

Analyst Interview

"CYBERDYNE's Challenges to Shape the Future"

We have invited Hidemaru Yamaguchi, an eminent analyst in the field of medicine and healthcare, for an interview with Yoshiyuki Sankai, President and CEO of CYBERDYNE, INC. (the "Company") to discuss the Company's challenges to shape the future. This interview took place on August 4, 2016 and is scheduled to be published in the Annual Report 2016, but its contents are being released early for the Company's shareholders.

Interviewer: Hidemaru Yamaguchi

Managing Director, Pharmaceutical & Healthcare, Citi Research

Hidemaru Yamaguchi joined Salomon Smith Barney (currently Citigroup Global Markets Japan Inc.) in April 1998 after working at Nomura Research Institute and Nomura Securities as an analyst since April 1988. He graduated from Tokyo University with a major in agriculture and received his MBA from UCLA in June 1997, where his major was finance and entrepreneurial studies. He is also a chartered member of the Security Analysts Association of Japan (CMA).

Acceleration of CYBERDYNE's business since its listing

Yamaguchi: Two years and four months have passed since CYBERDYNE was listed in the Tokyo Stock Exchange. Could you briefly summarize what happened in these years and the Company's current status?

Sankai: We have been accelerating our business ever since our listing. Firstly, the listing allowed us to firmly move toward obtaining medical device approval for HAL in Japan. Following our acquisition of this medical device approval in November, 2015, we importantly were able to receive a remuneration price for coverage by public health insurance for our device. In addition, we were able to expand our product lineup with HAL for Living Support (Single Joint Type), HAL for Care/Labour Support (Lumbar Type) and others, as well as make good progress with the development of new products such as the Vital Sensor toward their release in the market. The listing also provided us with many opportunities to collaborate with other companies, helped us acquire talented personnel and allowed us to organize the structure of the Company's internal systems.

Overcoming the most difficult obstacle of demonstrating medical effects for rare neuromuscular diseases ~ Toward expanding target diseases

Yamaguchi: You started with the acquisition of medical device approval for rare neuromuscular diseases. What is the strategy behind this? What is your strategy for expanding HAL's target diseases?

Sankai: HAL is a new medical device that has been tested for the treatment of 8 diseases grouped together as slowly progressive rare neuromuscular diseases in clinical trials. Until now, no treatment was available in modern medicine for these diseases, and while suppressing the advancement of these diseases would already be a valuable result, HAL was shown to go further and improve their diminishing functions. In Japan, randomized controlled clinical trials are the standard for obtaining medical device approval, so we conducted an investigator-initiated cross over trial led by Dr. Takashi Nakajima of the National Niigata Hospital at 10 different facilities. This trial was conducted in compliance with Good Clinical Practice ("GCP"), an internationally recognized standard for clinical study procedure that is considered especially important in the U.S. This GCP was crucial because it was important that these results for the treatment of notoriously difficult diseases be recognized internationally, and that each regulatory authority could acknowledge the immense potential that HAL possesses. These results led to the HAL's medical device approval and medical insurance coverage, and with its increased use in many hospitals, the road to expanding HAL's target diseases to stroke and spinal cord injuries should be easier. In other words, as an approved medical device that is covered by medical insurance, the hurdle for physicians to test this device on other target diseases under a clinical study should be much lower. In fact, preparations for the next clinical studies and clinical trials have already begun.

No limit to the number of treatment sessions covered by insurance for patients with slowly progressive rare neuromuscular diseases

Yamaguchi: The insurance reimbursement price was determined in April, 2016. How do you see this insurance price evaluation? Also, your business model in Germany where your company shared the insurance payments with the medical institutions attracted a lot of attention, but will the business model be the same in Japan?

Sankai: Although the insurance reimbursement price in Japan is a little lower than that of Germany, it is roughly at the same level. While the insurance in Germany will cover a treatment package of up to 60 treatment sessions, Japan's Ministry of Health, Labour and Welfare took the nature of the progressive rare neuromuscular disease into consideration and decided to continuously cover the treatment with insurance as long as an effect can be seen. The determination of this price involved the input of an organization of experts in this medical field, so I think it will remain at this level for a while. As for the business model in Japan, the basics are similar to what we have set up in Germany, but we have added a few improvements.

