Health Care Domain

Capitalizing on the Group’s comprehensive capabilities and network, the Health Care domain develops businesses for pharmaceuticals, diagnostic reagents and instruments, clinical testing, healthy support service, support for new pharmaceutical development, active pharmaceutical ingredients and intermediates, pharmaceutical formulation materials such as capsules, pharmaceutical equipment.

Business Lines by Segment

Health Care

The health care business comprehensively covers pharmaceuticals such as diagnostic reagents and instruments, clinical testing, as well as support for new pharmaceutical development. We also take on the challenge of creating new businesses, such as regenerative medicine, while aiming to expand into the health and medical businesses using ICT. In addition to disease treatments, MCHC is advancing operations with the ultimate aim of realizing a society where people can live long and healthy lives.

Masayuki Mitsuka
President and Chief Executive Officer, MTPC

Seiichi Kiso
President and Chief Executive Officer, LSII

Main Businesses and Products

Pharmaceuticals

Net sales approx. ¥430 billion

Growth into top-class drugs by IKUYAKU (drug fostering and evolution)

We have put on the market Remicade and Simponi, autoimmune disease treatments with two routes of administration for the diverse lifestyles of patients. These two drugs have grown into the top of their class in the autoimmune disease field, gaining traction through relationships of trust established with medical practitioners.

Drug discovery capabilities for world-first original drugs

Imureta® is a world’s first orally administered treatment for multiple sclerosis. It has been administered to more than 140,000 patients in over 80 countries including the U.S. and countries in the European Union.

* Out-licensed to Novartis Pharma AG and sold under the name Gilenya.

Pharmaceutical development support, clinical testing and diagnostic reagents, pharmaceutical formulation materials

Net sales approx. ¥120 billion

No.1 share in the world for HPMC* capsules

We have the No. 1 share in the world for HPMC capsules made of plant-derived raw materials, after being the first in the world to successfully commercialize them.

* HPMC: Hydroxypropyl methylcellulose

Contributing to the healthy promotion of sports as the only doping control laboratory in Japan

We contribute to a variety of international sporting events as the only doping control laboratory in Japan and the first in Asia that is officially accredited by the World Anti-Doping Agency.
### Opportunities and Risks

#### Strengths
- Broad business foundation covering sick care to health care and life care
- Ability to discover and post-marketing development in the pharmaceutical business
- Strong market position in the capsule business

#### Growth Opportunities
- Diversification of medical needs
- Growing demand in the healthcare field as elderly populations increase around the world
- Upward trend in use of Big Data via healthcare and medical ICT
- Government incentives to maintain health and prevent serious diseases to restrain growth in medical expenditures
- Government incentives to promote health checkups and self-medication

#### Risks
- Declined success rate for new drug development and increased R&D spending from stricter drug approval process
- Delayed global operations
- Various policies to control healthcare expenditures
- High ratio of long-listed drugs in the pharmaceutical business
- Lack of economic incentives in healthcare business

### Review of Segments in Fiscal 2015

#### Health Care

<table>
<thead>
<tr>
<th></th>
<th>Net Sales</th>
<th>Operating Income</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>¥554.0 billion</td>
<td>¥103.4 billion</td>
</tr>
</tbody>
</table>

#### Operating Income

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Billions of yen)</td>
<td>120</td>
<td>120</td>
</tr>
<tr>
<td>Volume difference</td>
<td>30.1</td>
<td>30.1</td>
</tr>
<tr>
<td>Cost reduction</td>
<td>4.1</td>
<td>4.1</td>
</tr>
<tr>
<td>Other difference</td>
<td>-7.1</td>
<td>-7.1</td>
</tr>
<tr>
<td>Total difference</td>
<td>103.4</td>
<td>103.4</td>
</tr>
</tbody>
</table>

(Note) Other difference includes costs associated with sales management.

