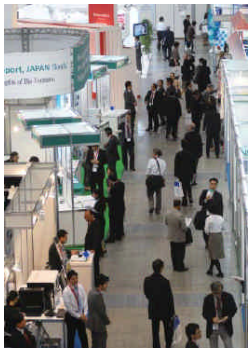
A Detailed Report on BioJapan 2011 World Business Forum

1. Summary

BioJapan 2011 World Business Forum ”New Bio Growth Strategy by Japan” was held from October 5, 2011 (Wednesday) to 7 (Friday) at the Pacifico Yokohama, which was the 13th convention of BioJapan, the oldest comprehensive international event on biotechnology held in Japan since 1986. The event was sponsored by the BioJapan organizing committee consisting of eight organizations related to biotechnology; including JBA and Nikkei Business Publications, Inc.; and co-sponsored by the city of Yokohama with special support from the city of Kawasaki and the prefecture of Kanagawa and support from 67 organizations; including Japanese government-affiliated agencies; such as the Ministry of Economy, Trade and Industry; and the embassies of various countries.



In all, 327 institutions and organizations (including 25 organizations from foreign countries), including business corporations, government agencies, universities, and regional clusters from 13 countries and regions, including Japan, participated, and a total of 20,600 people visited (last year, 25,532 people). Approximately 1,000 meetings for business partnering were arranged by using the Web Matching System, and the total number of meetings, including those held at display booths and conference rooms, was over 2,000 as in the event held last year. This fact indicates that the idea of using BioJapan as a place for achieving open innovation has become established.

A large number of key persons of Japanese and local governments visited the event venue. Since the importance of biotechnology has been increasing year after year, this event is expected to emerge onto a still wider stage.

2. Opening Ceremony

The guests who attended the ceremony include Keiro Kitagami, vice-minister of Economy, Trade and Industry; Yuji Kuroiwa, governor of Kanagawa Prefecture; Fumiko Hayashi, mayor of the city of Yokohama; and Atsushi Miura, deputy mayor of the city of Kawasaki. They expressed their expectations of the growth of industries based on biotechnology and *life innovation* and on BioJapan.

3. Keynote Speech

The keynote speakers were Yasuchika Hasegawa, president and representative director, Takeda Pharmaceutical Company Limited, and Stephan Tanda, chairman, EuropaBio, and a member of the Managing Board of Directors, Royal DSM N.V., Holland. Mr. Hasegawa gave a speech titled “The Growth Strategy in Japan” and proposed that Japan should promote growth strategy based on innovation. Mr. Tanda gave a speech titled “Life Sciences and Material Science-Building a Bio-Based Economy: A Bird’s Eyes View on Biotech Trends and Markets,” explaining the strategy of DSM and the status of biotechnology industries in Europe and appealed for building bio-based economy based on life science and materials science.

4. Welcome Reception

A reception was given on the evening of the first day (October 5) at the InterContinental Yokohama Grand Hotel, inviting 438 people, including guests related to corporations and researchers from Japan and foreign countries, guests related to government ministries, local governments, and public institutions related to biotechnology, and guests related to various regional clusters in Japan and foreign countries.

The reception started with a speech by Isao Teshirogi, president of the Japan Pharmaceutical Manufacturers Association, on behalf of the sponsor, followed by Kagamibiraki, a ceremony of breaking open a cask of sake, which was performed in a friendly mood by guests such as Kunihiko Fujii, chief of Commerce, Industry, and Labor Bureau, Kanagawa Prefecture; Mr. Masato Yamada, deputy mayor of the city of Yokohama; and Mr. Atsushi Miura, deputy mayor of the city of Kawasaki.

Then, Koichiro Aramaki, president of the Society for Techno-Innovation of Agriculture, Forestry, and Fisheries and Representative manager, Japan Association of Bioindus-tries Executives, toasted a successful BioJapan. During the ceremony, eight winners each of the Japan Bioindustry Association Award, Fermentation and Metabolism Research Grant, and the Grant for Research on Chemical and Biological Materials, which have been selected and given every year by JBA, were introduced. After lively conversation, the ceremony ended with a speech by Masanao Shimizu, chairman of the Board of Trustees, Kinki Bio-Industry Development Organization, with great success.

