

Strategy Recommendations for the Development of New Models in Korea's Biomedical Industry

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Abstract

The biomedical industry in Korea has achieved a rapid growth and a remarkable change thanks to active support by the government and continued efforts from businesses. In 2016, the government invested KRW 2.4748 trillion in the bio sector including biotech and healthcare, recording an annual growth rate of 7.3% over the last 5 years from 2012 to 2016. The market share of biotech industry in areas of pharmaceutical, medical devices, and medicine and healthcare has grown by 4.6%, 9.6%, and 10.6% each year on average during the period, amounting to KRW 1.88 trillion, 5.6 trillion, and 4.5 trillion, respectively. As a result, there has been world-class achievements with regard to the development of new drugs, an area that accounts for the largest share in terms of support by the government and size of the market.

Efforts to develop measures for enhancing the competitiveness of Korea's biomedical industry should be made in order to prepare for the upcoming era of bio-economy and nurture the bio sector as a new growth engine of the country. In this regard, this article aims to identify new and emerging models in the U.S. biomedical market and provide strategy recommendations for the development of biomedical industry in Korea based on the result.

New models in the U.S. biomedical industry are largely classified into 4 categories including (1) investment-led growth, (2) convergence of technology and healthcare, (3) precision medicine-led growth, and (4) Biocluster-centered growth. They are emerged along with the increasing recognition on the importance of technology-product-service integration and tend to focus on establishing innovative platforms based on new technologies, rather than pursuing growth led by pharmaceutical and medical devices.

The development of biomedical market and industry has a strategic significance to Korea in order to respond to the future society and grow its economy. It is considered that adopting strategies of convergence of technology and healthcare, precision medicine-led growth, and biocluster-centered growth among new biomedical industry development models in the U.S. to Korea will contribute to moving beyond narrow domestic market and taking a leap forward to become a global biomedicine powerhouse.

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1. Overview

The bio industry¹⁾ is gaining attention as a new growth engine and it consists of various areas due to its industrial use of living organisms. Also, the size of global market is expected to grow constantly in the future. Organization for Economic Cooperation and Development (OECD) further specified the bio industry by colors as red, green, and white, and predicted the emergence of the era of bioeconomy by 2030²⁾. In general, red, green, and white in the bio industry refer to medical, agriculture and environment, and biochemistry (new bio-based material, bioenergy, etc.), respectively. It is expected that the size of global bio market in the era of bioeconomy will increase to USD 4.4 trillion in 2030 from USD 1.6 trillion in 2015, exceeding the total share of combining the three major industries including semi-conductor, automobiles, and chemicals, which account for USD 3.6 trillion (Ministry of Science and ICT (MSIT), 2017).

The bio industry is a promising area, leading the 4th industrial in which innovative technologies, new industries for the future, and other value-added next things are created based on technological convergence. Korea, too, is paying close attention to the industry as a growth engine for the next generation. In particular, the government recently announced 「Bio-Economy Initiative 2025」, its 3rd basic plan to nurture the biotech industry, and proclaimed that it will secure the global dominance in the era of bioeconomy by increasing the nation's share of global bio market to 5.0 % by 2025 from 1.7 % in 2015 (MSIT, 2017). Considering the characteristics of the industry, securing the original technology and outstanding talents are essential to be ahead of the game on the global market and create decent jobs in biotechnology fields. The employment inducement coefficient of the bio

industry is a 15.8 %, which is higher than a 9.4 % of manufacturing sector (MSIT, 2017).

The purpose of this paper is to identify trends of the global biomedical industry among various sectors of the bio industry and provide strategy recommendations for the development of new biomedical industry in Korea. The scope of biomedical industry in this paper include pharmaceuticals, medical devices, and biomedical engineering (medicine and healthcare). To be specific, the biotech (medicine and healthcare) industry refers to biotech-based medicine and healthcare industries and it includes biomedicine, biomedical devices, bio tools and equipment, and bio service according to the bioindustry classification code (KS J 1009). The code consists of sectors related to the bio industry including biomedicine, biochemical and energy, bio food, bio environment, biomedical devices, bio tools and equipment, bio resource, and bio service. They are also included in areas of biotech and healthcare composed of pharmaceuticals, medical devices, and medicine and healthcare among the government's 9 R&D areas (ICT and SW, biotech and healthcare, energy and resources, materials and nano tech, mechanics and manufacturing, food, agriculture, forestry and fisheries, aviation, aerospace, and marine, traffic and construction, and weather and environment). Among them, the biotech and healthcare sector is classified into 7 technology areas such as new drugs, medical device, neuroscience, genome, stem cell, bio-convergence, and clinics and healthcare.

By taking into account the influence of the U.S. market over the global biomedical industry, changes in the U.S. market can be used as indicators for the development of Korean biomedical industry. The drug and medical devices industries of the U.S.

1) Bio industry is defined as an 'industry that creates various types of value-added products and services by using functions and information of living organisms based on biotechnology'

2) An economy that biotechnology contributes a significant share of economic output (OECD, 2009)

currently accounts for a 32.8 % and a 43.2 % of the globe markets, respectively (Korea Health Industry Development Industries (KHIDI), 2017). This paper intends to provide strategies for the development of Korean biomedical industry centering on the four new models appeared in the U.S. models including investment-led growth, convergence of technology and healthcare, precision medicine-led growth, and biocluster-centered growth.

