Outline and Strategies of Toray Life Science Businesses

Toray Industries, Inc.

Executive Vice President & Representative Director
Hiroaki Kobayashi

Managing Director, General Manager of Pharmaceuticals and Medical Products Division
Kouzo Nagai

Director, General Manager of R&D Division
Koichi Abe
Summary
Executive Vice President & Representative Director
Hiroaki Kobayashi

Outline and Strategies of Pharmaceuticals and Medical Products Businesses
Managing Director, General Manager of Pharmaceuticals and Medical Products Division
Kouzo Nagai

R&D Strategies of Life Science Businesses
Director, General Manager of R&D Division
Koichi Abe
### Positioning of Life Science Businesses in Toray

<table>
<thead>
<tr>
<th>&lt;Business Segment&gt;</th>
<th>&lt;Major Products&gt;</th>
<th>FY Mar/05 Net Sales</th>
<th>FY Mar/05 Operating Income</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibers &amp; Textiles</td>
<td></td>
<td>¥513.4 bill. (40%)</td>
<td>¥20.9 bill. (26%)</td>
</tr>
<tr>
<td>Plastics &amp; Chemicals</td>
<td></td>
<td>¥300.4 bill. (23%)</td>
<td>¥15.7 bill. (19%)</td>
</tr>
<tr>
<td>IT-related Products</td>
<td></td>
<td>¥219.1 bill. (17%)</td>
<td>¥28.3 bill. (35%)</td>
</tr>
<tr>
<td>Carbon Fiber</td>
<td>Composite Materials</td>
<td>¥44.7 bill. (3%)</td>
<td>¥5.6 bill. (7%)</td>
</tr>
<tr>
<td>Environment &amp; Engineering</td>
<td></td>
<td>¥148.7 bill. (11%)</td>
<td>¥4.3 bill. (5%)</td>
</tr>
<tr>
<td>Life Science</td>
<td>Other Businesses</td>
<td>¥72.3 bill. (6%)</td>
<td>¥6.5 bill. (8%)</td>
</tr>
<tr>
<td>Life Science: Pharmaceuticals and Medical Products</td>
<td></td>
<td>¥44.4 bill. (3%)</td>
<td>¥2.9 bill. (4%)</td>
</tr>
</tbody>
</table>

*Strategically Expanding Businesses (Life Science, IT-related Products, Environment, Safety, and Amenity) → Candidates for next core businesses*
Market Scale Forecast of Bio-related Industries Expected in 2010
(from 2002 Cabinet Office BT Strategy Outline)


- Environment / Energy: ¥4.2 trillion
  - Bio-processing: ¥3.6 trillion
  - Biomass: ¥0.2 trillion
  - Bioremediation: ¥0.4 trillion
- Bio-tools / Information: ¥5.3 trillion
  - Bio-tools: ¥3.1 trillion
  - Bioinformatics: ¥2.2 trillion
- Medical: ¥8.4 trillion
  - Pharmaceuticals / Medical products: ¥8.4 trillion
- Foods: ¥6.3 trillion
  - Health care foods: ¥3.2 trillion
  - Other food industries: ¥3.1 trillion
- Others: ¥0.8 trillion

Total: ¥25 trillion

Red Figures: Toray-related fields (Total: ¥15.1 trillion)
Organization of Toray Life Science Businesses

Toray Group
Life Science Businesses

**Pharmaceuticals**
Toray, Toray Medical

Feron*
Dorner* / Procylin (BPS)

**Medical Products**
Toray, Toray Medical

Toraysulfone*
Toraymyxin*
Inoue-Balloon Catheter

**Bio-tools**
(From FY Mar/07)
Toray
Kamakura Techno-Science
Toray Research Center

High performance DNA chips
Lab. on chips
Blood preprocess devices

**Life Science-Related Businesses**

- Animal drugs: Intercat*, Interdog*
- Water treatment systems: Membrane Bio Reactor
- Bio raw material polymers: Polylactic acid
- Bio process synthesis: Pyruvic acid, D-tartaric acid
Expansion of Life Science Businesses

Expected Net Sales ($ Billion)

