

# Progress toward achieving our long-term vision

**ANNUAL REPORT 2010** 

Year ended March 31, 2010 KYORIN Holdings, Inc.

# Profile

On July 1, 2010, KYORIN Co., Ltd. changed its name to KYORIN Holdings, Inc. Under its corporate philosophy of cherishing life and benefiting society by contributing to better health, the Kyorin Group has established a new long-term vision titled HOPE 100, the final year of which will coincide with the company's 100th anniversary in 2023. By promoting the faster development of superior new drugs, and diversifying its businesses to respond to expanding healthcare needs, the Kyorin Group will work to realize its role as a unique and valuable integrated healthcare organization, and to further enhance its corporate value.

# Holding Company Structure

KYORIN Holdings, Inc. serves as the umbrella organization for the entire Kyorin Group, and by taking on the management strategy function and ensuring efficient allocation and use of management resources, works to ensure that the Group achieves its comprehensive potential, and to improve consolidated business results.



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#### Disclaimer Regarding Forward-Looking Statements

Statements made in this annual report with respect to KYORIN Holdings, Inc.'s forecasts, plans, strategies and other statements other than those of historical facts are forward-looking statements about the future performance of the Company and its consolidated subsidiaries and are based on management's rational assumptions and beliefs in light of information currently available. As a consequence, readers should understand that, for a variety of reasons, actual results could differ materially from projections presented in this report. Key factors that could impact our results include, but are not limited to, economic conditions, social trends, competition from rival companies, laws and regulations, uncertainties in drug development and exchange rate fluctuations.

# **Consolidated Financial Highlights**

KYORIN Holdings, Inc. (formerly KYORIN Co., Ltd.) and Consolidated Subsidiaries (as of the end of the fiscal year ended March 31, 2010)

			Millions of yen
	FY2008	FY2009	Change (%)
Net sales	90,889	99,764	9.8
Operating income	8,952	13,261	48.1
Net income	2,037	8,848	334.3
R&D expenses	10,531	11,807	12.1
			Change (Points)
ROE (%)	2.1	8.8	6.7
ROA (%)	1.6	6.8	5.2
			Change (Yen)
Net income per share (yen)	27.24	118.37	91.13
Dividend per share (yen)	13.00	50.00	37.00
Please see the consolidated financial summary on pages 10 and 11 fo	or more detailed inforr	nation.	

HOPE 100 Stage 1

HOPE 100 Stage 1 is the new medium-term business plan, positioned as the first step in realizing the long-term vision of HOPE 100, and covering a six-year span between fiscal 2010 and fiscal 2015.

Business Strategy		<u>`</u> ,	p06
S trategy	The Kyorin Group will continue to make steady progress towards becoming a company that supports healthy lifestyles, as set forth in its long-term vision, diversifying its consumer healthcare business centered on its pharmaceutical business.		pee
Organizational Strategy		>	p09
<b>O</b> rganization	The Kyorin Group seeks to become a company in which employ- ees can feel a sense of pride and trust in the company and its organizations, and in which all Group employees are united in their work—in short, a leading company for job fulfillment.		
Performance Targets erformance	The Company will aim to achieve average annual growth in consolidated sales of 5% or more, with an operating income margin of approximately 15%.	>	p09

HOPE 100 is a long-term vision looking forward to 2023, the 100th anniversary of the founding of subsidiary KYORIN Pharmaceutical Co., Ltd. It encompasses our powerful goal of supporting healthy lifestyles through our business in the treatment and prevention of disease and the maintenance and promotion of good health, while achieving sound, sustainable growth.

# To Our Stakeholders



# Kyorin continues to fulfill its mission of cherishing life, and benefiting society by contributing to better health.

In the five years through fiscal 2009, the Kyorin Group has focused on becoming an integrated, trusted, and unique healthcare organization centered on global drug discovery operations under our medium-term business plan, Kyorin MIC-09\*<sup>1</sup>. Highlights of these efforts include, in fiscal 2005, adding as subsidiaries the generic drug manufacturer Toyo Pharma (now KYORIN Rimedio) and skin care-focused cosmetics manufacturer Dr. Program, along with the merger in fiscal 2008 of our joint venture with Nisshin Seifun Group Inc., Nisshin Kyorin Pharmaceutical Co., Ltd., with KYORIN

	Group Developments	Product Developments
FY05	<ul> <li>Toyo Pharma becomes a subsidiary (05.5)</li> <li>Dr. Program becomes a subsidiary (05.6)</li> <li>Shift to holding company structure (06.3)</li> </ul>	· Uritos licensed to LGLS (South Korea) (05.10) · KRP-203 licensed to Novartis (Switzerland) (06.2)
FY06		Sales of Tequin stopped (06.6) Rapid Tester in-licensed from Daiichi Chemical Pharma (06.9)
FY07		<ul> <li>HES business*<sup>2</sup> transferred to Fresenius Kabi (07.4)</li> <li>Uritos launched (07.6)</li> <li>Kipres fine granules 4mg launched (07.10)</li> <li>Milton CP launched (08.1)</li> <li>Kipres approved for secondary indication of adult allergic rhinitis (08.1)</li> <li>Pentasa received approval for juvenile use (08.2)</li> </ul>
FY08	• KYORIN Pharmaceutical merges with Nisshin Kyorin Pharmaceutical (08.10)	<ul> <li>Kipres tablet 5mg launched (08.4)</li> <li>KRP-108 in-licensed from SkyePharma (U.K.) (08.4)</li> <li>Sales of GATIFLO tablets stopped (08.9)</li> <li>Pentasa tablet 500mg launched (08.10)</li> <li>Uritos licensed to SPIMACO (13 countries in the Middle East and North Africa) (09.2)</li> </ul>
FY09		· Gatifloxacin ophthalmic solution licensed to Senju (China) (09.7) · Uritos licensed to Eisai (China, ASEAN countries, India, Sri Lanka) (09.9) · KRP-209 in-licensed from Merz (Germany) (09.11)

#### Major Developments Over the 5-Year Period

\*<sup>1</sup> The medium-term business plan for fiscal 2005–2009 focused on the keywords marketing, innovation, and challenge.

\*<sup>2</sup> Business relating to Hespander and Salinhes, plasma substitutes and extracorporeal circulation flow improvers

Pharmaceutical Co., Ltd. That same year, we also started independent manufacturing and marketing of Pentasa, a treatment for ulcerative colitis and Crohn's disease. We also launched Uritos, a therapeutic agent for overactive bladder in fiscal 2007, and made strategic marketing efforts aimed at enhancing the value and widespread use of mainstay products, including Kipres, Mucodyne and Pentasa, through product lifecycle management (additional formulations and indications, and changes in use and dosage). We licensed our own drug KRP-203 to Novartis in fiscal 2005 and in fiscal 2008 we in-licensed KRP-108 from SkyePharma, along with KRP-209 from Merz in fiscal 2009. As a result, fiscal 2009 consolidated sales reached ¥99.8 billion (a 1.5-fold increase over five years), with net income of ¥8.8 billion, both record results. ROE (Return on Equity) also exceeded our goal for the final year of the plan, at 8.8%.

The Kyorin Group continues to face an increasingly harsh business environment. To continue to realize the goals of our corporate philosophy and achieve sustainable growth in fiscal 2010 and beyond, we have established HOPE 100, a new long-term vision for the period through 2023, which will mark the 100th anniversary of KYORIN Pharmaceutical, our core subsidiary, as well as a new medium-term business plan, HOPE 100 Stage 1 (for fiscal 2010–2015), designed to reach the objectives of that vision. By building a diverse healthcare portfolio centered on our pharmaceutical business, we aim to meet the various health needs of consumers, distribute risk, and evolve into a company that supports healthy lifestyles.

In our pharmaceutical business, we will work to build and promote the multi-faceted business model we call our Pharma Complex Model. Under this model, we classify ethical drugs into new drugs, original drugs, and generic drugs, and by making aggressive use of our alliances with subsidiaries KYORIN Pharmaceutical and KYORIN Rimedio, and with institutions both at home and abroad, will work to efficiently and effectively promote the business. We will also push ahead to reform our new drug development and licensing process, both to expand the pipelines that are the source of our growth, and to support creation of new, world-class drugs that can be licensed out. In the consumer healthcare business, we will focus on making our skincare businesses. We will also take on the challenge of expansion overseas, centered on countries in Asia. With a decline in drug prices in the 6% range in fiscal 2010, our forecast is for consolidated sales of ¥100.3 billion, with net income of ¥8.5 billion, but by the last year of HOPE 100 Stage 1, in fiscal 2015, we aim to achieve consolidated sales of ¥140.0 billion and operating income of ¥20.0 billion.

Under HOPE 100 Stage 1, the Kyorin Group will work to strengthen its management base through balanced implementation of investments for growth, investments for business continuity, and shareholder returns. Our dividend policy targets a consolidated payout ratio to shareholders of 30%, and based on this, we plan to distribute a dividend of ¥35 per share for fiscal 2010 (of which ¥10 will be an interim dividend).

On July 1, 2010, the Company changed its name from KYORIN Co., Ltd. to KYORIN Holdings, Inc., but that has not changed our strong desire to realize our corporate mission of cherishing life, and benefiting society by contributing to better health. All of our employees remain sincerely committed to working together toward this goal.

I look forward to the continued support of all of our stakeholders.

