1. Industry Status and Prospects

Outline of Pharmaceutical Industry

Domestic market size

- In 2012, Korea’s production of pharmaceuticals increased by 0.75% to 15.71 trillion won over the preceding year; exports increased by 19.52% to 2.34 trillion won over the same period; and imports increased by 5.91% to 5.85 trillion won. (Market size: 19.23 trillion won; average annual growth rate over the past five years: 2.84%)

Local market size of pharmaceuticals

<table>
<thead>
<tr>
<th>Year</th>
<th>Production (Trillion won)</th>
<th>Exports USD 100 million</th>
<th>Imports USD 100 million</th>
<th>Market Size (Trillion won)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>13.89</td>
<td>1.27</td>
<td>11.48</td>
<td>4.13</td>
</tr>
<tr>
<td>2009</td>
<td>14.79</td>
<td>1.79</td>
<td>14.00</td>
<td>5.22</td>
</tr>
<tr>
<td>2010</td>
<td>15.71</td>
<td>1.78</td>
<td>15.40</td>
<td>5.42</td>
</tr>
<tr>
<td>2012</td>
<td>15.71</td>
<td>2.34</td>
<td>20.78</td>
<td>5.85</td>
</tr>
</tbody>
</table>

Increase ratio over preceding year:
- Production: 0.75%
- Exports: 19.52%
- Imports: 17.53%
- Market Size: 5.91%

Source: Yearbook of Food & Drug Statistics, KFDA (2013)

Status of pharmaceutical industry

Source: Yearbook of Food & Drug Statistics, KFDA (2013)
1. Industry Status and Prospects

Current number of pharmaceuticals producers

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of producers licensed</th>
<th>Number of production facilities</th>
<th>Share of production facilities (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>680</td>
<td>405</td>
<td>59.6</td>
</tr>
<tr>
<td>2002</td>
<td>711</td>
<td>506</td>
<td>71.2</td>
</tr>
<tr>
<td>2003</td>
<td>756</td>
<td>528</td>
<td>68.9</td>
</tr>
<tr>
<td>2004</td>
<td>714</td>
<td>553</td>
<td>77.5</td>
</tr>
<tr>
<td>2005</td>
<td>759</td>
<td>546</td>
<td>71.9</td>
</tr>
<tr>
<td>2006</td>
<td>781</td>
<td>570</td>
<td>73.0</td>
</tr>
<tr>
<td>2007</td>
<td>802</td>
<td>589</td>
<td>73.4</td>
</tr>
<tr>
<td>2008</td>
<td>830</td>
<td>587</td>
<td>70.7</td>
</tr>
<tr>
<td>2009</td>
<td>816</td>
<td>580</td>
<td>71.1</td>
</tr>
<tr>
<td>2010</td>
<td>849</td>
<td>656</td>
<td>77.3</td>
</tr>
<tr>
<td>2011</td>
<td>828</td>
<td>638</td>
<td>77.1</td>
</tr>
</tbody>
</table>

Source: Yearbook of Food & Drug Statistics, KFDA (2012)

Current status of producers of bio pharmaceuticals, medical herbs, non-pharmaceuticals and cosmetics (2011)

<table>
<thead>
<tr>
<th>Unit: each</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio pharmaceuticals</td>
</tr>
<tr>
<td>Pharmaceuticals</td>
</tr>
<tr>
<td>Medical herbs</td>
</tr>
<tr>
<td>non-pharmaceuticals</td>
</tr>
</tbody>
</table>

Source: Yearbook of Food & Drug Statistics, KFDA (2012)
Prospects of Korean Pharmaceutical Market

Expansion of healthcare service due to rapid aging

- As one of the most rapidly aging societies, Korea has the potential to become an R&D center for the advanced treatment of intractable diseases, including cancers.
- Korea will play a leading role in advanced medical services and the global pharmaceutical industry through its healthcare system with the help of large hospitals and convergence technologies such as BIT and BNT.

Increasing need for personalized/regenerative medicines

- Recently, demand for personalized medicines and medicines using tissues or stem cells (regenerative medicines) has been on the rise. In particular, Korea is at an advantage in stem cell research as its bioventures Medipost and Pharmicell have developed stem cell treatment using cord blood.
- The application of bio-technologies is rapidly expanding to relevant industries such as biochemistry, bioassay, bioinformatics, and bioenergy.

Securing global competitiveness through biomedicines

- Mid-sized pharmaceutical companies and bioventures are carrying out R&D and the commercialization of biosimilars with the support of government policies promoting the bio industry to become a global leader in biomedicine.
- Korean companies including Celltrion, LG Life Sciences, Hanwha Chemical and Samsung Biologics are actively penetrating the global market with biosimilars and biobetters.

