Overview of Pharmaceutical Business at JT

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Muneaki Fujimoto
President, Pharmaceutical Business

ひとのときを、想う。

FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements. These statements appear in a number of places in this presentation and include statements regarding the intent, belief, or current and future expectations of our management with respect to our business, financial condition and results of operations. In some cases, you can identify forward-looking statements by terms such as “may”, “will”, “should”, “would”,“expect”, “intend”, “project”, “plan”, “aim”, “seek”, “target”, “anticipate”, “believe”, “estimate”, “predict”,“potential” or the negative of these terms or other similar terminology. These statements are not guarantees of future performance and are subject to various risks and uncertainties. Actual results, performance or achievements, or those of the industries in which we operate, may differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, these forward-looking statements are necessarily dependent upon assumptions, estimates and data that may be incorrect or imprecise and involve known and unknown risks and uncertainties. Forward-looking statements regarding operating results are particularly subject to a variety of assumptions, some or all of which may not be realized.

Risks, uncertainties or other factors that could cause actual results to differ materially from those expressed in any forward-looking statement include, without limitation:
(1)decrease in demand for tobacco products in key markets;
(2)restrictions on promoting, marketing, packaging, labeling and usage of tobacco products in markets in which we operate;
(3)increases in excise, consumption or other taxes on tobacco products in markets in which we operate;
(4)litigation around the world alleging adverse health and financial effects resulting from, or relating to, tobacco products ;
(5)our ability to realize anticipated results of our acquisition or other similar investments;
(6)competition in markets in which we operate or into which we seek to expand;
(7)deterioration in economic conditions in areas that matter to us;
(8)economic, regulatory and political changes, such as nationalization, terrorism, wars and civil unrest, in countries in which we operate;
(9)fluctuations in foreign exchange rates and the costs of raw materials; and
(10) catastrophes, including natural disasters.

History

1987	Jun.	Announced entry into the pharmaceutical business.
1988	Jul.	Established the pharmaceutical business division.
1993	Sep.	Opened the Central Pharmaceutical Research Institute. (Takatsuki, Osaka Pref.)
1998	Dec.	Acquired >50% open stock of Torii Pharmaceutical Co., Ltd.(Torii).
1999	Jan.	Founded Akros Pharma Inc.. (U.S.)
	Oct.	Formed a business tie-up with Torii. (Torii is in charge of manufacturing and sales while concentrating R&D activities at JT)