#### Your Health is Kyorin's Mission.

July 2010

Masahiro Yamashita Representative Director, President and Chief Executive Officer

Manhino Manhito

# Feature

# New Medium-Term Business Plan

# HOPE 100 Stage 1

# Aiming to Realize Our Corporate Philosophy Under the Long-Term Vision of HOPE 100

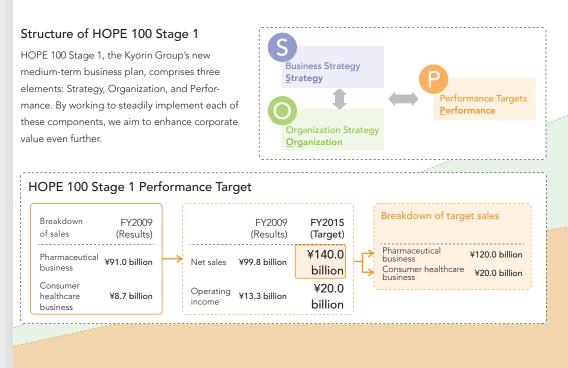
The Kyorin Group will promote diversified business expansion and development of the consumer healthcare business while retaining the pharmaceutical business at its core, and by 2023 be recognized both within and outside the Group as a company that supports sound and healthy lifestyles.

# Overview of HOPE 100 Stage 1

As the first step in achieving the Kyorin Group's long-term vision, HOPE 100 Stage 1 aims to bolster the forward momentum of its businesses by reorganizing them and building a framework for promoting each business.

HOPE 100 Stage 1 is an important first step to achieving the goal, stated in the HOPE 100 long-term vision, of our becoming a company which supports healthy lifestyles. In promoting HOPE 100 Stage 1, the Company will work to diversify its consumer healthcare business, while retaining the pharmaceutical business at its core. This term "diversify" encompasses our strong desire to ensure that each business within the Kyorin Group grows to become a core driver of future growth.

In addition, evolving into a company which supports healthy lifestyles, and contributes to individual health, requires that the Kyorin Group itself achieves sound growth. This includes not only financial good health, but also efforts to build a solid management platform to ensure that it remains healthy in terms of corporate governance, compliance, and corporate social responsibility.



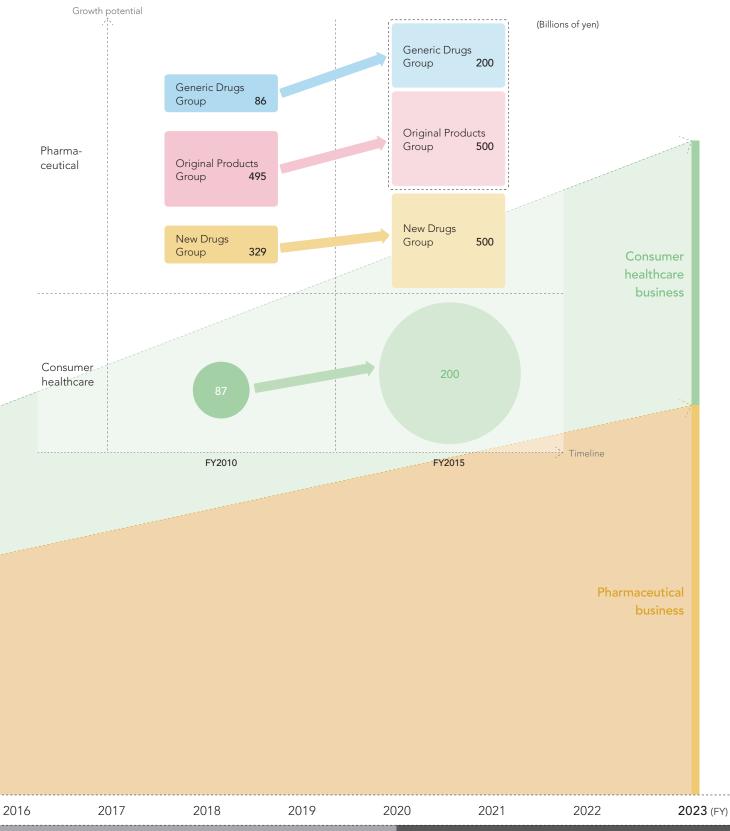
### Long-term growth (envisaged)

2009	2010	2011	2012	2013	2014	2015	
			Stage 1				

# The Kyorin Group Product Portfolio

The Kyorin Group is working to build a solid business foundation where our pharmaceutical and consumer healthcare business complement one another. This will help them in addressing the business risks inherent in today's changing market conditions.

### Business Portfolio Growth (Envisaged)



Stage 2 Stage 3

The Kyorin Group aims for stable, sustainable growth. To realize our future corporate vision, we must expand our pharmaceutical business, while building the core of the consumer healthcare business which complements it. To expand its pharmaceutical business, the Kyorin Group will work toward corporate growth by promoting a multifunctional growth strategy which calls for the diversified expansion of its healthcare business.

# The "SOP" Behind HOPE 100 Stage 1

HOPE 100 Stage 1, The Kyorin Group's new medium-term business plan, can be understood in terms of three elements: Business strategy; organization, which drives the execution of that strategy; and performance targets.

# Business Strategy Trategy

# **Overview of Business Strategy**

To become a company that supports healthy lifestyles, as stated in the long-term vision, the Company will build a diverse business portfolio centered on the core pharmaceutical business, and contribute to the health of individuals through the consumer healthcare business.

# Overview of the Multi-core Strategy

To strengthen its pharmaceutical business through multi-faceted expansion, and diversify business risk, the Company will aim for diverse expansion and growth in its consumer healthcare business.

#### Multi-core Strategy (MC Strategy)

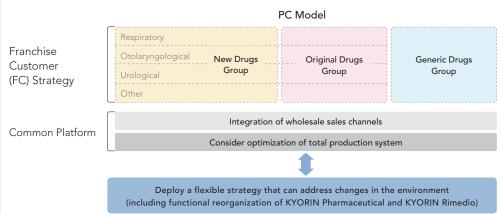
-Diversify the Consumer Healthcare Business Centering on the Ethical Drug Business-

Pharmaceutical Business	Consumer Healthcare Business
Pharma Complex Model (PC model) Multi-faceted business development (New drugs, original drugs, generic drugs)	Cultivate existing businesses and create new businesses

# Overview of the Pharma Complex (PC) Model

In order to respond to changes in business conditions, including trends in pharmaceutical administration policies, the Kyorin Group will work toward a multi-faceted expansion of its pharmaceutical business, aiming for sustainable growth. To do this, under the PC model the Company classifies ethical drugs into new drugs (drugs already launched or slated for development, which are protected by patents and exclusivity), original drugs, and generic drugs, enabling us to adopt a flexible strategy in responding to changing conditions.

### Diagram of Ethical Drugs Business Activity Under the PC Model



# **Pharmaceutical Business**

Based on the concept of the PC model for multi-faceted expansion of its pharmaceutical business, the Company classifies ethical drugs into three categories: new drugs, original drugs, and generic drugs. By coordinating the production activities, and a portion of the sales activities of subsidiaries KYORIN Pharmaceutical and KYORIN Rimedio on a common platform, and promoting alliances with companies outside the Group, the Company will aim to achieve sustainable growth by responding to the dramatic changes anticipated in its business environment and pursuing effective and efficient operations. The sales target in the pharmaceutical business for fiscal 2015 is based on developing our primary products including bronchial asthma and allergic rhinitis treatment Kipres and overactive bladder (OAB) treatment Uritos. We aim for total sales in the ethical drug business of ¥120.0 billion in fiscal 2015.

# **New Drugs**

Drugs already launched or slated for development which are protected by patents and exclusivity.

#### Key points

- Promote and maximize value of Kipres and Uritos
- Launch of KRP-108 and out-licensing of KRP-104

#### **Kipres**

The key attributes of Kipres, which has driven the growth of the Kyorin Group, include once-a-day oral administration, and the absence of drowsiness. It has contributed to the treatment not only of adult and childhood asthma, but with an added indication also helps to treat both seasonal and perennial allergic rhinitis (in adults only).

The Kyorin Group predicts demand for Kipres in 2015 will reach ¥100 billion for asthma (LT antagonists), and over ¥200 billion for allergic rhinitis (latent market for LT antagonists).

By tapping into latent demand among allergic rhinitis patients, we expect fiscal 2015 target sales to reach ¥40.0 billion as of the end of fiscal 2009, the Group's share of the LT antagonists market was approximately 30%.

#### **Uritos**

Key attributes of Uritos include its effectiveness against nocturnal symptoms of OAB, dose adjustment capabilities and twice-a-day administration. We plan to market an orally disintegrating (OD) tablet in fiscal 2010, and to bring to light new treatment needs for OAB patients through educational activities.

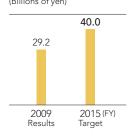
The Kyorin Group expects the number of patients being administered anticholinergic agents to increase from 1.2 million in fiscal 2009 to 2.4 million by fiscal 2015. Based on this predicted demand, the Group has set a sales target for Uritos in fiscal 2015 of ¥10.0 billion or more.

#### **KRP-108**

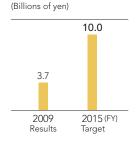
In development of KRP-108, the Company aims to apply in fiscal 2012, and bring the product to market in fiscal 2014. Characteristics of KRP-108 include its combination of ICS (fluticasone) and LABA (formoterol), and the selection of an optimal delivery device.

The market for inhaled asthma therapies reached ¥70.0 billion in fiscal 2009, and the market for combination ICS/ LABA products is expanding rapidly.