Korea’s Competitiveness

Stable investment destination in Asia, which is growing into the center of the global market

- Korea has the ethical work environment and IPR system necessary for cutting-edge technology research. Korea can also tap into the rapidly growing Asian market and its stable natural environment.

Medical system infrastructure for global clinical trials

- The number of clinical trials conducted in Korea for the development of new drugs increased from 503 in 2011 to 670 in 2012, i.e. an increase of 33% over 2011. Clinical trials by multinational pharmaceuticals companies represented 45% of the total. This is because the number of research-oriented universities and clinical experts increased in Korea, and because Korea is trusted as one of the best locations for global clinical trials due to its patient management and other medical systems.
1. Industry Status and Prospects

- Korea’s capability to conduct clinical trials developed as the number of global clinical trials increased rapidly from only five in 2000, when multinational clinical trials were allowed for the first time, to 303 in 2012, increasing exponentially by sixty times in only ten years.
- An analysis of global clinical trials registered on a formal website shows that Korea was ranked 6th globally in 2012, 4th in terms of the number of clinical trials conducted in a single country, and 15th in terms of the number of multinational clinical trials. In particular, Seoul has emerged as the world’s No. 1 clinical trial city and has become a clinical trial hub in Asia.
- The number of clinical trials in phase 1, indicating national competitiveness in new drug development, increased significantly from 19 in 2011 to 32 in 2012.

Clinical trials approved by the KFDA

Trend of local clinical trials conducted by multinational pharmaceutical companies

Large pool of R&D experts

- In connection with the development of a workforce capable of providing the basis for the development of bio engineering, Korea trained a total of 52,811 persons specializing in bio engineering (graduates from the bio engineering-related departments of vocational colleges or higher schools) in 2012. The number of trained persons is steadily increasing along with the active growth of the bio industries. The proportion of bio engineering graduates as a percentage of all college and university graduates increased from 7.01% in 2007 to 8.33% in 2012.
- As highly advanced human resources such as masters or doctorate degree holders accounted for 20% or more of the total, Korea actively trains superior research personnel.
- The number of personnel employed by local bio businesses increased significantly, to 32,004 persons, as of 2010, indicating an increase of 30% over the preceding year. Employees in the bio industries include 11,329 production personnel, 11,091 research personnel, and 9,584 sales and administrative personnel.

Training of bio engineering personnel

Breakdown of bio industry personnel for research, production, sales and administration (2011)

Source: Current Status and Introduction of Bio Industries in Korea, KРИBB (2013)

Solid competitiveness in theses and patented technologies

- The number of SCI theses authored by Korean scientists specializing in six bio science or engineering fields, including microbiology and pharmacology, in the past five years (2008-2012) ranked 8th globally. Their share also exceeds the Korean average.

### Number and share of SCI theses authored by Korean scientists in six bio science or engineering fields in the five-year period (2008-2012)

<table>
<thead>
<tr>
<th>Fields</th>
<th>Number of theses in the field</th>
<th>World ranking in number of theses</th>
<th>Share of total Korean SCI theses</th>
<th>Total no. of Korean SCI theses</th>
<th>Share of world total</th>
<th>Total no. of world SCI theses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunology</td>
<td>2,240</td>
<td>16th</td>
<td>1.88%</td>
<td>208,119</td>
<td>2.15%</td>
<td>104,346</td>
</tr>
<tr>
<td>Microbiology</td>
<td>3,724</td>
<td>8th</td>
<td>1.79%</td>
<td>208,119</td>
<td>4.48%</td>
<td>83,198</td>
</tr>
<tr>
<td>Molecular biology and genetics</td>
<td>5,259</td>
<td>12th</td>
<td>2.53%</td>
<td>208,119</td>
<td>3.01%</td>
<td>174,796</td>
</tr>
<tr>
<td>Biology and biochemistry</td>
<td>10,655</td>
<td>10th</td>
<td>5.12%</td>
<td>208,119</td>
<td>3.44%</td>
<td>309,366</td>
</tr>
<tr>
<td>Neuroscience and behavior science</td>
<td>4,866</td>
<td>14th</td>
<td>2.34%</td>
<td>208,119</td>
<td>2.26%</td>
<td>215,455</td>
</tr>
<tr>
<td>Pharmacology</td>
<td>6,990</td>
<td>8th</td>
<td>3.36%</td>
<td>208,119</td>
<td>4.24%</td>
<td>164,783</td>
</tr>
<tr>
<td>Total no. of bio science theses</td>
<td>33,734</td>
<td>11th</td>
<td>16.21%</td>
<td>208,119</td>
<td>3.21%</td>
<td>1,051,944</td>
</tr>
</tbody>
</table>