5. Seminars Given by the Sponsor

About 40 seminars were given on various topics during the forum period, and in total, approximately 5,000 people participated. Major seminars are as follows:

1) Forum for Innovative Regenerative Medicine "To accelerate developing medicine tasks and expectations for FIRM"

Moderated by Yasuhiro Yoshioka (chairman of the Steering Committee, FIRM/fellow, R&D Management Headquarters, Fujifilm Corporation)

Mr. Yoshioka explained how Forum for Innovative Regenerative Medicine (FIRM), a General Incorporated Association, was established and started its activities in this year to help early establishment of regenerative medicine.

Yuzo Toda, representative director/chairman of FIRM, gave a keynote speech on the definition of regenerative medicine, background and trend of the industrialization of regenerative medicine, and the significance of the establishment of FIRM, and he introduced the activities of FIRM. In his speech, he outlined a growth projection of the market size of the related industries in Japan (0.6 billion yen in 2010, 11.6 billion yen in 2015, 332.6 billion yen in 2030; the worldwide market size reaches 48 trillion yen in the future), circumstances of clinical trials and marketing approvals, and the *evolution* of drug development from low molecular weight compounds to single cells and multicellular tissues.

2) Explore the Future of In Silico Drug Discovery

Moderated by Hiroaki Hashimoto (editor-in-chief, Nikkei Biotechnology & Business)
A panel discussion was held by the following four persons to discuss the future development of innovation of the IT-based drug discovery in Japan.

• Information Technology Based Drug Design
Tatsuhiko Kodama (professor, University of Tokyo)

Potential drug targets in the future include (a) kinases and epigenomes, (b) cancer genomes, (c) microbial-derived biologically active substances, and (d) G protein-coupled receptors. (a) will make up 50% or more, probably. In particular, drugs targeted against kinases are suitable for IT-based drug discovery because existing drugs targeted against kinases require improvements. Moreover, drug discovery related to (d) by the use of computer science is developing more and more rapidly, as is apparent from recent submissions of articles on X-ray crystallography. Innovation in this technology must be promoted on a national policy.

• Predictive Computation of Pharmaceutical Protein-Ligand Affinity
Hideaki Fujitani (professor, University of Tokyo)

One of the most difficult problems in designing drugs with computers is to calculate the free energy of binding between the potential drug target protein and the ligand with the required accuracy. We developed a method for calculating free energy of binding with a high accuracy through simulation of all atoms by the molecular dynamics method. We named this method MP-CAFEE (massively parallel computation of absolute binding free energy).

• Practical Applications of IT-based Methods in Drug Discovery Projects
Toshio Goto (director, RIKEN)

Substantial developments have been made in the techniques for the structural analysis and binding energy measurement of proteins by X-ray. Using information obtained from these techniques, IT-based drug discovery is becoming utilized in the practice of drug discovery, but it needs more time to be one of the essential methods in pharmaceutical industry. However, efficient drug discovery has not been made possible with all targets by the use of current IT-based drug discovery; the following issues have been shown:
(a) With respect to new types of targets (such as epigenomes) and protein-protein interaction targets, which are highly expected as potential drug targets, experience shows that highly active inhibitors are seldom discovered.
(b) Methods of drug discovery based on IT provide few effective solutions to the improvement of pharmacokinetics (ADME) and toxicity (Tox), which is also required to conduct drug discovery.
(c) Since drug discovery research in the pharmaceutical industry is performed by weekly operating cycles of, for example, molecular design to synthesis, it is difficult to perform the number of calculations/analyses that are required (not less than 10 compounds) when high accuracy calculation techniques for drug discovery are used.

• Development of Fundamental Technologies that Support IT-Based Drug Discovery such as Discovery of Molecular Target Drugs
Gun Saito (director of Bio-Industry Division, Manufacturing Industry Bureau, Ministry of Economy, Trade and Industry)

Project for Developing Fundamental Biological Technologies for Accelerating Genome Drug Discovery is in effect from 2006 through 2012 in order to enhance the capabilities of the drug discovery industry in Japan for research and development. The project includes development of a technique to analyze the conformation of membrane proteins etc., a technique to analyze the interactions between membrane proteins etc. and molecules that bind thereto, a technique to design candidates for new drugs with computers, and a technique to efficiently manufacture new drug candidates.

