

# An Exclusive on LG Life Sciences



## **What were your greatest challenges when starting the company, and now in maintaining it?**

LG regarded life sciences as a future project and began to study related areas starting in the early 1980s. Since the life sciences business was thought of as a future project of the LG Group, it began with relatively sufficient support provided by the Group. As you know, however, the life sciences project requires an extremely large investment, particularly when the objective is to develop world-level new medicines.

It was not easy for the company to independently push the development of world-class new medicine as a pioneer when there was no industrial infrastructure or government support available. I believe the biggest difficulty was that LG, having had no experience in such a project before, made continuous human and material investments by looking only at the potentiality for a long period of time until Factive™ (quinolone antimicrobial agent) acquired approval from the US FDA.

Since then, we have faced challenges on how we can develop new medicines which will succeed in the global market, and on how we can become a customer-oriented company by increasing points of contact with customers and actually delivering significant value to customers.

## **Please share with us the background and the history of your company.**

LG Life Sciences (LGLS) started as a Korean-based genetic engineering department in LG Chemicals in 1981, and has invested steadily in the life sciences ever since. This effort has resulted in the commercialization of various biopharmaceuticals. These include interferon in 1989 (Intermax-gamma™) and 1992 (Intermax-alpha™), hepatitis B vaccine in 1992 (Euvax B™), human growth hormone in 1993 (Eutropin™), degenerative arthritis treatment in 2005 (Hyruan Plus™), recombinant human follicle-stimulating hormone (rhFSH) in 2006 (Follitrope™), and sustained-release human growth hormone (SR-hGH) in 2007 (Declage™). LG Life Sciences' vision is to become a "top-tier life sciences company with world-class new drugs." To this end, the next-generation quinolone antibiotic Factive™ was approved by the US Food and Drug Administration (FDA) in 2003, and the human growth hormone Valtropin™ was approved by the US FDA and the European Medicines Agency (EMA) in 2007. LG Life Sciences is expanding its strategic alliances and fostering its capabilities to identify candidate drugs for development.



## [ Special Feature ]

### **How does the Korean government give support and incentives to start up companies?**

The Korean government desires to strengthen its support to the biotechnology industry as a next-generation, promising industry following the information technology (IT) industry. Our company partially receives financial support from the government for R&D projects; however, the government's financial support is not yet satisfactory to foster the life sciences project to a world-class level.

### **What are the company's areas of focus/core business?**

From the conventional anticancer/antibiotic-centered new drug development, we now like to focus on the improvement of quality of life and the promotion of vitality by providing appropriate medicines for chronic disease, aging, and obesity as well as by globalizing biosimilar (generic) products.

### **What is your staff strength?**

LG has high-quality R&D experts, and many experts who have had global-level experience from LG are now widely distributed in Korea's life sciences industry. The main strengths of the staff include the ability to discover drug development candidate substances during the research stage, technologies related to the hepatitis B vaccine which is mass supplied through the United Nations (UN) organizations across the world, and production technologies for major bioproducts (such as erythropoietin and hGH).



## [ Special Feature ]

**Please share with us the technologies your company has patented or those that your research team is working on.**

LG Life Sciences has developed a unique drug delivery system platform technology using hyaluronic acid. Hyaluronic acid is an endogenous biological material that enables sustained release of the active biological ingredients, and is now applied to hGH and interferon alpha. In contrast to daily hGH, SR-hGH is a weekly formulation that significantly improves patient compliance. SR-hGH was launched in the domestic market as Declage™ in 2007, and is currently undergoing global phase III clinical testing. The SR platform technology is applied to other active biological ingredients as well, such as interferon alpha, which is under phase II clinical testing. This unique drug delivery system platform technology helps to develop novel biopharmaceutical products that are highly competitive and distinctive.

**What is your latest product or those in the pipeline? Are any of your products in clinical trials now?**

### *Infectious Disease*

We are mainly focusing on novel small-molecule drugs and biological drugs related to hepatic diseases. We have successfully entered into an exclusive licensing agreement with Gilead Sciences, Inc. that grants them commercialization rights to the caspase inhibitor LB84451. Phase II clinical tests for an antiviral agent have confirmed its superior effect in treating hepatitis B virus (HBV).

### *Metabolic Disease*

LG Life Sciences has decided to focus on metabolic diseases, as the market for diabetes and obesity treatments continues to grow. Currently, the dipeptidyl peptidase IV (DPP-IV) inhibitor is undergoing phase II clinical testing in Korea. Last year, we made a collaborative research agreement with Takeda Pharmaceutical Company on a small-molecule antiobesity program.

### *Cardiovascular Disease*

Our research has centered on antiplatelets for the prevention of coronary thrombosis, which can lead to myocardial infarction and angina pectoris. We are currently focusing on the development of safe and orally available antiplatelets. We have agreed to collaborate on research with Institut Pasteur Korea to develop PAR-1 modulators. In addition, animal-derived component-free recombinant human erythropoietin (EPO) is now undergoing phase III clinical tests.