### Stage of New Product Development

<table>
<thead>
<tr>
<th>Disease area</th>
<th>Development code/ Product name</th>
<th>Expected indications</th>
<th>Region</th>
<th>Phase</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-immune diseases</td>
<td>TA-650/ Remicade</td>
<td>Refractory Kawasaki disease, arthritis, nephrotic, and vasculitis Behcet’s disease</td>
<td>Japan</td>
<td>1</td>
<td>Approved</td>
</tr>
<tr>
<td>Diabetes and kidney diseases</td>
<td>TA-730<em>1</em>2</td>
<td>Type 2 diabetes mellitus/ head-dose combination with phentolamine, 3B</td>
<td>U.S.</td>
<td>3</td>
<td>Phase 3</td>
</tr>
<tr>
<td></td>
<td>MT-1490*</td>
<td>Secondary hyperparathyroidism in hemodialysis patients</td>
<td>Japan</td>
<td>1</td>
<td>Approved</td>
</tr>
<tr>
<td>Central nervous system diseases</td>
<td>SD-186/ Paliscil*</td>
<td>Amyotrophic lateral sclerosis</td>
<td>Japan, South Korea</td>
<td>2</td>
<td>Phase 2</td>
</tr>
<tr>
<td></td>
<td>MT-1313</td>
<td>Crohn’s disease</td>
<td>Japan, Europe</td>
<td>2</td>
<td>Phase 2</td>
</tr>
<tr>
<td></td>
<td>MT-8554</td>
<td>Nervous system</td>
<td>Japan</td>
<td>2</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Vaccines</td>
<td>IVI</td>
<td>Meningitis or pneumonia, dysentery and tetanus (Stage 2 vaccination)</td>
<td>Japan*</td>
<td>1</td>
<td>Approved</td>
</tr>
</tbody>
</table>

**Note:**
- *1 Licensing-out
- *2 We jointly developed with permission from the Research Foundation for Microbial Diseases of Osaka University

### APTSIS 15 Step 2 Review and Forecast

#### Health Care Operating Income

<table>
<thead>
<tr>
<th></th>
<th>2010 Result</th>
<th>2015 Result</th>
<th>2015 (APTSIS 15 Plan)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Billions of yen)</td>
<td>120</td>
<td>120</td>
<td>120</td>
</tr>
<tr>
<td>Total difference</td>
<td>100.0</td>
<td>103.4</td>
<td>110.0</td>
</tr>
</tbody>
</table>

The Health Care domain fell short of its operating income target under APTSIS 15 by ¥6.6 billion. This was due in part to a sharp decline in earnings for long-listed drugs as a result of stronger-than-anticipated government policies to encourage the use of generic drugs in the earnings base of the domestic ethical pharmaceutical market. It was also due to slow business development in the U.S., the world’s largest drug market, owing to the abandonment of a drug under development for treating kidney disease.

Amid rapid change in the business environment for this segment, the MCHC Group aims to sustain growth by accelerating global business development. At the same time, we are also expanding in the health and medical businesses that use ICT, and developing new businesses such as regenerative medicine.
Growth Strategies

**Business Portfolios (by Business Unit)**

- **Next-generation businesses**
  - Healthcare solutions
- **Ethical businesses**
  - Life science (Healthcare and medical ICT)
- **Businesses to be restructured**
- **Cash-generating businesses**
  - Life science (Drug development solutions)

**Policy**
- Aim at worldwide growth in ethical pharmaceutical business
- Establish and expand the health and medical business utilizing ICT and regenerative medicine business

**Key Strategies**
- Promote overseas business mainly in the U.S.
- Strengthen new drug creation abilities
- Maximize potential of new drugs and priority products by strengthening value development and sales
- Expand the healthcare and medical business utilizing ICT
- Promote the regenerative medicine business

**Plan Values APTSIS 20 Five-Year Plan (J-GAAP)**

<table>
<thead>
<tr>
<th>Operating income (Billions of yen)</th>
<th>¥110.0 billion</th>
<th>¥125.0 billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 Result</td>
<td>103.4</td>
<td></td>
</tr>
<tr>
<td>2020 Plan</td>
<td></td>
<td>(FY)</td>
</tr>
</tbody>
</table>