2. Status of the Global Biomedical Industry

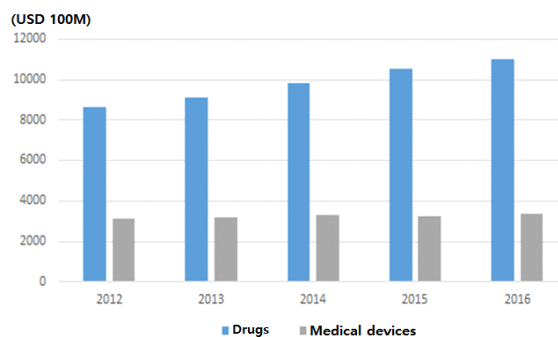
2.1 The Market Size of Global Biomedical Industry

The pharmaceutical market and medical device market accounted for USD 1.1042 trillion and USD 339.5 billion of the global biomedical industry in 2016 , respectively. The pharmaceutical industry, which took account the biggest share of the total, increased by 6.3% each year on average from USD 866.3 billion in 2012 and the medical device industry grew by 2.2% from USD 311 billion during the same period. The U.S. market had the largest share of the total as of 2016 with USD 362.1 billion, followed by China with USD 106 billion (9.6%) and Japan with USD 104.6 billion (9.5%). The U.S. accounted for the largest share of the global medical device industry in 2016 as well with USD 146.6 billion and a 43.2% of the total, and Japan and Germany recorded USD 25.2 billion (7.4%) and USD 25.1 billion (7.4%), respectively.

The size of global biotech market including industries such as medicine and healthcare, agri-food, environmental and industrial process, medical service and tech service grown to USD 353.9 billion in 2016 with an average annual growth rate of 8.8% from USD 252.4 billion in 2012. Among them medicine and healthcare-related biotech industry accounted for USD 237.2 billion (Biotech Policy Research Center, 2018). The U.S. had a largest share of 46.5%, worth USD 164.6 billion in 2016, followed

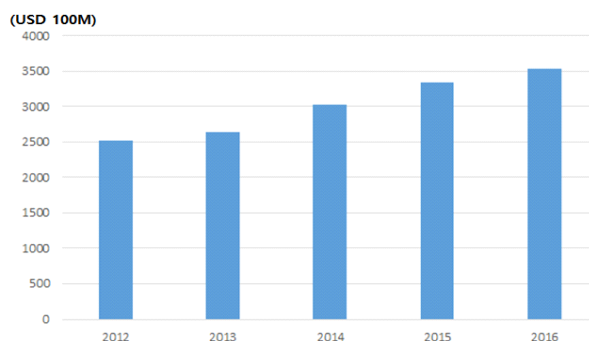
by Asia-Pacific (24.9% or USD 88.2 billion) and Europe (18.0% or USD 63.6%).

Figure 1. 2012-2016 Global Pharmaceutical & Medical Device Market Size



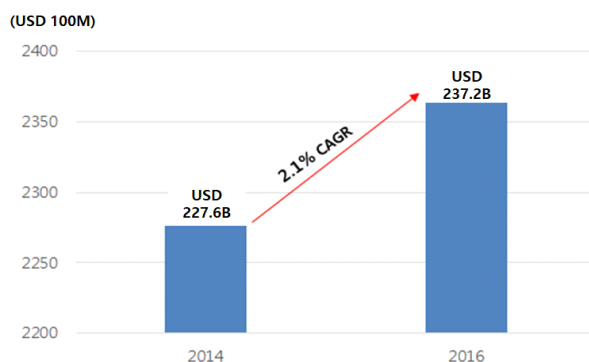
[Source] Korea Health Industry Development Industries, KHIDI (2017), cited.

Figure 2. 2012-2016 Global Biotech Market Size



[Source] Cho Sun-ja, et al., (2018), cited.

Figure 3. 2014-2016 Global Biotech Market Size (medical·healthcare)



[Source] Cho Sun-ja, et al., (2018), cited.

The size of biotech industry including medicine and healthcare sectors³⁾ grew by 2.1% each year on average to record USD 237.2 billion in 2016 from USD 227.6 billion in 2014.

2.2 Market Analysis of Global Biomedical Industry

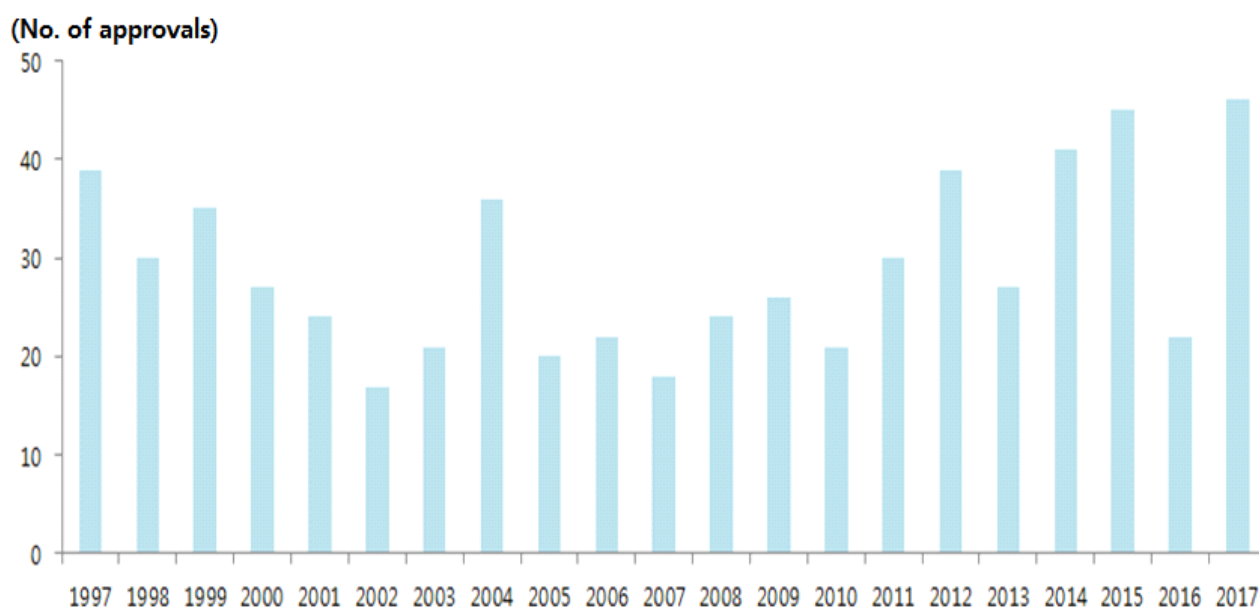
Although it is expected that the global biomedical industry will continue to grow thanks to the increase in the world population and life expectancy, there is a need to improve the production efficiency. The size of global biomedical industry by 2020 is predicted to reach USD 1.43 trillion and USD 423 billion for pharmaceutical and medical device industry, for each. In the meantime, the number of approvals for novel drugs (new molecular entity, NME) and biologic license applications (BLA) by