Vast number of potential patients ~ Possibility of new combinations with private insurance

Yamaguchi: While the utilization of public health insurance provides stabilization for your business model, there is a vast number of potential patients who could benefit from HAL, and when patients increase from expansion of target diseases in the future, I suspect there will be discussions on how far public health insurance can continue to provide coverage. Do you have plans for perhaps collecting payments from private insurance companies or out of pocket payments?

Sankai: Of course, I anticipated such a situation long ago, and have been in discussion with a number of notable Japanese and foreign insurance companies. In the future I think it will be very important to combine the scheme of public and private insurance, and I have been steadily moving this plan forward.

Fusing HAL with regenerative medicine ~ Research on functional improvement/regeneration of the brain, nerve and muscle systems

Yamaguchi: In Japan, research on regenerative medicine, especially around iPS cells, is very advanced. How do you see the prospects of synergy with HAL and regenerative medicine?

Sankai: HAL's intended purpose is to regenerate or improve the functions of the brain and nervous system that are innate to the human body. Humans are able to move because a feedback loop maintains the proper transmission of nerve-related bio-electrical signals between the brain and nervous system and the musculoskeletal system (motor nerve signals from the brain to the peripheral muscles, and sensory nerve signals from the periphery to the brain). However, once the patient's disease interferes with proper signal transmission and interrupts this feedback loop, the patient's ability to move becomes compromised. HAL detects bio-electrical signals in real-time,

completes a new connection between the human and the robot, and accelerates the establishment of a functional improvement and regeneration loop of the brain, nerve, and muscle systems. In addition to the medical device approval and insurance coverage I mentioned earlier, we also possess the international patent for this foundational principle, so HAL remains the only practically-implemented cutting-edge technology of its kind. Regenerative medicine can increase the number of nerve cells, and HAL can accelerate the functional regeneration and improvement by strengthening synaptic connections, so by combining HAL and regenerative medicine, we can expect an even greater treatment effect.

The world's first public health insurance coverage ~ HAL's unique motion principle

Yamaguchi: There are many devices with a similar appearance being developed and implemented around the world, especially in the U.S. How do you differentiate HAL from these other devices?

Sankai: What makes HAL unique is the fact that HAL is the only device in the world covered by public medical insurance, meaning HAL successfully provided enough medical evidence worthy of coverage. HAL has a unique motion principle, that utilizes bio-electrical signals that are related to commands from the user's brain in order to successfully fuse the functions of the human and the robot. This cyborg-type robot establishes an interactive biofeedback loop based on the signals that reflect the user's intent, and induces functional regeneration and improvement. This unique feature requires the proper detection of the user's voluntary signals and the establishment of this interactive biofeedback loop to be effective. The other devices are not designed to work in this way, and that is why HAL is a one-of-a-kind device.

High barrier for entry into the field ~ HAL's technology leads the world in both its motion principle and intellectual property

Yamaguchi: What is your take on the risk of other companies making devices that are similar to HAL? It is my understanding that HAL is a front-runner in its field but is it possible for others to catch up?

Sankai: In order to make a device with similar features, there are obstacles in terms of the basic and related patents, and several core technologies would be required, so catching up would be difficult. In recent years I have been seeing more robots that appear visually similar, but none of these devices have the features that embody HAL's core technology and none of them are covered

by public health insurance. As for the patents, generally speaking, a patent normally describes how things like mechanisms or electrical circuits were tweaked, but for HAL, the patent describes the principle of using brain and nerve derived signals to control a wearable robot as if it were a part of the wearer's body, leading to appropriate synaptic connections of the nervous system. The patent is for this principle and does not include the specifics of how we make this principle work, so it would be very difficult to enter HAL's territory. Of course we also have a patent for the principle of control that combines this method of voluntary control with a preprogrammed method of autonomous control. We jointly possess over 100 published patents with the University of Tsukuba that are in line with our business, and CYBERDYNE has the exclusive license to use them. Our patent structure is very strong.

Discussions with the FDA to clearly differentiate HAL from other devices

Yamaguchi: HAL has obtained medical device approval in the EU as well as in Japan, but what is the current status of FDA approval in the U.S. Also why are you setting up your U.S. subsidiary in Seattle?