Target net sales



# **Original Drugs**

For original drugs the Company uses life cycle management (LCM) to improve value and extend life cycles of the drugs.

### Key points

• The Kyorin Group works to improve the product value and extend the life cycle of key products such as Mucodyne and Pentasa

#### Mucodyne

We have implemented calculated, ongoing life cycle management of Mucodyne since its launch in 1981. In May of 2010, we launched Mucodyne DS50% as a new formulation based on patient needs for convenience and on indications. With the new Mucodyne DS50% formulation, we aim to expand uptake among patients from juveniles to adults. By providing information based on evidence, we also aim to increase prescription for use in patients with chronic respiratory disorder.

In sales targets for Mucodyne we aim to increase sales from ¥20.9 billion in fiscal 2009 to ¥24.0 billion by fiscal 2015.

### Pentasa

With Pentasa, we aim to establish both life cycle management, and a standard prescription for its use in treating ulcerative colitis. We will work to promote adoption of the 500 mg tablet, and popularize prescription of a 4 g dose for use in the active stage of ulcerative colitis, while also promoting simultaneous use of intestinal infusion to induce and maintain remission. We will also implement clinical trials of the new once-a-day dosage and administration for ulcerative colitis during remission, with the goal of improving compliance and maintenance of remission.

The Kyorin Group forecasts market growth in mesalazine formulations of over 5% per year until fiscal 2015, but we also expect increased competition due to the introduction of competing products (using identical ingredients). In view of this situation we have set our fiscal 2015 target sales for Pentasa at ¥19.0 billion or more, with sales of original drugs overall targeted to reach ¥50.0 billion (stable growth).

# Generic Drugs

Generic Drug Group

#### Key points

Stronger ties within the Kyorin Group
 Promote external alliances

In generic drugs, the Kyorin Group will work to strengthen collaboration within the Group, and move to aggressively promote external alliances. Specific initiatives will include integrating KYORIN Rimedio's wholesale channels (logistics) into KYORIN Pharmaceutical, and building an optimal production framework in and outside of the Group. We are also looking into work on biosimilar products. In addition, we are examining options for expanding the number of supplementary items added (more than forty items in six years) and we aim to reduce the cost of sales to below 60%.

As a result, in our sales targets for generic drugs, we aim to grow sales from ¥8.6 billion in fiscal 2009, to ¥20.0 billion by fiscal 2015.

# **Consumer Healthcare Business**

To respond to diverse health needs and supplement the growth of the pharmaceutical business, the Kyorin Group will grow the skincare business and bring it into profitability, and deploy its strategy for the Milton brand of baby bottle disinfectants. We will also work to create new businesses in healthcare-related fields which have the potential for future growth and synergies with our pharmaceutical business.

# Key points

- Expand and promote the skincare business
- Leverage Milton brand of baby bottle disinfectant
- Develop and operate new businesses

In our consumer healthcare business we are promoting growth in the skincare business, and business operations leveraging the Milton brand. We will also work to create new businesses in healthcare related fields and consumer markets that have potential synergies with our pharmaceutical business, further promoting our business diversification strategy. Through these measures, we aim to achieve more than two-fold growth in sales in the consumer healthcare business in fiscal 2015 compared with fiscal 2009, to ¥20.0 billion, on the creation of a balance between existing and new businesses.

Target net sales (Billions of ven)







# Organizational Strategy -

# Overview of Organizational Strategy

To execute the business strategy outlined above, the Kyorin Group must energize all of its people and organizations. We will work to become a leading company for job fulfillment, one in which employees can feel a sense of pride and trust in the company and its organizations, and in which all Group employees are united in their work.

In the formulation of its long-term vision and medium-term business plan, the Kyorin Group has reaffirmed the importance of its founding spirit, that "A business is as good as its people," and has decided to adopt people-oriented management. It is valuing our employees, and energizing our people and our organizations, that will drive the execution of our business strategy, and we recognize these as the most critical issues in achieving results. To accomplish this, under HOPE 100, we will strive to become a lead-ing company for job fulfillment, one in which employees can feel a sense of pride and trust in the company and its organizations, and in which all Group employees are united in their work. The first steps towards realizing this goal under HOPE 100 Stage 1 will include efforts to rebuild our human resources management in every Group company (hiring, training, evaluation, promotion, assignment, compensation, and benefits), and to revitalize communications.

# Performance Targets -----

Balance Between Investment and Shareholder Returns



# Performance Targets

	FY2015 (Target)
Consolidated net sales ¥1	40.0 billion
Pharmaceutical business ¥1	20.0 billion
Consumer healthcare business ¥	20.0 billion
Consolidated operating income ¥	20.0 billion

Under HOPE 100 Stage 1, in addition to quantitative performance targets, the Kyorin Group also aims to contribute to stakeholders. We have recognized that to achieve sound, sustained growth we need to strengthen our management base by balancing investments for growth, investments for business continuity, and shareholder returns.

We therefore plan to make aggressive investments for growth, acquire new business and products to reinforce the research and development pipeline in our core pharmaceutical business and proactively make strategic investments in new consumer healthcare operations. In deciding dividends we target a consolidated payout ratio of 30%.

# Consolidated Financial Summary

KYORIN Holdings, Inc. (formerly KYORIN Co., Ltd.) and Consolidated Subsidiaries (as of the end of the fiscal year ended March 31, 2010)

					Millions of yen
	FY2005	FY2006	FY2007	FY2008	FY2009
Results of Operations					
Net sales	74,054	77,093	81,070	90,889	99,764
Operating income	8,989	8,413	6,251	8,952	13,261
Operating income/Net sales ratio (%)	12.1	10.9	7.7	9.8	13.3
Net income	5,228	4,842	2,189	2,037	8,848
Net income/Net sales ratio (%)	7.1	6.3	2.7	2.2	8.9
Net cash provided by operating activities	10,548	5,005	4,444	4,575	12,027
Net cash used in investing activities	(7,085)	(3,140)	(6,144)	(4,229)	412
Free cash flow	3,463	1,865	(1,700)	346	12,439
R&D expenses	10,107	8,609	10,826	10,531	11,807
R&D expenses/Net sales ratio (%)	13.6	11.2	13.4	11.6	11.8
Capital expenditure	4,605	2,954	1,952	1,612	1,291
Depreciation expense	3,646	4,544	4,536	3,799	2,810
ROE (%)	5.6	5.0	2.2	2.1	8.8
ROA (%)	4.5	4.0	1.8	1.6	6.8
Financial Position at Year End					
Total assets	121,044	124,039	122,398	124,552	137,190
Total shareholders' equity	94,752	98,178	97,184	96,501	104,911
Total shareholders' equity ratio (%)	78.2	79.2	79.4	77.5	76.5
					Yen
Per Share Data					
Net income per share	69.74	64.97	29.26	27.24	118.37
Dividend per share	20.00	30.00	22.50	13.00	50.00
Dividend payout ratio (%)	28.7	46.2	76.9	47.7	42.2

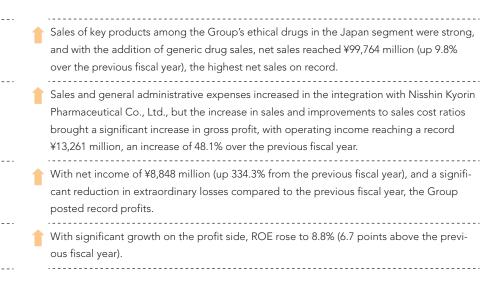
The figures for the fiscal year ended March 2006 are the consolidated figures for KYORIN Pharmaceutical Co., Ltd. The figures from the fiscal years ended March 2007 and onward are the consolidated figures for the former KYORIN Co., Ltd.