Vision of Business Expansion

FY Mar/05  Mar/11  Mar/16

Bio-tools
Medical Products
Pharmaceuticals
Characteristics and Issues of Toray Life Science Businesses

Life Science Businesses

Pharmaceuticals

R&D for Drug Discovery
- New drugs for unmet medical needs
- New indications of Feron* and Dorner*

Medical Products

R&D based on Extracorporeal Circulation
- Artificial kidney of the next generation under development
- Pipelines for novel medical devices

Bio-tools

Integration of Biotechnology & Nanotechnology
⇒ Generation of Innovative Bio-tools
- Research tools & diagnosis businesses (business model by alliance)
- Contents business (joint R&D with medical institutes)

★ R&D Expenditures/Rate to Net Sales: over 20%
  (about 25% of total R&D Expenditures)
## Pipeline of Pharmaceuticals & Medical Products

### [ Pipeline of Pharmaceuticals ]

<table>
<thead>
<tr>
<th>R&amp;D Themes</th>
<th>R&amp;D Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipruritic Agent (TRK-820)</td>
<td>Phase III</td>
</tr>
<tr>
<td>— Uremic Pruritis —</td>
<td></td>
</tr>
<tr>
<td>Antipruritic Agent (TRK-820)</td>
<td>Phase I</td>
</tr>
<tr>
<td>— Itching of Atopic Dermatitis —</td>
<td></td>
</tr>
<tr>
<td>Drug for Urinary Frequency (TRK-130)</td>
<td>Phase I</td>
</tr>
<tr>
<td>Analgesic for moderate to severe pains (TRK-091)</td>
<td>Phase II</td>
</tr>
<tr>
<td>Feron*(new indication) — Liver Cirrhosis —</td>
<td>Submitted</td>
</tr>
<tr>
<td>Feron*(new indication) — Combination Therapy with Ribavirin for Chronic Hepatitis C —</td>
<td>Phase III</td>
</tr>
<tr>
<td>Dorner*(slow released) — pulmonary hypertension —</td>
<td>Phase II/III</td>
</tr>
<tr>
<td>Dorner*(slow released) — chronic renal failure —</td>
<td>Phase II</td>
</tr>
</tbody>
</table>

### [ Pipeline of Medical products ]

<table>
<thead>
<tr>
<th>R&amp;D Themes</th>
<th>R&amp;D Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toraylite*(Dried product)</td>
<td>Preparing for Sale</td>
</tr>
<tr>
<td>Anti-thrombogenic PMMA membrane</td>
<td>Development</td>
</tr>
<tr>
<td>Oxidized LDL removal membrane</td>
<td>Development</td>
</tr>
<tr>
<td>Leukocyte removal column</td>
<td>Development</td>
</tr>
<tr>
<td>Catheter for atrial fibrillation</td>
<td>Development</td>
</tr>
</tbody>
</table>

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P I : Phase I Clinical Study  
P II : Phase II Clinical Study  
P III: Phase III Clinical Study
Summary
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<table>
<thead>
<tr>
<th>Year</th>
<th>Highlights</th>
</tr>
</thead>
<tbody>
<tr>
<td>1947 - 1953</td>
<td>Production and sales of penicillin</td>
</tr>
<tr>
<td>1970</td>
<td>Start in-house research for pharmaceuticals and medical products</td>
</tr>
<tr>
<td>1977</td>
<td>Launched Filtryzer* (kidney dialysis)</td>
</tr>
<tr>
<td>1978</td>
<td>Launched PGF2a (injectable solution, labor induction)</td>
</tr>
<tr>
<td>1983</td>
<td>Launched PGE2 (oral stabilization agent, labor induction)</td>
</tr>
<tr>
<td>1985</td>
<td>Launched Interferon-β (Feron*)</td>
</tr>
<tr>
<td>1986</td>
<td>Launched Anthron* (antithrombogenic catheter)</td>
</tr>
<tr>
<td>1988</td>
<td>Launched Inoue-Balloon Catheter (mitral stenosis)</td>
</tr>
<tr>
<td></td>
<td>Established Pharmaceuticals &amp; Medical Products Division</td>
</tr>
<tr>
<td>1992</td>
<td>Launched PGI2 derivative BPS (Dorner* / Procylin)</td>
</tr>
<tr>
<td></td>
<td>New indication of Feron* to active hepatitis C</td>
</tr>
<tr>
<td>1993</td>
<td>Launched Toraymyxin* (blood purification device for treating severe septicemia)</td>
</tr>
<tr>
<td>1994</td>
<td>Launched Toraysulfone* (kidney dialysis)</td>
</tr>
<tr>
<td>1997</td>
<td>New indication of Feron* to inactive hepatitis C</td>
</tr>
<tr>
<td>1999</td>
<td>New indication of Dorner* / Procylin to pulmonary hypertension</td>
</tr>
<tr>
<td>2002</td>
<td>Filed MAA for TRK-820 (antipruritic drug) in Sweden</td>
</tr>
</tbody>
</table>
Establishment of large scale production technology (Beads culture)