- Korea’s capability for creating bio engineering theses increased rapidly: world’s 10th highest in 2012 SCIE theses: Korean scientists published 420 theses in 1994, ranking 29th globally; 2,875 theses in 2002, ranking 15th globally; and 8,082 theses in 2012, ranking 10th globally.
- Theses related to bio engineering produced by Korean scientists and published in the world’s three major science journals, NSC (Nature, Science, Cell), have steadily increased in both quality and quantity, from 15 theses in 2008 to 22 in 2012.
NSC published theses authored by Korean scientists

<table>
<thead>
<tr>
<th>Year</th>
<th>01</th>
<th>02</th>
<th>03</th>
<th>04</th>
<th>05</th>
<th>06</th>
<th>07</th>
<th>08</th>
<th>09</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theses published on NSC</td>
<td>14</td>
<td>19</td>
<td>13</td>
<td>18</td>
<td>29</td>
<td>23</td>
<td>26</td>
<td>28</td>
<td>38</td>
<td>47</td>
<td>44</td>
<td>43</td>
<td>347</td>
</tr>
<tr>
<td>BT related theses</td>
<td>11</td>
<td>11</td>
<td>11</td>
<td>10</td>
<td>23</td>
<td>18</td>
<td>19</td>
<td>15</td>
<td>21</td>
<td>28</td>
<td>25</td>
<td>22</td>
<td>214</td>
</tr>
<tr>
<td>Weight of BT theses</td>
<td>78.6</td>
<td>57.6</td>
<td>84.6</td>
<td>55.6</td>
<td>79.3</td>
<td>64.3</td>
<td>73.1</td>
<td>53.5</td>
<td>55.2</td>
<td>59.5</td>
<td>56.8</td>
<td>51.2</td>
<td>64.1</td>
</tr>
</tbody>
</table>


Korean bioscience theses published

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>420</td>
<td>933</td>
<td>1,343</td>
<td>1,479</td>
<td>1,820</td>
<td>2,137</td>
<td>2,495</td>
<td>2,651</td>
<td>2,875</td>
<td>3,894</td>
</tr>
</tbody>
</table>


- The number of patent applications filed by Korean BT R&D programs increased at an annual average rate of 8.5% in the five years from 2007 to 2011.
- According to WIPO statistics for patent applications filed by country in 2012, Korea ranked 4th among the world’s top 20 countries, with 188,915 applications.
- Korean biotech patents filed with the USIPO increased from 8,598 (2011) to 9,190 (2012).
- Korea’s ranking in technological competitiveness rose from 14th (2012) to 11th globally (2013).
Various partners for R&D

- Many biotech companies continue to achieve success stories, including Celltrion, Medytox, Medipost, Seegene, Bioneer and Toolgen. They have achieved successful performances, thus making their advancement into the global market more likely, by accumulating specialized know-how and a platform in bio engineering. The number of biotech companies listed on the KOSDAQ increased from seven in 2000 or earlier to 57 in 2012, indicating a strong performance.
- Global pharmaceutical companies are seeking to forge partnerships with not only Korea’s mid-sized pharmaceuticals but also bioventures such as Celltrion and Crystalgenomics. For example, Celltrion has partnerships in place with Sanofi-Aventis, CDC, and A&G, and Samsung Biologics has also established joint ventures with Quintiles and Biogen Idec. LG Life Sciences has also signed an agreement with Takeda for joint research of obesity treatment. It has also signed a contract with Mochida of Japan for the joint development and sale of biosimilar products in 2012.

Korean government policies to promote the industry

- In 2012, the Korean government invested 2.58 trillion won, or 19% of its total R&D budget, in the bio sector.
- The government selected the bio industry as a new growth engine and has improved institutions and come up with support measures [BIO-Vision 2016].
- The government is focusing on the efficient management of national R&D programs, support measures, establishment of medical clusters and training of experts. [See 4. Government Policies and Incentives]
2. Global Competition and Investment

Domestic pharmaceutical companies are expanding investment in drug development, leading to more new drug approvals.

- Korean pharmaceutical companies have steadily invested in R&D. An analysis of the ratio of investment in R&D against sales revealed that Dong-A Pharmaceutical invested 83.4 billion won, or 9% of its sales; Green Cross invested 69.2 billion won, or 9.7% of sales; Yuhan Corporation, 47 billion won or 6%; Daewoong Pharmaceutical, 79.2 billion won or 11.7%; Hanmi Pharmaceutical, 79.5 billion won or 14.6%; Chong Kun Dang Pharm, 50.5 billion won or 10.95%; Jeil Pharmaceutical, 17.6 billion won or 3.8%; LG Life Sciences, 75 billion won or 19.7%; JW Pharmaceutical, 28.5 billion won or 7.2%; and Ildong Pharmaceutical, 28 billion won or 8.1%. The R&D investment ratio of these companies is comparable to that of leading multinational pharmaceutical companies.