Net sales

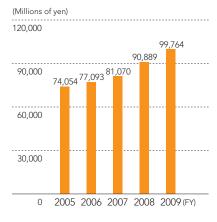
### **Operating income**

#### Net income

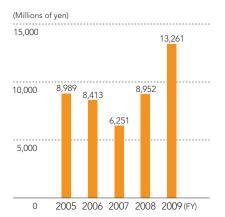
ROE



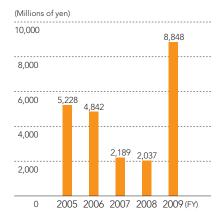
#### Net sales



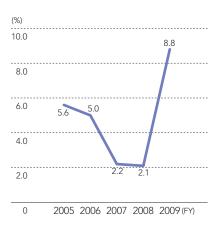
#### Operating income



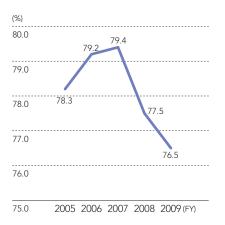
#### Net income



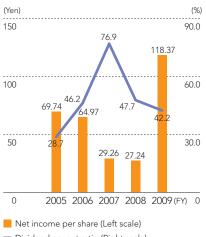
#### ROE



#### Total shareholders' equity ratio

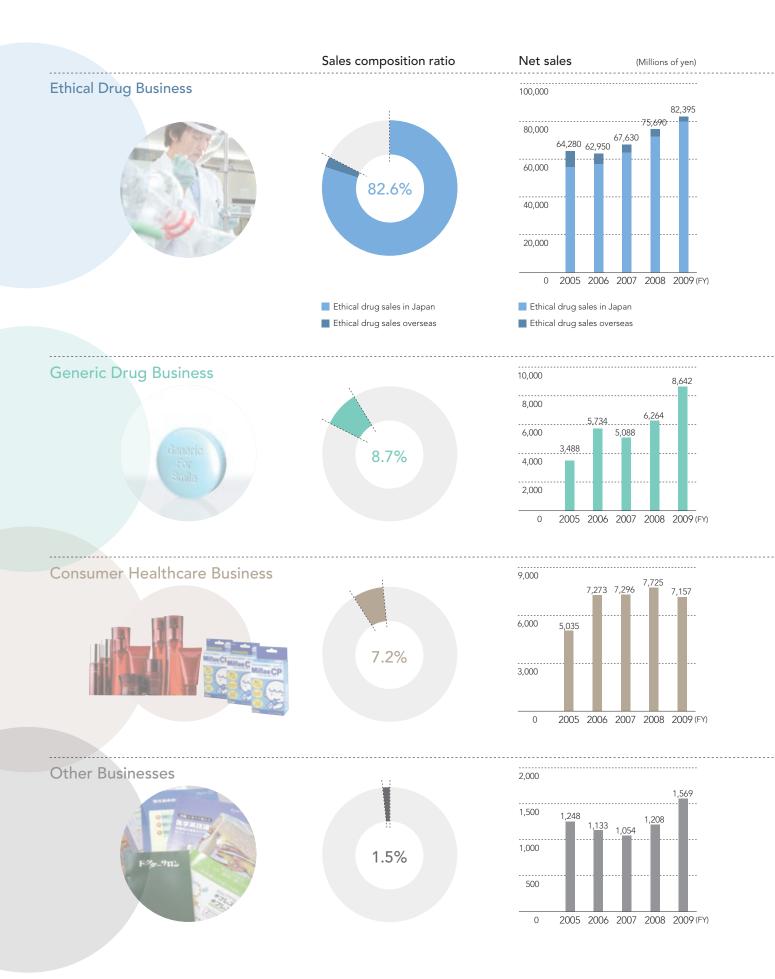


#### Net income per share/ Dividend payout ratio



Dividend payout ratio (Right scale)

# At a Glance



#### Outline of operations

Led by core company KYORIN Pharmaceutical Co., Ltd., the Kyorin Group is focusing sales activities in respiratory medicine, otolaryngology, and urology on advancement of its franchise customer strategy, as well as strengthening relationships with physicians and other medical professionals to enhance our domestic marketing platform.

Key products include Kipres, for treating bronchial asthma and allergic rhinitis; Mucodyne, a mucoregulant; Pentasa, for treating ulcerative colitis and Crohn's disease; and Uritos, for treating overactive bladder.

In research and development, the Kyorin Group has established a trilateral drug discovery network encompassing KYORIN Pharmaceutical Co., Ltd. (Japan), ActivX Biosciences, Inc. (United States), and Kyorin-Scotland Research Laboratories (Europe), promoting the efficient development of attractive new products.

### This business is led primarily by KYORIN Rimedio Co., Ltd., which focuses on the manufacture and sale of generic drugs.

We see considerable growth potential for generic drugs in Japan's ethical drug market, and their importance is growing as Japan's Ministry of Health, Labour and Welfare continues to promote the use of generic drugs as a means of curbing domestic healthcare costs. To capitalize on this opportunity, we are 1) strengthening sales capabilities by increasing the number of medical representatives and securing buyers; 2) lowering cost of sales ratios by increasing production rates; and 3) working to expand our product lineup by promoting more efficient, effective research and development.

In the consumer healthcare business, we are putting all our effort into expanding sales of Milton, a baby bottle disinfectant highly regarded by obstetricians and midwives. We are also working to strengthen sales of our core products—Switch OTC drugs. These are non-prescription drugs which incorporate proven ingredients from existing ethical drugs.

Dr. Program Co., Ltd., which develops and sells cosmetics using drug formulation technology, is rolling out skincare products targeting women over 40. The Kyorin Group is also working to enhance its lineup of high value-added products and to expand its base of repeat customers, rather than simply increase customer numbers, while also focusing on strengthening its operating base through collaboration between Group companies.

Other businesses include Kyobundo Co., Ltd., which is responsible for planning and production of promotional materials and advertising, and sales of medical promotional tools and packaging materials to third parties including KYORIN Pharmaceutical and KYORIN Remedio.

Within the Kyorin Group, Kyobundo is also responsible for working to enhance shared services, and for the creation of new businesses within the healthcare field.

# Segment Overview Ethical Drug Business

### **Strengths and Characteristics**

The ethical drug business is driven primarily by KYORIN Pharmaceutical, which uses its franchise customer strategy in focusing on respiratory medicine, otolaryngology, and urology. By concentrating resources on these key fields, and pursuing customer-centric, rather than product-centric sales activities, we seek to improve the accuracy of our customer targeting, consistently provide finely-tuned customer service, and strengthen the competitiveness of our domestic business base.

In research and development, we focus on developing new drugs, leveraging the highly creative drug discovery capabilities for which we have received global recognition.

### **Industry Trends**

While the domestic pharmaceutical industry is seeing the establishment of a new policy regarding premiums for promoting new drug creation and the elimination of off-label drug use, which in real terms will help maintain new drug prices, additional reductions to the price of longstanding items on the NHI drug price list, and further measures to promote the use of generic drugs, represent major changes in the business environment.

# **Consolidated Operating Results for Fiscal 2009**

In the midst of these conditions, in our domestic ethical drug business we continued to push ahead with our franchise customer strategy, while taking advantage of the strengths of our team-based sales system to expand market share through sales activities. As a result, segment sales rose ¥7,831 million, to ¥79,766 million, up 10.9%.

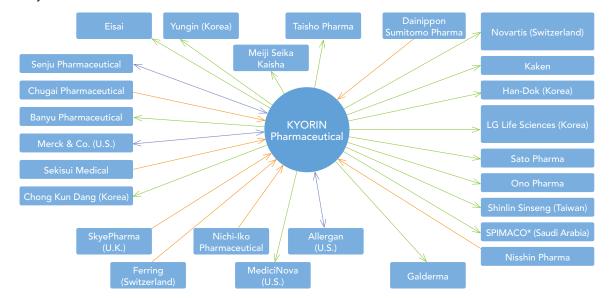
Sales of our principle products showed steady growth. Sales of Kipres, a treatment for bronchial asthma and allergic rhinitis, rose ¥4,001 million year on year, to ¥29,160 million, an increase of 15.9% due to growth in prescriptions for (adult) allergic rhinitis, and further market penetration of Kipres 4 mg fine granules (juvenile). Pentasa, a treatment for ulcerative colitis and Crohn's disease, saw sales increase ¥3,745 million to ¥19,421 million, up 23.6%, with the transfer of sales from the merger of Nisshin Kyorin Pharmaceutical with KYORIN Pharmaceutical on October 1, 2008, and increased market penetration of Pentasa 500 mg tablets with the approval of an additional indication and dosage for active-stage ulcerative colitis. Sales of Uritos, a treatment for overactive bladder, increased ¥1,740 million over the previous year to ¥3,703 million, up 85.0%. Sales of Mucodyne, a mucoregulant also showed stable growth, increasing by ¥300 million over the previous year to ¥20,940 million, up 1.5%. In other products, sales of Ketas, a treatment for bronchial asthma and cerebrovascular disorders, declined compared to the previous year's results.

In licensing activities, in July 2009 we signed an agreement with Senju Pharmaceutical Co., Ltd., granting them an exclusive license to market our Gatifloxacin ophthalmic solution in China, and in September of that year, we also signed an agreement with Eisai Co., Ltd. for exclusive development and marketing of Uritos tablets in China, India, Sri Lanka, and ASEAN countries. Overseas sales of ethical drugs fell by ¥1,126 million, due to a drop in sales of Gatifloxacin, ending the year at ¥2,629 million, a year-on-year decrease of 30.0%.

On the production front, we worked to develop efficient, high-quality production and stable supply systems at three



plants, including KYORIN Pharmaceutical's Noshiro Plant in Akita Prefecture and the Okaya Plant in Nagano Prefecture, as well as KYORIN Rimedio's Inami Plant in Toyama Prefecture.



#### Major Domestic and Overseas Alliances

\*SPIMACO: Saudi Pharmaceutical Industries & Medical Appliances Corporation

# KYORIN Pharmaceutical Co., Ltd. http://www.kyorin-pharm.co.jp/en/

As the core of the Kyorin Group, KYORIN Pharmaceutical focuses on the drug discovery business, working to fulfill its mission as a drug manufacturer through the creation of innovative new drugs, and strengthening its competitiveness in the pharmaceutical industry through the rapid expansion of business. We must secure a firm position amid the dramatic changes taking place in the pharmaceutical industry in Japan and overseas. We will therefore continue to pursue our business initiatives with the goal of becoming a unique and valuable company that contributes to healthy lifestyles.



#### Areas of Business

- Drug discovery research
- Research and development
- Manufacturing
- Sales



# **Generic Drug Business**

### **Strengths and Characteristics**

The Kyorin Group's generic drug business is a secondary business to the ethical drugs business, and is expected to play a major role in the future. It is centered around KYORIN Rimedio Co., Ltd., which provides highly reliable generic drug products to complement the Group's core new drug business. By integrating its wholesale channels with those of KYORIN Pharmaceutical Co., Ltd., the company is working to make effective, efficient use of a broad wholesale network as part of its sales efforts.

#### **Industry Trends**

Aimed at containing health care costs, measures to promote the use of generic drugs have brought rapid growth to Japan's generic drug market. The government has announced a numeric goal calling for generic drugs to represent a greater than 30% share in volume by fiscal 2012, and the market is expected to expand further going forward. As the government continues to promote measures to contain healthcare costs, generic drug manufacturers will be expected to play a larger role in providing a stable supply of high-quality drugs, and to contribute to reigning in the cost of healthcare.