the U.S. Food and Drug Administration (FDA) are on the rise.

Also, the number of pre-market approvals (PMAs) and humanitarian device exemptions (HDEs) by U.S. FDA increased for the last 10 years.

The total sales of biotech industries based on publicly traded companies of the U.S. in 2016 grew by 4% with USD 112.2 billion from USD 107.4 billion in the previous year and most of the profits came from major biomedical companies such as Gilead, Amgen, Biogen, and Celgen. However, the net profits and market capitalization decreased during the same period by 40% and 22%, respectively. As for Europe, the total sales and market capitalization of EU public companies in the same category increased by 19% with USD 27.2 billion, and 9%, for each, and their net profits declined.

Figure 4. No. of Novel Drug Approvals by U.S. FDA (1997-2017)



[Source] US Food and Drug Administration (2018), cited.

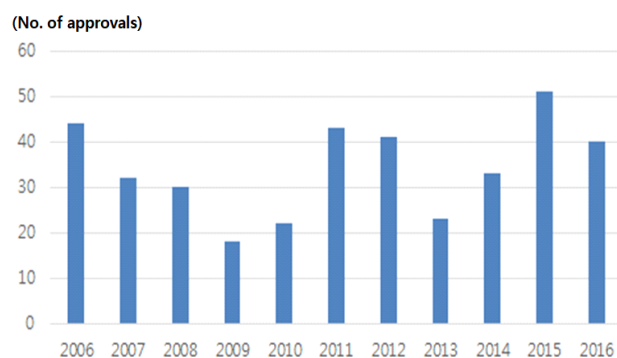
3) This sector partially overlaps with pharmaceutical and medical device industries due to the characteristics of medicine and healthcare category

Table 1. 2015-2016 Status of Biotech Companies listed in the U.S. and Europe Stock Markets

[Unit: USD 100M]

Item		2015	2016	Increase & decrease (%)
USA	Total sales	1,074	1,122	4%
	Net profit	153	92	-40%
	Market cap	8,912	6,986	-22%
Europe	Total sales	228	272	19%
	Net profit	10	-13	-235%
	Market cap	1,501	1,642	9%

[Source] Cho Sun-ja, et al., (2018), cited.

Figure 5. No. of PMAs and HDEs by U.S. FDA (2006-2016)

[Source] U.S. FDA (2017), cited.

3. New Models in the U.S. Biomedical Industry

As for the US, which accounts for a high share of the global biomedical market, new industrial models emphasizing the significance of convergence on technology, product, and service have appeared recently. They seek to develop innovative platforms based on new technologies, rather than previous approaches to the growth led by products. Such models can be classified into the following 4 categories: (1) investment-led growth; (2) convergence of technology and healthcare; (3) precision

medicine-led growth; and (4) Biocluster-centered growth.

3.1 Investment-led Growth Model

The investment-led growth model first appeared during the period of economic slowdown of the world in 2008 and 2010. In this model, corporate M&A was the main source of growth, not a growth based on R&D.⁴⁾ To be specific, this model can be classified as follows: (1) innovative new drug development; (2) specific disease-related drug development; (3) new drug development for prompt market entry; and (4) new drug development based on portfolio management and investment.

3.1.1 Innovative New Drug Development

Companies focus on the development of blockbuster drugs based on new technologies other than existing treatments. The issue of increasing R&D spending is resolved by building pipelines through M&As or other corporate activities.

3.1.2 Specific Disease-Related Drug Development

It is derived from the approach to develop

4) In this period, large biotech companies have cut back their R&D investment and established a growth model that seeks corporate growth through M&As on the back of their revenue

innovative new drugs and focuses on the development of rare disease-related drugs, with the aim of dominating the market by purchasing raw materials and pursuing M&As.

3.1.3 New Drug Development for Prompt Market Entry

This approach is to buy drugs of which FDA approval is expected for early entry into the market. This model is applicable to large pharmaceutical companies as it requires abundant capitals.

3.1.4 New Drug Development Based on Portfolio Management and Investment

This growth strategy is to invest and manage various sectors through affiliates rather than focusing on certain areas. In general, such portfolio management and investment sets a goal of a 5 to 10% annual growth.

3.2 Convergence of Technology and Healthcare

Convergence of technology and healthcare refers to a cross-sector convergence between the latest biomedical technology and innovative technologies such as big data and AI in real-time. There are three types of technology-medicine convergence; (1) convergence focusing on specific diseases; (2) convergence to adopt innovative technology; and (3) convergence to evolve into non-medical areas.

