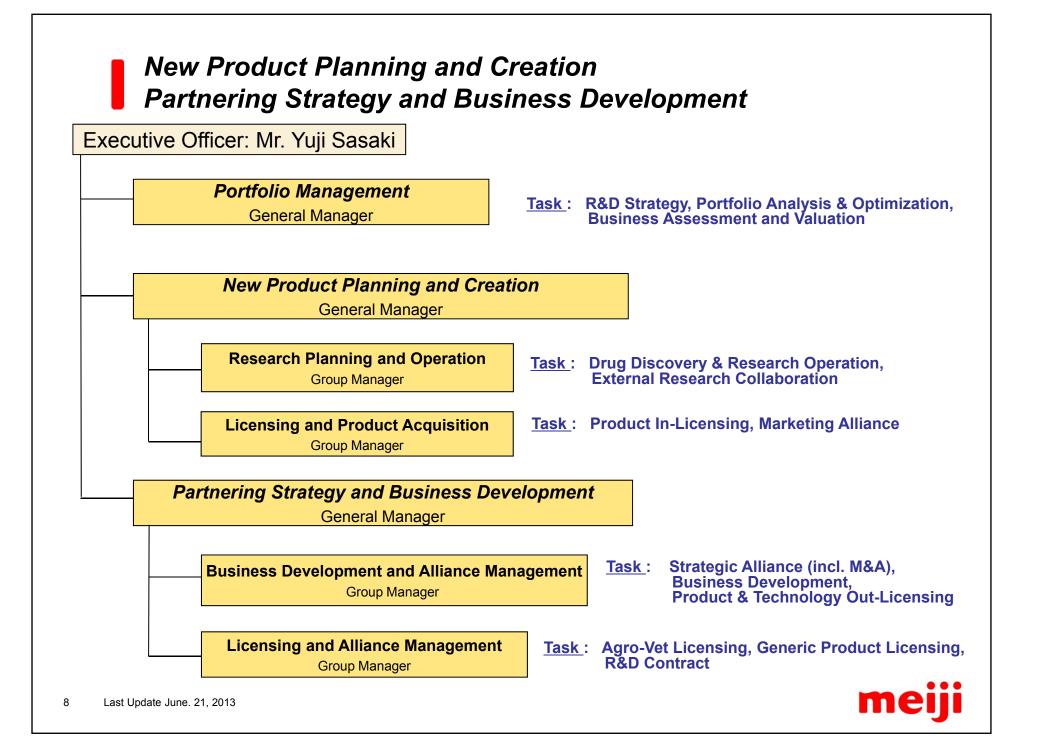
# 2020 Vision

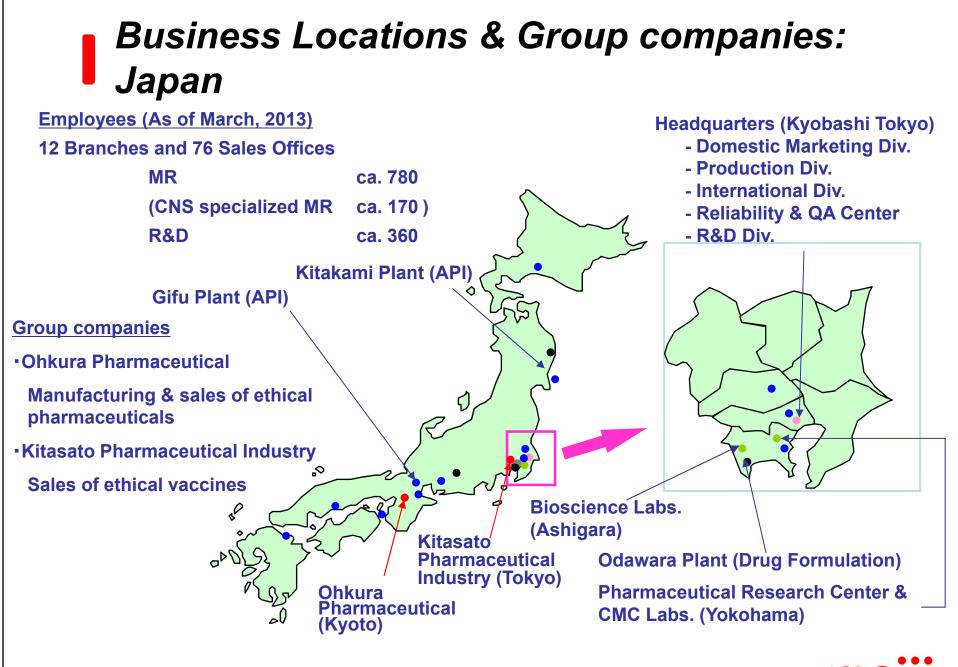
Contributing to the well-being of people worldwide through the research and development of ethical pharmaceuticals, agricultural chemicals and veterinary drugs, and by providing high-quality, low-priced generic drugs.

