How Korea’s pharma sector has leveraged significant new investments in R&D to transform itself into a true player in the global market

BE INSPIRED!

page 25
To the members of the international healthcare community:

As Minister of Health and Welfare, it is my great honor to introduce this special report dedicated to the healthcare industry in Korea. We are proud to share with you the capabilities of the Korean healthcare sector and life science sector through this platform.

Over the last twenty years, Korea has redefined its outlook on innovation and research in healthcare industries, and has undergone dramatic developments to improve healthcare infrastructure for the benefit of all Korean people. Despite recent economic challenges, Korea has placed the health and welfare of its people at the top of the national priority list, and is working with countries around the world to share our expertise with patients around the world. In the future, Korea will be seen as a leader and collaborator for healthcare systems, bringing the highest standards of care to patients around the world.

2015 represents an exciting time for the industry in general; with substantial investment being made into new drug development, and a trend towards exports and globalization across the industry, Korea is becoming an important player in the global healthcare community in a way it never has been before. Coordination and collaboration between all stakeholders will help our country to improve our competitiveness within Asia and worldwide, and to join the ranks of leaders of the global industry in the coming years.

With this special report on the industry, I invite all members of the global healthcare and life science community to take a look at the exciting opportunities that Korea has to offer, and the significant achievements that our country has, and will continue to make, within the healthcare and life science field.

Warm regards,

Moon Hyung-Pyo, Minister of Health and Welfare of Korea
The Healthcare & Life Sciences Review was produced by PharmaBoardroom.

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For exclusive interviews and more info, please log onto www.pharmaboardroom.com or write to contact@focusreports.net.

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Acknowledgements

For their support and contributions to this project:

Lee Kyeong-Ho, Chairman and CEO, KPMA
Lee Sang-Suk, CEO, KRPIA
Chang Seok-Goo, President, KIPPA
Suh Young-Ger, President, Korea Pharmaceutical Society
Amy Jackson, President, AmCham Korea
Deborah Chee, President, KoNECT

and to Moon Hyung-Pyo, Minister of Health and Welfare of Korea, for taking the time to provide us with an insightful and candid interview.

많은 응원과 도움을 주신 분들께 감사드립니다.
Are you looking to grow your business in a developed Asian market?

01 South Korea’s generic market is projected to grow on average 5% per year between 2013 – 2018 to a staggering $23.84 Bln.

02 South Korea closely ranks after China and India as the third “best outsourcing destination” in Asia.¹

03 Korea Drug Development Fund (KDDF) will promote the development of the Korean biotechnology sector in the Asia Pacific region aiming to produce 10 new treatments by 2019.

04 Investment in R&D and related facilities is very active and establishment of plants according to the international standards is increasing.

¹ The changing dynamics of pharma outsourcing in Asia, PwC.

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Though traditionally recognized for its pioneering efforts in industries such as electronics, shipping and automotive, Korea has taken advantage of its newfound global economic competitiveness to embrace pharma head on. Through government initiatives designed to promulgate growth in the pharmaceutical and biotech sectors, the country aims to become a top seven player and to create 20 new drugs by 2020 according to their Pharma Vision 2020.

Achieving these objectives is no small task; a number of barriers could hinder the process. Korea’s lack of experience in pharmaceutical R&D means that their ability to produce truly disruptive innovation may pale in comparison to the traditional pharma heavyweights of the US, Europe and Japan. Infrastructure for translational research is also underdeveloped. These challenges often lead to disagreement between industry and government authorities about where Korea’s health industry ought to go.

Regardless, the drive and ambition to become a leading player in the field continues to fuel Korea’s ever-growing international presence in pharmaceuticals. From Samsung to startups, companies of all shapes and sizes are getting involved, each trying to figure out their destiny within the Korean pharma ecosystem. While no one expects the next Sovaldi to emerge from a Korean laboratory, the country’s pharma industry certainly seems to be quite competent in terms of incremental innovation, and biosimilars are increasingly becoming an attractive opportunity in which Koreans can excel.

The race for innovative competitiveness continues in Korea today, and this report aims to illustrate some of the shining examples close to the finish line. 🌟
**THE ESSENTIALS**

**Korea In Numbers**

**ANNUAL GROWTH OF PHARMACEUTICAL SPENDING (IN REAL TERMS) SINCE 2009, KOREA AND OECD AVERAGE**

<table>
<thead>
<tr>
<th>Year</th>
<th>Korea</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>-2.5%</td>
<td>6.4%</td>
</tr>
<tr>
<td>2010</td>
<td>4.0%</td>
<td>6.0%</td>
</tr>
<tr>
<td>2011</td>
<td>-3.1%</td>
<td>-0.5%</td>
</tr>
<tr>
<td>2012</td>
<td>2.2%</td>
<td>-1.1%</td>
</tr>
</tbody>
</table>

*Source: OECD Health Statistics 2014.*

**MARKET VALUE**

- **18.6 USD BILLION IN 2013**
- **24.3 USD BILLION BY 2020**

**RANKED #**

- **14 BY IMS IN 2013**

**PREDICTED TO REACH**

- **4.86% OF THE COUNTRY’S MANUFACTURING GDP**
- **1.3% OF KOREA’S GDP**

**TOP 10 SOUTH KOREAN COMPANIES**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>2013 Pharma Sales ($M)</th>
<th>2012 Pharma Sales ($M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>YUHAN</td>
<td>862</td>
<td>689</td>
</tr>
<tr>
<td>2</td>
<td>GREEN CROSS</td>
<td>812</td>
<td>721</td>
</tr>
<tr>
<td>3</td>
<td>HANMI</td>
<td>667</td>
<td>607</td>
</tr>
<tr>
<td>4</td>
<td>DAEWOONG PHARMACEUTICAL</td>
<td>617</td>
<td>590</td>
</tr>
<tr>
<td>5</td>
<td>CHONG KUN DANG</td>
<td>512</td>
<td>415</td>
</tr>
<tr>
<td>6</td>
<td>DONG-A</td>
<td>452</td>
<td>827</td>
</tr>
<tr>
<td>7</td>
<td>JEIL PHARMACEUTICAL CO LTD</td>
<td>413</td>
<td>379</td>
</tr>
<tr>
<td>8</td>
<td>ILDONG PHARMACEUTICAL CO LTD</td>
<td>376</td>
<td>351</td>
</tr>
<tr>
<td>9</td>
<td>JW PHARMACEUTICAL</td>
<td>361</td>
<td>353</td>
</tr>
<tr>
<td>10</td>
<td>LG LIFE SCIENCES</td>
<td>305</td>
<td>290</td>
</tr>
</tbody>
</table>

*Source: SCRIP.*

**HEALTH EXPENDITURE GROWTH RATES (IN REAL TERMS) SINCE 2004, KOREA AND OECD AVERAGE**

**NEARLY 700 PHARMACEUTICAL MANUFACTURING COMPANIES IN KOREA**

Source: OECD Health Statistics 2014.

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## FDA Clinical Trial Approvals by Korean Pharmaceutical Companies, 2013

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>DRUG NAME</th>
<th>THERAPY AREA(S)</th>
<th>INDICATION(S)</th>
<th>STAGE(S) OF DEVELOPMENT</th>
<th>STAGE(S) OF DEVELOPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>GREEN CROSS CORPORATION</td>
<td>berococod alfa</td>
<td>Hematological Disorders</td>
<td>Hemophilia A</td>
<td>Phase III</td>
<td>Ongoing</td>
</tr>
<tr>
<td>GREEN CROSS CORPORATION</td>
<td>IVIG-SN</td>
<td>Immunology</td>
<td>Other Immunological Disorders</td>
<td>Phase III</td>
<td>Ongoing</td>
</tr>
<tr>
<td>GREEN CROSS CORPORATION</td>
<td>MG-1102</td>
<td>Oncology</td>
<td>Other Immunological Disorders</td>
<td>Phase III</td>
<td>Ongoing</td>
</tr>
<tr>
<td>GREEN CROSS CORPORATION</td>
<td>GGC-4401C</td>
<td>Hematological Disorders</td>
<td>Deep Vein Thrombosis</td>
<td>Phase I</td>
<td>Completed</td>
</tr>
<tr>
<td>GREEN CROSS CORPORATION /</td>
<td>margetuximab</td>
<td>Oncology</td>
<td>Bladder Cancer</td>
<td>Phase I</td>
<td>Ongoing</td>
</tr>
<tr>
<td>MACROGENICS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUKWANG PHARMACEUTICAL</td>
<td>YN-968D1</td>
<td>Oncology</td>
<td>Solid Tumor</td>
<td>Phase I; Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>HANNI PHARMACEUTICAL</td>
<td>HM-11260C</td>
<td>Metabolic Disorders</td>
<td>Type 2 Diabetes</td>
<td>Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>HANMI PHARMACEUTICAL</td>
<td>Insulin Human Long Acting</td>
<td>Metabolic Disorders</td>
<td>Type 1 &amp; 2 Diabetes</td>
<td>Phase I</td>
<td>Ongoing</td>
</tr>
<tr>
<td>HANNI PHARMACEUTICAL</td>
<td>HM-10460A</td>
<td>Hematological Disorders</td>
<td>Neutropenia</td>
<td>Phase I</td>
<td>Completed</td>
</tr>
<tr>
<td>SK CHEMICAL</td>
<td>Docetaxel Teva</td>
<td>Oncology</td>
<td>Non-Small Cell Lung Cancer</td>
<td>Phase III</td>
<td>Completed</td>
</tr>
<tr>
<td>SK CHEMICAL</td>
<td>NBP-603</td>
<td>Hematological Disorders</td>
<td>Hemophilia</td>
<td>Phase I</td>
<td>Ongoing</td>
</tr>
<tr>
<td>JW PHARMACEUTICAL</td>
<td>CWP-232291</td>
<td>Oncology</td>
<td>Acute Myelocytic Leukemia (AML, Acute Myeloblastic Leukemia)</td>
<td>Phase I</td>
<td>Ongoing</td>
</tr>
<tr>
<td>LG LIFE SCIENCES</td>
<td>LB-03002</td>
<td>Metabolic Disorders</td>
<td>Growth Hormone Deficiency</td>
<td>Phase III</td>
<td>Completed</td>
</tr>
<tr>
<td>HANALL BIOPHARMA</td>
<td>cobiomamide</td>
<td>Dermatology</td>
<td>Atopic Dermatitis</td>
<td>Phase II</td>
<td></td>
</tr>
<tr>
<td>HANALL BIOPHARMA</td>
<td>HL-143</td>
<td>Infectious Disease</td>
<td>Hepatitis C</td>
<td>Phase I; Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>HANALL BIOPHARMA</td>
<td>HL040</td>
<td>Cardiovascular</td>
<td>Hypertension, Hyperlipidemia</td>
<td>Phase I</td>
<td>Ongoing</td>
</tr>
<tr>
<td>SK BIOPHARMACEUTICAL</td>
<td>YKP-30811</td>
<td>Gastrointestinal</td>
<td>Constipation</td>
<td>Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>SK BIOPHARMACEUTICAL</td>
<td>SKL-NP</td>
<td>Central Nervous System</td>
<td>Diabetic Neuropathic Pain, Diabetic Peripheral Neuropathy</td>
<td>Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>SK BIOPHARMACEUTICAL</td>
<td>YKP-3089</td>
<td>Central Nervous System</td>
<td>Epilepsy, Partial Seizure</td>
<td>Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>VIROMED</td>
<td>VM-202</td>
<td>Cardiovascular</td>
<td>Critical Limb Ischemia</td>
<td>Phase II</td>
<td>Ongoing</td>
</tr>
<tr>
<td>CRYSTALGENOMICS</td>
<td>CG-100649</td>
<td>Immunology</td>
<td>Osteoarthritis</td>
<td>Phase I</td>
<td></td>
</tr>
</tbody>
</table>