<Product history>

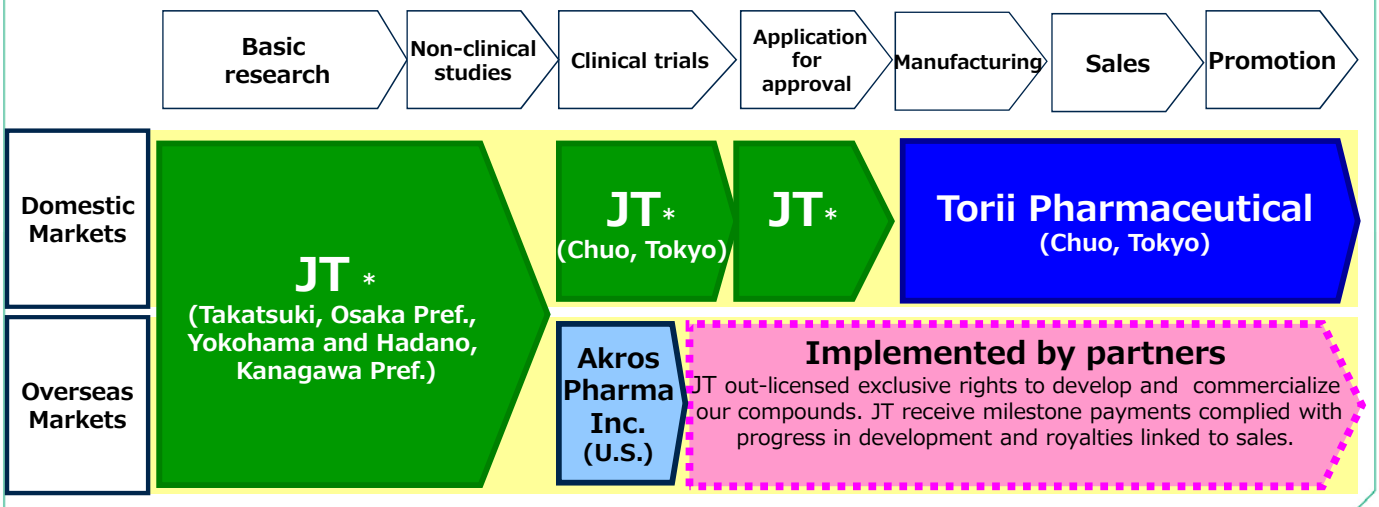
1998	Mar.	"Viracept Tablets", an anti-HIV drug : Approved in Japan.
2004	Mar.	"Viread Tablets", an anti-HIV drug (in-licensed from Gilead Sciences): Approved in Japan.
2005	Mar.	"Emtriva Capsules" and "Truvada Combination Tablets", an anti-HIV drug (in-licensed from Gilead Sciences) : Approved in Japan.
2009	Jan.	"REMITCH CAPSULES 2.5 μg", an oral antipruritus drug : Approved in Japan. Co-developed by Toray Industries, Inc.(Toray), Torii and JT.
2012	Aug.	"Stribild", an anti-HIV drug containing JTK-303(out-licensed to Gilead Sciences): Approved in U.S.. *A government office approved a new drug including JT's original compound for the first time.
2013	Mar.	"Stribild Combination Tablets", an anti-HIV drug containing JTK-303(out-licensed to Gilead Sciences): Approved in Japan.
	May	"Mekinist", an MEK inhibitor(out-licensed to GlaxoSmithKline): Approved in U.S.. *The rights to this drug has been held by Novartis since March 2015 due to a business transfer
2014	Jan.	"Riona Tablets", a therapeutic agent for Hyperphosphatemia (in-licensed from Keryx): Approved in Japan. Co-developed by JT and Torii.
		"CEDARTOLEN SUBLINGUAL DROP", a sublingual immunotherapy drug for Japanese cedar pollinosis: Approved in Japan. (developed by Torii)
2015	Sep.	"MITICURE House Dust Mite Sublingual Tablets", an allergen immunotherapy tablet for house dust mite allergy : Approved in Japan. (developed by Torii)
2016	Jun.	"Genvoya Combination Tablets", an anti-HIV drug containing JTK-303(out-licensed to Gilead Sciences): Approved in Japan.
	Dec.	"Descovy Combination Tablets LT/HT", anti-HIV drugs (in-licensed from Gilead Sciences): Approved in Japan.

Business model

Out-licensing

- Advantage: Cost efficiency / Good use of partner's expertise.
- Disadvantage: Time loss (We must stop development while we negotiate out-licensing agreement) / Profits must be shared with partners.

*Partially implemented by Torii(allergens, etc.)



Organization

Central Pharmaceutical Research Institute

- Pharmaceutical Frontier Research Laboratories
- Drug Metabolism & Pharmacokinetics Research Laboratories
- Chemical Research Laboratories
- Product Development Laboratories
- Biological/Pharmacological Research Laboratories
- Toxicology Research Laboratories

(Approx. 600)

R&D

Clinical development division

(Approx. 100)

Akros Pharma Inc.

(Approx. 50)

Clinical development

Torii Pharmaceutical

(Approx. 1,050 includes 500 MRs)

Manufacturing, sales and promotion

Approx. 1,800 of personnel

Approach to R&D focus area

- **Targeting diseases with strong Unmet Medical Needs**
- **Focusing First-In-Class(FIC) drugs**
- **Implementing a drug discovery strategy in view of a future paradigm shift in therapeutic method**
- **Specializing in small molecule compounds**

Current Focus Area

(i) Metabolic diseases

(ii) Autoimmune/Inflammatory diseases

(iii) Viral infection

(Reference) Torii's focus area and main products

① Renal diseases and hemodialysis
REMITCH CAPSULES, oral therapeutic agent for pruritus in hemodialysis patients; co-developed by JT, Torii and Toray
REMITCH OD Tablets, oral therapeutic agent for pruritus in hemodialysis patients; co-developed by JT, Torii and Toray
Riona Tablets, therapeutic agent for hyperphosphatemia; co-developed by JT and Torii