- Business Expansion through Proactive R&D Investment
- Further Expansion of the Generic Drugs Business
- Proactive Expansion of International Business, mainly in Asia and Emerging Countries



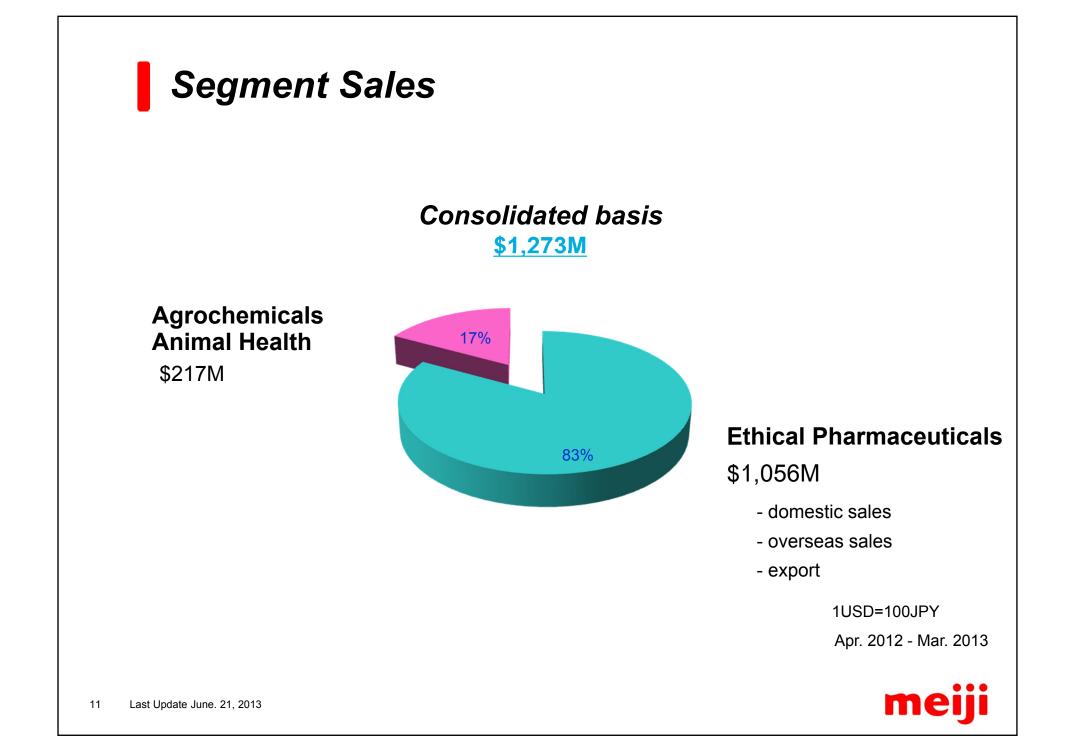






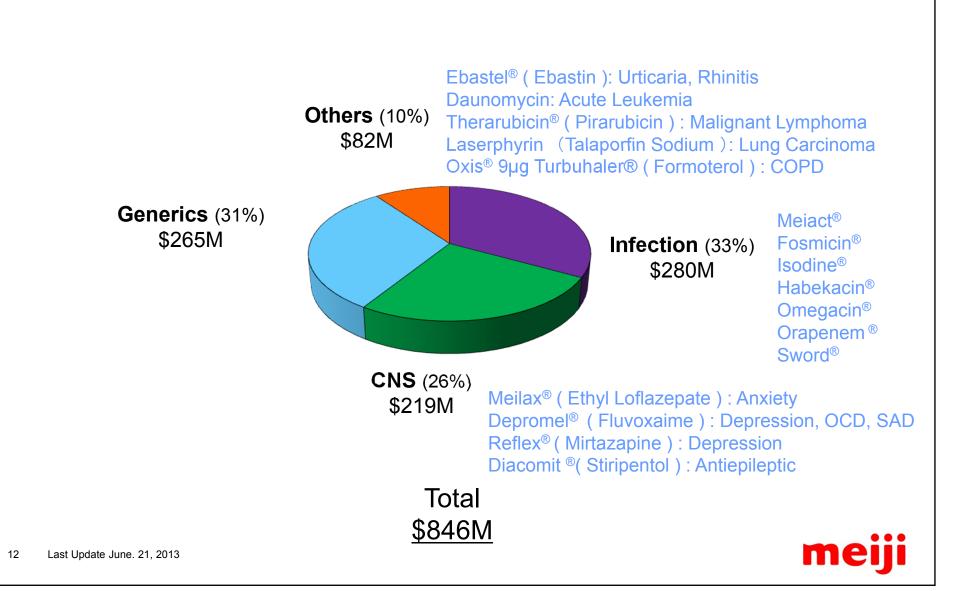






#### Ethical Pharmaceutical Sales by Therapeutic Area

in the Japanese market (Apr. 2012—Mar. 2013)



### **Ethical Pharmaceutical Leading Products**

in the Japanese Market (Apr.2012—Mar.2013)

Brand Name (Date of Launch)	Activity/Indication	Sales in Japan	Partner
Meiact ('94.6)	Oral cephem	\$167M	
Reflex ('09.9)	NaSSA* : Depression	\$136M	MSD
Depromel ('99.5)	SSRI: Depression, OCD, SAD	\$48M	Abbott
Vancomycin MEEK ('02.7)	Antibiotic	\$38M	Kobayashi Kako
Amlodipine ('08.7)	Ca antagonist	\$38M	
Fosmicin ('80.12)	Fosfomycin	\$36M	
Meilax ('88.12)	Benzodiazepine: Anxiety	\$34M	Sanofi-Aventis
Sulbacillin ('06.9)	Antibiotic	\$22M	
Orapenem ('09.8)	Oral carbapenem	\$21M	Pfizer
Isodine ('61.11)	Anti-septic	\$21M	Mundipharma
Donepezil ('11.11)	Anti-Alzheimer's disease	\$19M	