*Source: KHIDI.*

## Road Map for Innovative Korean Pharmaceutical Companies

### Type

#### Innovative Drugs (NME, NBE)

- **2012**: USA
- **2014**: EU
- **2016**: CHINA & PHARMERGING NATIONS
- **2018**: USA
- **2020**: EU

**Implications:**
- US’s standard-based development for global penetration

#### Generics *1*

- **2012**: WHO, PHARMERGING NATIONS
- **2014**: EU
- **2016**: USA

**Implications:**
- After early profit creation in pharmerging markets with more lenient regulations,
- Reinvestment for expansion to advanced markets

#### IMDs & BioBETTERS *2*

- **2012**: WHO, PHARMERGING NATIONS
- **2014**: USA
- **2016**: EU

**Implications:**
- Cultural acceptability

#### Botanical Drugs

- **2012**: CHINA
- **2014**: EU
- **2016**: USA

**Implications:**
- Utilizing current customers,
- Production capacity accumulation,
- Entering advanced markets

#### APIs

- **2012**: JAPAN
- **2014**: USA
- **2016**: EU

**Implications:**
- TAIWAN | CHINA

*1: Generics (Biosimilars, Generics, Vaccines)
*2: Incrementally modified Drugs (Chemical & Bio)

**Source: KHIDI.**
We don’t get to select the diseases to research. The diseases choose us. WE ARE PASTEURIANS.

Infectious diseases caused by viruses, bacteria, parasite or fungi take away millions of lives each year. Widely spreading with globalization, they can be a threat to you and your family at anytime. We must put a stop to it. But how? The answer is in humanism and innovation. Institut Pasteur Korea is a nonprofit drug discovery research institute committed to drive the convergence of Biology, IT and Chemistry in the pursuit of breakthrough technologies to save lives of children around the world and your loved ones. Playing a key role in the 32 Institut Pasteur International Network located worldwide, we have been at the forefront of fighting infectious and neglected diseases. Much of our success, including the discovery of tuberculosis drug candidate, has been driven through partnerships with global organizations who share Louis Pasteur’s vision of changing “infected” to “cured.” If you are interested in finding out Pasteurians’ journey to a cure, please contact us at publicaffairs@ip-korea.org or visit www.ip-korea.org for more information.
KOREA AND THE MIDDLE EAST

MOON HYUNG-PYO, Minister of Health and Welfare of Korea, discusses the results of his recent state visit to the Middle East with Korea’s President, and Korea’s assets and potential as a global healthcare partner in developing and pharmerging regions around the world.

HCLS: Minister Moon, you just returned from a tour of the Middle East. Could you give us an overview of some of the highlights of this trip?

MHP: While the Middle East and South Korea have cooperated for many years in the construction and energy sectors, our relationship in the healthcare sector is relatively new. This was the first time for a health minister to join the president during the state visit to middle-east countries, which is a testament to the fact that the healthcare sector is one of key pillars of the Park administration’s Creative Economy. Some GCC countries have chosen Korea as their healthcare partner as they are becoming more interested in setting up or improving their healthcare systems.

Here are some of the highlights made during the recent president state visit. First, the Korean government has signed a MoU with the governments of Kuwait and a cooperative arrangement with Sharjah, an emirate in the UAE, and explored areas of future collaboration with health ministries of those countries. Second, this trip has transformed many discussions and proposals made for the private sector into tangible outcomes. Some major Korean hospitals – St. Mary’s Hospital and Yonsei Severance Hospital for example – can join the healthcare sector of those nations under agreements made with local partners. The Marina Health Promotion Center, whose management and operation are commissioned to St. Mary’s Hospital, celebrated its opening in Abu Dhabi during the delegation’s visit. Yonsei Severance Hospital signed a cooperative agreement with its Saudi counterpart, Integrated Business Venture, to manage and operate a women’s cancer center scheduled to be open in 2016. Some Korean pharmaceutical companies made progress in Saudi Arabia, through export agreements and building a pharma-cluster.

HCLS: Could you tell us about some of the different segments of the healthcare and life science industry that stand to economically benefit from your trip?

MHP: There are some Korean hospitals, such as Seoul National University Hospital and St. Mary’s Hospital, which will generate revenues by operating local hospitals in the UAE, and bringing Korean professionals, as well as medical and pharmaceutical products, to the Middle East. This will hopefully have a huge ripple effect on the healthcare and life science industry by inspiring the younger generation to go into medicine, creating more jobs, raising global awareness of the Korean healthcare industry, and boosting Korean exports of pharmaceutical and medical products.
HCLS: What are some of the other countries, outside of the Middle East, that you are working to increase the Korean medical industries trade with?

MHP: Korea has received considerable attention from other countries due to the level of success our healthcare sector has achieved in such a short period of time, as well as the advanced level of Korean hospital information systems.

China is ranked first in terms of the number of patients visiting Korea, and has therefore emerged as one of the most important healthcare trade-partners, both regionally and financially. Last year, MoUs were made with some Chinese provincial governments to enable Korean hospitals and medical professionals to practice locally and to identify practical areas of mutual cooperation.

Strategic cooperation with CIS (Commonwealth of Independent States) countries, including Russia and Kazakhstan, is underway as their policies to modernize their healthcare systems have created more demand for quality healthcare services. As a result, more CIS patients are coming to Korea, and one Korean hospital, Gangnam Severance Hospital, opened a medical checkup center in Kazakhstan in 2014.

In Latin America, the government of Ecuador granted homologation (an automatic approval system) to Korean pharmaceuticals, which demonstrates the safety and efficacy of Korean drugs. Many Korean pharmaceutical manufacturers – e.g. Boryung Pharm, Green Cross and Celltrion – have made export contracts with countries in this region, and one particular contract with Mexico was very impressive.

HCLS: Why is the Korean industry the best partner for these countries around the world?

MHP: There are several critical factors. First of all, Korea has great human resources in this sector. Most of Korea’s brightest students opt to study medicine or pharmacy in university, where well-organized educational programs and courses are provided. In the past, Korea’s pharmaceutical makers focused mostly on generics. However, today they are in the process of transforming into brand-name manufacturers by investing more in R&D and developing innovative drugs. The Korean government is very active in helping the drug industry to become truly world-class. With all of these factors combined together, Korea’s healthcare industry will soon join the ranks of global healthcare power houses.

In addition, Korea is one of the best countries in terms of clinical trial capacity. With 22 new drugs already introduced by the Korean industry, there are several more waiting to be launched in the marketplace. We are hoping that Boryung’s Kanarb will secure number one market share in Korea among original ARB hypertension drugs. Also, we cannot ignore the great potential that Korea’s medical device industry possesses. It has a competitive advantage combined together with Korea’s advanced ICT sector. Korea’s medical device industry will certainly play a significant role in telemedicine.
THE STEPS TO HEALTH ECONOMY 2030

JUNG KEE-TAIG, the president of the Korea Health Industry Development Institute (KHIDI) outlines his “Health Economy 2030” for Korea, and highlights the institute’s domestic and international collaborations.

HCLS: KHIDI aims to help Korea become a health technology powerhouse by 2020. What are some of the ways in which this will be achieved?

JKT: I changed KHIDI’s vision slightly when I started earlier this year, which involves supporting Korea’s healthcare industry by creating value from the perspective of a “Health Economy” by 2030. Health Economy 2030 is my vision, encompassing everything from health services and medical devices to health promotion activities, while linking incentives to them. KHIDI’s objective is essentially focused on developing and supporting the healthcare industry. Furthermore, medical costs in Korea are the most rapidly increasing within the OECD; by discovering ways to reduce the growth of medical costs, we will create value from new angles.

KHIDI: How does KHIDI help small to medium sized companies become more competitive domestically and internationally?

JKT: We cannot replace their business activities. For example, it is very difficult for small to medium-sized medical device companies to sell their own products to large hospitals because almost all physicians in Korea are very accustomed to leading American or European medical devices. Even if a small Korean company develops very innovative products and they are not used to it, only a slight issue will make it difficult for small companies to commercialize their innovative products. KHIDI moderates this process through a medical technology experiment lab in which we receive input from experts and professionals and pass on these feedbacks to the small companies, who then modify their products before giving them back to the hospitals.

HCLS: What is your assessment of the attractiveness of local Korean pharmaceutical companies as potential partners for out-licensing products around the globe?

JKT: Traditionally, Korean companies are not very interested in innovation because of drug reimbursement policies.
The Korean drug companies now have to create innovation by investing more in R&D and creating a network with international companies. After this change, Korean companies’ attractiveness will be heightened; most of them are owned by the founders, so they can make decisions very quickly and sustainably. That can be an advantage. Already, many of them set up a plan to go abroad and collaborate with global leaders. With the help of KHIDI some companies have succeeded in exporting their products and establishing pharmaceutical production clusters in the Middle East and Latin America. KHIDI is supporting a wide range of activities of pharmaceutical companies.

**HCLS:** Earlier this year, KHIDI created Biopolis with A*STAR in Singapore. What are you hoping to achieve from this?

**JKT:** A*STAR created this ecosystem and cluster, as they were slightly ahead of us in terms of commercializing their R&D activities. Korea recruits and retains the most intelligent people in the medical profession for the last 20 years and have brought out creative and innovative ideas in research activities. However, we have not been very successful in commercializing the ideas, so we cooperate with a leading agency (A*STAR) that has a global reputation for commercializing its R&D activities. KHIDI has therefore focused on how to commercialize (Phase III-IV clinical trials) and linking that commercialization to the world. Collaborating with A*STAR has been very fruitful; they share the Asian spirit and Western philosophy. We have already established an MoU with A*STAR and proposed a Medtech Development Center. KHIDI has supported the joint R&D work between a Singaporean and Korean company, mostly venture-funded, and helped bring them to commercialization. From the Singaporean perspective, the advantage is that most Western companies only did research for profit, without establishing physical factories or operation in Singapore. We want to have a more physical presence.

**HCLS:** How do you rate the entrepreneurial spirit of Korean companies?

**JKT:** This is a fragile point in Korea; I often discuss with my staff how to motivate and create entrepreneurship in the biomedical area. To create an ecosystem in this area, we need to disseminate entrepreneurship in the biomedical area. Creating an educational institution can be one approach, but we want to do it more efficiently by collaborating with bigger tech groups. Since we have a technological commercialization center here, we want to utilize our biomedical center and collaborate with local universities like KIST. The Chair Professor at KIST received a large grant from the government and has created an innovation center in collaboration with KHIDI. We will continue to establish similar relationships with universities across Korea.
The idea of Korea becoming a top-tier nation in pharmaceuticals was carefully outlined in 2012 by the government through its Pharma Vision 2020, which details a number of ambitious goals:

- Become a top seven global pharma powerhouse by 2020.
- KRW 10 trillion (USD 8.9 billion) between 2013 and 2017 allocated by Korean government for R&D.
- 20 new drugs to be produced by 2020.
- Two Korean companies in global top 50.
- Global market share to increase from 2 to 2.5 percent.
- Pharma exports from 12.5 percent to 46 percent of total production.
Preface: Investment by Korea’s government in financing pharmaceutical and biotech companies aims to put Korea on the global map of innovation. Here’s how it works.