### **Consolidated Operating Results for Fiscal 2009**

Sales in the generic drug business in the fiscal year ended March 2010, increased with expanded sales of both mainstay and new products, and the effects of a change in KYORIN Rimedio's fiscal closing from January 31 to March 31, resulting in a transitional consolidated fiscal period of 14 months. Sales were up ¥2,377 million from the previous period, at ¥8,642 million, an increase of 38.0%. With toll manufacturing of mainstay products for KYORIN Pharmaceutical, and an increase in sales of its own mainstay and supplementary products, KYORIN Rimedio was able to raise plant utilization rates, thus reducing its cost ratios. In addition, it successfully moved into profitability on efforts to break away from price-cutting wars, and worked to strengthen its profit structure.

### KYORIN Rimedio Co., Ltd.

#### http://www.kyorin-rmd.co.jp/ (Japanese Only)

As the generic drug business subsidiary of the Kyorin Group, KYORIN Rimedio Co., Ltd. aims to become a highly reliable generic drug manufacturer. It will strive to improve product quality and win the trust of healthcare professionals, and to provide products that patients can use with confidence. To contribute to better patient health and play a critical social role in containing healthcare costs and helping to maintain Japan's social security infrastructure, KYORIN Rimedio will continue to ensure a stable supply of quality products and information, and to deliver distinctive, reliable generic drug products to the market as a generic drug company.



#### Areas of Business

- Research and development
- Manufacturing
- Sales

# **Consumer Healthcare Business**



### Strengths and Characteristics

Starting with our Milton brand of baby bottle disinfectant, we will develop a consumer healthcare business that takes a broader approach to health issues, focusing on prevention, maintenance and improvement.

Milton is easy to use and effective against spore-forming bacteria, which are generally difficult to disinfect using heat. For this reason, the product is highly regarded not only by consumers, but also by obstetricians and midwives.

Dr. Program Co., Ltd., which develops and sells skincare products, has advanced technology which uses nanocapsules, also utilized in drug applications, in formulating highly concentrated beauty ingredients.

### Industry Trends

With a change in disease structure brought on by the aging population and an increase in sufferers of lifestyle-related diseases, curbs on healthcare costs, and a stronger awareness of health issues, peoples' health needs are shifting away from treatment and towards prevention. Healthcare needs are expected to grow even further going forward.

# Consolidated Operating Results for Fiscal 2009

In the consumer healthcare segment in fiscal 2009, sales were down ¥568 million year-on-year, to ¥7,157 million, a drop of 7.4%. Sales of Milton were up slightly year on year. At the same time, however, Dr. Program, which pursued initiatives to reform its business structure to improve profitability, saw its sales drop by ¥751 million, a decline of 19.5% from the previous period, partly due to the effects of changing its fiscal year end in the previous period.

\*Due to a change in the settlement date for Dr. Program, figures for the year ending March 31, 2009, reflect 14 months of sales.

# Dr. Program Co., Ltd. http://www.drprogram.co.jp/ (Japanese Only)

Dr. Program has gained the support and trust of its customers, and grown its business since it was established, based on providing highly safe and effective cosmetics. In this business, we manufacture products based on nanocapsule technology–a drug formulation concept that we have cultivated through research into new beauty



Ics. In this business, we manufacture products based on nanocapsule technology–a drug formulation concept that we have cultivated through research into new beauty enhancing compounds and development of technologies for penetration of compounds. Going forward, the company will continue to listen closely to its customers, working to create completely new value in the market and contributing to the beauty and good health of women everywhere.

#### Areas of business

• Development and sales of skincare products

# **Research and Development**

The Kyorin Group's research and development activities are pursued through a trilateral drug discovery network encompassing KYORIN Pharmaceutical Co., Ltd. in Japan, ActivX Biosciences, Inc. in the United States, and Kyorin-Scotland Research Laboratories in Europe. Taking advantage of the close ties between divisions, which work to verify the synthesis, pharmacology, ADME (Absorption, Distribution, Metabolism, Excretion), and safety of new drugs, we work to promote the efficient development of attractive new products.

In particular, we have focused management resources on development of our proprietary drugs in the key areas of infectious, immunological/allergic, and metabolic diseases.

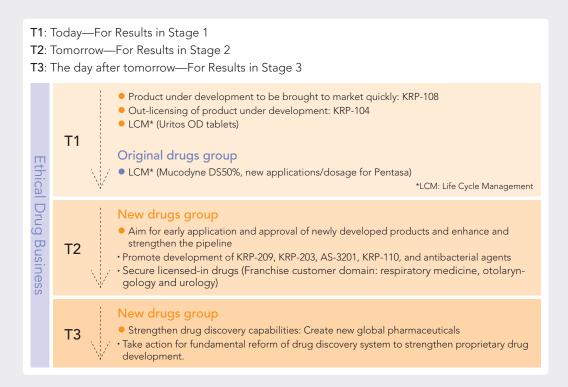
In development in Japan, in December of 2009 we began Phase III clinical trials of a new, once-a-day dosage for Pentasa, a treatment for ulcerative colitis and Crohn's disease. Also in December of 2009, we received approval to change the daily maximum dosage (change in administration and dosage) of imidafenacin, a treatment for overactive bladder, and in the same month, we filed a new application for an oral disintegrating tablet. In January of 2010, we received approval for the manufacture and sale of mucoregulant Mucodyne DS50%, with sales commencing in May of the same year. Additionally, in March 2010 we completed Phase IIb clinical trials of KRP-104, an anti-diabetes agent.

Overseas, Phase IIb clinical trials of the KRP-104 anti-diabetes agent began in November of 2009. On November 5, 2009, we signed a license agreement with Merz Pharmaceuticals of Germany for KRP-209 (Neramexane), a tinnitus treatment, giving us exclusive license in Japan for the development, manufacture, and sale of this drug.

Research and development expenses in the period were ¥11,807 million, a year-on-year increase of 12.1%.

### Focus on Timelines in Research and Development

Under the new HOPE 100 Stage 1 medium-term business plan, we will pursue initiatives to be implemented as research and development activities with close attention to the plan's timeline, from T1 through T3, based on the stage at which results of the initiatives are realized. Under the new medium-term business plan, development of proprietary drugs is focused on the key areas of respiratory, urologic and infectious disease and others. As we move forward we will work to rebuild our drug discovery network. Under our medium-term business plan will aim to introduce the bronchial asthma treatment KRP-108 within fiscal 2014, and out-license KRP-104, our anti-diabetes agent. At the same time, we will work actively on the lifecycle management (LCM) of our pharmaceuticals.



# Products Under Development

(As of May 11, 2010)

# Ph II~Application

Compound/Code	Therapy area/Action	Origin	Features	Comments			St	age			
						Pre-clinical	Ph I	Ph II	Ph III	Application	
Pentasa Tablets	Ulcerative colitis	Ferring Pharmaceuticals	New dosage regimen for ulcerative colitis in the remission phase		Domestic				12/2009		
lablets		rnarmaceuticais	(once a day)		Overseas						
AS-3201 Tablets	Diabetic neuropathy	Dainippon Sumitomo		<ul> <li>Co-development with Dainippon Sumitomo</li> </ul>	Domestic			3/2005			
		i     	the cell, and improve diabetic neuropathy	• PhIIb (9/2007)	Overseas						
KRP-104	Anti-diabetes agent	glucose through suppression degradation of insulin-releasir	glucose through suppression of the degradation of insulin-releasing	glucose through suppression of the degradation of insulin-releasing	glucose through suppression of the (Domestic PhIIb com- degradation of insulin-releasing pleted (3/2010))	Domestic			2/2008		
			hormone. Diabetic therapy with fewer side effects than existing treatments is expected.		Overseas			9/2007			
KRP-108	Anti-asthmatic	SkyePharma	An ICS/LABA combination product, which offers better compliance and		Domestic			8/2008			
		convenience to the patients.		convenience to the patients. (Domestic Ph II ⊂ completed (4/2010)) O		Overseas					

\*Eisai :Describe the latest change \*\*United States: Abbott, Europe: Mundipharma

Other Comments
Orally Disintegrating Tablet of Immidafenasin (INN), a Drug for Overactive Bladder: Application (12/2009)
Mucoregulating drug "Mucodyne DS50%": Approval (1/2010) Launch in the market (5/2010)

# POC Project (Pre-clinical~Ph I)

Compound/Code Therapy area/Action; Origin Features Comments Stage

						Pre-clinical	Ph I	Ph II	Ph III	Application
KRP-203	Transplantation and autoimmune diseases treatment	1	An immunosuppressant with a novel mechanism called an S1P-agonist. It may have a better safety profile than previous ones as	• License agreement with Novartis (2/2006)	Domestic		In preparation			
			well as an excellent effect under concomitant use with other types of immunomodulator.		Overseas		7/2007			
KRP-110	Opioid-induced constipation and Intractable pruritus	In-house	A highly selective µ-opioidreceptor antagonist. It is expected to block constipation induced by opioidanal- gesics without interrupting the		Domestic					
	, 1 1 1 1 1 1 1	, 1 1 1 1 1 1	analgesic effect of opioids. It is orally effective in various itching models, indicating potential of a novel anti-itch drug for intractable pruritus.		Overseas		In preparation			

Amorol fine HCI nail lacquer and KRP-105 have been deleted from the list of products under development since both products were discontinued from the standpoint of our R&D strategy.
 The standard on information disclosure has been changed and the products, which have been selected enter the clinical stage, will be disclosed. Therefore, KRP-107 and KRP-109 have been deleted from this list, while
 the development of KRP-107 and KRP-109 will be continued.