3.2.1 Convergence Focusing on Specific Diseases

It is related to the application of innovative therapy for the treatment of certain diseases. Immunocyte

therapy and Chimeric Antigen Receptor-T (CAR-T) cells are examples of this approach.

3.2.2 Convergence to Adopt Innovative Technology

This approach provides comprehensive treatments and diagnosis ranging from diverse diseases and it is mainly applicable to medical devices and medical research areas from the long term perspective. Genome editing, nano technology, and 3D printing are the most well known examples.

3.2.3 Convergence to Evolve into Non-Medical Areas

This type of convergence creates an industrial value in the biomedical industry⁵⁾ based on the convergence of big data, AI and other innovative technologies in non-medical sectors. Clinical Decision Support System (CDSS) is considered as a result of convergence to evolve into non-medical areas.

3.3 Precision Medicine⁶⁾-Led Growth

The precision medicine-led growth is to explore effective treatment methods by using not only physical attributes, but also big data on genes, disease, lifestyle of individuals with regard to treatment and health management. The recent phenomenon of population ageing continues to increase medical expenses, and calls for a paradigm shift in healthcare are growing due to the decline of clinical trial productivity for the development of new drugs⁷⁾, limitations on standard drug treatment that takes effect on 25 to 80 percent of the patients by disease.

This model classifies diseases in detail based on

5) IBM converged AI on biomedical big data to develop 'Watson for Oncology' Watson is trained by Memorial Sloan-Kettering Cancer Center (MSKCC) in the U.S. as a medical service platform (CDSS)

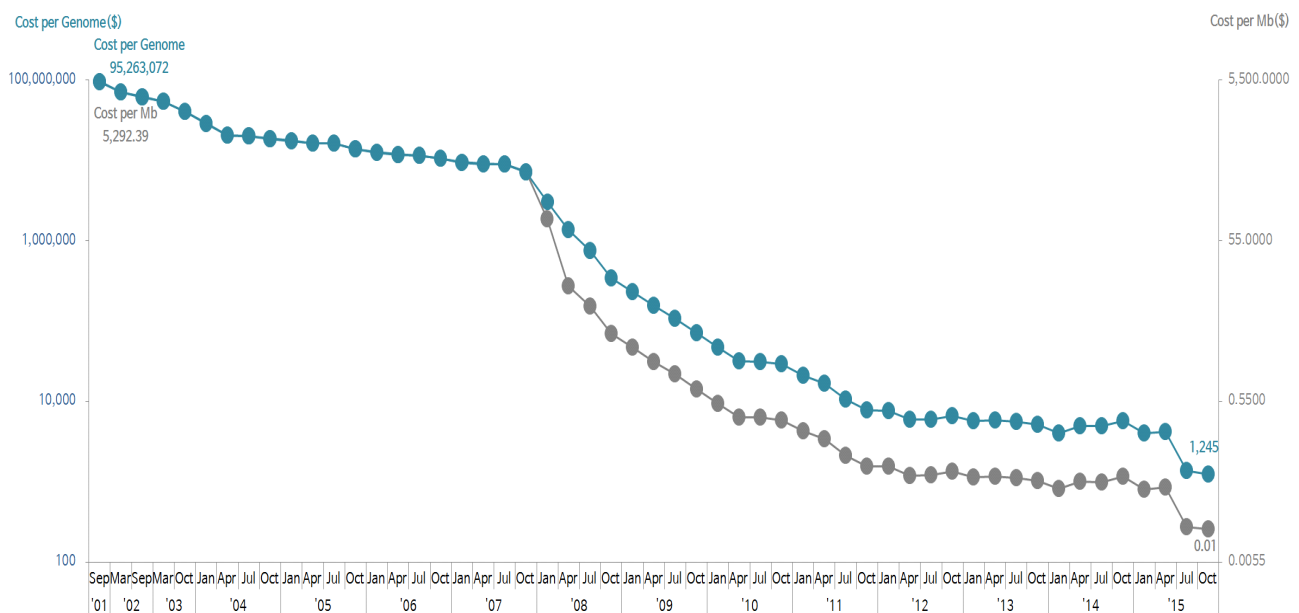
6) Precision medicine led by a great advance of genome sequencing can be considered as an expansion of a more familiar concept of personalized medicine

7) "Clinical new drug trial productivity declines... decrease by half in every 9 years", 「Sluggish global R&D investment on the development of new drugs and breakthrough of Korea's clinical trials」, Korea National Enterprise for Clinical Trials (KONECT), 2018

the health information of a large number of cohorts as well as patients who are responsive to certain drugs and therapies to improve treatment efficiency and reduce medical expenses. For instance, timely prescription of targeted therapies to patients can minimize the confusion in selecting antitumor agents and reduce unnecessary medical spending. This growth model is mainly led by a remarkable progress in genome sequencing of the recent and reduction

of analysis cost. Research efforts related to genome sequencing required a huge money. The Human Genome Project, a project to read nature's complete genetic blueprint for building a human being for the first time, spent about USD 2.7 billion in R&D over 10 year until the project is complete in 2003. However, the time and cost of genome sequencing has reduced significantly with the emergence of Next Generation Sequencing.

Figure 6. Cost Reduction Trajectory for Genome Sequencing



[Source] National Human Genome Research Institute (2016), cited.