3) A New Era of Genome-designed Synthetic Biotechnology

Moderated by Satoshi Harashima (professor, Osaka University)

The following seminars were given by the New Energy and Industrial Technology Development Organization (NEDO), an independent administrative agency:

• Recent Advances on New Breeding Technology - More than just a trend -
Satoshi Harashima (professor, Osaka University)

The aim of breeding microorganisms is to design the optimal genome that produces the desired substance from existing genomes. Past breeding technologies required a vast amount of time and labor to produce, for example, the desired protein by breeding yeast. In future breeding techniques, syntheses of optimal genomes based on rational design, production of vast number of types of genomes starting from existing genomes, and techniques for screening cells with optimal genomes are important. The importance of developing the next-generation breeding techniques as an example of genome manufacturing biotechnology was described with some exemplary applications.

• Challenge to the Limits of Bioproduction - Strategy for Break-through the Envelope of Process Efficiency -
Hideharu Anazawa (director, JBA)

Japan has a history of breeding amino acid fermentation microorganisms and has been strong in the research and development in this field. Directions for innovative technical development have recently been proposed that led to epoch-making improvement in productivity as compared to conventional fermentation methods.

One of them is the synthesis of the total genome of microorganisms, which was proposed by C. Venter, and the other is the minimum genome factory (MGF) study, which was started as a study of the NEDO project. In the MGF study, host strains containing a genome that is reduced to 25% to 30% of the original genome were produced by drastically reducing the genes that were not required to produce the desired substance and breeding strains containing a genome that was optimized for fermentative production. With these strains, the productivities of the desired substances have been greatly improved compared to the maximum productivities by conventional strains. For the future, the technique of breeding MGF strains is expected to be widely applied to other microorganisms and cells.

• Perspectives for Recently Emerging Genome Synthesis Technology: Universal Applicability, Rapidity, and Cost
Mitsuhiro Itaya (professor, Keio University)

Genomes are extremely large and fragile, and thus are really hard to handle. Although genome sequences are inexpensive, genome synthesis is expensive and takes a long time, and thus researchers cannot afford an error. Genomes are readily broken outside cells, and hosts other than *Escherichia coli* must be used to maintain them by cloning.

Keio University and Venter Laboratory succeeded in genome synthesis using *Bacillus subtilis* and *Saccharomyces cerevisiae*, respectively, as hosts. However, in this genome synthesis technique, there are many issues to be overcome with respect to universal applicability, rapidity, and cost. Cost and rapidity are particular bottlenecks in the universal application of this technique as a fundamental technology. Mr. Itaya described the aim of genome design and a perspective on synthetic genomes corresponding to the size.

• Evolutionary Engineering of Metabolic Networks
Daisuke Umeno (associate professor, Chiba University)

Now is the age of “writing” genomes on a large scale. Writing genomes that code for gene functions is an inefficient operation. To overcome the issue, the construction of the metabolic network of the host and systematized techniques for installing it are essential. First, metabolic pathways must be designed, and then they must be constructed with their control units.

Mr. Umeno explained the construction of regulatory networks for the purpose of productivity improvement referring to the biosynthesis of carotenoids and discussed how to construct complex integrated gene functions and how to utilize molecular breeding techniques in that process.

4) iPS Cell R&D Update

Moderated by Mitsuru Miyata (Executive Leader Writer, Nikkei Business Publications, Inc.)

• Induction of Pluripotency by Defined Factors
Shinya Yamanaka (Director, Center for iPS Cell Research and Application, Kyoto University)

iPS cells were first produced in 2006 from mouse fibroblastic cells and in 2007 from human fibroblasts and are characterized by high proliferative capacity and the capacity to differentiate into any type of cell (pluripotency). A group from the University of Wisconsin once announced that the efficiency of differentiation-induction from iPS cells was far lower than that from embryonic stem cells (ESC). However, with technical improvements that have been achieved in a short period of time by the Center for iPS Cell Research and Application, not less than 90% of iPS cells now have differentiation capacity under induction.

The Ministry of Education, Culture, Sports, Science and Technology started the program “Highway Toward the Practical Use of Regenerative Medicine” in 2011. By using iPS cells prepared from the cells of patients in cell transplantation, ethical problems as well as rejection can be avoided. However, this practice has the disadvantage that it requires a huge amount of money and time. That is why the concept of iPS cell banks (preparing and stocking cells from the specimens of volunteers) has been developed, but the problem of transplant rejection remains. Since rejection depends on individual differences in human leukocyte antigens (HLA), we intend to build a cell bank of iPS cells prepared from the cells of HLA homo donors. The use of iPS cells is not limited to regenerative medicine: there are attempts to utilize iPS cells in drug discovery. For instance, in the development of a therapeutic drug for patients with amyotrophic lateral sclerosis (ALS), the iPS cells of patients are differentiated into motor neurons and used for screening new drugs. Furthermore, in therapeutic drugs for heart disease, which have a drawback of long QT symptoms, it is under consideration to differentiate iPS cells into cardiac cells and use them for screening such adverse drug reactions to ascertain the possibility of adverse drug reactions in an early stage of drug development.