# In Licensing (Fiscal 2009)

Compound/Code	Therapy area/Actior	Origin	Features	Comments			S	tage		
						Pre-clinical	Ph I	Ph II	Ph III	Application
KRP-209	Tinnitus	Merz	by tinnitus mainly through its two	with Merz (11/2009) (Ph I clinical trial in Japan (single dose PK) in US	Domestic			In preparation		
			pharmacological properties: 1)NMDA antagonistic activity and 2)Nicotinic acetylcholine antagonis- tic activity	completed by Merz (3/2010))	Overseas				***	

\*\*\*Merz

### Licensing Development

Compound/Code	Licensee- Collaborative-	Therapy area/Action	Origin	Comments			S	tage		
Compound/Code	research	Inerapy area/Action	Origin	Comments		Pre-clinical	Ph I	Ph II	Ph III	Application
Alphagan/ AlphaganP	Senju Pharmaceutical	Glaucoma	Allergan (US)	<ul> <li>Licensed from Allergan (Cross license of gatifloxacin ophthalmic solution)</li> </ul>	Domestic				7/2007	
Alphagane	Fharmaceutical			License-out to Senju (5/2004)	Overseas					
Ketas	MediciNova (US)	Multiple sclerosis treatment	In-house	<ul> <li>KYORIN grants MediciNova an exclusive license in all countries worldwide except for Japan, China, South Korea and Taiwan to develop, munifacture and sell the compound and products for the</li> </ul>	Domestic					
				multiple sclerosis indication.(10/2004) • Result of PhII was reported in April 2008.	Overseas			8/2005		
KCA-757	MediciNova (US)	Anti-bronchial asthma and	In-house	<ul> <li>KYORIN grants MediciNova an exclusive license in all countries worldwide except for Japan, China,</li> </ul>	Domestic					
		astrima and Interstitialcystitis agent		In all countries wondwide except for Japan, china, South Korea and Taiwan to develop, manufacture and sell the compound and products • Interstitial cystitis: Result of Ph II/III was reported in January 2007 and development ceased • Bronchial asthma: Clinical trial oversea was discontinued.	Overseas			5/20	11/2006**** 05*****	
KRP-203	Novartis (Switzerland)	Transplantation and autoimmune diseases	In-house	<ul> <li>An immunosuppressant with a novel mechanism called an S1P-agonist. It may have a better safety profile than previous ones as well as an excellent for the state of the state o</li></ul>	Domestic					
		treatment		effect under concomitant use with other types of immunosuppressants.	Overseas		7/2007			
****Anti-bronchial A	sthma *****Intersti	itial cystitis								

# **Corporate Social Responsibility**

The starting points of the Kyorin Group's corporate social responsibility (CSR) endeavors are to cherish life and benefit society by contributing to better health, together with Kyorin's corporate branding aimed at making that philosophy a reality. For sustainable growth, Kyorin has made a commitment to all stakeholders to help bring about a happy society and will continue to work to realize that goal by providing trusted products and services, and by fulfilling its corporate social responsibility in the areas of environmental and industrial safety and hygiene and through activities that contribute to health and society.

#### **Ongoing Environmental Initiatives**

The main subsidiary of the Kyorin Group, KYORIN Pharmaceutical, is implementing the following activities on an ongoing basis.

- 1. Preventing global warming
- Reduce the amount of fuel used by installing cogeneration systems and using smaller boilers
- Reduce power consumption by controlling airconditioning settings to 27 °C in summer and 21 °C in winter
- Use eco-cars and hybrid vehicles to improve fuel efficiency and reduce exhaust emissions
- 2. Reducing waste volume
- Reduce waste emissions and promote recycling towards achieving zero final landfill
- 3. Managing chemical substances
- Manage substances covered by the Pollutant Release and Transfer Register (PRTR) law, and evaluate methods for reducing amounts used and the use of alternatives
- 4. Preventing atmospheric pollution
- Measure and control the amounts of soot and smoke, nitrogen oxides (NOx) and sulfur oxides (SOx) emitted by boilers and generators
- 5. Preventing water pollution
- Process wastewater, including by primary processing plants, and management of pH, biochemical oxygen demand (BOD) and suspended solids (SS) levels
- 6. Preventing deforestation
- Recycle paper, use recycled paper and promote a paperless office environment
- 7. Preventing destruction of the ozone layer
- Swiftly replace equipment that uses specified chlorofluorocarbons
- 8. Preventing ground subsidence
- Check for ground subsidence and improve utilization of piped water
- 9. Preventing contamination of soil and surface water
- Locate tanks above ground, install oil barriers and implement emergency response training
- 10. Noise reduction
- Take steps to measure and manage noise levels
- 11. Preventing foul odors
- Install draft chambers and use scrubbers to remove odors

# Measures Relating to Industrial Safety and Hygiene

In 2004, KYORIN Pharmaceutical obtained occupational health and safety management system certification (OHSAS 18001) for all production and research divisions, and in 2005, consolidated its ISO 14001 and OHSAS 18001 measures. The Rimedio Center of KYORIN Rimedio obtained ISO 14001 certification in 2008 and OHSAS 18001 certification in 2009.

#### 1. Rate and severity of work accidents

As a result of measures implemented to prevent work accidents, the frequency and severity of such accidents are much lower than the industry average. There have been no fatal accidents since the start of operations. 2. Vehicle accidents

Despite setting a target of a year-on-year reduction of 30% in the number of vehicular accidents per branch, in fiscal 2009 there were 182 accidents, more than the previous year. Kyorin views this matter very seriously, and as such, is implementing various accident-prevention measures. For fiscal 2010, the Company has set per store targets intended to hold accidents on a Company-wide basis to no more than 108.

#### Corporate Social Responsibility

In recognition of the importance of its corporate social responsibility, the Kyorin Group is enhancing its corporate ethical standards and putting in place a system of compliance in line with the approach set out below.

#### **Compliance Measures**

#### Basic policy

An enterprise should pursue profits through fair competition as an economic entity, and at the same time should be a force for the greater good of society.

Based on its corporate philosophy to cherish life and benefit society by contributing to better health, the Kyorin Group will conduct its activities in every country based on a high standard of corporate ethics, respecting human rights and observing all laws, as well as standards of conduct and the spirit thereof.

#### Measures

To ensure the Group's activities are based on a high standard of corporate ethics, the Company has drawn up the Kyorin Corporate Charter and the Kyorin Compliance Guidelines, and instituted a Compliance Committee.

- The Kyorin Corporate Charter was developed to specify matters of corporate ethics and compliance in accordance with our corporate philosophy, and serves as the starting point for our corporate activities.
- The Kyorin Compliance Guidelines complement the Kyorin Corporate Charter by clarifying the standards to be followed for sound and proper business activities.
- 3. In March 2006, the Compliance Committee was established to provide overall supervision of corporate ethics and compliance systems. Each company has a compliance promotion manager who is responsible for the understanding and instilling of corporate ethics and compliance.

#### Education and training

In-house training courses are conducted to promote understanding of and instill corporate ethics and compliance.

- Compliance managers organize education and training courses on corporate ethics and compliance, which are conducted at each level of the organization on a company-wide basis, and run instructional activities for company officers and employees.
- Details relating to corporate ethics and compliance are incorporated into job function-specific training conducted by each division to promote understanding and instill a sense of ethics and awareness of compliance among employees.

#### **Risk Management Measures**

The passing of the Corporation Law in May 2006 made it necessary to set up an internal control system. Kyorin established a Risk Management Committee in order to prevent risks from materializing and deal with any risks that do materialize. Also, a risk management promotion manager has been appointed at each company to raise awareness relating to risk management.

#### Local Community Activities

#### Cherry blossom viewing party

The Kyorin Discovery Research Laboratories hold an annual party for viewing the blossoms on cherry trees that are more than 40 years old. As usual, this year's party had many participants. The occasion was also used as an opportunity to explain Kyorin's environmental and occupational safety activities.

#### Summer evening parties

Each year, the KYORIN Pharmaceutical Development Research Laboratories and various plants hold summer evening parties to which local residents are invited. These are popular events that provide an opportunity to further promote understanding of the Company's activities.

#### Local cleanup activities

For several years, the Okaya Plant has been a "foster parent" responsible for beautifying a section of the shore of Lake Suwa as part of the Lake Suwa Adoption Program.

Employees also help to keep the lakeside park clean. Employees of the Noshiro Plant participate in voluntary activities to maintain the "Kaze-no-Matsubara," a pine forest and recreational area that acts as a barrier protecting the locality from winds.

In our head office, employees participate on a voluntary basis in cleanup campaigns carried out twice a year by the local Chiyoda City authorities.

#### Distribution of Doctor Salon booklets

Radio Nikkei broadcasts Doctor Salon, a program aimed at physicians. These broadcasts have been compiled into booklets, which KYORIN Pharmaceutical's medical representatives distribute during their monthly calls on doctors. A wide range of diseases is covered, providing timely coverage of current topics, making the booklets very popular with primary care physicians.

#### Supporting sporting events

The Kyorin Group supports sporting events that help to promote health. Starting in the fiscal year under review, the Group has also become a co-sponsor of the Giants Academy, where members of the Yomiuri Giants baseball club provide year-round baseball instruction to children. We also co-sponsor the Giants' Cup.