Ebastel ('96.6)	H₁antagonist: Urticaria, Rhinit	is \$18M	Dainippon Sumitomo
Omegacin ('02.3)	Carbapenem	\$14M	Pfizer
Habekacin ('90.12)	Aminoglycoside: MRSA	\$13M	

\* NaSSA : Noradrenergic and Specific Serotonergic Antidepressant



## **Product Pipeline : Infection Disease**

#### [Infectious Disease]

	Compound	Activity	Indication	Status	Partner
<b>■</b> ★	<b>ME</b> 1111	Antifungal	Onychomycosis	Phase I	
	Sym006	Polyclonal human antibodies	<i>Pseudomonas aeruginosa</i> infection	Preclinical	Research Collaboration with Symphogen

★ Meiji Seika Pharma original compound

Developing outside Japan



## New Product Pipeline : CNS

#### [CNS]

	Compound	Activity	Indication	Status	Partner
•	ME2136 (Asenapine)	SDA	Schizophrenia	Phase III	MSD (in-license)
•	Depromel (Fluvoxaime)	SSRI	Obsessive Compulsive Disorder ( Pediatric )	Phase III Line Extension	Abbvie (in-license)
•	ME2112 (Ziprasidone)	SDA	Schizophrenia	Phase II	RaQualia (in-license)
•	Reflex (Mirtazapine)	NaSSA	Fibromyalgia	Phase II Line Extension	MSD (in-license)
•	ME2125 (Safinamide)	MAO-B inhibitor	Parkinson's Disease	Phase I	Newron (In-license)