3.4 Biocluster-Centered Growth

The Biocluster-centered growth model refers that multinationals establish a regional hub and grow together based on their network and it is expected that the number of clusters will gradually increase. Bioclusters in Boston and San Francisco are examples of successful Biocluster-centered growth models that ensure a high efficiency in terms of information exchange and collaboration among cluster members, transfer and take over business, and investment. In

particular, Bioclusters enable prompt transfer and taking over of business as it is easy to search the information among companies belonged to the cluster, based on the convenience in information search among companies within the cluster. For example, Greater Boston, the best biocluster of the U.S., is considered as a benchmark for all bioclusters as it has very favorable conditions to hire outstanding talents thanks to the fact that about 1,000 biotech companies and the world's renowned universities such as Harvard and MIT are located nearby.

Table 2. Best U.S. Bioclusters Ranking 2017

Rank	Cluster	Weighted Score	Rank	Cluster	Weighted Score
1	Greater Boston	82.3	9	Los Angeles/ Orange County	47.4
2	San Francisco Bay area	79.7	10	Chicago Metro	40.1
3	San Diego	65.8	11	Minneapolis-St. Paul	39.1
4	Raleigh-Durham	65.4	12	Westchester County,NY	35.3
5	Philadelphia	54.7	13	Denver Metro	34.2
6	Maryland Suburbs/ DC Metro	54.3	14	New York City	33.7
7	Seattle-Bellevue	48.0	15	Long Island,NY	23.2
8	New Jersey	47.5	16	Central & Southern FL	21.7

[Source] JLL 「Cluster Report」 (2017), cited.

Bioclusters provide their members with a favorable environment in terms of geological locations and securing of competitive edges and have a positive effect on regional economy. Hence, it is expected that bioclusters will continue to expand and develop in the future. Venture businesses and startups working in this sector can take advantages on collecting market trends and information and responding to changing environment by creating a network with biotech companies. The establishment and expansion of bioclusters can also revitalize regional economies with regard to population increase and job creation by promoting company relocation and the inflow of capitals.

4. Status Analysis of Korea's Biomedical Industry

The biomedical industry in Korea has achieved a rapid growth and remarkable changes thanks to active support by the government and continued efforts from businesses. In 2016, the government

invested KRW 2.4748 trillion in the bio sector including biotech and healthcare, recording an annual growth rate of 7.3% over the last 5 years from 2012 to 2016 (MSIT, 2018). The biomedical industry accounts for a 13.0% of the government's total R&D spending (KRW 19.44 trillion as of 2016) and which is the second largest following the ICT·SW sector (KRW 2.8267 trillion). To be specific, the R&D expenditure on the development of novel drugs takes the largest share among the 7 areas of biomedical industry with 26.8% or KRW 664.1 billion in 2016, followed by clinics and healthcare (24.1%), bio-convergence (19.8%), medical device (14.6%), stem cell (7.4%), neuroscience (3.6%), and genome (3.6%).

In 2016, the size of domestic pharmaceutical, medical device, and biotech industries (medicine and healthcare)⁸⁾ accounted for KRW 18.8 trillion, 5.6 trillion, and 4.5 trillion, respectively, and the pharmaceutical industry has the largest share of the total. Among medicine and healthcare related industries, the biotech industry recorded the highest annual growth rate with 10.6% over the past five years (2012-2016), followed by medical device industry with

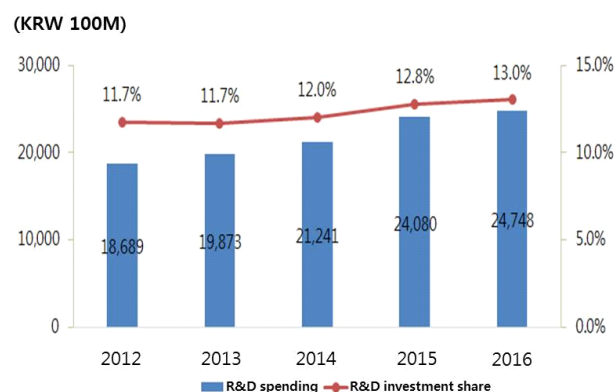
8) This sector includes biomedicine and bio-medical devices industries and partially overlaps with pharmaceutical and medical device industry due to the characteristics of medicine and healthcare category (KoreaBio, 2017)

9.6% and pharmaceutical industry with 4.6%.

The pharmaceutical industry in Korea, which takes the largest share among the biomedical industry and receives the biggest government support, continues to achieve the world-class outcome recognized by the citizens. Celltrion's Remsima, the world's first biosimilar monoclonal antibody medication, was approved by the U.S. FDA in 2016, and it has been sold more than the original drug in Europe where it is approved and released on the market in 2013. Hanmi Pharma sealed deals on 6 licenses in 2015 for KRW 7.8 trillion with Sanofi over technology transfer of biomedicines. Also, Samsung BioLogics completed the construction of its plant #3, a biomedicine manufacturing facility, in 2017 and became the largest contract manufacturing organization (CMO) service provider in the world by industry with the total capacity of 362,000L.

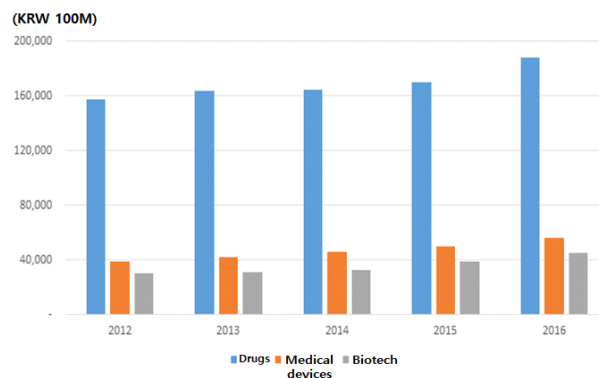
Despite such remarkable achievements, the biomedical industry in Korea accounts for less than 2% of the global market over the past 4 to 5 years⁹⁾. Hence, efforts should be made to improve industrial competitiveness in consideration of environmental difference between Korean and overseas markets. For instance, the sum of R&D expenditure of Korea's top 10 pharmaceutical companies is far short from that of a global drug maker.