**Natural Human Interferon- β : Feron***

The world first interferon product

Launched in 1985 (Toray, Daiichi)

Indication: Hepatitis B & C
Melanoma/Brain tumors

World first structure elucidation of mouse interferon-β
(Tokyo Univ. & Toray)

Fibroblast cells on the beads

Stable PGI2 derivative (beraprost sodium): Dorner*/Procylin

The world's first orally active PGI2 derivative

Launched in 1992 (Toray/Astellas, Kaken)

Indications :
- Chronic Arterial Occlusion (ulcers, pain, chill)
- Pulmonary Hypertension

Improvement in
- efficacy
- pharmacokinetics

Chemical structure of Dorner *
Toray Products (Medical Products 1)

Filtrizer* • Toraysulfone*

1977 Filtrizer* Launched
Hemodializer made of PMMA hollow fibers with excellent absorption characteristics

1994 Toraysulfone* Launched
Hemodializer of polysulfone hollow fiber with high performance

Toraymyxin*

1993 Launched
Only one blood purification device on which polymyxin B immobilized

• Severe septicemia
• Integration of in-house technology (Chemical·Fiber·Plastic·Bio)
Inoue-balloon Catheter

1988 Launched (Marketing in 80 countries worldwide)

First catheter for treatment of mitral valve

1. Inflation of balloon
2. Image of treatment

Anthron*

1986 Launched

*Easy sliding in blood vessels and antithrombotic

Catheter coated with Anthron* (heparinized hydrophilic material)

Prevention of complication by thrombus at diagnosis or treatment

Appearance

Outer Ø : ca. 2mm
Inner Ø : ca. 1mm

<table>
<thead>
<tr>
<th>Condition</th>
<th>Control</th>
<th>Silicon</th>
<th>Anthron*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlebitis (%)</td>
<td>21</td>
<td>81</td>
<td>18</td>
</tr>
<tr>
<td>Thrombus (%)</td>
<td>21</td>
<td>47</td>
<td>24</td>
</tr>
</tbody>
</table>
Net Sales of Pharmaceuticals and Medical Products Businesses

Consolidated Net Sales

(¥ B)

FY Mar/91 Mar/98 Mar/99 Mar/00 Mar/01 Mar/02 Mar/03 Mar/04 Mar/05

Net Sales of Pharmaceuticals and Medical Products Businesses
Alliance in Japan (pharmaceuticals)
- Feron*: Daiichi Pharmaceutical, Toray Medical
- Dorner*: Kaken, Astellas
- Antipruritic agent: JT/Torii, Maruho

Marketing in Japan (medical products)
- Toray Medical (TMC)
- Dialyzer, Toraymyxin*, other equipment (IBC, catheter)

Marketing in Europe (medical products)
- TMC-TEL/agency
- Dialyzer, IBC, etc. 22 countries

Alliance in Europe (pharmaceuticals)
- Antipruritic agent: Acologix, Maruho
- Dorner*: Sanofi-Aventis

Alliance in Asia (pharmaceuticals)
- Dorner*: Astellas

Marketing in Asia, Oceania (medical products)
- TMC/agency
- Dialyzer, IBC, etc. 15 countries