O Developing in Japan



### New Product Pipeline : Unmet Medical Needs

#### [Unmet Medical Needs]

	Compound	Activity	Indication	Status	Partner
•	ME2906	Photosensitizer	Glioma Esophagus Cancer	NDA Clinical Research	
•	ME3113 (Udenafil)	Phosphodiesterase V inhibitor	Benign Prostatic Hyperplasia	Phase IIb	Dong-A (In-license)
	DMB-3111 (Biosimilar)	Monoclonal Antibody	Breast Cancer	Preclinical	Dong-A

Developing in JapanDeveloping outside Japan



## Partners' Development Activities

#### [International Development]

	Compound	Activity	Indication	Status	Partner
	LS11 (ME2906)	Photosensitizer	Hepatocellular Carcinoma Metastatic Colorectal Cancer Benign Prostatic Hyperplasia	Phase III Phase III Phase I	Light Sciences Oncology (out-license)
<b>□</b> ★	ME3301	Anti-inflammatory	IBD, Allergic Rhinitis	Phase II	Amalyte (out-license)
<b>■</b> ★	CP8816 & CP8863	Progesterone receptor modulator	Endometriosis	Preclinical	Tokai (out-license)
■ ★	MN-447 (CP4715)	GP I bIIIa & αvβ3 receptor dual antagonist	Acute Ischemic Heart Disease Cerebral Infarction	Preclinical	MediciNova (out-license)

★ Meiji Seika Pharma original compound O Developing in Japan

Developing in JapanDeveloping outside Japan



# **Recent Alliance Deals**

Year	Partner	Type of Collaboration
Apr/2013	MSD	In license of Asenapine / Schizophrenia in Japan
Oct/2012	OHKURA	Distribution of Check hMPV / Diagnostic reagent kit in Japan
May/2012	AstraZeneca	Distribution of Oxis® 9µg Turbuhaler®28doses / COPD in Japan
May/2012	OHKURA	Distribution of Check AD / Diagnostic reagent kit in Japan
Apr/2012	R-Pharm	Out license and Distribution of MEIACT MS® and ADANT® in Russia
Apr/2012	Thien Thao	Distribution partnership of Meiji products in Viet Nam
Jan/2012	Newron	In license of Safinamide / Parkinson's Disease In Asia
Dec/2011	OHKURA	Distribution of Check RSV/ Diagnostic reagent kit in Japan
Sep/2011	Dong-A Pharm	Strategic Partnership for global R&D of Biosimilars
Sep/2011	Dong-A Pharm	In license of Udenafil / Benign Prostatic Hyperplasia in Japan
Jul/2011	Alere Medical	Distribution of Clearline®InfluenzaA/B/(H1N1)2009 / Diagnostic product for Influenza in Japan
Mar/2011	RaQualia	In license of Ziprasidone / Schizophrenia in Japan
Jan/2011	Fresenius Kabi Japan	Strategic Partnership of oncologic generic products in Japan



#### Strategic Alliance to Strengthen Generic Business

Global Alliance with Dong-A Pharmaceutical

(September 14<sup>th</sup>, 2011)



- Collaboration on Monoclonal Antibody of Biosimilars
  - DMB-3111 selected for development for oncology indications
  - •Two more to be selected within a year
- Joint Venture established for global supply and commercialization
- c-GMP manufacturing facility to be constructed in Incheon Free Economic Zone

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## Partnering Interest

- Product In-license & Research Collaboration
  - Infectious and respiratory diseases
  - CNS diseases
  - Diseases with unmet medical needs

(Oncology, Inflammatory & rare diseases)

- Marketing Collaboration
  - ENT
  - Pediatric
  - Psychiatry & Neurology
  - Respiratory
  - Hematology







