Progress on the 2nd Medium-Term Management Plan

August 8, 2017

Tatsuo Higuchi
President and Representative Director, CEO
Otsuka Holdings Co., Ltd.
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Agenda

- Summary of 2017 Plan
- Pharmaceutical business update
  - Performance and projections of FY2017
- Nutraceutical* business update
  - Progress of product development and global business operations
  - Significance of Daiya Foods acquisition

*nutrition + pharmaceutical
Summary of 2017 Plan
Summary of 2017 Plan

A year to strengthen the business foundation for sustainable growth from 2019

- Maximize value of global products
- Aggressive R&D investments to achieve sustainable growth
- Enrich product pipeline and acquire new technologies in core therapeutic areas
- Maintain over 10% OP margin in nutraceutical business
- Increase operational efficiency through optimal resource allocation
Pharmaceutical business
Towards Sustainable Growth

- Confirming a good sales progress of new products
- ¥430+α billion sales target for new products in 2018 unchanged
- Aggressive investment starts out for 3rd Medium-Term Management Plan

Sales (¥ billion)

- 183 +new pipeline (2015A)
- 271.3 +new pipeline (2016A)
- 338 +new pipeline (2017E)
- 430+α (2018E)
- 80

New drugs in Japan*

- 80
- 183 +new pipeline
- 271.3 +new pipeline
- 338 +new pipeline
- 430+α

New pipelines

- TAS-102
  P3: Gastric cancer 3rd line
  EU: Launched in 9 countries

- SGI-110
  P3: Treatment naïve AML
  Study completion Dec’17**

- Abilify Maintena
  Bipolar disorder
  Approved

- brexpiprazole
  P3: AD agitation
  Study completed

- tolvaptan
  P3b: ADPKD
  Positive result

* New drugs in Japan: products launched or to be launched there between 2009 and 2018, excluding three global products and next-generation products above.  ** Source: ClinicalTrials.gov

Global products: tolvaptan(SAMSCA/JINARC), brexpiprazole(Rexulti), Abilify Maintena,
Next-generation products: TAS-102(Lonsurf), SGI-110
New pipelines: Nuedexta, Onzeta Xsail, AVP-786, centanafadine, vadadustat
Regional Expansion of New Products – Apr 2014 (start of 2nd mid-term plan)
## Regional Expansion of New Products

**– Aug 2017 : current status**

### Start of 2nd mid-term plan

### Current

### Final year for 2nd mid-term plan

<table>
<thead>
<tr>
<th>Products</th>
<th>EU</th>
<th>JP</th>
<th>US</th>
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<tr>
<td><strong>Ability Maintena</strong></td>
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<td><strong>REXULTI</strong> brexpiprazole tablets</td>
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<td><strong>Lonsurf</strong></td>
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* "JINARC", the brand name of tolvaptan for ADPKD indication outside Japan.

** Not approved in the corresponding areas as of 31 July, 2017. Brand names to be determined on approvals.
### Regional Expansion of New Products – FY2018: final year for the 2nd mid-term plan

#### Start of 2nd mid-term plan

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<tr>
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<td>✓</td>
<td>✓ (plan)</td>
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#### Final year for 2nd mid-term plan

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** Not approved in the corresponding areas as of 31 July, 2017. Brand names to be determined on approvals.
Initiatives for Sustainable Growth (1H2017)

- New challenges to highly unmet needs
- Aggressive investment for sustainable growth beyond 2018

**CNS**
- centanafadine
  - ADHD
  - P3 to be initiated
- fremanezumab
  - Episodic Migraine
  - P3 to be initiated (Japan)

**Oncology**
- KEYTRUDA
  - Co-promotion (Japan)
- SGI-110
  - r/r MDS** in P3
- SGI-110
  - r/r AML*** in P3

**Cardiovascular Renal system**
- tolvaptan
  - ADPKD P3b
  - Positive result
- vadadustat
  - Renal anemia in P3
- REXULTI
  - LAI in P1
- AVP-786
  - Neurobehavioral disinhibition associated with TBI*
  - P2 to be initiated
- LONSURF
  - Colorectal cancer
  - 2nd line
  - P2/3 to be initiated

*Neurobehavioral disinhibition associated with Traumatic Brain Injury (TBI)
** relapsed/refractory myelodysplastic syndromes
***relapsed/refractory acute myeloid leukemia
Progression of Late-stage Projects in Core Areas

Otsuka-people creating new products for better health worldwide

Creating unique and innovative products

Building new categories/markets

Developing global business

Late-stage projects* (P2 or later)

Projects to be started in 2017** (P2 or later)

Started projects as of 2017Q2

CNS 14 projects

Oncology 17 projects

Others 15 projects

8 projects

5 projects

5 projects

SGI-110 r/r MDS : P3
SGI-110 r/r AML : P3
TAS-115 prostate cancer : P2
tolvaptan SIADH : P3