	Project	Partner	Indication	Status
NCE	HBV	—	Hepatitis B	Phase II
	Caspase	Gilead	HCV, NASH	Phase II
	DPP-IV	—	Diabetes	Phase II
	Antiobesity	Takeda	Obesity	Research
	Anticoagulation	Pasteur (Korea)	Anticoagulation	Research
Biologics	SR-hGH (US/EU)	BioPartners	Short stature (once a week)	Phase III
	rFSH	—	Infertility	Phase III
	EPO	—	Anemia	Phase III
Vaccine	DTaP-HepB	Kaketsuken	Diphtheria, tetanus toxoids, pertussis adsorbed, hepatitis B	NDA
	DTwP-HepB	—		Phase III

## [ Special Feature ]



### What is your blockbuster product?

LGLS's blockbuster products (annual sales >10 billion Korean won) include Eutropin™ (Valtropin™), Zanidip™, Hyruan™/Hyruan Plus™, Euvax-B™, and Espogen™.

*Eutropin™ (Valtropin™)*, a human recombinant growth hormone, is an FDA- and EMEA-approved biopharmaceutical that has maintained 65% market share since its first year of launch in 1996 in the growth hormone market dominated by Eli Lilly, Serono, and Novo Nordisk.

*Zanidip™ (lecarnidipine)* is in-licensed from Recordati, Italy, and has — since it was first launched in 2000 — successfully penetrated into the established and highly competitive market, achieving higher sales growth than Pfizer's Novarsc.

*Hyruan™/Hyruan Plus™* is a hyaluronic acid (HA) preparation manufactured by LGLS's unique biofermentation process. It was launched in 2005 and has rapidly become a leader in the HA market, with a compound annual growth rate of 215% and a 2007 market share of 60%. It obtained the CE mark in May 2007 for sales in the European market.

*Euvax-B™* contains the recombinant hepatitis B antigen for disease prevention with quality certification by the World Health Organization (WHO), and is supplied to UN agencies like UNICEF and PAHO.

*Espogen™* is a human recombinant erythropoietin and has been dominating the EPO market for 10 years.

	Ingredients	Mechanism Description	Indication
Eutropin™ (Valtropin™)	Human recombinant growth hormone	Insulin-like growth factor production	Growth hormone deficiency
Zanidip™	Lecarnidipine	Calcium channel blocker	Essential primary hypertension
Hyruan™/Hyruan Plus™	Sodium hyaluronate	Anti-inflammatory, analgesic, and lubricant activity	Deformative osteoarthritis of the knees and shoulder periarthritis
Euvax-B™	Hepatitis B surface antigen	Hepatitis B antibody production	Prevention of hepatitis B
Espogen™	Human recombinant erythropoietin	Red blood cell production	Anemia in chronic renal failure

## [ Special Feature ]



### Has your company marketed any products to the market yet?

LGLS is the no. 1 global pharmaceutical company in Korea, and is on its way to becoming a world leader. We have an extensive sales and marketing network spanning over 75 countries with LGLS technology-based products. Among these products, Factive™ is a representative Korean drug which is at present the only US FDA-approved novel drug in Korea. Factive™ is a dual-targeting fluoroquinolone antibiotic that sells in over 15 countries. Also, LGLS is a major hepatitis B vaccine supplier for UN agencies, and has exported it to more than 75 countries worldwide.

Last year, in addition to the success achieved in the domestic market, Hyruan Plus™ (an osteoarthritis treatment) achieved CE marking and is now marketed to over 20 countries including Europe. Hyruan Plus™ is a highly purified HA, processed by microbial fermentation which is ensured to be BSE-free. Showing LGLS's advanced bioengineering technology, LGLS has developed one of very few biosimilar recombinant human erythropoietins and follitropins that are registered and marketed to over 15 countries. Besides Euvax B™ and Factive™, we also have many infertility treatments, ophthalmic surgical interventions, diagnostics drugs, animal drugs, and pharmaceutical drug intermediates that are exported all over the world.

### Ultimately, who are your target audience or clients?

The principle idea of the LG Group is to prioritize customers' benefit; as a daughter company of the LG Group, LG Life Sciences shares the same principle. As expressed in our slogan, "bringing health and youth", we at LGLS have and will continue to strive to be a total healthcare company that truly cares about the customers' health and youth as a number one priority. This means that our clients include anyone who is seeking a better and more advanced quality of life in terms of health. As people's expectations go beyond merely having a healthy body, our clients are ultimately not limited to people who are suffering from illness, but also include all who wish to be physically and mentally young and healthy.

### How does your company get its funds from? Who are your investors?

LGLS was listed on the Korea Stock Exchange on August 16, 2002. LG Corp., as the holding company of the LG Group, owns 30.4% of the total shares issued.

Collaboration Type	Collaboration Institute
Research collaboration in cardiovascular disease	Institut Pasteur Korea
Research collaboration in antiobesity program	Takeda (Japan)
Research collaboration in liver disease (caspase inhibitor)	Gilead (US)

## [ Special Feature ]

### **Does LG Life Sciences have any collaborations with local institutes or foreign ones? Please share with us the main important collaborations.**

In 2007, we secured collaborations with Gilead Sciences, Inc., Takeda Pharmaceutical Company, and Institut Pasteur Korea. We have entered into an exclusive licensing agreement with Gilead, focused on caspase inhibitors for the treatment of fibrotic diseases. A research collaboration agreement to discover, develop, and commercialize antiobesity drugs has been made with Takeda. Lastly, we agreed to conduct collaborative research on finding drug candidates for cardiovascular diseases and commercializing drugs with Institut Pasteur Korea. We are willing to have even more collaborative researches in the future.