• Modeling with Pluripotent Cells in Regenerative Medicine
Juan Carlos lzpisúa Belmonte (Center for Regenerative Medicine in Barcelona)

The Center for Regenerative Medicine in Barcelona, which is the largest research institution for regenerative medicine in Spain, is studying the aging process of humans with iPS cells. HGPS, which is one type of progeria, is caused by abnormalities in lamin A, a nuclear protein. In order to elucidate the mechanisms of aging, iPS cells were established from the skin fibroblasts of patients with HGPS, differentiated into various types of cell, and used for analyzing the accumulation of progerin, a product of lamin A, and its effects. As a result, lamina A and progerin, which are expressed in skin fibroblasts, were found to be inhibited by reprogramming, and the expression of them was hardly observed in iPS cells; the cells were in a normal condition. However, in the vascular smooth muscle cells (VSMC) that were differentiated from the iPS cells, a high level of progerin was expressed, and the manifestation of aging, such as morphological defects and DNA damage, was observed. The speaker and colleagues think that an experimental system in which human aging can be observed in vitro in a short period of time can be established and are currently studying the introduction into cells of genes in which mutation of lamin A is inhibited with the aim of curing HGPS.

5) Biological Resource & CBD/Nagoya Protocol

Moderated by Katsuhiko Ando (director, Biological Resource Center, National Institute of Technology and Evaluation [NITE])

Almost a year has passed since the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing (ABS) was adopted at the 10th Conference of Parties (COP10) to the Convention on Biological Diversity. At BioJapan 2010 held last year, while focusing on ABS, a wide variety of topics that were directly related to the industrial world were discussed in order to convey the situation immediately before COP10. This year, examples of utilizing overseas genetic resources were discussed, considering that the Nagoya Protocol has entered into force.

6. Business Partnering

Business partnering presentations were held as one of the means for achieving *open innovation*, the largest objective of BioJapan. This year, 88 presentations were given by companies to introduce their excellent new technologies and ideas. Individual meetings using the Web Matching System were also actively held. The system is used to search for business seeds and alliance partners and helps arrange meeting dates in accordance with the schedules of both parties on the web. The number of meetings held in business meeting areas was 952 (336 on the first day, 341 on the second day, 275 on the last day), and the total number of meetings including those held in individual booths was approximately 2,000.

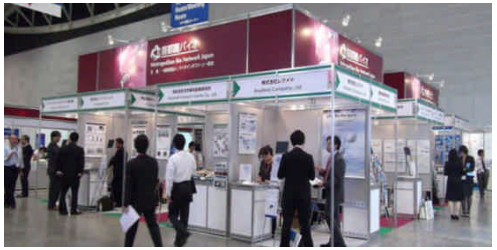
7. Alliance Promotion and the National Capital Region Bionetwork

Alliance promotion provides an opportunity for bioventure companies, in cooperation with bioclusters around Japan, to introduce their core competences and business plans to the drug industry in Japan and foreign countries. The promotion aims to help bioventure companies to form an alliance or make M&A deals with pharmaceutical companies, initiate collaboration, and earn funding in order to accelerate commercialization.

A total of 33 bioventure companies (7 companies in the drug discovery sector, 23 companies in the sector of support for drug discovery, and 3 companies in the healthcare sector) around Japan gave their presentations, including those in English, in 50 sessions. A total of 1,171 people attended those sessions.

The National Capital Region Bionetwork was established as a part of the Industrial Cluster Plan, and has engaged in various activities to help start and develop bioventure companies in the greater Kanto region. Companies in the network collaborated to participate in the exhibition to help expand the market, which is a burden for venture companies.

This year, a total of 21 companies, consisting of 6 companies in the drug discovery sector, 9 companies in the R&D instruments/reagents/services sector, 4 companies in the IT/bioinformatics sector, 1 company in the environment/energy sector, and 1 company in the contract research sector, participated in the exhibition.