**R&D investment by Korean pharmaceuticals**

<table>
<thead>
<tr>
<th>Pharmaceuticals</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dong-A Pharmaceutical</td>
<td>9% (83.4 billion won)</td>
</tr>
<tr>
<td>Green Cross</td>
<td>9.7% (69.2 billion won)</td>
</tr>
<tr>
<td>Yuhan Corporation</td>
<td>6% (47 billion won)</td>
</tr>
<tr>
<td>Daewoong Pharmaceutical</td>
<td>11.7% (79.2 billion won)</td>
</tr>
<tr>
<td>Hanmi Pharmaceutical</td>
<td>14.6% (79.5 billion won)</td>
</tr>
<tr>
<td>Chong Kun Dang Pharm</td>
<td>10.95% (50.5 billion won)</td>
</tr>
<tr>
<td>Jeil Pharmaceutical</td>
<td>3.8% (17.6 billion won)</td>
</tr>
<tr>
<td>LG Life Sciences</td>
<td>19.7% (75 billion won)</td>
</tr>
<tr>
<td>JW Pharmaceutical</td>
<td>7.2% (28.5 billion won)</td>
</tr>
<tr>
<td>Ildong Pharmaceutical</td>
<td>8.1% (28 billion won)</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>10.00%</strong></td>
</tr>
</tbody>
</table>

Source: Survey data of companies

- Korean pharmaceutical companies have continually developed new drugs, starting with SK Chemicals’ Sunpla Inj. in 1991, and are showing outstanding achievements in biosimilar, which is creating a new global trend. For example, the bioventure ISU Abxis has developed the world’s first antibody biosimilar, and the world-class biosimilar business Celltrion proved the bioequivalence of Remicade biosimilar (target disease: rheumatoid arthritis) in June.
- FCB Phamicell, a Korean biotech company, was licensed to sell its stem cell treatment, Haticellgram-AMI (treatment for myocardial infarction), for the first time in the world. By September of 2013, three more items had been licensed, including Cartistem by Medipost (for the treatment of arthritis) and Cupistem by Antrogen (for the treatment of fistulas caused by Crohn’s disease).
## New Drug Approvals in Korea

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of companies</th>
<th>Name of products</th>
<th>Efficacy</th>
<th>Date licensed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>JW Pharmaceutical</td>
<td>Q-roxin Tab 100mg</td>
<td>Simple urinary tract injection (cystitis, urethritis), pelvic injection, cervicitis</td>
<td>May 6, 1993</td>
</tr>
<tr>
<td>2</td>
<td>SK Chemicals</td>
<td>Sunpla 50mg</td>
<td>Combined with 5-Fluorouracil to treat advanced, metastatic, or post-op recurrent gastric cancer patients</td>
<td>July 20, 1993</td>
</tr>
<tr>
<td>3</td>
<td>CJ Cheiljedang</td>
<td>Pseudovaccin Inj.</td>
<td>Prevention of Pseudomonas aeruginosa infection in patients 18 years or older with major burn (10-50% of total body surface area)</td>
<td>Jan. 26, 1995</td>
</tr>
<tr>
<td>4</td>
<td>Daewoong Pharmaceutical</td>
<td>Easyef Topical Solution 0.005%</td>
<td>Diabetic foot ulcer, Traumatic and surgery wounds, pubic bone graft enhancement, burns, varicose ulcer, decubitus ulcer</td>
<td>March 4, 1997</td>
</tr>
<tr>
<td>5</td>
<td>Dong Wha</td>
<td>Milican Inj.</td>
<td>Treatment of hepatica</td>
<td>May 28, 1997</td>
</tr>
<tr>
<td>6</td>
<td>Guju</td>
<td>Apitoxin Inj.</td>
<td>Pain relief for osteoarthritis</td>
<td>Nov. 29, 1999</td>
</tr>
<tr>
<td>7</td>
<td>Bulkwang Pharmaceutical</td>
<td>Levovir Cap. 10mg</td>
<td>Suppression of viral reproduction in hepatitis B patients with confirmed replication of active virus and increase in serum transaminase [ALT or AST] level</td>
<td>June 13, 2001</td>
</tr>
<tr>
<td>8</td>
<td>LG Life Sciences</td>
<td>Factive Tab 320mg</td>
<td>Acute exacerbation of chronic respiratory disease [chronic bronchitis], community-acquired pneumonia, sinusitis, otitis media</td>
<td>Dec. 27, 2002</td>
</tr>
<tr>
<td>9</td>
<td>Chong Kun Dang Pharm</td>
<td>Camotobell Inj.</td>
<td>Treatment of resistant or recurrent ovarian cancer that failed with standard chemotherapy</td>
<td>Oct. 22, 2003</td>
</tr>
<tr>
<td>10</td>
<td>Yuhan Corporation</td>
<td>Revanex Tab 200mg</td>
<td>Short-term treatment of duodenal ulcer, improvement of mucosal lesion in acute and chronic gastritis, short-term treatment of gastric ulcer</td>
<td>Sept. 15, 2005</td>
</tr>
<tr>
<td>11</td>
<td>Dong-A Pharmaceutical</td>
<td>Zydena Tab 100mg/200mg</td>
<td>Treatment of erectile dysfunction</td>
<td>Nov. 29, 2005</td>
</tr>
<tr>
<td>12</td>
<td>Daewon Pharm</td>
<td>Pelubi Tab</td>
<td>Alleviation of symptoms and signs of osteoarthritis, alleviation of lumbar pain (pain in the waist)</td>
<td>April 20, 2007</td>
</tr>
<tr>
<td>13</td>
<td>SK Chemicals</td>
<td>Mix Tab 50mg/100mg</td>
<td>Treatment of erectile dysfunction</td>
<td>July 18, 2007</td>
</tr>
<tr>
<td>15</td>
<td>Boryung</td>
<td>Kanarb Tab 60mg/120 mg</td>
<td>Essential hypertension</td>
<td>Sept. 9, 2010</td>
</tr>
<tr>
<td>16</td>
<td>Shin Poong Pharm</td>
<td>Pyramax Tab</td>
<td>Treatment of acute malaria injection not involving complications from Plasmodium falciparum or Plasmodium vivax</td>
<td>Aug. 17, 2011</td>
</tr>
<tr>
<td>17</td>
<td>JW Pharmaceutical</td>
<td>Zepeed Tab 100mg/200mg</td>
<td>Treatment of erectile dysfunction</td>
<td>Aug. 17, 2011</td>
</tr>
<tr>
<td>18</td>
<td>Ilyang Pharm</td>
<td>Supect Caps 100mg/200mg</td>
<td>Treatment for adult patients in chronic phase of Philadelphia chromosome-positive chronic myeloid leukemia that exhibits resistance or intolerance against neoadjuvant chemotherapy involving imatinib</td>
<td>Jan. 5, 2012</td>
</tr>
<tr>
<td>19</td>
<td>LG Life Sciences</td>
<td>Zemiglo Tab 50mg</td>
<td>Supplement for diet and exercise therapy to enhance blood glucose control in insulin-independent diabetic patient</td>
<td>June 27, 2012</td>
</tr>
<tr>
<td>20</td>
<td>Chong Kun Dang Pharm</td>
<td>Duvie Tab 0.5mg</td>
<td>Supplement for diet and exercise therapy to enhance blood glucose control in type II diabetic patient</td>
<td>July 4, 2013</td>
</tr>
</tbody>
</table>