*as of 2016 year end **including transition from P2 to P3 (oncology 3 projects, others 1 project)
CNS - Comprehensive Contribution to Medicine through Product Evolution -

**Contribution in addressing unmet medical needs**

- Neurological diseases
  - NUEDEXTA
  - AVP-786
- Psychiatric diseases
  - REXULTI
  - Abilify

**Medical treatment optimization**

- Digital health solutions
- Digital medicine
  - Solutions for adherence issue
  - Long acting injectables
    - Abilify Maintena

- Abilify
- REXULTI
Franchise

Contribution in addressing unmet medical needs

Neurological diseases
- fremanezumab
- NUEDEXTA

Psychiatric diseases
- centanafadine

Solution

Medical treatment optimization

Digital health solutions

Digital medicine (resubmitted)

Solutions for adherence issue

CNS - Comprehensive Contribution to Medicine through Product Evolution -

- AVP-786
- REXULTI

Psychiatric diseases
- Abilify

Long acting injectables
- Abilify Maintena
- REXULTI-LAI
Growth Strategy of Oncology Business

**Solid tumors**

**Hematologic cancers**

**Challenge**

**Become a global category leader**

**Access to state-of-the-art science**

- **Keytruda**
  - Co-promotion in Japan

- **Lonsurf**
  - Colorectal cancer 2nd line

- **Antimetabolites and molecular-targeted drugs**

- **Enhancing global presence**

**Scientific Advances**

- **Epigenetic drug discovery**
  - SGI-110
    - P3 studies for AML/MDS initiated

**Original platforms**

**Global sales & marketing resources**
Nutraceutical business
Solutions for Yet-to-be-imagined Needs

- New product category of “conditioning nutrition” to support athletic performance

- New solution for “quality sleep” by regulating biological rhythms

  ✓ Conditioning food as the basis of performance that offers new values by addressing the unmet needs of body conditions
  ✓ Containing lactic acid bacteria B240, BCAA + Arginine and whey protein to maintain physical functions

  ✓ Sleep supporting product to regulate sleep-wake rhythms, enhance quality of sleep and help in maintaining a rested, energetic back-to-work feeling
  ✓ *Food with Function Claims* containing asparagus-derived ingredient expected to improve sleep patterns with disrupted biological rhythms and enhance the quality of sleep and wellbeing
Global Business Expansion (1H2017)

New factory of gluten-free products in operation

Otsuka Nutraceutical (Thailand) Ltd established

Entering a new category of plant-based products
Daiya Foods Inc.

- Rapidly growing plant-based food company in North America
- High CAGR of 47% (2014-2016)

Sales

- CAGR(2014-2016) 47%
- FY2014: 36.6
- FY2015: 52.8
- FY2016: 79.5

Cheese alternatives

Yogurt alternatives

Dressings and Desserts
Significance of Daiya Foods acquisition

- Plant-based food creates synergy among Otsuka business portfolio
- Expand nutraceutical footprint in North America by acquiring a new category where significant growth is expected
- Accelerate mutual growth by sharing experties of Otsuka and Daiya in R&D and manufacturing
- Expand Daiya’s business into Europe and Asia

Dairy Alternatives – Retail Sales (USA)

- **Natural and healthy**
  - Plant-based food
- **Gluten-free**
- **Supplement/functional**
- **Organic**

**Growth potential**

*Company data **source: Euromonitor, Market & Market, OC&C Strategy Consultants S.a.r.l. analysis
Size of circle shows market size of each category in 2016

CAGR (2016-21)

<table>
<thead>
<tr>
<th></th>
<th>2011A</th>
<th>2016A</th>
<th>2021E</th>
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<tbody>
<tr>
<td><strong>Yogurt</strong></td>
<td>1.5</td>
<td>2.2</td>
<td>3.0</td>
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<tr>
<td><strong>Cheese</strong></td>
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<td>0.2</td>
<td>0.5</td>
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<tr>
<td><strong>Ice Cream</strong></td>
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<td></td>
<td>0.3</td>
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<tr>
<td><strong>Milk</strong></td>
<td>0.2</td>
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<td>0.5</td>
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Source: Euromonitor, OC&C Strategy Consultants S.a.r.l.
Profitability Improvement and Structural Reform

Accelerate global expansion

Foster new products

Review business assets that support value chain

Structural reform

Maintain over 10% OP margin

NC operating profit

Operating profit
Operating profit margin

(¥100Mil)

0 500


Operating profit
Operating profit margin

10.9% 10.4%

7.1% 8.7% 8.5% 8.8%

7.0%

0.9%

* Unaudited indicators for same financial period (Jan-Dec 2014)
Summary of 2017 Plan

- **A year to strengthen the business foundation for sustainable growth from 2019**

  - Maximize value of global products
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