#### Employee Voluntary Community/ Health Activities (Kyorin Smile Program)

The Kyorin Group launched its corporate branding program in March 2006. To help achieve a happy society, the aim of the corporate branding program is to change the awareness and actions of each and every employee by promoting the Kyorin Smile Program, a set of employee initiatives for making a contribution to society and people's health. The activities in this program include giving blood, local beautification schemes and monetary donations.

In fiscal 2009, the Kyorin Group donated a total of ¥191,790 contributed by employees to Unicef. This money is being used for funding a sanitation improvement project in Burkina Faso in West Africa. The Group also collected 2.3 kilograms of used stamps, which were donated to the Japanese Organization for International Cooperation in Family Planning (JOICFP). The stamps will be used to help fund White Ribbon Campaign activities aimed at protecting the lives of mothers and babies throughout the world.

# Corporate Governance

#### **Basic Management Policies**

As a group our corporate philosophy is to cherish life and contribute to society by contributing to better health. To realize this philosophy we will pursue diverse expansion and development of our consumer healthcare business under our long-term vision HOPE 100 (Aim for Health Of People and our Enterprise), aiming to be a group that supports sound and healthy lifestyles.

#### **Basic Policy on Corporate Governance**

The key management goal for KYORIN Holdings, Inc. is to continue raising shareholder value. To achieve this goal requires fostering a management environment that enables us to build trust with stakeholders and the general public. Therefore, having given better corporate governance a high priority, we seek to ensure prompt decision-making, strong monitoring of the appropriateness of management, and ethical and transparent corporate activities. To ensure transparency and fair disclosure, we release appropriate information without delay for the benefit of shareholders and investors. Within our website, we have created an investor information section on which we list business performance data, information presented at meetings, our securities report, news releases and other corporate information, enabling anybody to access information about Kyorin at any time. In the future, we intend to actively increase our disclosure of information, and expand and improve our communications with all stakeholders.

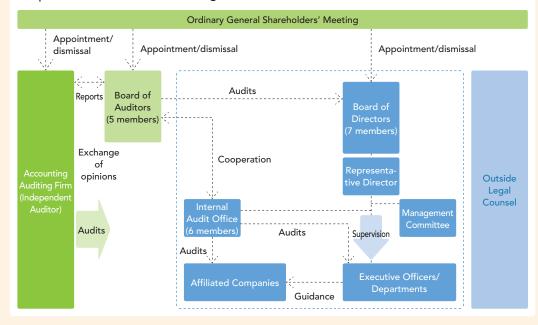
We are an audit- and committee-based company under Japanese law. The Board of Auditors endeavors to fully demonstrate its auditing and supervising functions and ensure the transparency of the decisions being made by the Board of Directors. Corporate auditors conduct audits in line with an auditing policy and plan set by the Board of Auditors at the beginning of each fiscal year. Corporate auditors carry out a diverse range of activities in fulfilling their auditing function. In addition to participating in important meetings, including those of the Board of Directors and the Management Committee, corporate auditors implement comprehensive audits by checking documents and other materials relating to key decisions and inspecting departments, facilities and Group companies.

In recognition of our corporate social responsibility, for every Kyorin Group company we appoint compliance and risk management officers. In addition, we have established a groupwide compliance and risk management system that is administered by the Compliance Committee and Risk Management Committee. We are establishing guidelines for each affiliated company based on the Kyorin Compliance Guidelines and will set up a system for employees to report and seek advice about possible irregularities. In addition to the above measures, we will create management guidelines for affiliated companies and build a system of support that respects their autonomy. Under this system, we will receive regular business reports from these companies and hold meetings with their management before deciding important issues. The Internal Audit Office conducts audits of affiliated companies based on internal audit guidelines. Based on the results of these audits, departments that oversee the operations of the affiliated companies issue instructions or warnings and provide appropriate guidance.

#### Management Organization and Internal Control System

#### 1. Management Organization

To clarify the roles of directors, who are responsible for making business decisions and supervising business execution, and executive officers, who are responsible for business execution, Kyorin has established an executive officer system. The Board of Directors usually meets once a month, deciding important operational matters after debating the issues as well as supervising each director's duties. To oversee business execution, we established a Management Committee, comprising the president and directors, which discusses key operational matters concerning the Group.



#### Corporate Governance and Management Structure (As of June 24, 2010)

We also utilize a corporate auditor system with two statutory corporate auditors and three outside corporate auditors. By capitalizing on such auditing and supervisory functions, we are building a system that facilitates highly transparent decision-making.

#### 2. Basic Philosophy and Status of Internal Control System

Kyorin is building an internal control system in accordance with the following basic policy: In keeping with our corporate philosophy of "cherish life and benefit society by contributing to better health," we undertake our activities in Japan and overseas guided by a high standard of corporate ethics as we respect human rights and comply with the letter and spirit of all laws and codes of conduct.

- We established the Compliance Committee, which is chaired by a director in charge and includes the participation of the Director of the Internal Audit Office who serves as a member of the committee. Thoroughgoing guidance is provided to executives and regular employees via training programs, while the Corporate Ethics Hotline has been set up for consultations and reporting matters concerning internal violations.
- ② We are building and operating a structure for reducing and preventing risks. As part of this structure, we established the Risk Management Committee, chaired by a director in charge, with the General Affairs Department responsible for overseeing the committee. For risks concerning compliance, the environment and accidents, we also formulated the Risk Management Guidelines and the Corporate Ethics and Compliance Guidelines as part of a quick-response structure. Additionally, to handle crisis management when dealing with any contingencies, we have set up the Contingency Measures Headquarters under the leadership of the president.
- (3) In accordance with the Documentation Management Guidelines and other internal regulations, we carry out the appropriate preparation, preservation and management of information regarding directors' decisions, their execution of other duties and reports concerning directors.
- ④ To ensure that auditors effectively perform audits, the accounting auditing firm explains the details of the accounting audit to the auditors and exchanges various information while cooperating with the Internal Audit Office in ensuring appropriate communication and effective auditing.
- (5) Along with establishing compliance committees and risk management committees at each Kyorin Group company, the Compliance Committee and Risk Management Committee oversee and promote compliance and risk management for the entire Group. In addition, we have built a structure for consultation and reporting that covers the whole Group.

We will create management guidelines for affiliated companies and build a system of support that respects their autonomy. Under this system, we will receive regular business reports from these companies and hold meetings with their management before deciding important issues.

The Internal Audit Office performs audits of affiliated companies based on internal audit guidelines. Depending on the results of these audits, departments that oversee the operations of the affiliated companies issue instructions or recommendations and provide appropriate guidance. Moreover, we are also building a structure that enables managers to prepare reliable internal control reports for financial reporting. Under this structure, the Internal Audit Office also evaluates and reports on internal controls related to financial reporting based on the newly established Standards and Practice Standards for Management Assessment and Audit Concerning Internal Control Over Financial Reporting.

#### 6 Basic rationale on the elimination of anti-social forces and the establishment of related measures

Giving consideration to our corporate philosophy, we formulated the Kyorin Corporate Charter to ensure a high standard of corporate ethics and thoroughgoing compliance. This charter clearly states that we will "stand firmly against any anti-social forces or groups that pose a threat to the order and safety of society."

The Company will eliminate any relationships with and strongly confront anti-social forces or groups. As an internal structure for overall monitoring of our corporate ethics and our compliance structure, we established the Compliance Committee, with the director in charge of the committee also handling overall coordination. As the department in charge of compliance, the General Affairs Department is working to strengthen and promote a wider permeation of corporate ethics and compliance through education and other measures in collaboration with relevant departments.

We have also established standard measures to prepare for any possible undue demands from anti-social forces. To this end, we have built a structure that includes designating a "person responsible for prevention of undue claims" at our Head Office and all branch offices to respond to encounters with any anti-social forces or groups. We also maintain close communications with police departments with relevant jurisdictions, special crime prevention units and legal advisers to ascertain the latest trends and gather other information on anti-social forces or groups as well as for guidance, consultation and assistance. Also, we have prepared Responding to Telephone Calls and Visits to the Company During the Initial Phase of Claim-related Problems as a manual, to ensure that employees make appropriate initial responses. In this manner, we have established a structure for properly responding to any demands from anti-social groups.

#### 3. Audit Organization

#### ① Internal Auditors

Internal audits are conducted by the Internal Audit Office, which is staffed by six employees, reports directly to the president and is independent from other sections. Based on yearly auditing plans, the Internal Audit Office regularly assesses and evaluates the effectiveness and efficiency of the legal compliance and internal control systems in every section of the parent and Group companies. After an audit, the office communicates any problems or areas that need improvement directly to the president and makes the appropriate recommendations. (2) Corporate Auditors

Corporate auditors conduct audits in line with an auditing policy and plan set by the Board of Auditors at the beginning of each fiscal year. In addition to participating in important meetings, including those of the Board of Directors and the Management Committee, corporate auditors implement comprehensive audits by checking documents and other materials relating to key decisions and inspecting departments, facilities and Group companies.

#### 3 Status of initiatives for strengthening the functions of corporate auditors

Kyorin has three outside auditors who are neutrally positioned and not compromised by relationships with management or parties having a special interest. These outside auditors all have a considerable level of knowledge of corporate legal matters, and matters of finance and accounting. We utilize their specialist understanding and wide-ranging knowledge and experience to strengthen and enhance our auditing functions. In terms of independence of outside auditors, we do not consider auditors from major shareholding companies and key trading partners to be truly independent. To ensure that execution of duties by directors is legal, transparent, and fair, we believe that outside auditors who have a high level of neutrality that is not compromised by a relationship with management or parties having a special interest, and for whom there is no risk of forming a contradiction of interest with general shareholders, are the most independent.