Marketing in Middle East, Africa (medical products)
- TMC/agency
- Dialyzer, IBC, etc. 9 countries

Alliance in North America (pharmaceuticals)
- Antipruritic agent: Acologix
- Dorner*: UT

Marketing in North and South America (medical products)
- TMC-TOMAC/agency
- Dialyzer, IBC, etc. 9 countries

Marketing in Asia, Oceania (medical products)
- TMC/agency
- Dialyzer, IBC, etc. 15 countries

Alliance in Asia (pharmaceuticals)
- Dorner*: Astellas

Marketing Network

Alliance in Pharmaceuticals

Strategic Alliance in Pharmaceuticals Businesses and Marketing Network of Medical Products Businesses
Characteristics and Basic Objectives of Pharmaceuticals Businesses

Characteristics of Pharmaceuticals Businesses

- Centralize resources in research oriented drug discovery and line extension of existing products
  
  Characteristics:
  Development of bio-active substances (interferon, prostaglandin, opioid, etc.)
  Creation of innovative drugs
- Clinical development: Mainly Toray in Japan, through alliance outside Japan
- Marketing: Consign marketing to appropriate business partner (new business model)
  Partial sales of Feron* at Toray Medical (TMC)
- Licensing to be one of business pillar

Basic Objectives

R&D for Drug Discovery:
  Focusing on innovative drug discovery in areas of unmet medical need
  Line extension of existing products

- Strengthen profit-structure through sales expansion of existing product line and corporate-structure reinforcement
- Marketing will be done mainly through alliance for the near-term
- M & A is in vision as a constructive alternative
Antipruritic Drug (TRK-820)

New (antipruritic) drug for treatment of pruritus uncontrolled by current medication

Mechanism of Action: opioid kappa agonist (Basic Patent)

Characteristics:
1. Inhibition of pruritus in humans (5μg/body) <right figure>
2. No potential to induce dependency

Indication:
Intractable pruritus in hemodialysis patients, pruritus associated with liver injuries and skin diseases (atopy, pruritus senilis, etc.)

Mechanism

Before After 2 weeks

TRK-820

Control group

TRK-820

Weak → pruritus → strong

Itching signal

TRK-820

Sensory Nerve

Factors causing pruritus

Skin
Drug for Urinary Frequency (TRK-130)

Non Anticholinergic Mechanism: Control of Neuronal Signal Transduction

**Mechanism:**
Inhibit the abnormal signal transduction on overactive bladder (Basic Patent)

**Characteristics:**
Free from Anticholinergic side effects (e.g. dry mouth, residual urine)

**Indication:**
Overactive Bladder (Urinary Frequency (UF), Urinary Incontinence (UI))

**Mechanism**

- **Dysfunction (Abnormal Signal)**
- **Anti-UF effect**

**Anticholinergics**

- Dry Mouth
- Residual Urine
- Hypersensitivity
- Overactivity

**Bladder**

**TRK-130**

**Site of Action**

- Cause of UF
- Anti-Ch side effect

**Trun**

**Hypersensitivity**

**Overactivity**

**Drug for Urinary Frequency (TRK-130)**

**Table:**

<table>
<thead>
<tr>
<th>TRK-130 (mg/kg, p.o.)</th>
<th>Frequency (Voids/3hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>15</td>
</tr>
<tr>
<td>0.03</td>
<td>10</td>
</tr>
<tr>
<td>0.10</td>
<td>5</td>
</tr>
<tr>
<td>0.30</td>
<td>3</td>
</tr>
<tr>
<td>1.00</td>
<td>1</td>
</tr>
</tbody>
</table>

* Significance level
Analgesic for Moderate to Severe Pains (TRK-091)

Sustained-release tablets containing Tramadol Hydrochloride as an active ingredient
(once-daily oral dose)

Analgesic Mechanism:
Weak opioid-receptor agonist having norepinephrin- and serotonin-reuptake inhibitory activity

Characteristics:
(1) Analgesic activity considered intermediate between nonsteroidal anti-inflammatory drugs (NSAIDs) and potent analgesics (morphine etc.)
(2) Reduction of the side effects observed in NSAIDs (gastrointestinal ulcer/hemorrhage, hepatopathy, nephropathy, etc.)