In February 2015, the Korean Ministry of Health and Welfare announced the start of a second round of financing to the biopharmaceutical industry, as part of the Global Pharmaceutical Industry Development Fund (GPIDF). A total of USD 123 million will be invested in Korean pharmaceutical and biotech companies for the purpose of financing overseas M&A/joint ventures and the development of overseas facilities for production or R&D, including global clinical trials. The Ministry of Health and Welfare has contributed USD 18 million to the fund directly, while the Korean Development Bank, the Industrial Bank of Korea, Korea Investment and Securities, Korea Investment Partners, and others contributed the remaining funds; Korea Investment Partners will be managing the portfolio. Targeted primarily at small and medium-sized pharmaceutical enterprises with strong product candidates, the investments will be made for eight years, with an option for a two-year extension.

This funding round is a small part of a much broader government initiative in support of the Korean life sciences industry that began in the mid-2000s. Korea’s budding clinical trial industry was targeted first, and the government partially funded the development of 15 world-class clinical trial centers at major teaching hospitals, which allowed Seoul to climb from 12th to first place worldwide in terms of clinical trials on a per city basis between 2007 and 2012. Another mechanism, the USD 1 billion Korea Drug Development Fund established in 2011, was created with the goal of developing ten new drugs by 2019 by supporting specific private R&D projects from the pre-clinical stages through commercialization. The GPIDF’s first round of funding of USD 92 million took place in 2013, and was one of the first manifestations of the government’s pledge to invest USD 8.9 billion for pharmaceutical R&D between 2013 and 2017. The ultimate goal of these combined efforts is the achievement of the “Pharma 2020 Vision”, which is for Korea to develop 20 new drugs and rank seventh globally in terms of new drug development by 2020.
RISE OF THE MACHINES

Preface: Korea’s prowess in technology has ample potential in the medical devices arena. By combining Korea’s traditional IT strength with health-based technologies, the possibilities are endless.

Written after interviews with: Song In-Keum, former chairman of the Korea Medical Devices Industry Association (KMDIA), Hwang Haelyung, CEO of Lutronic, Kim Byung-Jang, CEO of Mega Medical, and Hwang Hui, president of HKT and chairman of KMDIA.

The medical device industry is one of the fastest growing industries in Korea, ranked seventh at present,” notes Song In-Keum, former chairman of the Korean Medical Devices Industry Association (KMDIA). “After Japan, South Korea was the next country in Asia to really embrace the medical technology sector. We have accommodated and accepted advanced technology and thus medical devices here are extremely well developed. Furthermore, Koreans have excellent human resources capacity due to a very talented workforce.” Moreover, “the Korean government is providing immense support to ensure the growth of medical technology in Korea, and is being championed by many multinationals as well. For example, Siemens and GE recently invested substantially in Korea for the manufacturing of products here, and they export up to KRW 300 billion (USD 300 million) from this country alone.”

Hwang Haelyung, CEO of Lutronic, explains that Korea’s excellent engineering resource is an asset across the medical device industry. “Using Lutronic as an example... we need people with experience in physics and optics, engineers who can build robust, reliable and high power electrical systems, IT engineers to develop detectors and signaling resources that function within billionths of a second, and programmers to design powerful but user-friendly interfaces, not to mention some mechanical engineers familiar with manufacturing processes. Korea has an abundance of individuals with this type of experience. They lack exposure to the life science industry and biological science, but with some guidance and direction, they are usually very able to adapt to these types of challenges.”

Korea’s chaebol conglomerates such as Samsung and LG have played a pivotal role in educating and developing these talented engineers over the last three. “Korea’s strength is in our IT capabilities, which will help us develop U-healthcare and telemedicine solutions,” begins Kim Byung-Jang, CEO of Mega Medical. “The conglomerates and multinationals have recognized this and are targeting much of their invest-
After Japan, South Korea was the next country in Asia to really embrace the medical technology sector. We have accommodated and accepted advanced technology and thus medical devices here are extremely well developed.

Unfortunately, the potential success of these multinationals in Korea, be it Siemens or Samsung, remains largely independent of the wide array of midsized Korean medical device firms. Regarding the Korean medical device industry in general, Kim says “we have all the pieces in the sense that we have excellent hospitals and doctors, CROs, and the presence of many multinational medical device companies, but as of yet, there is a lack of collaboration and partnerships between these players.” While the industry has many of the necessary pieces for success, they lack capital and experience. The Korean pharmaceutical industry is at a similar stage, yet the biggest pharmaceutical players remain independent of the chaebols, and have found opportunities to collaborate with multinational pharmaceutical companies giving them access to more R&D capital.

In the medical device industry however, “the local producers have not been particularly willing to cooperate with importers and multinationals,” says Hwang Hui, President of HKT and newly appointed chairman of the KMDIA. “There are relatively few Korean companies in the medical device industry that have entered into R&D partnerships, or production agreements with large multinationals.” As the chairman of the KMDIA, Hwang “would like to start making a concerted effort to facilitate and encourage partnerships between local and international players, as I believe it would not only help increase demand for Korean production, but also hopefully foster MedTech innovation in Korea.”
HAKIM DJABALLAH arrived to Institut Pasteur Korea (IPK) as CEO in July 2014 with an aim to return to the French institute’s focus on infectious diseases. He outlines the complexities of Korea’s research industry and stresses the importance of knowledge-sharing for success.

FIGHTING INFECTIOUS DISEASES
Hakim Djaballah,
Institut Pasteur Korea

KNOWLEDGE SHARING: KEY FOR SUCCESS

HCLS: What were the most important changes you made since you arrived here?
HD: I want to implement greater collaboration within Korea to make IPK the main stakeholder in the country in terms of drug discovery. Secondly, our institute needs to become a hub of access to the outside world, connecting Korea through our institute to industries in the US and Europe where we have connections with the relevant people.

HCLS: What are some of IPK’s most important research projects?
HD: I have refocused our research. Historically, Institut Pasteur has been driven by infectious diseases, and I want to return to those roots. We will dedicate almost 90 percent of our work to infectious diseases and will also continue with oncology. IPK has one of the most advanced infectious disease programs in HCV, which is rampant in Korea. We have a molecule in preclinical development funded through the Korea Drug Development Fund. Some think Sovaldi has cornered the market for HCV, but Korea actually refused to sign Gilead’s letter of agreement for pricing. Having an HCV product that will fulfill the needs of the Korean market that can help the government with costs would be a huge accomplishment for IPK to give back to Korean society.

We also have a full program for influenza combined with other respiratory viruses, but our latest project focuses on Ebola. IPK recently became part of the Ebola task force at Institut Pasteur, which has been very active in this area this year. IP has a well-connected network in Africa, so we can get field data and blood samples to understand disease diagnostics and discovery. IPK can bring in dismantled viruses that we can screen for compounds for already approved drugs and we can repurpose them for the disease, or we can discover novel ones. I am more interested in understanding the host virus interaction, finding genes in humans that facilitate infection and spread the virus. That could potentially be a new point of intervention in terms of vaccine, cure or even diagnostics. My aim is to achieve that and create an accurate diagnostic kit in under an hour.

In oncology, IPK collaborates with Asan Medical Center to tackle hepatocellular carcinoma, which is extremely prevalent in Korea and the surgery for it is insufficient. We try new methods of screening instead of classically killing the tumor. In the short to medium term, some of our projects for next year will focus on antibacterial resistance. Our focus will be on drug discovery and diagnostics with the hope to identify new molecules that can make the transition into clinical development and biomarkers. Obtaining biomarkers for Ebola will be huge. It means we can stratify the African population in terms of who is vulnerable and who is not.
to spin off companies. Korea has a very strong VC presence and ironically they prefer to make their income through interest or short-term lending rather than actually investing in companies.

IPK succeeded in spinning out a company called Qurient, which has been an outstanding example of publicly-funded innovation. By generating value around small molecules, we can convince investors to establish a company and use VC money to develop molecules, potentially for the Korean market. If that molecule turns out to be unique and has special values, that company will either be acquired or the compound will be licensed to someone else for development. We are balancing between the two, and spinning out is more advantageous than licensing.

HCLS: Do you plan to expand IPK’s international scope through new collaborations?
HD: More partnerships are always welcome, but simultaneously I have to create a happy medium of balance between the work that we do, the work that those companies want to do, and local pharmaceutical and biotech companies’ interests. Pharmaceutical companies in this part of the world are very interested in working with us because they have already decided they do not want to build infrastructures for screening. It helps to build partnerships with big pharma, but simultaneously I need to balance it with our own internal programs and collaborations within Korea.

HCLS: How can you take advantage of Korea’s strong biotech sector?
HD: Korea is one of the few countries with vast amounts of public money in biotech and pharmaceuticals. For us, the model is very simple. We will deploy our biology, identify molecules, use our chemistry capabilities to optimize them, and then valorize the molecule. My hope would be to license those molecules to Korean companies as new entities that they can develop. Any molecule of that stage does not generate much revenue in terms of registered income. It is a symbolic entrance to the negotiation. The money you make is milestone-based; when you reach certain points of development, the royalties bring the success. The other option is to spin off companies. Korea has a very strong VC presence and ironically they prefer to make their income through interest or short-term lending rather than actually investing in companies.

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HCLS: Where can we expect to find IPK by 2020?
HD: Having a local HCV drug would be a tremendous success for my tenure. Addressing neglected diseases, especially for Ebola, in the diagnostic area would also be a huge accomplishment. Discovering new molecules would be even better. But my main goal is focused on education and training. I want to provide an opportunity for people to train at my institute and feel that the values we use here to do research are Western. This opens the opportunity for people to be creative and to talk. Scientists alone have no value, but scientists talking to each other have great value.
THE INNOVATION TIPPING POINT
Paradoxical Policies

**PARADOXICAL POLICIES**

**Preface:** Korea has some of the lowest price drugs among OECD countries, in stark contrast to the government’s aim to promulgate innovation. At what point along the scale does the innovation tipping point occur?

**Written after interviews with:** Kim Oak-Yeon, managing director of Janssen Korea, Jung Kee-Taig, president of KHIDI, and Amy Jackson, president of AmCham Korea.

As defined in the Pharma Vision 2020 objectives, the Korean government has made supporting pharmaceutical innovation a top priority. Great efforts have been made to encourage innovation through investment in research infrastructure, funding for venture companies, and several research clusters such as the Osong Bio Technopolis.

Yet, one of the most commonly cited challenges in the industry is poor market access for innovative pharmaceutical products due to extremely low reimbursement pricing, at about 45 percent of the OECD average. Kim Oak-Yeon, managing director for Janssen Korea, says that due to poor market access for these innovative products, “we have recently had to make difficult decisions to not launch a product in Korea, because the current policy doesn’t recognize the value of highly innovative products.” Some general managers point out that some innovative products are reimbursed at lower prices than their generic equivalents. GMs in Korea also note that some products in the country are even reimbursed at lower prices than their generic equivalents. However, poor market access doesn’t only affect multinationals; even innovative Korean companies such as Medipost are also struggling to commercialize their leading products.