**Investment amount (Five-year plan, total)**

- ¥460.0 billion

**R&D investment (Five-year plan, total)**

- ¥440.0 billion

**APTSIS 20 Action Plans**

- **Ethical Pharmaceuticals**
  - Invest ¥400 billion in R&D and create new drugs that can be deployed worldwide
  - Achieve domestic sales of ¥300 billion (new drug and priority product sales ratio of 75%) by strengthening value development and sales especially in new drugs and priority products
  - In the U.S., establish a sustainable growth platform by establishing business platforms with strategic investments of ¥200 billion or more, including M&A and by building a product lineup with open shared business (OSB**)

* MOHC registered trademark No. 5085432

- **Life Science**
  - Expand the healthcare-medical business that utilizes ICT (health prediction support, diagnostic support, etc.) by viewing the progress of the use of digital information as a business opportunity
  - Obtain early approval of regenerative medicine products that use Muse cells in 2019
  - Improve profitability and expand business by global spread in the capsule business
### FOCUS | Pharmaceutical Business

#### Priority Measures

**Establish a sustained growth platform by developing business in the U.S.**

Amid rapid changes in the business environment for ethical pharmaceuticals, in its aim for sustained growth in the pharmaceutical business, MTPC must quickly roll out a business platform for marketing drugs on its own in the U.S., the world’s largest pharmaceutical market, and maximize the value of priority products by strengthening value development and sales in the domestic market, while enhancing its presence in priority disease fields.

In June 2016, MTPC filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for Radicapt (MCI-186), which was approved in Japan as an additional indication for amyotrophic lateral sclerosis (ALS) in June 2015. On the assumption the drug will be approved in fiscal 2016, we are making its market launch our highest priority. As the first step for MCI-186, we plan to make the necessary preparations for creating a product lineup for nervous system disorders and rare diseases, such as putting in place a marketing structure focused on medical specialists. We plan to invest more than ¥200 billion over the course of the medium-term management plan (fiscal 2016-2020), including M&A, to expand the business foundation in the U.S. By fiscal 2020, we target sales of ¥80 billion in the U.S. Moreover, we aim to build up our product lines in the U.S. by acquiring products and products under development through various types of partnerships with academia, venture companies and pharmaceutical companies, in addition to our own pharmaceutical discovery capabilities.

**Build business foundation in specialty fields in the U.S.**

- **Build a product lineup, with MCI-186 (indication: ALS) as the first step**
- **Establish a marketing organization that meets the needs of specialists in such fields as neurology**

#### Key Strategies

- **Promote the regenerative medicine business**
- **Strengthen product lineup through utilizing ICT and regenerative medicine business**
- **Aim at worldwide growth in ethical pharmaceuticals, in its aim for sustained growth**
- **Expand the healthcare-medical business that utilizes ICT (health care and medical ICT)**
- **Life science**
- **Ethical pharmaceuticals**

### POINT of VIEW | Solutions for Social and Environmental Issues

#### MOS Indices

- **H-3** Contribute to achieving healthy and hygienic lives through products and services

#### MCHC Group Target

**Improve the index of product provision in the health field by 14 points and growth in sales of related products and services in the medical field to 60% in fiscal 2020**

Contribute by providing valuable products and services in the health care and medical fields while accelerating global development

Qualicaps, an affiliate of LSII that produces and sells capsules for drugs and health foods, has produced and sold capsules for drugs and health foods, as well as pharmaceutical processing equipment, since its establishment in 1965 with global operations centered on Japan, the U.S. and Europe.

In December 2015, Qualicaps acquired Genix Industria Farmaceutica Ltda. and turned it into a consolidated subsidiary with the objective of acquiring production and sales bases while tapping into the pharmaceutical market in Latin America, which is projected to grow an average of 5-8% annually through 2019. Genix has more than 50% of the hard capsule market in Brazil.

Amid growing awareness of health around the world, companies have been developing a variety of products for the growing markets of health foods, medical foods and supplements. In these fields, we anticipate stronger demand for capsules and technologies for printing on tablets.

Qualicaps has established strong relationships with customers and business partners in Latin America, in addition to Japan, Europe and the U.S., and is aggressively developing business in these regions.