Under our adopted system, if someone discovers that an executive officer or employee is acting in contravention of either laws and regulations, or the Company's Articles of Incorporation, they immediately notify the corporate auditors. We are working to establish an environment conducive to more efficient audits by corporate auditors by coordinating closely with executives and regular employees and by fostering deeper understanding of audits.

Furthermore, we assign auditing staff to assist the duties of the corporate auditors as necessary, and these human resources are carefully checked by directors and auditors to ensure that they are independent.

Among the corporate auditors, Seiyu Miyashita has experience as a director and head of accounting of KYORIN Pharmaceutical Co., Ltd. while Masaji Obata has extensive knowledge of company law as a lawyer. They each therefore have considerable knowledge concerning finance and accounting.

#### (4) Independent Auditors

In accordance with the Corporation Law and the Financial Instruments and Exchange Law, we receive annual audits by Ernst & Young ShinNihon LCC. We benefit from its valuable advice as an accounting auditing firm, as well as from its services as an auditor of our financial accounts. The following certified public accountants performed the audit of KYORIN Holdings, Inc.

#### (Names of certified public accountants)

Mari Sono, designated limited liability partner and engagement partner

Yasuharu Nakajima, designated limited liability partner and engagement partner

A further 11 certified public accountants and 17 assistant accountants assisted with the audit.

The Board of Auditors provides a forum for close, regular exchange of information with the Internal Audit Office and the accounting auditing firm, thereby enhancing the auditing system.

# 4. Overview of Personnel, Capital and Trading Relationships Between the Company and the Outside Directors and Outside Auditors None to report.

#### 5. Compensation of Directors and Corporate Auditors

In fiscal 2009, ended March 31, 2010, compensation paid to directors and corporate auditors was ¥338 million: ¥309 million to 11 directors (excluding outside directors), and ¥29 million to 2 corporate auditors (excluding outside auditors).

There were no payments to directors corresponding to employee salaries.

Remuneration for outside directors totaled ¥15 million for 3 directors.

#### 6. Number of Directors

The number of directors is limited to 15 as set out in the Company's Articles of Incorporation.

#### 7. Conditions for Resolution on Appointments of Directors and Corporate Auditors

The Company's Articles of Incorporation stipulate that a resolution to appoint a director or corporate auditor must be by majority vote of attending shareholders holding at least one-third of the voting rights of shareholders who are eligible to exercise voting rights.

#### 8. Ordinary General Shareholders' Meeting Matters That May Be Resolved by the Board of Directors

#### 1 Acquisition of treasury stock

Pursuant to the provisions of Article 165, paragraph 2 of the Corporation Law of Japan, the Company's Articles of Incorporation stipulate that the Company may acquire treasury stock by resolution of the Board of Directors. The aim is to allow management to exercise capital policies as deemed appropriate in response to changes in the operating environment, by allowing the Company to acquire treasury stock through market transactions, etc.

#### 2 Decision-making body for cash dividends from retained earnings

Pursuant to Article 459, paragraph 1 of the Corporation Law of Japan, and except where otherwise specified in a separate applicable legal or regulatory provision, the Company's Articles of Incorporation stipulate that cash dividends are to be decided by resolution of the Board of Directors, and not the ordinary general shareholders' meeting. The aim is to allow management to exercise capital policy as deemed appropriate.

#### 9. Requirements for Special Resolution by the Ordinary General Shareholders' Meeting

Pursuant to Article 309, paragraph 2 of the Corporation Law of Japan, the Company's Articles of Incorporation stipulate that special resolutions by the ordinary general shareholders' meeting must be passed by at least a two-thirds majority vote of attending shareholders holding at least one-third of the voting rights of shareholders eligible to exercise voting rights. The aim is to lower the required quorum for a special resolution of the ordinary general shareholders' meeting to facilitate operation of the meeting.

# Directors, Auditors and Corporate Officers

(As of June 24, 2010)



Representative Director, President and Chief Executive Officer Masahiro Yamashita



**Executive Director** Keiji Hirai KYORIN Pharmaceutical Co., Ltd. Representative Director, President and Chief Executive Officer



Senior Executive Director Minoru Hogawa Management Planning Finance & Accounting



Senior Executive Director Takashi Matsuda KYORIN Rimedio Co., Ltd. Representative Director, President and Chief Executive Officer



Senior Executive Director Toyozo Goho Corporate Communication Information System Management



**Executive Director** Tomiharu Matsumoto Mitsutomo Miyashita General Affairs & Human Resources Legal



**Executive Director** Intellectual Property

Senior Corporate Auditors

Seiyu Miyashita Shigeru Abe

# Corporate Auditors

Masaji Obata Junji Honda Yasuyuki Hirota

### Senior Executive Officers

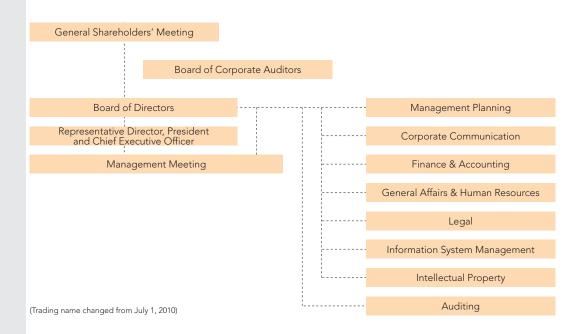
Takayoshi Ishizaki Yoh Ito Satoru Kanai

# **Corporate Officers**

Haruki Watanabe Takashi Nishino

# **Organization Chart**

(As of April 1, 2010)



# Major Subsidiaries and Affiliates

(As of July 2010)

Consolidated Subsidiaries	KYORIN Pharmaceutical ( Capital: Percentage of ownership: Head office: Operations:	¥4,317 million
	<b>Kyobundo Co., Ltd.</b> Capital: Percentage of ownership: Head office: Operations:	¥12 million 100% Kyorin Nishi-Shinjuku Building, 25-13, Nishi-Shinjuku 6-chome, Shinjuku-ku, Tokyo 160-0023 Sales promotion, advertising planning and production
	<b>KYORIN Rimedio Co., Lto</b> Capital: Percentage of ownership: Head office: Operations:	¥1,200 million
	<b>Dr. Program Co., Ltd.</b> Capital: Percentage of ownership: Head office: Operations:	¥251 million 100% 3rd Floor, 4-40, Minami-Aoyama 5-chome, Minato-ku, Tokyo 107-0062 Sales and purchase of skincare products
KYORIN Pharmaceutical Subsidiaries	ActivX Biosciences, Inc. Capital: Percentage of ownership: Head office: Operations:	US\$1 100% 11025 N. Torrey Pines Rd. La Jolla, California 92037, United States Discovery and evaluation of candidate compounds
	<b>Kyorin USA, Inc.</b> Capital: Percentage of ownership: Head office: Operations:	US\$500,000 100% 500 Frank W. Burr Boulevard, Teaneck, New Jersey 07666, United States Research and analysis of other companies' technologies and collection of information concerning clinical trials
	<b>Kyorin Europe GmbH</b> Capital: Percentage of ownership: Head office: Operations:	50,000 EURO 100% Kaiserstrasse 8, 60311 Frankfurt am Main, Germany Research and analysis of other companies' technologies and collection of information concerning clinical trials
Equity-Method Affiliates	Nippon Rika Co., Ltd. Capital: Percentage of ownership: Head office: Operations:	¥411 million 29.2% 2-2, Nihonbashi Honcho 4-chome, Chuo-ku, Tokyo 103-0023 Production and sales of pharmaceuticals, reagents, intermediates and other products

# Corporate Information (As of July 2010)

KYORIN Holdings, Inc.	Head Office		
(Trading name changed from July 1, 2010)	5, Kanda Surugadai 2-chome, Chiyoda-ku, Tokyo 101-8311		
	Phone: +81-3-3293-3451		
	URL: http://www.kyorin-gr.co.jp/en/		
Establishment	1958		
Common Stock	¥700 million		
Outstanding Shares	74,947,628		
Shareholders	3,934		
Major Shareholders		Percentage of total shares outstanding	
	Minoru Ogihara	8.17%	
	Hiroko Ogihara	6.86%	
	Apricot Co., Ltd.	6.67%	
	Yoshiko Ogihara	3.90%	
	The Master Trust Bank of Japan, Ltd. (Trust Account)	3.70%	
	Mykam Co., Ltd.	3.66%	
	Japan Trustee Services Bank, Ltd. (Trust Account)	3.20%	
	Keiko Sakurai	2.48%	
	Yutaka Ogihara	2.48%	
	Mariko Ogihara	2.35%	
Listing	Tokyo Stock Exchange, First Section		
Transfer Agent	Mizuho Trust & Banking Co., Ltd.,		
	2-1, Yaesu 1-chome, Chuo-ku, Tokyo 103-0028		
	Phone: +81-3-3278-8111		



**KYORIN** Holdings, Inc.

5, KANDA SURUGADAI 2-CHOME, CHIYODA-KU, TOKYO 101-8311, JAPAN CORPORATE COMMUNICATION TEL +81-3-3293-3414 E-mail http://www.kyorin-gr.co.jp/contact/ URL http://www.kyorin-gr.co.jp/



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