Source: Yearbook of Food & Drug Statistics, KFDA (2013)
Growth of Korea’s bioventures

Medipost: Approval of stem cell-based treatment

- Medipost’s Cartistem (target disease: degenerative arthritis), the world’s first treatment using allogeneic stem cells, was approved by the Korea Food and Drug Administration in January 2012, and first used in an operation at Samsung Medical Center in the same month. It also won the approval of the U.S. Food and Drug Administration for clinical trials, a world’s first for a medicine based on stem cells extracted from cord blood.
- Medipost applied for approval for the phase 2 trial of the stem-cell* based Pneumostem, medicine for lung disease** (May 2012).

* Using mesenchymal stem cells extracted from cord blood
** Bronchopulmonary dysplasia, main culprit of neonatal death and complications

Joint projects and investment promotion of Crystalgenomics

- Joint research with AstraZeneca to develop new antibiotic drugs (2010), joint research with MD Anderson Cancer Center for osteoarthritis (2010)

Foreign Investment

Venture investment of 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.

Joint venture of GlaxoSmithKline (2010)

- GSK engaged in equity participation (9.9 percent) in Dong-a Pharmaceutical, establishing a division (joint venture) dedicated to GSK’s products. This division will continue to discuss how to maximize synergy effects by using the infrastructure and expertise of GSK for Dong-a products’ penetration into the global market, jointly developing and commercializing generic drugs and fostering stronger cooperation.

Joint venture founded by Samsung for the bio industry (2011, 2012)

- Samsung founded a bio drug CMO factory in the Incheon Free Economic Zone by setting up a joint venture company called Samsung BioLogics with Quintiles, a global CMO company, in order to launch its bio industry. Samsung also founded another joint venture company with Biogen Idec, actively investing in the biotech area in order to develop new “global blockbuster” bio drugs.
Joint venture between 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.

Foundation of Global Research Institutes

GE Healthcare (2007, 2009)

· GE Healthcare founded the Electronic Medical Recording R&D Center (2007). The EMR project GE is conducting in Korea includes solutions to manage intensive care units, operating rooms and emergency rooms, electronic charts and the interworking of inspection equipment.
· GE Healthcare founded U-Health Global R&D Center in Songdo, Incheon, in 2009, with the support of matching funds from the Ministry of Trade, Industry and Energy and Incheon City. It plans to make a 6 billion won investment for six years.