Indication:
Chronic pain (upper or lower back pain, osteoarthritis), cancer pain, post-operative pain

Release mechanism of Tramadol Hydrochloride in the matrix-type sustained-release tablets

Licensed from Mundi Pharma
Feron* / Dorner* slow released

Feron* : Liver cirrhosis /
Combination therapy with Ribavirin for chronic hepatitis C

Characteristics : Antiviral and antifibrotic effects of Feron* delay the progress of liver cirrhosis and hepatocellular carcinoma in Chronic Hepatitis C patients

Background : Chronic Hepatitis C patients
World wide : 170 million patients (about 4 million people are newly infected with Hepatitis C virus each year in the world)
Japan : 2 million patients (WHO report 1999)

Many of Hepatitis C patients progress to cirrhosis and the cancer of liver
If progress to cirrhosis and the cancer of liver can be delayed, the meaning in the medical treatment is high

Dorner* slow released : Chronic renal failure / Pulmonary hypertension

Characteristics : Prevention of progression for chronic renal failure preceding ESRD for which existent drugs are insufficient
1. The concept was proved in pilot clinical studies in human and cat
   (1) increase of renal blood flow, (2) protection of blood endothelial cell,
   (3) prevention of inflammatory cytokine production
2. Sustained release formulation

Chronic renal failure :
• Existent drugs are insufficient
• 30,000 CRF patients enter ESRD a year in Japan
• Total number of ESRD patients : 250,000 (Japan)

Effect of Dorner* on renal blood flow in rats
Normal Renal failure Dorner* treated

Chronic renal failure :
• Existent drugs are insufficient
• 30,000 CRF patients enter ESRD a year in Japan
• Total number of ESRD patients : 250,000 (Japan)
Basic Objectives of Medical Products

Characteristics of Medical Devices

- R&D by in-house polymer technology and establishment of business in 3 areas
  - Dialysis: PMMA membrane, polysulfone membrane, machine
  - ER • ICU: Toraymyxin*
  - Catheters: Inoue-balloon catheter, PU-Celsite, Anti-thrombotic catheter, Protect, etc.
- Integration of manufacturing & marketing (Toray • TMC)
- Ensuring business base through global expansion by TMC

Basic Objectives

- To create new products by frontier material technology
  - Business development by innovative devices for extracorporeal circulation and catheter for treatment of atrial fibrillation
- Secure profit by efficient manufacturing and sales
Development Pipeline of Medical Products

**Dialyzer: Toraylite***

- Plan for launch in 2006
- Dried Toraysulfone*
- Characteristics: light, easy priming
- Patient No. (EU/US 500,000; Japan 250,000)

**EU • ICU**

**Leukocyte removal column**

- Plan for launch in 2008
- Removal of activated leukocyte
- Indication: Crohn’s disease, Ulcerative colitis etc.

**Catheter**

**Balloon for atrial fibrillation**

- Plan for launch in 2008
- First balloon type ablation catheter in the world
- Circular ablation: reduction of operation time
• Promote development of existing products to ensure business expansion in or around 2010
• Promote R & D of new pharmaceuticals and medical products for further business development in or around 2015
• Strengthen profit-structure through sales expansion of existing product line and corporate-structure reinforcement
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R&D Expenditure and Personnel

R&D Expenditure (¥ Billion)

- Approx. ¥ 40 billion

R&D Personnel (Persons)

- Approx. 2,900

R&D Expenditures / Net Sales (excluding affiliated trading companies) = 4.5%
(life sciences ≥ over 20%)
### Features of Toray’s R&D

#### Advantages
1. Culture and history that create innovative technologies
2. Various kinds of specialists groups in many fields
3. Unified R&D structure
4. Leading company in academia/industry / government collaboration
5. Advanced analytical capabilities : TRC