### **What is the company's 5-year plans/goals/aims and strategies?**

First of all, LG, after acquiring a good position in the local market, plans to make inroads into the advanced market, and create a drug portfolio that comprises the products for four major diseases — cardiovascular disease/diabetes, musculoskeletal disease, aging, and central nervous system disease — to create a footing for continued growth. As for the development of new drugs, we plan to discover, within 5 years, two new drug candidates directed at the global market in bioproducts and synthetic/natural products, based on which we intend to leverage our high growth in order to reach our ultimate target as a global top tier company.

### **Which specific areas does your company think is worth investing in in the future?**

As an alternative to overcoming the limitations in developing products suitable for aging societies (such as dementia, obesity, and antithrombotic drugs) and in developing new chemical drugs using the existing methods, biogeneric (biosimilar) products, antibody agents, and cell therapy seem to be promising fields.

### **What is your view of the biotechnology and pharma industry in Korea? Is it growing as fast as it should, and is it comparable to the US and Europe?**

Even though Korea's biotechnology industry is considered as the most promising industry where Korea can grow along with IT, the actual economic level is far below expectations. First, compared with such developing countries as India and China, the scale of industry, related technologies, and infrastructure are growing very passively. This in turn means that, while many companies have a keen interest in sales in the local market, most of them are not concerned with the competency of our biotechnology and pharmaceutical industry.

Recently, some companies are seeking advancement in overseas markets after experiencing the limits of overcompetition in the local market. However, the truth is that they only desire to conquer the limitation of sales in the local market, rather than placing a value on advancing as a global market player armed with the required competency. In terms of growth speed, there is nothing, as mentioned above, that Korea can particularly boast of compared with India and China. The typical, mature industry in the US and Europe is growing somewhat slowly; however, Korea's growth speed is not enough for it to become a biotechnology power that can compete with pharmaceutically advanced countries such as the US and Europe.

To obtain a competitive edge relative to the US and Europe, which boast of a strong market scale and industrial infrastructure, it is necessary to expand the infrastructure for R&D activities in the pharmaceutical field, select potential sectors, and concentrate on their growth more effectively.

## [ Special Feature ]



**In-Chull Kim, PhD**  
President & CEO of LG Life Sciences, Ltd.

**Dr In-Chull Kim** was born on July 7, 1951, in Seoul, Korea. He attended Seoul National University in Seoul, and graduated with Bachelor's and Master's degrees in pharmacology in 1974 and 1977, respectively. He studied at the University of Illinois, USA, and received a PhD in pharmacology in 1985.

Prior to coming to LG Life Sciences (LGLS), Dr Kim spent some time in the USA. He worked as a postdoctoral fellow at the Rockefeller Foundation, joined Duke University Medical Center as a researcher in 1986, and then moved to GlaxoSmithKline in 1988 and served as a head researcher there for 5 years.

Dr Kim came back to Korea in 1993 to join the company Lucky, and then was promoted to vice president in 1995 when Lucky changed its name to LG Chem. While at LG Chem, he worked as the head of the Pharmaceutical Development Lab until 2001.

In 2002 (when LGLS was spun off from LG Chem), Dr Kim was relocated to the head of Business Development. He was then promoted to executive vice president in charge of the Sales Division in 2005. In 2006, Dr Kim was appointed as president and CEO of LGLS.

### **How about the clinical trial industry in Korea? Can you share with us its current status?**

*Number of clinical trials conducted in Korea*

Year	2002	2003	2004	2005	2006
Global Companies	35	71	81	145	168
Domestic Companies	33	78	63	93	96

The number of clinical trials approved by the Korean FDA has been dramatically increasing since 2002, when the investigation new drug (IND) system was introduced.



#### *Contact Details:*

#### **LG Life Sciences**

Address: LG Twin Tower, East Tower  
20, Yoido-dong,  
Youngdungpo-gu  
Seoul, Korea

Tel: +82 2 3773 1114

Fax: +82 2 3773 7012

URL: [www.lgls.co.kr/eng](http://www.lgls.co.kr/eng)

### **What is your view of the standard of research in biomed sciences in Korea?**

As mentioned earlier, given that Korea's pharmaceutical industry has been engrossed in the growth of sales through various kinds of drugs imported from overseas, it has tended to grow without creating a proper foundation for biomedical research. Over the past few years, several companies including ours have started setting standards, but they do not cover all stages of drug development. On the other hand, India, even though it entered this business late, has constructed standards of research unique to their industry that can independently cover all stages of drug development and satisfy all of the standards of the advanced markets, while at the same time nurturing their own strengths. Compared with the case in India, I think that we have not yet established any concrete standards unique to Korea. ■