“Korean companies are starting to innovate and bring their innovative products to market… they do not want to launch here because the price is too low. It is really hurting the development of the domestic industry and Korea’s future economic growth.”

*Amy Jackson*

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**KIM OAK-YEON**
Managing director of Janssen Korea

**AMY JACKSON**
President of AmCham Korea
The other result of these inadequate reimbursement policies has been to minimize the incentive to innovate. Jung Kee-Taig, president of the Korea Health Industry Development Institute (KHIDI), explains that “traditionally, Korean companies were not very interested in innovation because of drug reimbursement policies,” and that “because of the drop in prices for generics, Korean pharmaceutical companies have not had much incentive to innovate.” Amy Jackson, president of the American Chamber of Commerce (AmCham) in Korea, echoes this remark saying “Korean companies are starting to innovate and bring their innovative products to market... they do not want to launch here because the price is too low. It is really hurting the development of the domestic industry and Korea’s future economic growth.”

This lack of recognition of the value of innovation has also reduced Korea’s attractiveness as a partner or destination for R&D activities such as contract and clinical research. As one general manager aptly explains, “drug pricing is the other hurdle to bringing R&D activities to Korea, as it’s just too low to justify investing in R&D in the country when we could invest instead in a country that rewards us for our innovation.”
THE IMPORTANCE OF TRANSPARENCY IN A VOLATILE MARKET

With a wealth of experience in different countries around the world, Christophe Piganiol came to Korea as general manager of Zuellig Pharma in 2010. Today he discusses the importance of transparency in a volatile market and the introduction of new business models to satisfy customer demand.

**HCLS:** What was your initial strategy upon arriving, and how did you react to the 2012 price cuts?

**CP:** My strategy was centered on agility. When you have even slight visibility in Korea, you can change and adapt, and your team will support you as long as there is a sense of purpose.

When the price cuts hit us, the impact was huge because of the unpredictability. In Korea, original drug prices are at 45 percent of the OECD average. New products do not get high prices and it creates a huge strain on the market, both for manufacturers and for distributors like Zuellig Pharma as our fee is based on sales. Thankfully, with a little foresight we were able to predict these cuts and therefore questioned where we could develop new services. After ensuring that our distribution business could stand alone, we decided to innovate and develop new business models with new services. This involved venturing into more complicated industries where the margin pressure might be different.

Firstly, Zuellig Pharma Korea entered into logistics together with distribution, which was synergistic. We also tapped into the OTC and medical device market, the latter with Roche Diagnostics. Essentially the company spread its risk from both an industry and service perspective. Secondly, we needed to look for different business models. While the focus had been either on logistics or distribution, there are also intermediary models which can be applied to different product lines of a business.

**HCLS:** Wholesalers are numerous and generally have a small market share. Would a move towards direct access rather than wholesaler model imply?

**CP:** The government has put in place a “dual punishment” system for the whole industry at the end of 2010 to avoid fraud. This law punishes both the giver and receiver and pays the whistleblower. There are many ongoing prosecutions, so the government is actively controlling this and it is encouraging for Korea’s medical society. In this way, more transparency is better for everyone. However I do not think this will bring more direct business for manufacturers. Pharmacists typically have a few wholesalers they order from because receiving hundreds of shipments is counterproductive. Thus there is a need for consolidation. Whether we still need a large number of wholesalers is still up for debate. If you look at most modern countries, wholesaling is quite lean. Korea has about 2,000 wholesalers, which is many for the size of the country and market. It doesn’t matter whether it makes sense or not; this is the history of Korea and the future is equally unpredictable. But Korea’s environment is certainly very different from other markets. Nevertheless, the situation is getting tougher with price cuts and more requirements for logistics, for which we are prepared.
**HCLS:** What makes Zuellig Pharma Korea the strategic partner of choice for the industry?

**CP:** Zuellig Pharma has a solid operational background. We go through many audits each year from multinationals, but this helps you raise your own bar in terms of transparency and customers’ trust. Secondly, in distribution you need credit management. As tough as it can be, local companies can be conflicting because they do not see the point of guarantees. This is the difficulty of operating in a local market with international standards. We are very strict on our credit management and how we handle finances and the credit situation with customers. As the market is typically underfunded, we are collateralized. Looking at the balance sheet of companies in wholesaling, typically you do not have a strong balance sheet. Therefore you rely on credit guarantee from banks. Zuellig Pharma has been here for many years and has a strong background. The ability to take risk or not take risk on credit can sometimes be a bit tough but this is what makes us successful across Asia. Our margins are razor thin and credit management is a key success factor in distribution here. Aside from that, we also have our commercialization piece, with which we are also very transparent and where we respect protocols we agree to. Given the free trade laws in Korea, in theory we could sell products at any price, respecting pharmaceutical laws that state that you cannot sell lower than you can buy. However, we commit to selling at a certain price for our client, we fulfill that commitment. We have very strong collaborative spirit with our clients.

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“When I left Janssen, I never imagined joining a Korean company,” recalls Choi Tae-Hung, sipping a freshly brewed yujacha tea in his office on a crisp autumn morning as he gazes down at the busy, sundrenched streets of Seoul below. “I thought that the global business of Korean pharmaceutical companies would be very limited due to a lack of competitive R&D or marketing capabilities.” Choi spent two decades at Janssen before moving on, but when he did, it was to become president of Korean pharmaceutical company Boryung in 2013. “After speaking to a number of people within the industry, I realized that everyone was talking about big changes in strategic direction for domestic pharmaceutical companies. The new focus for these businesses was on the global market,” explains Choi.
Korea’s chaebols, the country’s large conglomerates, have in large part been responsible for building the country’s reputation in the fields of electronics, shipbuilding and automotive. Today, Korea’s government is looking to develop growth in new sectors outside of this traditional base; pharma has been selected as one of these new sectors. The race is now on to position Korea as the Asian hub for pharma R&D and new drug development (NDD), something that only a few years ago would have been unthinkable: a situation mirrored in other Asian countries such as Taiwan and Singapore.

“In the past, Korea’s pharmaceutical makers focused mostly on generics,” admits Korea’s Minister of Health and Welfare Moon Hyung-Pyo. “However, today they are in the process of transforming into brand-name manufacturers by investing more in R&D and developing innovative drugs. The Korean government is very active in helping the drug industry to become truly world-class. With all of these factors combined together, Korea’s healthcare industry will soon join the ranks of global healthcare power houses.”

“Korea is in a unique position in terms of new drug development,” explains Lee Kyeong-Ho, chairman and CEO of the Korea Pharmaceutical Manufacturers Association (KPMA). Indeed, Korea has already successfully brought 22 new drugs to the market between 1999 and 2014, two of which have been approved by the US FDA. “Korean companies have had an interesting experience in developing innovation, but not game-changing innovative new drugs which require significant money and manpower that we do not have enough of yet,” Lee continues. “Nevertheless, we do have successful experience in creating incremental innovation, and this has been an excellent experience for Korean companies,” he adds.

Leading the charge in boosting Korea’s regional competitiveness for pharma and R&D is the Korea Health Industry Development Institute (KHIDI), Korea’s sole public institution designed to foster growth in the healthcare industries, like pharmaceuticals, healthcare technology, cosmetics, and health systems. “It has already been eight years since global healthcare was selected as one of 17 growth engines of our nation, and we have been somewhat successful in inbound business like attracting foreign patients and physicians for training,” remarks Jung Kee-Taig, president of KHIDI. “In terms of outbound business, we hope to create those success cases more frequently and this business can be a mature and major industry for Korea’s growth by 2020.” “Koreans really want to win and be number one in everything, rather than being perceived as the little brother of China or Japan,” says UCB Korea managing director Tom Roberts.

There is a solid support system behind Korea’s Pharma Vision 2020. “The level of quality approval in Korea compared to Europe and the US for products like biologics is usually the same; sometimes it is even better but this is not recognized worldwide,” says Chung Seung, Minister of Food and Drug Safety. Since becoming Minister in 2013, Seung has already taken a number of efforts to ensure the Ministry actively participates in forums, working groups and international organizations to promote Korean medical products. In July 2014, Korea officially joined PIC/S, which created a framework where international creditworthiness of domestic medical products’ quality can be elevated. “We will actively provide support to develop biological products such as stem cell therapy products by fully implementing a ‘Support Scheme for Global Biological Products’, which aims at becoming one of the world’s top seven powerhouses in the biological product field by 2017. The Ministry will rigorously support commercialization of vaccines, biosimilars, stem cell therapy products and gene therapy products. We will also support domestic pharmaceutical companies advancing into the global vaccine market while also expanding our self-sufficiency rate from 32 to 70 percent in the domestic vaccine market over the next six years.”

However, becoming a top-tier nation for pharmaceuticals will take time.
Innovating healthcare for patients

At Novartis, we want to discover, develop and provide high-quality healthcare solutions to address the evolving needs of patients and societies worldwide. We believe that our diverse healthcare portfolio, our dedication to innovation, and our responsible approach will enable us to fulfill our mission to care and to cure.
and effort. Hakim Djaballah, CEO of Institut Pasteur Korea, believes that without attracting the international know-how necessary for solid tech transfer, the goals of Pharma Vision 2020 are more of a dream than reality. “The infrastructure for basic research is already in place and translational research is beginning to take off, but the infrastructure to take that into a product still does not exist,” comments Djaballah. “Compared to other countries with facilities for API production, Korea is still at the starting line. It does not mean they cannot achieve it; Korea is geographically attractive and the country just needs to invest in building the industry scale infrastructure to produce APIs.”

Local flagship company Boryung has found success with its newly developed angiotension receptor blocker (ARB) Kanarb. Nine molecules currently exist worldwide in this category of antihypertensives, and Kanarb is currently ranked eighth. “Boryung is the only domestic company that has developed a drug from start to finish, including outlicensing. Of course, other companies have developed new chemical entities (NCEs). But in terms of experience Boryung is different. From discovery and development to product launch and internationalization, Boryung has experiences that other companies cannot imitate,” explains Choi Tae-Hong, Boryung’s president. “Given Kanarb’s competitiveness, multinationals are our new competitors.”

Could Boryung be one of the two top 50 companies that are planned in Korea’s Pharma Vision 2020? “Our own strategic objective is not to make Boryung a top 50 company in terms of sales size, but rather to make Boryung the best company in Korea in terms of marketing and R&D capability,” Choi reveals. “My dream is for Boryung to be at least number one in Korea. I do not know what the company’s rank in 2020 will be globally, but that is not so important as long as we achieve our strategic goal year by year.”

Hanmi is a Korean pharma heavyweight, and is the highest R&D spender in the Korean pharma sector, with KRW 100 billion (USD 90 million) invested in 2013. “We can lead Korean pharmaceutical companies in the R&D field,” believes Lee Gwan-Sun, Hanmi’s CEO. “We are interactive in some external R&D activities from recent venture companies and from a very early stage we can select some candidates or compounds which can be a synergy with our current pipelines. In that sense, Hanmi can be a role model.”