Figure 7. 2012-2016 National Biohealthcare & Biomedicine R&D Spending



[Source] KISTEP (2017), cited.

Figure 8. 2012-2016 Domestic Biomedicine Market Size



[Source] Modified from KHIDI data (2017), KoreaBio (2017).

Table 3. R&D Expenditure of Top 10 Global/Korean Pharma Companies

Top 10 global pharma companies (unit: USD 100M)			Top 10 Korean pharma companies (unit: KRW 100M)	
1	Roche	114.2	Celltrion	2,640
2	Johnson & Johnson	99	Hanmi Pharma	1,624
3	Novartis	90	Samsung Bioepis	1,537
4	Pfizer	78.7	Green Cross	1,170

9) The volume of Korean biomedical industry accounts for about 1.9% of GDP and its constant contribution to the national economic growth is insignificant (Hong Jeong-eun, et al., 2017)

Top 10 global pharma companies (unit: USD 100M)			Top 10 Korean pharma companies (unit: KRW 100M)	
5	Merke	71.9	Daewoong Pharmaceutical	1,080
6	AstraZeneca	58.9	Chong Kun Dang	1,022
7	Sanofi	54.5	Yuhan	865
8	Eli Lilly	52.4	Dong-A ST	726
9	BMS	49.4	JW Pharmaceutical	316
10	GSK	49.4	Boryung Pharmaceutical	290

[Source] Jang Jong-won (2017), cited.

5. Conclusions and Recommendations

The development of biomedical industry in Korea holds a strategic importance in responding to the future society and for the growth of national economy. For Korea to achieve per capita GDP goal of USD 30,000 and maintain the status, securing new growth drivers are necessary. The biomedical industry is a knowledge intensive and high value-added sector that is highly dependent on essential patents and technology. Considering the capability of Korea in this field, the domestic biomedical industry has a competitive edge sufficient to lead the future of national economy. According to 「BCI 2017」, Korea ranked the 4th among 21 emerging countries (BCI index: 72) with regard to the competitiveness of biopharmaceutical and medical technology(Pugatch Consilium, 2017).

In case of the biomedical industry in Korea, it is more proper to adopt tailored approaches such as bio intellectual properties, rather than the investment-led growth model. Also, there are certain limitations to apply investment-led growth models of the U.S. directly, considering competency gaps

between biomedical companies in Korea and those in the U.S., which lead the global market. As for Korea, it is better to pursue the development of new drugs targeting niche markets¹⁰⁾ or concentrating its efforts on out-licensing of bio intellectual property to seize an opportunity for the entry into the global market. For venture businesses and SMEs, they need to focus on out-licensing of intellectual properties such as candidate substances of new drugs, new technologies, etc. Also, SMEs should secure competencies sufficient enough to lead the development efforts till the clinical trials, and establish models on collaboration between global companies. For large companies, they need to enter into the global market promptly through M&As with promising venture businesses and SMEs and substance purchase strategy, rather than investing in highly competitive areas such as generic drugs and biosimilar medications.

Korea has global competitiveness when it comes to the technology-medicine convergence model. Hence, the government should provide policy support and improve related systems and institutions on a constant basis to apply innovative biotechnology at

10) The rare disease treatment market has a relatively less influence over global pharmaceutical companies and can expect supports by the government such as conditional approval and tax exemption (Kim Geun-hee, 2018)

sites and encourage companies to create outcomes. In particular, the country has outstanding technological competencies in gene editing¹¹⁾ and stem cell and gene treatment¹²⁾, which have a high value as innovative biomedical technologies, as well as ICT-based biomedical technologies. Therefore, policy support by the government is needed to vitalize the domestic market.

Due to the characteristics of the bio industries, it is possible to sustain dominance over the market if novel drugs and new medical technologies are promptly on the market and established themselves as standard treatments¹³⁾. Based on outstanding competencies in AI, Korea's leading biotech companies including Lunit and Vuno have developed a CDSS using CT-X ray imaging tools, and they are exploring ways for application.

In order to ensure the creation of truly meaningful market values with the adoption of new technology and convergence of advanced technologies, we need to make efforts to gather opinions at sites, provide institutional support without suspension, and continue to improve related laws and regulations. With the aim of becoming one of the world's top seven powerhouses in biotechnology by 2020, the government has established a series of strategies and visions including a strategy for the future of biotechnology and measures to improve bio-regulation in 2014, a strategic plan to foster new bio industries for the future in 2015, and a mid-term strategy to foster the bio industry (2016-2018) in 2016, and established strategies for the development of technologies such as stem cell, gene treatment, and ICT-based medical devices as well as ones to advance regulatory management of the industry. It

also established strategies for the development of fast track screening of new products and technologies, and installation and operation of a consultative body for regulatory improvement in cross-sector convergence of high-tech industries.

The testing on certain types of genes by private institutes were temporary allowed in 2016. Although, deregulation on innovative technologies is gradually taking place, gene therapy researches are still restricted under the related laws and regulations¹⁴⁾. Therefore, efforts should be made to expand the biomedical technologies converging ICT along with technological development and adoption of new technologies, such as regulatory reform with regard to personal data protection, collection, sharing, and integration of medical information, and security concerns, and estimation of proper medical charges for new devices. Progress has been made in this regard. For instance, Ministry of Food and Drug Safety (MFDS) has established guidelines on the assessment of new medical devices based on big data and AI in December, 2017. Another recommendation is to hold public meetings led by the market participants from all sectors of the bio industry to identify items to be improved with regard to demand-based systems and regulations, and connect the technology with sites.