Sankai: Because a category for "powered exoskeletons" already existed within the FDA, we were pressed to proceed with our application in that category. While FDA's medical device approval is independent from discussions for insurance coverage, for our future business development in the U.S. market, it is important that HAL is recognized as a different device than the others "powered exoskeletons" in the market. We are therefore discussing ways in which we can establish this differentiation with the FDA.

We decided to set up our U.S. subsidiary in Seattle because there is a highly esteemed medical network with a team of leading experts in the field of neurology that is working with HAL in the West Coast. This team is also well connected with the medical team in Germany, forming a global platform for research on HAL in the two countries that lead the world in medicine.

HAL (Lumbar Type) moves as intended ~ Scientifically shown to reduce strain in the lower back

Yamaguchi: Lets talk about HAL (Lumbar Type). There are many other similar devices in this field as well. What makes HAL (Lumbar Type) different?

Sankai: HAL (Lumbar Type) also uses the basic principle of HAL, and is controlled by a healthy wearer's bio-electrical signals related to the commands from the brain and nervous system, so its support is not triggered by any buttons or joysticks. When a wearer tries to lift an object, the weight of the object affects the amount of signal produced by the wearer, and since HAL uses these signals to control the amount of support to provide, HAL's support is automatically adjusted to fit the needs of the wearer. Furthermore, another important fact is that HAL is the first product in the world to be medically and scientifically analyzed, designed and developed to reduce the stress applied to the lower back. HAL (Lumbar Type) creates an appropriate, safe working environment in physically demanding professions by reducing strain on the lower back, preventing lower back pain and allowing workers to continue working longer in their careers.

A new cornerstone for early detection and prevention ~ Daily measurements of arteriosclerosis and cardiac function with the Vital Sensor

Yamaguchi: Can you explain the specifics of the business plan for the Vital Sensor?

Sankai: We are developing and planning to produce several types of Vital Sensors. The first one that will go through the approval process, productization, and business modeling is a palm-sized device that can detect measurements of arteriosclerosis and heart function equipped with communication systems that are compatible with IoT. It is a device whose data has been compared to that of the much larger devices currently used in hospitals, and a strong correlation has been confirmed. Until now, measurements of arteriosclerosis and heart function could only be done in hospitals, but this device allows users to make daily measurements at home or at the workplace. The easily portable size of the device and its communication systems to manage data are extremely important features from the perspective of early detection and prevention, making it possible to formulate a good business plan. Currently, we have completed the product model, and have started discussions with the PMDA (Pharmaceuticals and Medical Devices Agency). In other words, we have started preparations to distribute the Vital Sensor as a medical device. Furthermore, all of CYBERDYNE's devices are equipped with communication systems that are IoT compatible, so CYBERDYNE will be able to manage all of the data collected from this Vital Sensor, all of the different types of HAL (Medical Use, Living Support, Single Joint Type, Lumbar Type), and the cleaning and transport robots.

Creating future airports with Cybernic technology ~ Integrated application of big data

Yamaguchi: I have noticed that you started an operation targeting airports using devices like the transport robot. Right now, the focus seems to be on Haneda Airport, but how are you planning to develop this business?

Sankai: This is a project to create the future of airports. There are tasks conducted at the airport such as transportation, cleaning, and loading and unloading luggage that we want to support with our robots. Most of the workers involved in these tasks often must bend at the waist, causing a lot of strain on the lower back. From a safe working environment perspective, this enterprise between CYBERDYNE and Haneda Airport is meaningful and significant. This is also a sign that the products we have been rapidly developing since our listing are now reaching a stage where they can be implemented in new business fields. It is also important to note that all of these robots and devices have communication systems that are IoT compatible, so the collected data can be made available to the airport's data management, providing valuable and useful information. Last year we began with the domestic terminal, and this year, after some improvements were made, we have expanded operations to the international terminal. Because airports are typically designed with the same format, once this system is all compiled, we can work together with other airport management organizations to expand our technology across the globe.

The next-generation multipurpose robotized production facility that surpasses Industry4.0 ~

Combining the skill of experienced engineers with robots and AI

Yamaguchi: Your Company is coming out with new products one after another, but how is your production capacity?