IPK (Institute Pasteur Korea) – 2004, Pangyo Techno Valley, Gyeonggi Province

· Jointly founded by the Institute Pasteur, a French research institute for life science and biotechnology, and the Korea Institute of Science and Technology. IPK conducts research on developing vaccines and medicines and identifying causes of diseases commonly seen in Korea including leukemia, hepatitis and gastritis and diseases seen around the world, such as malaria.
3. Prospects by Sector and Region

Bio-clusters in Korea

Daegu Medivalley

- The medical cluster and R&D cluster have been established in Daegu as part of a national project.
- The cluster conducts specialized R&D, accommodating 5 medical schools, 29 general hospitals, 30 herbal medicine clinics and more than 18,000 medical employees based on excellent medical infrastructure.
- The cluster accommodates global pharmaceutical companies and IT-based medical equipment companies.

Osong Biovalley

- As of the end of 2013, Osong Biovalley was occupied by six government agencies including the Ministry of Food and Drug Safety (MFDS), National Institute of Food and Drug Safety Evaluation (NIFDS), Korea Health Industry Development Institute (KHIDI), Korea Centers for Disease Control and Prevention (KCDC), Korea Human Resource Development Institute for Health & Welfare (KOHI), and Korea National Institute of Health (NIH).
- An agreement has been signed to found the Korea-Germany Research Institute for Stem Cells and Regenerative Medicines with BCRT, a German stem cell research center.
- Diverse Korean biotech companies have occupied the valley, ranging from manufacturers of bio drugs to cosmetics and medical equipment and appliances. As of October 2013, some 60 companies had secured a space in the valley, including 36 bio pharmaceutical companies (53.3%), 20 medical equipment and appliance companies (33.3%), and four health or functional food companies. (32 companies have started operations to date.)

Pangyo · Gwanggyo Techno Valley in Gyeonggi Province

- Easy to recruit highly skilled workers thanks to geographical proximity to the capital city of Seoul; active partnership in place with the Institute Pasteur Korea and other large global clinical trial centers.
- Adjacent to foreign-invested companies such as GE Healthcare and Siemens, and large local pharmaceutical corporations.
- A total of 203 companies had occupied the valley as of 2013.

Incheon Free Economic Zone Bio Complex

- Based on the benefits offered by the Incheon Free Economic Zone, which supports global business operations, many companies have already occupied a space in its Bio Park, including the following: Celltrion (research and production facilities for bio drugs), Berna Biotech Korea (production and research facilities for Quinvaxem, a type B hepatitis vaccine), i-sense (production facilities for blood analyzers and immunity sensors), KD Corporation (production facilities for drug separators),
Hanil Science Industrial (research center for lab appliances and bio equipment), EONE Life Science Institute (research center for inspection and diagnosis techniques), Daifuku Korea (research center for experimental appliances and bio equipment), En-Biotech (advanced water treatment training center of Veolia Water Asia Pacific), POSCO Global R&D Center, Songdo Global University Campus, Songdo Science Village, BioResearch Complex, Samsung Biologics, Dong-A Pharmaceutical, and Ajinomoto-Genexine.

**Daedeok Innopolis**
- Hub of future-oriented convergence industries that facilitates market-centered research based on the capability of existing complex focused on basic science and technology research
- Accommodating government-funded research centers including the Korea Research Institute of Bioscience and Biotechnology and the Korea Research Institute of Chemical Technology

**Jeju Healthcare Town**
- Jeju Healthcare Town, which recently broke ground, aims to become a specialized cluster for medical tourism. China’s Greenland Group has decided to invest in this region with confidence in its potential, and Samsung C&T is also considering investing.

**Industrial clusters in Seoul**
- Various incentives provided in the clusters in Magok, Digital Media City and Gongneung
- Infrastructure in place for R&D of cutting-edge convergence technologies
Korea’s promising biomedical clusters

Current Status and Introduction of Bio Industries in Korea, KOTRA (2013)

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Main fields (functions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Daegu Medivalley</td>
<td>Pharmaceuticals/BT/medical equipment [R&amp;D and production]</td>
</tr>
<tr>
<td>2 Osong Biovalley</td>
<td>Bio, pharmaceuticals and medical equipment [R&amp;D]</td>
</tr>
<tr>
<td>3 Daedeok Innopolis</td>
<td>Bio and pharmaceuticals [R&amp;D]</td>
</tr>
<tr>
<td>4 Wonju Medical Appliance Cluster</td>
<td>Medical equipment [R&amp;D and production]</td>
</tr>
<tr>
<td>5 Techno Valley in Gyeonggi Province</td>
<td>Pharmaceuticals and health [R&amp;D and production]</td>
</tr>
<tr>
<td>6 Incheon Free Economic Zone Bio Complex</td>
<td>Bio and health [R&amp;D and production]</td>
</tr>
<tr>
<td>7 Jeju Healthcare Town</td>
<td>Health [R&amp;D and leisure]</td>
</tr>
</tbody>
</table>
Increasing share of bio sector investment in Korea’s total R&D investment

The Korean government invested a total of 2.702 trillion won in the bio sector in 2012, representing an increase of 6.6% over the preceding year.