#### Core Tech.
- Organic Synthetic Chemistry
- Polymer Chemistry
- Biochemistry

#### Advanced Tech.
- Nanostructure Design/Control
- New Polymer
- Bio/Nanotechnology
- Protein, Cell

#### Advanced Materials
- Nano-structured Materials
- Environmentally Friendly Materials
- Advanced Electronics Materials
- Advanced Display Materials
- Drug Discovery/Innovative Therapy
- Bio/Nanobio Materials

#### Business Network
- Fibers & Textiles
- Plastics & Films
- Water Treatment
- Composite Materials
- Electronics & Information Related Products
- Chemicals
- Pharmaceuticals & Medical Products
- Amenity
- Uniform & Advanced Textiles
- Affiliated Companies

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Innovation and Technology Integration

- Polymer Chemistry
- Biochemistry
- Nanostructure Design/Control
- New Polymer
- Bio/Nanotechnology
- Protein, Cell

- Nano-structured Materials
- Environmentally Friendly Materials
- Advanced Electronics Materials
- Advanced Display Materials
- Drug Discovery/Innovative Therapy
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**TORAY**
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- Polymer Chemistry
- Biochemistry

Advanced Tech.
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- New Polymer
- Bio/Nanotechnology
- Protein, Cell

Advanced Materials
- Nano-structured Materials
- Environmentally Friendly Materials
- Advanced Electronics Materials
- Advanced Display Materials
- Drug Discovery/Innovative Therapy
- Bio/Nanobio Materials

Life Sciences Network
- Pharmaceuticals
- Medical Products
- Bio-tools
- Animal Drugs
- Water treatment
- Bio raw material polymer
- Bioprocess Synthesis

Technology Integration
R&D Policy in Life Science Fields

Pharmaceuticals
- Inquiring to Synthetic- & Bio-pharmaceuticals
- Focusing for Drug Discovery

New Drugs in Focused diseases

Innovative Therapy

Organic Synthetic Chemistry

Biochemistry

Bio-tools
- Generation of Tailor-made Medicines
- Integration of Polymer, Nanotech. and Biotech.

Medical Products
- Deepening of Innovative Medicines
- Integration of Polymer and Biotech.

Innovative Dialyzers

High Performance Medical Columns

Kidney Field Information & Estimation

Technology of Pharmacology

Innovative Therapy

Advanced Nanotechnology

Polymer Chemistry

Polymer Materials

Bio chips

Blood preprocess devices

Venture Companies

Leading Pharmaceutical Companies

Universities Clinics

National Projects

Information of Disease Markers

Tools for Drug Discovery

DDS Materials

Technology of Pharmacology

Estimation of Safety

Information of Disease Markers

R&D Policy in Life Science Fields

Technology of Pharmacology

Kidney Field Information & Estimation
R&D Strategy of Bio-tools

Universities
Kyoto Univ. (cancer) etc.

Clinical Tests
Clinical Info.

Specimens (cells or tissues)
Specimens (blood)

Genetic Info.
(DNA chips)
Protein Info.
(Blood preprocess devices)

Creation of Integrated Database
Narrowing down of Disease related Genes / Proteins
Exams / Diagnostic Markers
Proof of relation with Disease
Drug Development Target Molecule

Development of Exam / Diagnostic Tools
- High-performance DNA chips
- High-performance Protein chips

Development of New Drugs

Patient

Hospitals

Toray

Development of Bio-tools
High Performance DNA Chips

What is DNA Chip?

DNA Chips are tool for analyzing of gene Info.

Assignments of Conventional DNA Chip

- Signal<Noise
- Irregular for detecting
  : Low signal strength and stability

Low sensitivity
Low quantitativeness
Low reproducibility

High Performance DNA Chips

- High Signal
- Low noise

Original Resin

Probe DNA

Unique structure by micro fabrication

Sample amount of biopsy: 1mg

★ Development of DNA chip with unique structure by micro fabrication of original resin.
★ Realization of high sensitivity, high quantitativeness, high reproducibility and high speed detecting.
Continuous introduction of new products strengthened by Toray’s advanced materials and technologies
Accelerating speed of R&D by effective alliance formation
Descriptions of predicted business results, projections and business plans contained in this material are based on assumptions and forecasts regarding the future business environment, made at the present time.

The material in this presentation is not a guarantee of the Company’s future business performance.