Sankai: The first stage of construction on our facility in Fukushima is now complete, and a ceremony will be held on August 22. This base will be made into a next-generation multipurpose robotized production facility. An organization that is serious about its cutting-edge technology cannot be satisfied with simple robotization. Typically with robotization, the intent is to reduce manufacturing costs by automating simple routine processes for mass production. However, in state-of-the-art manufacturing enterprises, experienced engineers and skilled workers who add ingenuity are the ones who are thriving. CYBERDYNE's next-generation multipurpose robotized production facility will be a robotized system that learns and evolves alongside these experienced engineers and skilled workers. Upon completion, this next-generation production base will

combine Cybernic technology that collects and amasses information from humans with artificial intelligence and robots, and will surpass standards set by Industry4.0. On the other hand, processes that can be conducted via routine will be efficiently handled through collaboration with three cooperative companies. One of these companies is world-renowned and typically does not participate in assembly of other companies' products, but they have agreed to make an exception for CYBERDYNE and we are very grateful. It is our intent to contribute toward a win-win relationship with these collaborative companies.

Creating the next enterprise using big data on physiology and environment

Yamaguchi: Earlier when we were talking about IoT, you mentioned big data or the collection of various data, but how are you planning to use this information?

Sankai: While I could talk about what is being prepared, the timing is not yet appropriate for such a discussion, so please stay tuned for future announcements. However, if you can just imagine what things you can do with such information, I think it is clear that there are many possibilities. We will be collecting information from humans, and information from robots while they do tasks like cleaning. I think I will leave it at that.

Another thing I can talk about in terms of using and analyzing the data we collect is "learning." A key point for robots is learning. By using HAL, the user's physical functions and nervous system change, and for HAL to fit to each person's unique characteristics, it must be equipped with an adaptive learning function. Back in the late 80s, I was involved in the research and development efforts in Japan on the learning mechanism of the neural network that formed the core of deep learning. At the time, I had come up with an algorithm that was seemingly good, but due to lack of processing power, I had to give up on its development. The processing power available now is on a different dimension compared to back then, and I am excited that a very interesting era has finally arrived.

Furthermore, if I may add another point, if you want to proceed with how we can use big data, what else would we need other than "data" and "learning"? The answer of course is computers. Thus, we have partnered and invested in a company that is independently developing supercomputers to handle the information of the new age. This partnership may also have a large influence on our future business.

CYBERDYNE's market scale spans solutions to social problems itself, not just robots

Yamaguchi: I am often asked by investors about your company's market capitalization. At about 400-500 billion yen, your company's market capitalization is staggeringly large compared to other robotics companies in the world. The high evaluation reflects the high level of appraisal your technology has received, as well as an anticipation for the creation a large new market. However, among some investors, there are opinions that perhaps the market capitalization is too large compared to the current size of the company. As the CEO, how do you interpret this criticism?

Sankai: If you compare us to other robotics companies, it may appear that way, but for CYBERDYNE, the field of robotics is only a part of its business field. CYBERDYNE is a company that solves social problems using innovative Cybernic systems, and establishes new markets through advancements of innovation. At its core, the company is built around Cybernic systems, a new field involving the fusion of human, robot, and information systems. CYBERDYNE's business development will lead to a social and industrial transformation, where we believe that our cutting edge devices developed with Cybernic technology will lead the way in bringing about drastic changes in the lifestyles of people in society and the way industries are structured. I am thoroughly excited for what lies ahead, and will continue to work hard and bring happiness to our many investors.

Significance of both innovation and steady monetization

Yamaguchi: This is another point I am often asked about, but your company has only posted deficits so far, though not by a large amount. It seems like the company is approaching the stage where the business is steadily strengthening, sales are rising, and profits are expected, but there are several investors who are worried that you may still struggle to become profitable. How do you feel about your setup in terms of increasing revenue?

Sankai: In Japan, we were able to establish a steady economic cycle with the coverage of the treatment with HAL by public health insurance. We will further strengthen this steady economic cycle by expanding HAL's target diseases.