8. Academic Seeds Presentations

These presentations are given to excellent or large companies in Japan and foreign counties in order to rapidly develop prominent technological seeds in major universities and research institutes in Japan into educational-industrial joint studies or technology transfers. A total of 20 universities and institutes presented the latest achievements in healthcare/drug discovery, food, metabolomics, cleaning soil contaminated with radio-activity, bioenergy, biorefinery, bio-device, disease model organisms, etc. through a total of 51 sessions.

These participating universities and institutes also made full use of the Web Matching System to actively hold individual meetings as opportunities to grasp chances for biobusinesses including introduction of technique, co-development, collaborative research, and investment.

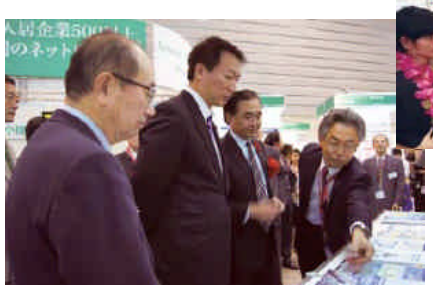
9. Postscript

Although there were some effects from the Great East Japan Earthquake, which occurred in March, such as canceling participation from overseas countries, BioJapan 2011 was completed with great success. We are grateful to the dedicated cooperation and support of many persons including exhibitors, speakers, visitors, supporting government agencies/organizations, local governments, and concerned personnel.

In particular, since large pharmaceutical companies exhibited alliance booths as in the last year in cooperation with the Japan Pharmaceutical Manufacturers Association, a large number of persons dealing with medical devices participated from Japan and foreign countries. This year, the extent of business matching was widened from healthcare and pharmaceutical sectors to medical devices, functional foods, cosmetics, and biofuels. Furthermore, the scale of academic seeds presentations was larger than those in the last year. After completion, many participants reported achievements, indicating that this event helped gain a foothold in actual alliance for collaborative research. Participation of medical universities involved in regenerative medicine made this event a solid platform for future industry-university alliances by their presentations on their cutting-edge outcomes. In addition, the active exchange that occurred among bioclusters all over Japan, biotechnology-related organizations, national and local government agencies, and corporate personnel have made BioJapan an intersection of activities for various persons related to biotechnology all over Japan.

These days, a further acceleration of open innovation is positioned as a key issue of Japan. As before, JBA will confer with industry, academia, legislators, and bureaucrats about various problems that bioscience and the biotechnology industry face. In doing so, JBA will focus on making BioJapan effectively function and develop as an opportunity to grasp new business chances related to biotechnology and dispatch information on excellent biotechnologies in Japan.

The next BioJapan2012 will be held from October 10 (Wednesday) to October 12 (Friday) at Pacifico Yokohama under the title “New Era of Open Innovation in Asia” on the major themes of life (healthcare/drug discovery, medical devices), functional foods, cosmetics, green (biorefinery, biomass plastics, environment, food), and bioclusters and venture businesses. You can expect BioJapan as *an opportunity to achieve open innovation*.



Organizer's Seminars in BioJapan 2011

In BioJapan 2011, JBA supported seminars on major themes of green (biorefinery, biomass-based plastics, environment, food), life (healthcare/drug discovery, medical devices), and bioclusters and venture businesses.

1. Green Innovation Summit

Date : October 7, 2011 (Friday) 12:30 to 14:30
Moderator : Hideaki Yukawa (director, Research Institute of Innovative Technology for the Earth [RITE], a Public Interest Incorporated Foundation)
Speakers : Kenji Fujiyoshi (chairman, Japan Chemical Industry Association)
Shigeki Suzuki (managing officer, Toyota Motor Corporation)
Colin Michinson (Genencor Biomass Applications director)
Steen Riisgaard (Novozymes A/S president and CEO)

In an opening speech, Mr. Yukawa explained as follows: Biofuels are in the phase of commercialization. From now on, the world's attention will be focused on biochemicals. The market size that the biorefinery plan assumes is estimated to reach approximately 230 billion dollars (approximately 20 trillion yen) in 2020, in which 67 billion dollars (approximately 6 trillion yen) will be bio chemicals.