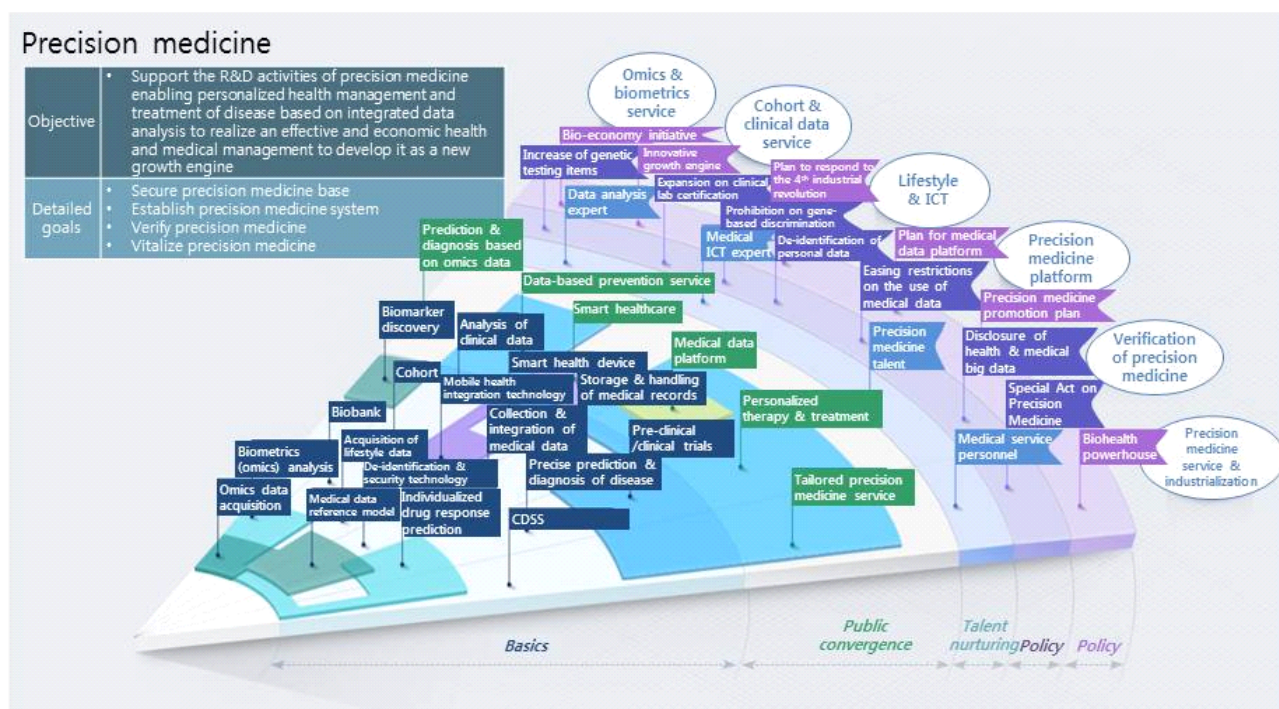
The U.S. is investing USD 250 billion in the Precision Medicine Initiative each year and the UK is also injecting KRW 110 billion into the 100,000 Genome Project annually. Korea, too, needs to industrialize related technologies promptly by focusing on the precision-centered growth model with which many science and technology powerhouses such as the U.S. and UK are heavily investing.

11) Succeeded in genetic modification of human embryos (2017) and found a solution to prevent immune responses to DNA scissors for gene editing application (2018)

12) Korean companies developed 4 out of 6 stem cell treatments released to the world and 20 gene therapies are on clinical trials

13) Following products should have a better efficacy and there are certain limitations on patient recruitment for clinical trials

14) The scope of genetic research is defined by Article 47 of Bioethics and Safety Act. Ministry of Health and Welfare (MOHW), a government agency which is in charge of the act, has installed and run the 2nd Public-Private Council for Bioethics to discuss directions for revision of the act (MOHW, 2017)

Figure 9. Precision Medicine R&D PIE (Platform for Investment & Evaluation)

The precision medicine-led growth requires a seamless connection of components including creation of medical big data platforms on a large number of cohorts, data acquisition and analysis of human genome and health data in large quantities, development of tailored drugs and healthcare services, institutional and systemic support, and sharing and expansion of the outcomes. The government has announced R&D PIE, a package-type precision medicine R&D investment platform that supports ‘technology-talent nurturing-system-policy’ comprehensively as a part of its 2018 plan to innovate R&D investment, and provided guidelines on role sharing between private and public parties, and key technologies to commit its budget (MSIT, 2018).

Under the government initiative, early

industrialization¹⁵⁾ based on the precision medicine-led growth model is expected to lead the development of domestic biomedical industry in general by encouraging active engagement of multiple stakeholders including sequencing companies, pharmaceutical and medical device companies, general hospitals, universities, and the government-funded and private institutes. This model may bring new values to the market and allow people to feel the stance of Korean biomedical technology on the global stage by making investments in industrial contents based on innovative technologies, rather than investing in technologies directly to establish basic infrastructure.

We need to benchmark the U.S. bioclusters to build creative ecosystems led by the market participants. The Broad Institute, a leading research

15) As of 2017, Korea ranked at the 6th in the global clinical trials market (Seoul ranked the 1st at city rankings) and has one of the world’s best sequencing companies. Likewise, the country has met various conditions to grow led by precision medicine.

institute of Greater Boston jointly established by Harvard University and Massachusetts Institute of Technology (MIT), is run autonomously and flexibly based on the partnership among the biocluster members. This type of ecosystem with market-led value chains is relatively less dependent on the government and has an effective structure to boost investment by external players and participation of companies.