Founded in 1984 and listed in 2002, with three production centers and three R&D facilities, Daehwa Pharmaceutical’s anticancer drug DHP107 aims to provide an oral version of Paclitaxel – a new ‘Made in Korea’ product. As Lee Han-Koo, president of Daehwa, explains, “there is no such thing as a single injection for oncology. One drug has to be used in conjunction with other anticancer drugs, such as enhancers that need to be interactive with each other. DHP107 avoids this situation altogether.” After finishing clinical trials, Lee hopes to receive approval for DHP107 by the end of 2015 and start marketing the product first in Korea and then to other emerging markets in the region. Daehwa currently exports to 22 markets worldwide; Lee is bullish about future growth: “Of course we will expand to satisfy all
How can chaebols influence Korea’s life science sector?

Korea’s economy has been dominated for decades by chaebols, large family-owned business conglomerates like Samsung, Hyundai, and LG, known for their hierarchical structures and success in Korea’s traditional sectors. However, a number of these big businesses are today making investments in the life sciences area – and those that started early are leading the pack: LG Life Sciences, for example, was the first Korean company to have a new drug approved by the US FDA.

In 2011 the country’s biggest chaebol, Samsung, created a joint venture with Biogen Idec to form Samsung Bioepis, an offshoot of the Samsung group dedicated exclusively to the research and development of biosimilars. By 2016, the company already expects to launch its first product. “Because of the Samsung brand on our back, we have been able to attract the best talent pools and that is where many other Korean CEOs’ biggest nightmare begins; attracting the right people,” says Christopher Ko, CEO of Samsung Bioepis. “When we announced the foundation of Samsung Bioepis, the development status of our project was at an early stage. But Biogen Idec saw our potential and our willingness to work hard. They believed our story because the Samsung group was behind it, and this has helped in terms of obtaining necessary technology and guidance. The Samsung brand will continue to place us at the forefront of the competition.”

Earlier, in 2009 MSD launched a partnership with Samsung to develop biosimilars. “At that time, MSD was just starting in biopharmaceuticals, and Samsung had not done much in healthcare,” explains Don Hyun, president of MSD Korea. “Nevertheless, Samsung came up with some in-licensed products and within a year and a half they had three promising molecules. By creating a global partnership, Samsung was able to carry out clinical valuation development and product registration, while MSD retained global commercialization rights. We are looking forward to the addition of those products towards the end of 2015.”

Although not a chaebol per se, KT&G, Korea’s biggest tobacco company, created its Life Sciences division in 2002 as a venture project that has dabbled in creating drugs across a wide spectrum of indications. James Jun, CEO of KT&G Life Sciences said most of these projects to focus on just two products in-depth. “The first project is mainly focused on accelerating biogenesis in mitochondria, which targets ME-LAS Syndrome,” he quips. “Our other project focuses on studying Type-2 diabetes. I believe these two products have very new mechanisms for which the global market is demanding. If these projects succeed, KT&G Life Sciences will go for an IPO, at which point we will consider receiving funding from the outside and manage itself as a venture company.” Jun certainly hopes KT&G will develop the first Korean blockbuster people’s needs,” he explains. “However, the methods of expanding could be diversified. For example, we have recently signed a technical contract with Iran. We send the products first and will build a plant later. We also will have made our spot in Chengdu, China. Furthermore, following the market situation and requests, we will expand our business territory to the whole world.”

Ambition and innovation is not limited to the biggest or best funded Korean labs; domestic companies of all sizes and levels of experience are prioritizing R&D investment and planning to develop new drugs in the future. Korea Pharma is a prime example, and Chairman Park Jae-Don explains they have become involved in several R&D projects with a few different partners over the past few years. One such project is a “pre-clinical trial for a dementia treatment based on osmotin, an ingredient extracted from tobacco leaves, in conjunction with Kyeong-Sang University,” while they are also working with an overseas partner to develop a product
that treats disease caused by bacteria resistant to CEPA antibiotics, and are currently conducting late phase clinical trials.”

“Most Korean pharmaceutical companies think they need to develop new drugs by following a manual, without having the necessary technology or infrastructure first, or in other words, without the capacity to do so,” says Kim Won-Bae, vice chairman of Dong-A Pharmaceutical, another Korean giant with ambitions to enter the global top 100 pharma companies in the next ten years. “Rather, we think we should focus on what we are capable of doing. So we deal with traditional drugs that have already been verified and used.” In 2014, the US FDA approved Dong-A’s antibiotic tedizolid marketed under the name Sivextro, the second ever such approval for a Korean innovative drug.

BURGEONING BIOTECH

One of the pillars leading the growth of Korea’s pharmaceutical industry is biotech, as seen through the large amount of resources being expended in this area by both the government and the private sector. One of the leading forces in expediting Korea’s growth in biotech is the Korea Research Institute of Bioscience and Biotechnology (KRIBB). Its current president, Oh Tae-Kwang, has been working to restructure the institute to best fit the needs of Korea’s next generation of scientists, by fusing Korea’s strength in IT and nanotechnology with biotechnology. “KRIBB wants to serve an important role in composing the bio industry ecosystem,” Oh remarks. “We are building a system for 20 major companies and 130 small and medium-sized enterprises to collaborate together over five sectors. Previously, these sectors worked independently and without coherence; now they interact with each other extensively, which will lead them to the global market.” KRIBB’s vision is to be a global research institute leading bio-innovation by 2018, with a goal of producing five world-class platform technologies by that time as well as having one of the top research infrastructures in the world.

The market in Korea is abounding with numerous ambitious startup biotech companies. Abion, originally a startup venture of Seoul National University to provide molecular pathology analysis services in 2007, is one such example. In 2009, the company began conducting studies for potential new pharmaceutical development and in just a few short years has three new projects in the pipeline, most notably a siRNA therapeutic project for the development of a chemo-radio sensitizer for the treatment of advanced cervical cancer and head and neck cancer caused by HPV. “Our primary target market for siRNA therapeutics is the US market,” says Abion’s CEO Shin Young-Kee. “The number of patients with advanced cervical cancer is relatively small; however it is a good market to validate whether our concepts on siRNA therapeutic development are correct or not. We consider the key pharmerging countries such as Russia, China or India as secondary markets in the future.”

“With the health policy institute in Osong, the ministries and national agencies across the river in Sejong, there is no other city in the world where you can find as much political and regulatory infrastructure in close proximity to a healthcare and life science cluster.”

Lee Si-Jong, governor of Chungcheongbuk-do
Many of these bioventures have benefited from the support and protection of one of the national or provincial government’s various biotech incubator projects. The province of Chungcheongbuk-do has developed the largest and most extensive of these centers, the Osong Bio Valley. “We had set the goal of attracting six national health policy institutes to this cluster and have succeeded, and already have more than 60 different pharmaceutical and biotech companies that have established offices within the Osong complex,” explains Lee Si-Jong, governor of Chungcheongbuk-do. “With the health policy institutes in Osong, the ministries and national agencies across the river in Sejong, there is no other city in the world where you can find as much political and regulatory infrastructure in close proximity to healthcare and life science cluster. In two or three years time we will have developed a rectangular belt of R&D clusters for different niches in healthcare,” explains Lee. “We expect to see some tangible success of these development projects within that timeframe.”

Medipost, one of the 60 life science companies with facilities in Osong, was founded in 2000 as a public umbilical cord blood bank by Yang Yoon-Sun, a former clinical pathologist at Samsung Medical Center in Seoul and medical professor at Sungkyunkwan University and Korea University. In 2012, the company’s lead product Cartistem was approved for marketing by the MFDS and is currently undergoing an FDA approved Phase IIa trial in the US. Stem cell therapies such as Cartistem “are such a revolutionary, innovative area of medicine, there is no existing regulatory framework in place,” says Yang, who highlights that “Medipost is playing a key role in this process in Korea and elsewhere, because we are working closely with regulators for these regulatory changes.”

In the field of oncolytic viral therapies, SillaJen is a global leader and has published several papers in Nature and Nature Medicine on their groundbreaking work. CEO Moon Eun-Sang describes their lead product candidate, an oncolytic vaccinia virus that they call Pexa-Vec, as a “bona fide medical breakthrough of immense proportions,” one that “doesn’t represent just a cancer treatment, but an actual cure for cancer.” SillaJen is “the first company to try to develop an oncolytic vaccinia virus,” says Moon, who adds that they “can deliver the vaccinia virus to tumors intravenously as well as intratumorally, while the other oncolytic candidates that are suitable for solid tumor cancers must be injected intratumorally.” Clinical trials have generated a lot of excitement so far, and Moon explains that “in our phase II A trial, out of 30 patients, 21 demonstrated partial tumor responses, and four were completely cured.” “At present,” he concludes, “we are preparing to begin a global phase III clinical trial for Pexa-Vec’s efficacy as a treatment for hepatocellular carcinoma.”
MASTERS OF THEIR OWN DESTINY

Minister of Health Moon Hyungpyo accompanied Korea’s president on a state visit to the Middle East in February. “This was the first time for a health minister to join the president during the state visit to Middle East countries,” explains Moon, “which is a testament to the fact that the healthcare sector is one of key pillars of the Park administration’s Creative Economy. Some GCC countries have chosen Korea as their healthcare partner as they are becoming more interested in setting up or improving their healthcare systems.” Over 150,000 people from across the globe have come to Korea to take advantage of its health services.

Some countries have begun to look to Korea as a model and partner. Thus far, the most prevalent form of partnership has been that of Korean hospitals opening affiliates all across Asia, the Middle East and even the United States. Kim Han-Joong, chairman of the strategy committee at CHA Health Systems and board member of Samsung, believes that the strength of Korea’s future global contribution to health lies in its ability to export health systems and health technology. “We have well-trained health professionals and cutting-edge facilities and equipment in our hospitals. Compared to the population, there is an abundance of hi-tech equipment in Korean hospitals, because the competition among hospitals here is very high. In terms of equipment competition, Korea’s strength is in the area of information technology-biotechnology (IT-BT) convergence technologies as well as stem cell research and cell therapy.”

Kim concludes with Korea’s plan of action for the coming years: “This country has developed healthcare systems based on the welfare model, but now we must turn from a welfare to industry model. Secondly, until now, the government has controlled much of the system, but it must become more market oriented. Thirdly, our interest has been historically limited to the domestic market; Korea must move from a domestic model to a global market.”

KONECTING THE DOTS

The growth of clinical trials in Korea has been remarkable in recent years. The number of clinical trials performed by multinationals has shot up from five in 2000 to 303 in 2012, with 367 clinical trials performed by local companies. In the same year, Seoul was ranked the number one city worldwide for clinical trial competitiveness according to the US National Institute of Health, and Korea is ranked tenth worldwide.

Why has Korea become such a favorable country for doing clinical trials? Liz Chatwin, country president of AstraZeneca Korea, explains: “The clinical research facilities of institutions like Samsung Medical Center or Seoul National University are much better than
anywhere else in the world, even the US. This is because they have a coordinated approach to research with all the phases of research under one roof. The implication of this is that institutions can mix expertise in pre-clinical research, translational science and clinical development in one place. They can then do clinical research very efficiently.” Chatwin also attributes a well-tailored patient database to this efficiency. “Hospital patients can be identified rapidly to fit particular criteria for a clinical trial,” she remarks. “Because the big institutions treat almost every type of patient with almost every diagnosis in their center, they can recruit individuals for just about any clinical study very quickly.”