Mr. Fujiyoshi mainly explained the commitment of the Japan Chemical Industry Association. In particular, to disprove the ungrounded notion that the chemical industry is a "dark industry", he described the results of quantitative evaluation of the amounts of exhaustible resources used and the amounts of greenhouse gases (GHG) used throughout the lifetime of chemicals and chemical synthesis products on the whole by life cycle assessment (LCA) approaches. From the viewpoint of "avoided emissions" of GHG, he showed the contribution of the chemical industry to reduce environmental load compared to the inconveniences resulting from not supplying chemicals and chemical synthesis products to the world. The GHG-reducing effects of heat insulating materials in the living climate and the desalination of seawater with reverse osmotic membranes have been shown to be extremely high. The speaker also explained the shift of raw materials to nonedible biomass to reduce the use of exhaustible resources and the development of biocatalysts with low environmental load.

Mr. Suzuki explained the commitment of Toyota Motor Corporation to achieving a green society. The company aims to minimize the negative aspects (exhaust gas, accidents, etc.) of automobiles and maximize the positive aspects (convenience, amenity, etc.) of them. The company is committed to the commercialization and production of hybrid automobiles and more evolved plug-in hybrid automobiles and electric automobiles as well as the greening of interior and exterior materials.

In addition, the company has recently succeeded in the development of an extremely efficient biocatalyst to be used for producing biofuels from herbaceous nonedible biomass. The company attracted attention for its systematic effort to achieve zero emission of GHG by systematic integration of housing/solar system and plug-in electric automobiles in cooperation with a group company involved in housing business.

Mr. C. Michinson explained the situation of the research and development of biocatalysts that enable the production of biofuels on an industrial scale. On August 12, 1999, the U.S. government announced its policies related to the development and wide-spread use of bio-based products and bioenergy as one of the strategies for biotechnology for the 21st century.

In tandem, DuPont announced its basic plan for shifting its chemicals/chemical synthesis products/polymers to bio-based products. Ethanol, buhanol, succinic acid, 1,3-propanediol, isoprene, etc., have already been bio-processed, and the production of biofuels and biopolymers (polybutylene succinate terephthalate, poly-trimethylene terephthalate, polyisoprene, etc.) on an industrial scale is reaching realization. In particular, the company plans to achieve the production of a tire ("biotire") using polyisoprene produced as a biosynthesized rubber in 2016, which will have an incalculable impact on the industry.

Mr. S. Riisgaard explained the inevitability of shifting to biorefinery and the role of enzyme catalysis, the technology for which company has an edge, in achieving the shift. The production of ethanol derived from cellulose, to which the company is committed in various regions of the world, will presumably start in 2012 in Europe, 2013 in North America and China, and in early 2014 in South America. Behind the rapid development toward the commercialization of fuels derived from nonedible biomass is an increasingly active cooperation among companies and industries forming value chains.

1. Life Innovation Summit

(Partnerships among Pharmaceutical Companies, Bioventures, and Academia in Asia)

Date : October 5, 2011 (Wednesday) 15:00 to 17:00
Moderator : Isao Teshirogi (president, Japan Pharmaceutical Manufacturers Association)
Speakers : Tatsumi Yamazaki (chairman of Steering Committee, JBA)
Greg Wiederrecht (vice president & head, Merck & Co. Inc.)
Hao Yan (president & CEO, EPS Corporation)
Jonghoon Choi (chief researcher, Korea Bio-Economy Research Center)

In an opening speech, Mr. Teshirogi explained the objectives of the seminar as follows: Globalization in recent years means an alliance between academia and venture businesses, not among big companies. As the world pharmaceutical market is growing by approximately 7% to 8% a year, the market share of Japan, the United States, and Europe is declining while that of Asia is rising. The population in Asia is predicted to grow explosively by 2050, which will increase the demand for drugs in Asia. In the United States, many drugs are originated from academic ventures.

Although it is acknowledged that Japan and Europe are competent in basic studies, they are definitely behind in commercialization. It is meaningful to consider how we will be better at drug discovery.

Mr. Yamazaki explained pharmaceutical development in the future and JBA's commitment as follows: As developments are made in genome analyses and iPS cells, what is under discussion is what types of medical treatment will be practiced in future. While new fields of treatment emerge, such as regenerative medicine and vaccines, it is important to inhibit unexpected side effects. Furthermore, in an age of individualized medicine, treatments are required to take the QOL of individuals into account.