Established in 2017 to serve as a base to nurture biomedical startups in Korea, Seoul Biohub¹⁶⁾ supports biotech companies throughout their entire life cycle from the establishment to technology commercialization based on the support by the government. The location of Seoul Biohub serves as an advantage on the creation of biomedical clusters based on the academia-industry-research institute network thanks to close proximity to Korea Institute of Science and Technology (KIST), Korea University, Kyung Hee University, and Kyung Hee University Medical Center.

The government support during the entire life cycle of businesses enables them achieve the outcome promptly. Hence, we should find ways to encourage the private sector to voluntarily join the hub to maximize the benefits of government support. As the country needs to pursue a chase strategy in the global bioindustry market, we need to focus on ensuring the stability in the biomedical ecosystem during the early and growth period, and creating synergy effects with the private sector, and securing a foothold for the entry into the global market.

References

- Biospectator (2017), "R&D spending of Korea's top 10 biomedicine companies lag behind...by 72 times' from global counterparts," August 19.
- Cho Sun-ja-Kim Mu-woong (2018), "Status and prospect of global bio industry," BioINdustry, 122.
- Deloitte (2017), 2017 global life sciences outlook.
- Deloitte (2017), The hospital of the future How digital technologies can change hospitals globally.
- Ernst & Young, (2015), Health reimaged extract from Megatrends 2015.
- Ernst & Young, (2016), Medical Technology Report.
- Ernst & Young, (2016), Pulse of the Industry.
- Goldman Sachs & Co. (2017), Convergence of Healthcare and Technology.
- Health Korea News (2014), "Clinical new drug trial productivity declines... decrease by half in every 9 years," December 8, 2014.
- Hong Jeong-eun (2017), "Status and issues of the Korean biohealth industry," BIO ECONOMY BRIEF.
- Hyundai Research Institute (2016), Features and implications of the bio industry in 2016.
- JLL (2017), An evolving industry: Today's clusters creating tomorrow's breakthroughs.
- KHIDI (2018), Analysis of the medical device industry in 2017.
- Kim Jeong-gone-Lee Seo-jin (2016), "Strategy and implications on ICT-based medical industry of advanced countries," KIEP World Economy Brief, 16(23).
- KoreaBio (2017), 2016 Status survey of the Korean bio industry.
- Korea Health Industry Development Industries (KHIDI) (2018), Analysis of the pharmaceutical industry in 2017.
- Korea Institute of S&T Evaluation and Planning (KISTEP) (2009), Policy direction and implications to achieve the bio-economy by 2030.
- Korea Institute of S&T Evaluation and Planning (KISTEP) (2017), 2015 analysis of the government R&D investment portfolio on new drug development.
- Korea Institute of S&T Evaluation and Planning (KISTEP) (2017), Analysis of 2016 national R&D projects.
- Korea National Enterprise for Clinical Trials (KONECT), (2018), Sluggish global R&D investment on the development of new drugs and breakthrough of Korea's clinical trials, Quarterly Magazine KoNECT,(11).
- Korea Venture Capital Association, (2017), Venture Capital Market Brief, December 2017.

16) Plans to open research building and community building in 2018, and global collaboration complex in 2023 in the ground area of 3,729m²

Kwak Su-jin (2016), "Status and challenge of gene treatments in Korea to enter into the global market," KHIDI Brief, 2016-16.

Maeil Business News (2018), "Korea ranks 6th in number of clinical trials," January 15.

MARKETLINE (2017), Global Biotechnology.

Ministry of Science and ICT (MSIT) (2015), Biotechnology in Korea 2014.

Ministry of Science and ICT (MSIT) (2017), Bioeconomy innovation in 2017 will lead innovative growth·future·employment·public health.

Ministry of Science and ICT (MSIT) (2017), The 3rd Basic Plan to Nurture the Biotech Industry.

Ministry of Science and ICT (MSIT) (2018), 2019 Government R&D investment directions and guidelines (planned).

Ministry of Commerce Industry and Energy (MOTIE) (2017), 2015 Survey Report of Korean Biotechnology Companies.

Ministry of Health and Welfare (2017), 2017 Advanced biomedicine industry white paper.

Moon Se-young·Jang Ki-jeong·Kim Han-hae (2016), "Winning strategy for precision medicine," KISTEP InI, 15.

Newspim (2018), "From niche market to government support

...benefits to the development of rare disease treatments", April 24.

Pharmaceutical Executive (2017), STRATEGY THAT WORKS BEYOND 2020.

Presidential Advisory Council on Science & Technology (2014), Strategies for the future of bio industry and measures to improve bio regulations.

Pugatch Consilium (2017), "ASCENDING TO THE PEAK OF BIOPHARMACEUTICAL INNOVATION," BCI 2017.

PWC (2017), "20 years inside the mind of the CEO... What's next?."

PWC (2017), "2017 Pharmaceuticals and Life-Sciences Industry Trends."

PWC (2017), "GAAP-Issues and solutions for the pharmaceuticals and life science industries."

Special Committee on Bio (2016), A mid-term strategy to foster the bio industry(2016-2018, planned).

The Export-Import Bank of Korea (2017), Status of the global pharmaceutical industry and competitiveness of the Korean industry: focusing on biomedicine.

Woo Chang-woo·Kim Mu-woong (2015), Status and prospect of global bio industry, BioINdustry, 99.