<table>
<thead>
<tr>
<th>6T</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>Weight</td>
<td>Amount</td>
<td>Weight</td>
</tr>
<tr>
<td>IT</td>
<td>23,571</td>
<td>18.9</td>
<td>26,468</td>
<td>19.4</td>
</tr>
<tr>
<td>BT</td>
<td>23,252</td>
<td>18.6</td>
<td>25,808</td>
<td>19.0</td>
</tr>
<tr>
<td>NI</td>
<td>5,947</td>
<td>4.8</td>
<td>6,445</td>
<td>4.7</td>
</tr>
<tr>
<td>ST</td>
<td>6,846</td>
<td>5.5</td>
<td>7,015</td>
<td>5.2</td>
</tr>
<tr>
<td>ET</td>
<td>21,873</td>
<td>17.5</td>
<td>22,533</td>
<td>16.6</td>
</tr>
<tr>
<td>CT</td>
<td>1,071</td>
<td>0.9</td>
<td>1,148</td>
<td>0.8</td>
</tr>
<tr>
<td>Subtotal</td>
<td>82,562</td>
<td>66.1</td>
<td>89,387</td>
<td>65.7</td>
</tr>
<tr>
<td>Others</td>
<td>42,336</td>
<td>33.9</td>
<td>46,720</td>
<td>34.3</td>
</tr>
<tr>
<td>Total</td>
<td>124,898</td>
<td>100.0</td>
<td>136,107</td>
<td>100.0</td>
</tr>
</tbody>
</table>


Focus of BT Investment

Enhancement of infrastructure and competence in genome research

- Focus of investment: Expanding investment to strategically enhance national infrastructure* for production and analysis of genome information and training more experts in bioinformatics, which is Korea’s weak spot; strengthening linkages between government-led R&D projects and relevant infrastructure
  * Korea Bioinformation Center, Genome Information Computation Center (planned)

Facilitation of brain research such as cranial nerve fusion

- Focus of investment: Expanding investment in the research of cranial nerve fusion and making strategic investment to build up international network and enhance infrastructure* including human resources and large-scale equipment
  * Government-level brain research institute, brain imaging equipment, high-performing parallel-type electronic infrastructure for analysis and modeling of brain functioning, brain tissue bank, infrastructure for animal test to treat brain diseases
More efficient investment in drug development and stronger cooperation between ministries

- Focus of investment: Larger investment in pan-governmental life-cycle R&D for more efficient development of new drugs, support at the bottleneck stage to reduce burden of R&D on Korean pharmaceuticals, larger investment in the identification of candidate materials and bridging studies including non-clinical or initial clinical trials to remove barriers to drug development.

* Joint project of Ministry of Education, Science and Technology, Ministry of Trade, Industry and Energy and Ministry of Health and Welfare, with 1.06 trillion won budget according to the result of a preliminary feasibility test. Each ministry contributed KRW 5 billion in 2011, the first year of the project.

Commercialization of advanced medical technologies (U-health, regenerative medicines)

- Focus of investment: Expanding investment in core technologies to secure competitiveness in U-health and regenerative medicines and laying a foundation to help companies enter the industry; forming a large-scale cohort* to encourage systematic linkages between sensors, equipment, networks and medical systems

* Cohort study: A type of longitudinal study used in epidemiology, which follows a group of people to determine the correlations between certain factors

Major Support Measures for Pharmaceutical Industry (Ministry of Health and Welfare)

Market-friendly regulations - streamlining the pricing system and the process of approving new technology pharmaceutical products

- Prices of generics for drugs from innovative pharmaceuticals: 68 percent of original drug prices for the first year (59.5 percent for generics for drugs from other pharmaceuticals)
- Establishing a transparent and predictable mid- and long-term pricing system (operating a drug-pricing system council)
- Utilizing clinical test results of researchers for the approval of stem cell therapy products and simplifying clinical trials of self-treatment medicines by simultaneously approving the phase-1 and phase-2 trials

Expansion of government R&D support/efficiency in R&D systems

- Government support for R&D for drug development soared to KRW 206 billion in 2012 from KRW 145.5 billion in 2011. In particular, funds for stem cell therapy products jumped to KRW 33 billion in 2010.
- Improving the R&D support system in a more researcher-focused manner, so that when research is concluded earlier than planned, support for follow-up studies and incentives are provided.
4. Government Policies and Incentives

Tax incentives and financial support

- The scope of corporate tax breaks has been expanded to more R&D projects for drug development.
  + Technologies for new growth engines: Currently focusing on stem cell therapy products and others (total of 4) among many types of biomedicines → vaccines have been added.