“With 50 million citizens all covered by a single public healthcare system, Korea has a much bigger pool than other countries in term of people exposed to clinical trials,” adds Deborah Chee, president of the Korea National Enterprise for Clinical Trials (KoNECT). “The size of our economy and the characteristics of Korea’s population as the fastest-growing ageing society worldwide provide us great potential. Our disease patterns are similar to that of western countries; for the elderly, the government focuses primarily on cancer and neurodegenerative diseases.”

"Korea’s strength is in the area of IT-BT convergence technologies as well as stem cell research and cell therapy."

Kim Han-Joong, chairman CHA Strategy Committee and board member Samsung

Chee, whose goal is to increase Korea’s clinical trial positioning from tenth to fifth worldwide, notes that there are currently 13 supported regional clinical trial centers across the nation with financial support from the government and with matching funds from hospitals. Furthermore, in 2012 the government launched a program to identify new Global Centers of Excellence for Clinical Trials, of which KoNECT has selected five so far. “These centers should further the clinical trial capability of Korea, especially focusing on specialized areas like complex clinical trials, studies in special populations, and patient-oriented Phase I clinical trials,” says Chee. “Korea is contracting more global Phase I studies for indications like oncology. So far about 160 sites have been accredited by the Ministry of Food and Drug Safety.”

The explosion in number and quality of trials in Korea certainly makes an attractive case to attract multinational CROs; but to what extent do these companies actually contribute to Korean research? Jack Lee, president of Korean CRO LSK Global, notes that the recent arrival of global CROs has drastically changed local CROs’ sponsorship base. Moreover, global CROs present in Korea have the financial muscle to hire the best Korean talent, having been trained by local CROs. “CRAs of
global CROs do not complete the life cycle of studies as CRAs hop around from one CRO to next,” laments Lee. “They spend a couple years at each company and very few see a study from beginning to end. Global CROs do not contribute at all to Korean clinical drug development technology, because all the protocols, data management, statistics and project management are done at these companies’ headquarters. It is nonsensical to believe that because we are active in global clinical trials, Korea will benefit from such activities. Global CROs do not teach us anything. They just use our trained labor, stolen from companies like mine. To them, Korea is like a clinical trial assembly plant country.”

Albert Liou, Vice Chairman of PAREXEL Asia Pacific, takes a different tone on this issue, arguing that while “the clinical development industry in Korea has become more competitive, but also more collaborative.” “Local CROs have their own strengths, including government support and a general ‘home team advantage’, while we have different strengths and assets as a global CRO, specifically our technological capabilities.” As the local CROs have developed, PAREXEL has “greatly developed our role as a healthcare consultant,” explains Liou. “Often, the Korean CRO will manage trials conducted in Korea,” he says, while “PAREXEL provides eClinical trial technology, safety monitoring, and project management for trials conducted in

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**An Elderly Crisis**

Korea is a large market: with a population of 50 million, the pharmaceutical market was valued at USD 18.6 billion in 2013, making it the 14th largest in the world. “Korea has always been a consumer nation for innovative new drugs rather than a developing nation,” says Lee Sang-Suk, CEO of the Korea Research-based Pharmaceutical Industry Association (KRPIA). The market’s value is forecast to rise to USD 24.3 billion by 2020; much of this growth caused by the country’s rapidly aging population. In 2013, the number of people aged 65 and over in Korea reached six million, or 11.7 percent of the total population. But the real worry for Korean policymakers is the projected growth of this aging population: by 2050, the number is due to rise to 33 percent.

“We forecast that in 2017, Korea will be an aged society and a super aged society by 2026, which tells us to prepare for an aging era in overall society,” cautions Kim Choon-Jin, chairman of the Health & Welfare Committee of the National Assembly of Korea. “Especially in the near future, the baby boomer generation of more than 7.1 million people will enter into the senior citizen class. This generation possesses a higher education level and diverse society experience compared to current senior citizens. Considering the changing features of society, it is necessary to reform and implement systems that prepare for the future.” On top of that, Korea has been categorized as a “low birthrate country” for the last 13 years, with an average birthrate of 1.13 children in 2013. It is perhaps this looming threat that led the Korean government to follow up on its 2006 price cuts with another round of cuts in 2012, which saw prices drop by an average of 14 percent. Consequently, drug prices were reduced to 45 percent of the average of OECD countries. However, the country’s drug expenditure compared to 2007 increased by 1.2 percent, still twice that of the average of OECD countries. A pre-emptive price cut could stop this figure rising even higher as the population ages, but it may damage the development of the pharma sector that the government is counting on.

“The government has repeatedly said that it wants to nurture and develop the pharmaceutical industry. However, not recognizing the value of innovation will be ma-
major hurdle for the government trying to achieve its Pharma Vision 2020,” warns the KPMA’s Lee. “There is a disconnect between what the Korean pharmaceutical industry wants to do and what the Korean government wants to do,” argues Roberts of UCB. “Korea’s Pharma Vision 2020 aims to make the country a top seven player within a very small amount of time, but price controls make it almost impossible for some companies to stay in business.”

FREE TRADE EVOLUTION

Following the implementation of the Korea-US free trade agreement (KORUS FTA) in 2012, Korea has lowered its import tariffs, enhanced its regulatory transparency, and attracted an influx investment from multinational pharmaceutical companies, especially in the form of JVs with domestic players. “Korea has signed free trade agreements with a number of parties; one part of that agreement was to ensure a proper IP protection scheme. Most relevant for us is the patent linkage system, implemented in March 2015, which will allow the base requirements to be met for proper protection of IP rights in the pharmaceutical sector.” says Lee Sang-Suk, CEO of the Korea Research-based Pharmaceutical Industry Association (KRPIA).

In addition to Korea’s excellent clinical trial infrastructure, multinationals also have at their disposal a plethora of local companies and research institutes with which they can work hand in hand to each other’s mutual benefit. Novartis, which registered more clinical trials in Korea in 2013 than any other multinational, has found strategic ways to team up with the local community to further enhance Korea’s creative economy. “One way is through co-marketing and distribution partnerships,” says Brian Gladsden, president of Novartis Korea. “In this way we can complement each others’ skills and capabilities in the marketplace.

Two of UCB’s products were launched last year with non-reimbursement status because the Korean health authorities’ suggested reimbursement prices were just slightly too low to be profitable (nine percent of US prices). This is not only a big concern for Roberts, but many other multinational CEOs constantly facing similar situations. “Multinationals, who can teach people here about the innovation process, will slowly either withdraw or transform their business into cash cow enterprises and sell old products,” Roberts comments. “There are many companies with great products in the pipeline that may not be able to launch due to the current pricing situation. Korea is a modern, fully developed country that is rivaled in size with many European countries. The pricing situation, combined with a 44 percent OECD pricing average, is not conducive to this 2020 Vision.” All eyes will be on Korea as one of the first super-aged societies, to see whether legislators can find a sustainable solution that balances access to innovation with good financing.
Executive talks

The long-term perspective
Chun Young-Chin founded PMG Pharm (Pionex Management Group) in 2001. From its origins as a small medical distribution company, he has successfully built it into a rapidly growing drug manufacturer, specializing in a number of diseases.

“The Korean pharmaceutical industry has experienced dramatic changes regarding its policies and market environment inside and outside of Korea for the last ten years, but pharmaceutical companies have done well to manage these crises. I think that we should recognize that crisis causes problems that the pharmaceutical industry must tackle, and there should be a supporting plan to realize the visions and strategies that the Korean government has proposed through the Pharma Vision 2020.”

Korea’s big data opportunity
Combining Korea’s expertise in technology with healthcare, SCL has grown to become the largest diagnostics service provider in the country: today, the company examines around 30 million cases per year.

“As this is a diagnostic center, we deal with non-patients (healthy people), as well as patients from all of Korea’s hospitals. SCL takes all the information we get from every patient to a data warehouse. Thus, in other words, data implementation business is our most important research business today,” explains Lee Kyoung-Ryul, chairman of the SCL Healthcare Group. SCL has pioneered some groundbreaking technology in recent years, including a device that tests for 56 different congenital metabolic diseases in newborn babies. “As central laboratory, SCL Lab screens 30 percent of clinical specimens of total newborn babies,” Lee reveals. “The data we have covers a broad range of information. It is panoramic data compared to other organizations. The fact that we have the largest market share in Korea means that we have a significant amount of data. We are planning to cooperate with pharmaceutical companies, institutions, and biotech companies in Korea and abroad with this well-organized data.”

to offer more to our customers and reach more patients. In addition, potential R&D collaborations could provide huge opportunities for both partners in Korea. Many domestic companies are looking to increase their R&D capabilities and are investing significantly in this area.” Through the Novartis Venture Fund, investing in smaller companies in Korea also shows promise. “As of today, we have invested in three local companies and hopefully there will be an opportunity for similar investments in the future,” continues Gladsgen. “This provides a unique opportunity for knowledge-sharing, R&D capability-building, education and training. I believe that further collaboration between multinational and domestic companies, and investments in smaller Korean companies, are very much aligned with the Pharma 2020 Vision to grow the Korean pharmaceutical industry.”

“Many Korean companies can be highly effective partners from the distribution and promotional perspective,” concludes Gladsgen. “Many of these businesses have long histories here, which provide in-depth local knowledge and expertise. Through mutually beneficial partnerships we can benefit from the local expertise and domestic partners can learn from the global experience of multinational companies as well. This is increasingly important as many domestic companies have aspirations to increase their presence worldwide. In addition, with the increased investment in R&D by many local players, multinationals have an excellent opportunity to partner on innovative new drug development that can ultimately benefit patients globally.”
Examples of collaboration

GE Healthcare (2009)
GE Healthcare founded U-Health Global R&D Center in Songdo, Incheon, in 2009, supported by matching funds from the Ministry of Trade, Industry and Energy and Incheon City. The company will invest KRW 6 billion (USD 5.45 million) over six years.

Novartis (2008-2010)
From 2008 to 2010, Novartis selected three of Korea’s bioventures (Neomics, Pharmabcine, Quroscience) through KOTRA’s Global Alliance Project and made equity participation.

GlaxoSmithKline (2010)
GSK engaged in equity participation (9.9 percent) in Dong-a Pharmaceutical, establishing a division dedicated to GSK’s products through JV, developing and commercializing generic drugs and fostering stronger cooperation.

Samsung (2011, 2012)
Samsung BioLogics with Quintiles. It also founded another joint venture company with Biogen Idec.

Ajinomoto and Genexine (2012)
Ajinomoto, a Japanese company specializing in the development and production of food, amino acid and other chemical compounds, has signed an agreement with Genexine, a Korean bio venture business, to invest in a joint venture business for the production of cell cultivation media.

Source: Invest Korea

Impact of the potential Korea – China FTA

What are the major implications of the Korea-China FTA that received preliminary approval in February 2015?
The significance of this FTA is much greater than that of the previous FTAs with the EU and US, primarily because we actually face some significant tariffs in China. Furthermore, since it is physically such a close market, the tariffs are actually the primary barrier, instead of a relatively minor one compared to shipping and transport costs. Thus, the FTA will radically change trade conditions between China and Korea once ratified, and make exporting to China much more feasible for companies in Korea.