② Skin diseases
ANTEBATE, topical corticosteroid

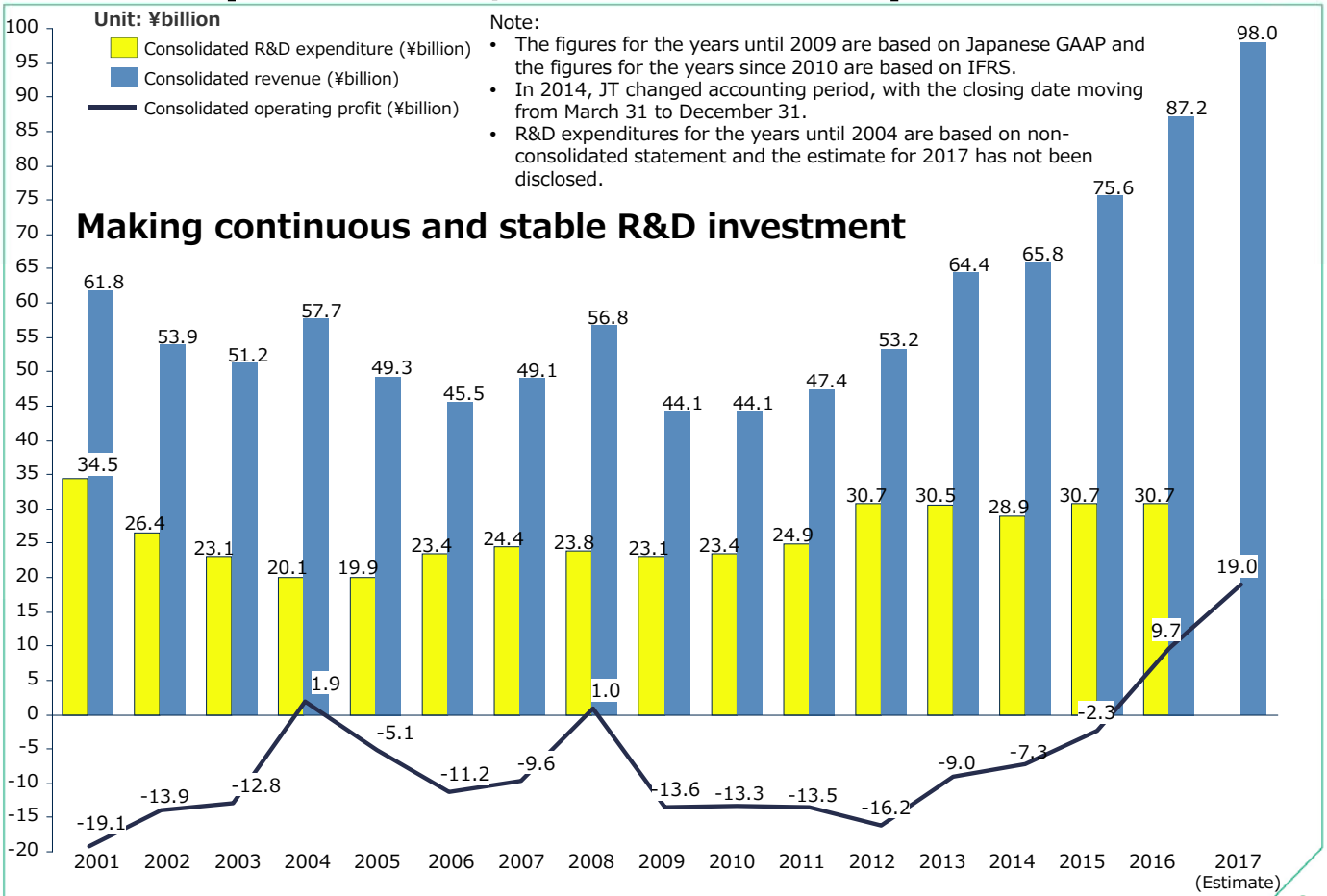
③ Allergens
CEDARTOLEN SUBLINGUAL DROP, allergen immunotherapy drugs
MITICURE House Dust Mite Sublingual Tablets, allergen immunotherapy tablet

④ HIV infection
Truvada Combination Tablets, **Stribild Combination Tablets**, **Genvoya Combination Tablets** and **Descovy Combination Tablets**

Torii is working in close cooperation with JT to search and develop new in-licensed compounds, and also devotes efforts to develop new dosage form and additional indication of existing products, and R&D in allergens.