- New financing to fund R&D related to exports (Export-Import Bank)*, and financing for policy loans related to drug development and equipment investment**
  + Support for overseas phase-3 clinical trials up to 100 billion won, 8-year maturity, prime rate 0.5 percent
  ** Korea Finance Corporation-Export-Import Bank – up to 8-year maturities, prime rate of up to 0.5 percent

Biofund to Nurture Bio Industry

Seoul Biotech Fund

- In 2009, Seoul City and the Ministry of Trade, Industry & Energy created a 100 billion won fund through a public-private joint investment. It invests more than 60 percent of the entire fund in mid-sized companies with sales revenue of more than 30 billion won or unlisted small or medium ventures in the biologics or medical equipment industries. (GP: Oxford BioScience Partners & Hanwha VC)

Businesses provided with Seoul city government biotech promotion funds

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Main business lines</th>
<th>Date invested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kang Stem Biotech</td>
<td>Stem cell therapeutics</td>
<td>July 6, 2011</td>
</tr>
<tr>
<td>Earlogic</td>
<td>Medical hearing testing instruments</td>
<td>Sept. 27, 2011</td>
</tr>
<tr>
<td>Crystalgenomics</td>
<td>Innovative new drug development</td>
<td>Jan. 17, 2012</td>
</tr>
<tr>
<td>PCL</td>
<td>Vitro diagnostic reagent</td>
<td>Mar. 27, 2012</td>
</tr>
<tr>
<td>Pathway Genomics</td>
<td>Genome analytical tests</td>
<td>April 4, 2012</td>
</tr>
<tr>
<td>Pharmapcine</td>
<td>New therapeutic antibody drugs</td>
<td>April 24, 2012</td>
</tr>
</tbody>
</table>

Source: Korea’s industries and economy, Contact Korea (2010)
KDDF (Korea Drug Development Fund)

From March 2013 to February 2014, the KDDF invested a total of 39.9 billion won (36.7 billion won in R&D and 3.2 billion won in operation) in a bid to secure an advanced R&D platform for the development of new drugs targeting global markets.

Pan-governmental life-cycle drug development

- Identify and invest in innovative new drug projects aiming for the world market.*
  - No investment made in generic drugs and drugs targeting the domestic market

- To accelerate the development of new globally viable drugs by exploring new drug seeds at home and abroad in collaboration with best partners using the Connect and Development strategy

- Pan-governmental investment from all the relevant ministries including the Ministry of Science, ICT, and Future Planning, the Ministry of Trade, Industry & Energy, and the Ministry of Health and Welfare, in all stages, ranging from the identification of candidate materials to clinical trials

- New drug development projects are being explored, planned, selected and followed up on continuously throughout the year in an approach similar to that adopted for private business projects by global pharmaceuticals investing in new drug development.

- A system that supports the entire cycle pipeline of new drug development (including the implementation of projects corresponding to every stage of new drug development), or project portfolios investing in every stage (candidate material, pre-clinical, phase-1, phase-2, phase-3 clinical tests) without being limited to certain stages
5. Relevant Organizations

Ministries and Government Agencies

- Korea Food & Drug Administration [http://www.klda.go.kr]
- Health Insurance Review & Assessment Service [http://www.hira.or.kr]
- Korea Intellectual Property Office [http://kipo.go.kr]
- Statistics Korea [http://kostat.go.kr]
- Korea Customs Service [http://www.customs.go.kr]
- Rural Development Administration [http://www.rda.go.kr]
- Korea Health Industry Development Institute [http://www.khidi.or.kr]
- Korea Orphan Drug Center [http://kodc.or.kr]

Industry Associations

- Korea Pharmaceutical Manufacturers Association [http://www.kpma.or.kr]
- Korea Biotechnology Industry Organization [http://www.koreabio.org/]
- Korea Drug Research Association [http://www.kdra.or.kr]
- Korea Pharmaceutical Traders Association [http://www.kpta.or.kr]
- Korea Venture Business Association [http://www.kova.or.kr]
- Korean Research-Based Pharmaceutical Industry Association [KRPIA] [http://www.krpta.or.kr]
- Korea Food Industry Association [http://www.kfia.or.kr]
- Korean Pharmaceutical Association [http://www.kpanet.or.kr]
- Korean Hospital Association [http://www.kha.or.kr]
- Korean Medical Association [http://www.kma.org]
Invest KOREA’s Global Network

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