Positioned between Asia’s two largest markets, China and Japan, and with favorable trade conditions with both, Korea will be an ideal location for business to enter the region and locate manufacturing facilities. Furthermore, the FTA will also make it easier for Chinese companies to enter Korea, and our agreements with the US and EU will make us an attractive platform for them to export their products to the rest of the world. The government is formally promoting this “entry point” mechanism.
MEGA MEDICAL’S ANTI—OBESITY EXPANSION

KIM BYUNG JANG, the CEO of Mega Medical, a Korean medical equipment manufacturer specialized in the ENT area, discusses his firm’s recent expansion into the anti-obesity segment, their strategy for building a global business, and the overall potential of the Korean medical equipment sector.

HCLS: Korea relies primarily on imported medical devices for its medical infrastructure. What led to this disparity?
KBJ: Korea still lags behind the US in the medical sector overall. We’re quite good at manufacturing, particularly in electronics, but there is a lot of catching up to do in terms of R&D infrastructure, experience, and product sophistication before we will be able to produce more advanced kinds of equipment. So, for the time being, we’re still reliant on the US.

HCLS: What steps do you think the industry needs to take to close this gap?
KBJ: We have excellent hospitals and doctors, CROs, and the presence of many multinational medical device companies, but as of yet, there is a lack of collaboration between these players. Global medical device manufacturers tend to have consulting contracts with doctors in the US for instance, so early stage clinical trials are conducted there more frequently. For Korea to compete globally, we need to improve the environment for collaboration between doctors in hospitals, physicians who are conducting clinical trials, and engineers in the medical device companies.

HCLS: Mega Medical aims to be the top company in the ENT clinic system field and Korea’s top company in the obesity market in 2015. How successful have you been in reaching this goal?
KBJ: The ENT area is going smoothly. We have been introducing our new business model for obesity in recent years. We used to simply sell devices, but the healthcare model in Korea isn’t well designed for this because doctors are used to dealing with patients, not clients; regardless of the potential of our devices, the market for anti-obesity equipment isn’t very well organized. Doctors are the first clients for companies like us, and simply selling devices to sell devices doesn’t give our clients what they need. Cell-Line is our solution to this problem, and is going very well.

HCLS: Can Mega Medical export anti-obesity clinics to countries with significant obesity problems, such as the US and UK?
KBJ: We are not competitive in the market for simple devices. Our long-term strategy is to establish an international network of cell-line slimming clinics. We have a lot of work to do before we enter developed countries, but we can go to China, Southeast Asia, and the Middle East markets as soon as we establish a strong foundation in the domestic market.
**TACKLING OBESITY**

Kim Byung Jang, Mega Medical

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**HCLS**: You have already opened several “Cell-Line Slimming Clinics” in various countries across the globe. Why did you expand into this business, and how much does it contribute to your revenue?

**KBJ**: Growth in our old business model has become difficult, so we began looking for other markets to create by offering a unique business model.

Since 2011, we have established and refined the business model and clinical system. At this point the existing clinics generate ten percent of total sales, but we expect this to grow to 90 percent in the future. Through this network we effectively build a closed platform; clients joining the Cell-Line Slimming Network will be reliable revenue source as we provide them with pharmaceuticals, health foods and medical supplies. We currently have 22 clinics in our network, which we would like to expand to 500 domestically; we also plan to go abroad.

While the ENT and body slimming markets may seem unrelated, they share an important connection. Government cost reduction initiatives mean many private clinics are looking for new revenue streams outside of the national insurance scheme; aesthetics and obesity are two of these key areas. Korea has about 2,400 ENT hospitals, and 1,500 are our clients, yet there are 35,000 private clinics in Korea. Many clinics are interested in supplementing their insurance-based revenue with income from aesthetics clients, but since they are used to dealing with “patients” and not “clients”, they struggle to manage services for these clients. By joining our network, we manage these issues for them.

**HCLS**: Where will we find Mega Medical by 2020?

**KBJ**: We will be listed on KONEX (Korea New Exchange) during the first half of this coming year and we are planning to be listed on KOSDAQ (Korea Securities Dealers Automated Quotations) within two years. We have a 100 billion won (USD 91 million) sales target for 2020, and 90 percent of that will come from our Cell-Line business.

Mega Medical also exports many of its products to over 50 countries worldwide. What is the response globally to the Mega Medical brand?

**KBJ**: We have entered many different countries, but the size of the ENT device market in general is relatively small. Our main competitors are products from Germany, which are very high quality, but in general we receive positive responses because our products are reasonably priced for the quality. But in terms of quality and complexity, countries like China are catching up very quickly. We are consequently placing more attention into our unique Cell-Line network business model.

Hospitals are very interested in exporting their organizational systems and the government supports this idea. Software and hardware should be exported together, but only if an integrated solution is offered; Cell-Line provides this solution for slimming clinics.

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RISING STAR
A Casual Break From Retirement

A CASUAL BREAK FROM RETIREMENT

CHOIE HYUNG-SIK spent the majority of his career in major pharmaceutical companies in Korea, ranging from well-known multinationals like Janssen to prominent local players such as Chong Kung Dang. Shortly after opening his own pharmacy, Choie was invited to run a bioanalytics spinoff of SCL Healthcare group called BioCore.

In July 2000, the Korean government established an important policy separating prescription and dispensing,” explains Choie. “Subsequently, many pharma companies wanted to start making innovative prescription drugs, and the market moved more from OTC to prescription medicines. As the Korean government registered approved generic drugs after bioequivalence testing, bioequivalence then became a business in Korea and BioCore was established as a bioequivalence study company at that time, in May 2001.”

Since then, BioCore has led the bioanalytical market and currently controls 26 percent of the total analytical CRO market, and has since become well positioned for Phase I pharmacokinetic studies.

Perhaps most excitingly, BioCore is developing accelerator mass spectrometry (AMS) technology alongside Eckert & Ziegler Vitalea Science (EZVS) for preclinical and Phase I trials using microdosing, which is very important for Korean CROs. “Even if we are the number one company in this industry, BioCore is still very small and illustrates why we do not have the capability to go abroad,” remarks Choie.

“Our first strategy is for Korean pharma companies to use this technology in Phase I studies. Many Korean pharma companies go to foreign CROs. We must recognize our

While we are still focusing on chemicals, biologics are the future of the pharma market, so our bioservices will probably increase in the coming years.”

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BioCore currently runs two business divisions. The first is for new drug development to support pharmacokinetic and bioequivalence studies, which represents 75 percent of business. The other is its life science department, which focuses on diagnostic kits. “Our mother company, SCL Lab, is a reference lab,” states Choie. “Disease diagnosis requires blood, urine or tissue samples to collect data. Not every hospital can analyze everything all of that data due to lack of HR and technology. SCL Lab collects those specimens and transports them to a central lab, which are analyzed and delivered the next day to doctors. This company also analyzes biomarkers for diagnostic kits, which BioCore researches and manufactures. But our main business is bioanalytics. This gene analysis is very important for new technology in order to grow our current life science division.”

In five years, Choie expects new drug development and diagnostics to represent equal parts of the business. “BioCore is still small, with limited financial resources for research,” he concludes. “While we are still focusing on chemicals, biologics are the future of the pharma market, so our bioservices will probably increase in the coming years. Once our diagnostic kit division attains some financial power we will reinforce this kind of analytical CRO business.”

capabilities, which is why we are already established a partnership in 2012 with Quintiles Asia, who recognized our capability. The same is true of EZVS. Well-known partnerships mean that BioCore is getting recognized step by step.” Choie is primarily aiming at offering BioCore’s services in the local market; nevertheless, the company is already cooperating with well-known international companies, such as PRA in the Netherlands and Quotient in the UK.

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WANT TO BE THE BEST? STUDY PHARMACY!

Preface: Seoul National University’s College of Pharmacy has consistently been ranked one of the best in its field worldwide for a number of years and represents a solid opportunity for Korean students to expand in a promising career.

Written after interviews with: Suh Young-Ger, president of the Korea Pharmaceutical Society and Lee Bong-Jin, dean of the College of Pharmacy at Seoul National University.

As part of the Vision 2020 Effect, many of Korea’s youth are increasingly enrolling in university programs dedicated to healthcare and life sciences. Among these institutions, the College of Pharmacy at Seoul National University (SNU) stands out as a leader in its field.

The college was ranked fourth worldwide for total number of publications and citations between 2007 and 2011, and the only college worldwide ranked in the top five for nearly all benchmark indicators. “When I was an undergraduate student here, there was no experimental equipment, facilities or grants available to students,” recalls Lee Bong-Jin, current dean of SNU’s College of Pharmacy. “At that time, everyone went abroad instead. After acquiring their PhDs overseas however, all of these students came back to Korea. Today, these same people are the ones contributing to the current competitiveness and success of this college, as well as others in Korea.”

The college is also making strides to improve its capacity in the clinical sector. While courses previously had a primary focus on medicine, the four-year degree at the college has now been extended to six years, with the last two years focused on in-depth practical experience in hospitals. The first class of this new course will graduate in 2015. “We hope that the change in the system will be effective,” concludes Suh Young-Ger, former dean of the college and president of the Korea Pharmaceutical Society. “2015 will be a very important starting point. We expect that the six-year program will help citizens and government recognize our improvement in education and that the internship helps budding pharmacists to be closer to patients, especially in drug prescription.”

SUH YOUNG-GER
President of the Korea Pharmaceutical Society

LEE BONG-JIN
Dean of the College of Pharmacy at Seoul National University
The Korean Institute of Toxicology (KIT) is a government-funded research institute that evaluates the safety of medicine, bio-related products and chemicals. PharmaBoardroom talks to the institute’s president, LEE SANG-JOON, about his current operations and his vision for the future.

**HCLS:** What role does KIT play today in the CRO sphere?

**LSJ:** Established in 1980, KIT plays a leading role in improving advanced technology and building the research framework for safety assessment in Korea ranging from tests for general toxicology to tests for environmental toxicology. In addition, we also make up the core infrastructure of Korea’s biotechnology industry and the basic research base for public health and human welfare.

**HCLS:** Safety assessment technologies are critical to the development of any drug, most notably in preclinical and Phase I studies. For you, what are your biggest challenges today leading the institute?

**LSJ:** Experiments on animals are cruel, expensive, and often inapplicable. However, finding an alternative to animal testing is a challenge we face. We are working hard to find alternatives to animal testing such as in vitro methods. However, there are a lot of limitations when using a well-defined in vitro system that can often lead to new drugs not making it to market.

As a countermeasure, we take animal welfare seriously and were accredited for the first time in Asia as a qualified institute for AAALAC in 1998. More than ten percent of our employees possess a DVM, (Doctorate of Veterinary Medicine), which compared to the worldwide average is significant.

**HCLS:** KIT uses non-human primates during pre-clinical trials due to their similarities with humans. What is the importance of non-human primates testing and how do you position yourself against other similar research facilities?

**LSJ:** Given that non-human primates are the human’s closest relatives, the toxicity test using such animals produces the most reliable data that can be easily extrapolated to the clinical studies.