Not only therapeutic drugs but also diagnostic agents and medical devices need to be integrated in one science. A new open innovation is required for that purpose. Thus, JBA have participated in BIO-Asia, BIO-China, Global Bio&Medical Forum (Seoul), and Bio Taiwan to try to make use of Asian advantages for bio innovation. We planned to establish the "Council of the Asian Bioindustry Associations", an integrated council on the development of bioindustry, whose members are Japan (JBA), Korea (KoreaBio), China (Beijing, Shanghai, CAS), and Taiwan (ITRI). The members contribute information on their own activities and integrate knowledge and information.

Mr. Wiederrecht spoke of the importance of open innovation in pharmaceutical development and alliance in the future. Recently, the pharmaceutical market has shifted from low molecular weight pharmaceuticals to biopharmaceuticals, from industrialized countries to emerging countries, and from megablockbusters to a wide range portfolio.

While the U.S. economy slowed down and fell into single-digit growth rates since 2008, the market size for biopharmaceuticals has become 2.5 times than that for biotechnological drugs. Major pharmaceutical companies have begun various reforms, and the roles of pharmaceutical companies, academia, and venture capitals are changing. As partnering becomes vigorous, many companies are reducing research and development expenditure. Morgan Stanley reported that former "research and development" should be changed to "search and development." Many companies changed their business models because introduction of compounds from outside the company is three times as efficient as research and development. However, Merck is maintaining its research capacities exactly because good partners can be obtained.

In the past one century, innovation meant establishing large research institutes to develop technologies and high-margin drugs and invest the profit earned therefrom into the next research. However, in open innovation, knowledge is allowed to flow in and out on purpose to accelerate inner innovation and expand outer markets. Outside professionals and outside research and development are utilized, while maintaining the company's own research and development capacities. Merck is strengthening its partnerships with universities and actively participating in joint ventures.

Mr. Yan explained the activities of EPS Corporation as follows: EPS started cooperation between Japan and China in the healthcare industry three years ago. The company has been involved in clinical development in Asian countries as of seven to eight years ago. Since studies for the purpose of filing applications for marketing approval are increasingly conducted in Japan, Korea, and Taiwan, EPS Asia Pacific was established in Shanghai as the headquarters for clinical studies conducted in the Asia-Pacific region. Japan still seems to have an edge over China in the healthcare sector. EPS China was established to start providing drugs and healthcare services because Japanese products have not gained recognition in Chinese market. Technologies are to be introduced from outside the company, and alliance with Chinese partners is needed for venturing in China because China has the healthcare/insurance system and market needs that are different from those in Japan. The company is making a platform to accommodate funding from Chinese funds and government measures for the promotion of biotechnology industry.

Mr. Choi spoke of changes in healthcare in Asia as follows: As the aging of society progresses in the future, we need to establish a reliable healthcare system, but the systems in Europe and the United States cannot directly be introduced in Asia. A cost effective healthcare system is needed. That is where collaboration within Asia is possible and various technologies must be introduced. We need a cost-effective healthcare system based on human genome information. Since mutation is different from race to race, biotechnology revolution is increasingly facilitated as human genome information increases. The biotechnology revolution will occur when the cost of sequencing a total genome becomes 1,000 dollars or less. The collaboration for the next generation healthcare system in Asia is based on genome information of Asians and is aimed at a cost-effective system. Japan and Korea can contribute technologies and capital, and China can contribute market. Since Asians have many cultural and racial similarities, collaboration might as well be focused on the development of regionally specific healthcare.

3. Cluster Summit

(Global Collaboration among Bioclusters)

Date : October 6, 2011 (Thursday) 9:30 to 11:30
Moderator : Tsuneaki Sakata (visiting professor, Osaka University)
Speakers : Ulf Aberg (Denmark: senior business development manager, Invest in Skane)
Karimah es Sabar (Canada: SVP Business & Strategic Affairs, Center for Drug Research and Development)
Andy Gearing (State of Victoria, Australia: CEO, Biocomm Squared)
Mario Pennisi (State of Queensland, Australia: CEO, Life Science Queensland Limited)
Takashi Miki (Bureau director general, City of Kobe)
Yoshifumi Ikeda (Bio Project producer, Kurume Research Park Co. Ltd.)

In reference to four bioclusters in foreign countries and Kobe and Kurume, the present state, method, and issues of cooperation between bioclusters and the industry in Japan were explained.