<<Status of clinical development (as of the end of June 2017)>>
- **JTT-751** (Riona Tablets), iron-deficiency anemia (Oral)- Phase 2 (co-developed by JT and Torii)
- **TO-203**, house dust mite induced allergic asthma (Allergen Immunotherapy)(Sublingual tablets)- Phase 2/3 completed
- **TO-203**, house dust mite induced allergic rhinitis in children (Allergen Immunotherapy) (Sublingual tablets) -Application
- **TO-206**, Japanese cedar pollinosis (Allergen Immunotherapy)(Sublingual Tablets)- Application

R&D expenditure, revenue and profit



Profit growth drivers

■ Progress in R&D/market launch

- ➢ Reaping the fruits of past R&D activities
- ➢ Steadily launching new drugs

● Major products recently launched

Stribild Combination Tablets (antiviral agent for HIV)
- ・Overseas Out-licensed to Gilead Sciences FDA approval in Aug. 2012
- ・Japan Sold by Torii MHLW approval in Mar. 2013

Genvoya Combination Tablets (antiviral agent for HIV)
- ・Overseas Out-licensed to Gilead Sciences FDA approval in Nov. 2015
- ・Japan Sold by Torii MHLW approval in Jun. 2016

Mekinist (MEK inhibitor)
- ・Worldwide Out-licensed to GlaxoSmithKline and Novartis* FDA approval in May. 2013

*The rights to this drug has been held by Novartis since March 2015 due to a business transfer

Riona Tablets (therapeutic agent for hyperphosphatemia)
- ・Japan Sold by Torii MHLW approval in May. 2014

■ Revenue

- ➢ Growing sales of out-licensed products
  Increased royalty revenue from out-licensed products / Milestone revenue related to the progress in drug development
- ➢ Driving growth of domestic revenue with recent launch of anti-HIV drugs, Riona Tablets, etc.

Pipeline (as of the end of June 2017)

Code/*development phase (Generic name)		Potential Indication/ Dosage form	Mechanism	In-house/licensing	Supplementary explanation
JTZ-951	Japan: Phase 2 Overseas: Phase 1	Anemia associated with chronic kidney disease /Oral	HIF-PH inhibitor	In-house *Out-licensed to JW	(Competing candidates) Roxadustat: Global Ph3 Daprodustat: Global Ph3
JTE-052	Japan: Phase 3	Autoimmune/ allergic diseases /Oral, Topical	JAK inhibitor	In-house Co-development with Torii *Out-licensed to LEO	Most advanced clinical study is for atopic dermatitis in Japan
JTE-051	Overseas: Phase 2	Autoimmune/ allergic diseases /Oral	Interleukin-2 inducible T cell kinase (ITK) inhibitor	In-house	No program in clinical stage is reported from any companies
JTT-251	Overseas: Phase 1	Type 2 diabetes mellitus /Oral	PDHK inhibitor	In-house	No program in clinical stage is reported from any companies
JTK-351	Japan: Phase 1	HIV infection /Oral	HIV integrase inhibitor	In-house	—
JTE-451	Overseas: Phase 1	Autoimmune/ allergic diseases /Oral	RORγ antagonist	In-house	While competition to develop RORγ antagonist drugs is intense, JT is not lagging behind competitors.
JTT-751 (ferric citrate)	Japan: Phase 2	Iron-deficiency anemia/Oral	Oral iron replacement	In-license (Keryx Biopharmaceuticals) Co-development with Torii	*Additional indication

Notes:
- The clinical trial phases presented above are based on the first dose.
- Out-licensed to JW Pharmaceutical (South Korea) under a license agreement for exclusive rights to development and commercialization in South Korea for application to oral medication.
- Out-licensed to LEO Pharma (Denmark) under a license agreement for exclusive rights to development and commercialization in the world outside Japan for topical use in dermatological indications.

For the future

- **R&D investment**
  - Continuous and stable R&D investment independent from revenue fluctuations
- **Open innovation**
  - Creation of FIC new drugs that fulfill Unmet Medical Needs.
    - New drug targets
    - Drug Efficacy / Development technologies
    - Advancing into cutting-edge fields (leading to future drug creation)
  - Active engagement in partnering and licensing rather than public invitation programs.
    - Building mutual trust and respect
    - Dispatching researchers

    *Reference
    Public invitation programs: a[3], COCKPI-T FINDS, TaNeDS, PRISM
    Comprehensive partnerships: AK Project, TK Project
- **Enhancement of in-licensing** (expansion of the domestic pipeline)
  - Group-wide in-licensing activity in co-operation with JT and Torii
  - Participating in BIO conferences / Organizing partnering conferences (overseas)

Conclusion

- **With the entire group working together to deliver new drugs to patients as soon as possible.**

  - **3 Key Principles**
    - Carrying on full effort for the patients
    - Targeting FIC, small molecule compounds
    - Continuous and stable R&D investment

  - **4 Key Strategies**
    - Continue to out-license our New Molecule Entities globally
    - Put more emphasis on in-licensing for the Japanese Market
    - Determine indications and clinical development plan with both global licensing and domestic sales franchise in mind
    - Contribute to JT Group profit through R&D for products of next generation and maximizing the value of existing products