This is especially true for non-human primate tests frequently used for bio-technological pharmaceuticals (biologics) because it is often difficult to predict the toxicity of such products in human based on rodent toxicity results. We try not to use non-human primate testing, but often there is no effective replacement.

Over the past five or six years, many domestic and international pharmaceutical companies have been interested in the development of biologics, and KIT has lots of experiences in performing studies with antibodies, recombinant proteins, hormones and oligonucleotides. Especially in the testing of oligonucleotides, KIT is one of the top organizations in the world. Having many DVMs is a strong advantage in testing with non-human primates. A certified animal clinic is located inside KIT, so that a full veterinary service is provided to non-human primates if necessary. Animal welfare is a priority to us, and we have been accredited and certified at the very highest level.
TOXICOLOGICAL INNOVATION
Lee Sang-Joon, Korea Institute Of Toxicology

HCLS: The institute engages in research in a number of areas, such as toxicogenomics. What are some of the most exciting projects you are currently working on?

LSJ: We have focused on developing the alternative toxicity method based on omics, stem cell, tissue engineering, imaging, and in silico technology. For omics technologies, we have investigated the toxicity biomarkers using genomic approaches to monitor the toxicity such as hepatotoxicity. For the stem cell and tissue engineering technology, we are developing the alternative cell models for hepatotoxicity, cardiotoxicity, and neurotoxicity. Recently, we have started to investigate the in silico model to predict toxicity based on experimental toxicity data and omics data as well as public database.

HCLS: The institute has been accredited by a number of regulatory authorities around the world. As a result of these international safety accreditations, do you believe the institute can serve as a leader for safety in the region?

LSJ: GLP started in the US, Europe and Japan. Initially, it took us some time to catch up, and required us working with foreign companies in order to gain the necessary experience. We had the talent to become a work leader within the bio-sciences, but we lacked the experience. Now we are building up our experience in the field, and it is time for Korea to take the lead.

HCLS: How will you succeed in the long-term?

LSJ: The corporate growth of the private sector is key to the joint growth of the organization. KIT is aiming to be a top ten CRO by 2020. To achieve our goal in five years, we will need to increase our budget to USD 100 million per annum, 50 percent of which will come from overseas sources. As well as develop our five core technology areas; I am confident that if we achieve these steps, we will be a top ten CRO in the world by 2020. ☺
MOON EUN-SANG, SillaJen’s CEO shares his passion for his company’s oncolytic vaccinia virus, and its potential to revolutionize the treatment of solid tumor cancers, even arguing that it may eventually constitute ‘a cure for cancer’.

**HCLS:** How would you assess the potential for Pexa-Vec, your lead-product candidate?

**MES:** The truth is that it is a bona fide medical breakthrough of immense proportions, one that will bring about great benefits for humanity. A lot of people involved in the project couldn’t believe what we were doing at first, but the truth is that Pexa-Vec doesn’t represent just a cancer treatment, but an actual cure for cancer. The vaccinia virus we have engineered will seek out cancerous cells, infect and destroy the cells, but not before reproducing and spreading to other cancer cells, and triggering a strong immune-response from the patient. In our Phase II A trial, out of 30 patients, 21 demonstrated partial tumor responses, and four were completely cured. More than ten percent of the patients were cured which is truly incredible, especially given their prior prognosis. At present, we are preparing to begin a global Phase III clinical trial for Pexa-Vec’s efficacy as a treatment for hepatocellular carcinoma (HCC).

**HCLS:** There are a few companies that have been involved with Pexa-Vec project previously, how did SillaJen end up in control?

**MES:** The project originated as a collaboration between Jennerex, a California-based biotech venture, and scientists at Busan National University, as well as Dong-A University. At the time, SillaJen was just a small CRO with modest laboratory capabilities that worked on the project starting in 2006. Also, it is important to recognize that we were involved with the earliest stage of research activities related to Pexa-Vec, much of which had been carried out in Korea, ranging from toxicology and pharmacokinetic tests, to animal testing and phase I clinical trials. Once Pexa-Vec reached Phase II, we started conducting trials worldwide.

In late 2013, a Phase II B clinical trial for Pexa-Vec failed to meet its overall survivability endpoint, and Jennerex lacked the capital to continue development without a new investment. Many of the existing investors were quite discouraged by this failure, which made it an ideal moment for SillaJen to step in and take a stronger financial position in the company, and since we had been carrying out the research activities for Pexa-Vec for so many years, it was clear to us that the trial failure was not indicative of Pexa-Vec’s potential. This was the point in time where I stepped in, and managed to raise USD 150 million from Korean investors to fund our acquisition of Jennerex.

**HCLS:** Why were you confident that the trial failure wasn’t a negative sign for the drug’s potential?

**MES:** The Phase II B trial results were unfortunate but avoidable. Ironically, the Phase II A results were so strong, so marvelous, that some of the doctors...
conducting our trial were very excited and became somewhat aggressive in their patient recruitment, choosing a number of patients in the very late terminal stage. As a result many of the patients didn’t survive long enough for the Pexa-Vec to take effect, and moreover, out of the 86 patients recruited, 30 percent didn’t survive long enough to get a second injection, when our treatment protocol calls for series of six injections. Thus, we see this failure as a failure of the trial and the trial design, not of the candidate; the same patients may have responded well to Pexa-Vec if their treatment had begun sooner. As we move forward with our Phase III HCC trial, we are very confident that Pexa-Vec will meet the expectations set by the Phase II A trial.

HCLS: A number of other companies are developing oncolytic vaccines using other viruses; why is a vaccinia-based virus so revolutionary compared to these others?

MES: For reference, vaccinia virus infects internal organ tissue cells, and therefore can be engineered to attack cancerous organ tissue, which includes most forms of solid tumors. The other oncolytic products in development use other viruses, such as the herpes-simplex virus that infects skin and mucosa cells, or HIV, which attacks blood cells, and thus can be used to fight skill and blood cancers. We are the first company to try to develop an oncolytic vaccinia virus.

Of the viruses that could be used to fight solid tumors, the team working on this project decided back in the early 2000s that the vaccinia virus was the best after a long series of tests in which it outperformed adenovirus and herpes-simplex, among others. Apart from its ease of use as a biotech platform, the primary advantage is that we can deliver the vaccinia virus to tumors intravenously as well as intratumorally, while the other oncolytic candidates that are suitable for solid tumor cancers must be injected intratumorally.

HCLS: Given your current pipeline, what is your current vision for SillaJen as a mature company?

MES: Well, my vision is that we will lead a medical revolution. The cure for cancer is not science fiction; we have completely cured patients with a wide variety of cancers, spanning from hepatocellular carcinoma (HCC), recurrent HCC, breast cancer, melanoma, colorectal cancer, renal cell carcinoma, nearly ten percent of all of those that we've treated. There is still a lot of work to be done, and we are now trying to find the common factor between the patients that we’ve been able to cure so we can understand why they responded so strongly while others didn’t. We are also working on more advanced versions of our oncolytic vaccinia viruses that are somewhat immune-resistant, allowing them to attack the cancer cells for longer and lowering dosage requirements, and that are engineered to target specific tissue types more precisely so that they can be delivered more effectively to the tumor cells.

“My vision is that we will lead a medical revolution. The cure for cancer is not science fiction; we have completely cured patients with a wide variety of cancers.”
PIONEERING STEM CELL PRODUCTS

YANG YOON-SUN, the founder of Medipost, the producer of the only approved allogenic stem cell product in the world, discusses their development goals for the coming years and the potential for regenerative medicine to revolutionize a variety of healthcare practices.

HCLS: Medipost’s stated vision is to be the world’s leading stem cell and regenerative medicine company; how would you assess Medipost’s current position relative to this goal?

YYS: Medipost was founded in 2000, as a regenerative stem cell company in Korea. Our goal is to develop new drugs from stem cells derived from umbilical cord blood. We already have approval from the Korean MFDS for our first product, Cartistem, and over 2,000 patients have received regenerative knee-cartilage treatment.

There are many companies and research centers working to develop stem cell technologies and treatments, but we are one of a mere handful to have already commercialized a product. In fact there are currently only five approved stem cell products worldwide at the moment, and our Cartistem is the only one that has meaningful sales in the market for treatment of osteoarthritis patients.

We are conducting clinical trials not only in Korea but also in the US and other countries for Cartistem to support its approval in other markets. In addition to Cartistem, we have two more products in the clinical pipeline which are Pneumostem and Neurostem at Phase II clinical trial for broncho-pulmonary displasia and for Alzheimer’s disease, respectively. Moreover, I think we have the expertise and technology needed to be a contender for the “number one stem cell and regenerative medicine company,” including our advanced proprietary technologies for collection and differentiation of umbilical cord blood derived stem cells and optimization of cell functionality and viability.

“...There are currently only five approved stem cell products worldwide at the moment, and our Cartistem is the only one that has meaningful sales in the market for treatment of osteoarthritis patients.”
**HCLS:** While your pipeline is very highly innovative with regards to Neurostem and Pneumo stem, your first commercialized stem cell product is Cartistem in Korea. How would you assess Cartistem’s performance so far?

**YYS:** Even though stem cells are a topic of discussion world-wide, successfully launching the product is completely different story. As I mentioned, there are only five approved stem cell products, and Cartistem is only one that is making practical sales in the market currently, and is also the first ‘allogenic’ stem cell therapy product. Since its launch, Cartistem has been used to treat more than 2,000 patients, which has helped to verify and reinforce the safety and efficacy claims that were established in clinical trials. It is still early days, but this level of success so far makes me very confident for the future.

This is in part because the market for Cartistem is very large, as there are a lot of degenerative osteoarthritis and cartilage injured patients, and there is not much competition in Korea for this type of product, so we have a lot of potential for domestic growth. As far as potential sales overseas, the doctors in the US have given us very positive responses so far, indicating that our product has exceeded their expectations in clinical trials, so we are confident that once we receive FDA and other foreign approvals our sales will rapidly accelerate.

**HCLS:** As one of the key success stories of the Korean biotech sector, and now a company with global profile due to your leadership in allogenic stem cell treatments, what is Medipost’s role in building the reputation and prestige of the Korean biotech industry around the world?

**YYS:** I would address this question by first pointing out that because stem cell therapies are such a revolutionary, innovative area of medicine, there is no existing regulatory framework in place for these products except in just a few countries around the world; without actual products to consider, it isn’t possible to develop suitable regulations. Some existing regulations can be used or adapted, but a new framework must be developed through trial and error, and as such current regulations are still flexible and constantly changing, even for FDA in the US.

Medipost is playing a key role in this process in Korea and elsewhere, because we are the one bringing these first products to consider to the regulatory authorities, and the ones asking questions about testing requirements, verifications, approvals, and so on. The requirements for toxicity testing, efficacy evidence and mass production standards for stem cell products have been changed significantly over the last few years, and Medipost has been working closely for these regulatory changes. Furthermore, the MFDS has become a leading regulatory administration in this field, and now serves as a point of reference with regards to stem cell regulatory standards in the world.

Regarding Medipost’s role in building Korean biotech’s reputation, we are certainly leaving a mark and impressions by bringing these highly innovative stem cell products to regulators around the world. Beyond that, I feel that we have a responsibility to lay some groundwork for other stem cell companies so they don’t have to go through all of the trials and errors that we have so far, plus, we would rather lead the market and help set the standards than follow.
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