Mr. Aberg spoke of Medicon Valley (MV) located on the border of Denmark and Sweden. With a sufficiently large ambient population of 3.5 million, the region plays the role of “gateway port” to the European market of 500 million people for Japanese companies. In recent years, since Takeda Pharmaceutical Company Limited bought Danish Pharma and Nycomed, the relationship with Japanese companies has increased. The region accommodates six large pharmaceutical companies and has an edge in diabetes, obesity, neuroscience, etc. The number of Danish biotechnology companies are increasing, and approximately 160 Danish companies are located here today. The number of development pipelines in this country ranks third in Europe, and the country exports a large amount of pharmaceutical products. MV is an optimum window for Japanese companies to establish local subsidiaries, start collaborative businesses in Europe, establish a hub for FS, gain information on the basic studies conducted in local universities, introduce drug candidates, and perform M&A with local companies.

Ms. Sabar explained how the Center for Drug Research and Development (CDRD), a unique organization that support academic drug discovery, works. It is an open-innovation-type nonprofit government-private organization established about five years ago. The organization supports the development of seeds that are expected to be commercially successful by such means as subsidizing POC study research fund. When drug discovery with CDRD was successful, the project is then transferred to CDRD-Venture Inc. to start commercial development in cooperation with venture businesses etc. The CDRD has collaboration agreements with excellent universities and research institutes in many countries as strategic partners. In Japan, the CDRD has an alliance with the University of Tokyo TLO. On average, the CDRD is capable of spending 18.5 million dollars per project. The spending is originally funded by large pharmaceutical companies such as Pfizer, Johnson & Johnson, and Roche, and the provincial government of British Columbia. The center has a support infrastructure corresponding to pharmacology, toxicity, medicinal chemistry, and pharmaceutical preparation. Taking advantage of the cooperation with a large number of organizations in foreign countries, the CDRD helps development in cooperation with brains around the world.

Mr. Gearing explained the strength of Australia in biotechnology, which is backed by the thriving Australian economy. Australia has a history of more than 100 years of research and development, 9 universities, and 15 laboratories. Australia has completed the deployment of large-scale devices such as NMR and the formation of a clinical trials network. Available funds include angels within the wealthy population and venture capital firms. The country has a wide scope of experience in bio-venture, research and development by pharmaceutical companies, business development, management, and marketing and can provide services such as various consultation, finance, and technology evaluation. The activities of CSIRO (the Commonwealth Scientific and Industrial Research Organisation) have so far been successful, and CSIRO has a translation budget of about a billion dollars, including investments from the commercial sectors.

Mr. Pennisi explained the Queensland Clinical Trials Network (QCTN) for supporting clinical trials and Life Science Queensland, a new organization involved in the field of biotechnology, such as agriculture. The QCTN was established in 2005 and now has over 100 member companies. Japanese companies attempting to expand to Europe and the United States with a new drug can conduct bridge studies on the QCTN and file an application in Europe and the U.S. Based on the success of the QCTN, Life Science Queensland was established in 2011 in order to expand the activities of the QCTN from the medical field to all fields related to biotechnology, such as agriculture.

Mr. Miki explained the status of the rapidly developing Kobe Biomedical Innovation Cluster. The cluster was established as a part of the millennium project in the 1990s and has rapidly been growing since 2003. The cluster is home to 11 core facilities, including the International Medical Device Alliance, and over 200 healthcare companies. The construction of the next generation super computer “K” in the cluster was decided in 2007, and the computer is scheduled to start operation in the spring of 2012. In the cluster, 4,400 people are employed, and 203 companies are located. To contribute to Asia in the field of measures to address the aging of society, the cluster, centering around the city of Kobe, aims to be the No. 1 biomedical cluster in Asia.

Mr. Ikeda explained the 10 years of the history of Kurume Research Park since its opening as well as its active commitment to collaboration with overseas organizations. MOU has already been concluded between the research park and Korea, China, and Australia. What was difficult with MOU with Australia was the difference in the regulatory system. For example, there is a distinction between a physician-initiated clinical study and a clinical study sponsored by a company in Japan. In the cluster, 2,782 people are employed, and 63 companies are located. The number increased by 70% in 10 years. As achievements, 64 products have been commercialized, a budget of 5.6 billion yen was acquired, and one company went public (IPD). In the future, the research park will correct the overdependence on drug discovery and focus its efforts on biomass, biotools, medical devices, and functional foods.