If we were to compete in an existing market, we would have to focus on competitive pricing or improved functionality. However, since becoming listed, CYBERDYNE's business has been the social problem of super aging societies in developed nations itself. This unexplored field has "No Market, No User, No Industry, No Professional, No Social Rule," and we are looking to replace

these 5 "No's" with "New." For this reason, it is necessary to establish a steady economic cycle where profits are made within the cashflow, as well as the foresight to strategically lay the foundation for the next step of business development.

One of the steady economic cycles I mentioned involves medical insurance, which is embedded in the social system. This medical insurance system is built to allow for companies to establish a reliable economic cycle, but the hurdle to enter this system is very high, even for large companies. Entering this system is a step-by-step process, making sure to obtain approval from the regulatory agencies and receive a clear declaration from insurance systems to cover treatment with the device. CYBERDYNE's HAL has cleared these hurdles in the medical insurance systems in a way that is beneficial for the company, the patients and the medical industry. As a result, we were able to obtain insurance coverage for treatment with the device, and have set up a steady economic cycle. We have made agreements and are making final arrangements with hospitals that are set to be the central bases for HAL treatment in each region, and with their cooperation, we will collect post-market surveillance information, advance our efforts to expand target diseases, and develop the business more efficiently.

As for laying the foundation for the next step in business development, I have mentioned our plans on big data, plans to develop future social infrastructure such as our work at Haneda Airport, and most recently our work in combining HAL with regenerative medicine to develop innovative composite medical technology. Expectations in this field are extremely high. The field of regenerative medicine is nearing the end of a long long tunnel. In other words, it will soon take the next step into the world of applied treatment. Several clinical trials have already begun. The doctors in the medical industry who want to maximize the effects of treatment believe that our HAL will serve an extremely important role in achieving functional regeneration of the nervous system and physical functions.

Advancing the business with carefully selected, highly talented personnel

Yamaguchi: My impression is that you have hired many engineers and scientists with Ph.D.'s, but what is your current situation?

Sankai: Since our listing, only 6 new R&D members have been hired. Typically, increases in R&D members lead to concerns over an increase in R&D costs, but we are conducting things very

efficiently. The R&D members that I have personally instructed toward their Ph.D.'s and a few very talented R&D hires act as project leaders, forming teams of other employees and R&D support members. In a short amount of time, these teams have increased the number of products in our lineup fivefold. Most of the project leaders hold a Ph.D., and since they were carefully selected, each has the ability of 3 to 5 normal hires.

Yamaguchi: As you expand to other markets abroad, I assume you will need someone responsible for the business overseas, as well as marketing efforts, correct?

Sankai: Yes. Such staff is necessary in both the headquarters and at each domestic and foreign subsidiary. Excellent personnel including foreign natives are gathering to work for us.

Peaceful use of technology ~ a statement of intent regarding CYBERDYNE's role as a company.

Yamaguchi: Finally, the US has one of the strongest military industries in the world and cannot be separated from its robot industry, and I want to once again ask and confirm the meaning behind why you keep the two fields separate?

Sankai: CYBERDYNE's role is to develop technologies and a business that focus on solving social problems. The energy and environment issue is a good example of a social problem that we humans must face, but another crucial issue is the super-aging society. Whether we can solve this issue will directly affect the way society continues to exist, and we therefore believe that there will be demand for this business.

As for our thoughts on military use, we wanted to make it very clear to all of the shareholders which direction this company is moving toward, and how resolved it is to stay on course, and so we used the key words "Peaceful use of technology" as a statement of intent in the prospectus at the time of the company's listing. Furthermore, we were able to be listed using class shares with different voting rights to ensure this intent.

For example, take a situation where rescue workers have to enter a disaster zone where many unknown particles are drifting through the air. The worker must wear protective gear and various sensors, and must also carry heavy gear like a gamma camera. Once the protective gear is worn, the heat inside will reach dangerous levels, so a cooling device must also be carried. The worker must conduct dangerous rescue work under all of these conditions, exposing himself to many risks. A device like the full-body HAL can provide a solution to these issues by protecting the wearer from

radiation, chemicals, and even biological threats, and can help carry the weight of the cooling device and a 15kg gamma camera. But this is just about as far as the line goes in terms of the technology that the company is willing to develop in the gray area between industry and military use. It is important to maintain a firm philosophical foundation in the company, and every employee must keep this in mind from the start of technology development through its social implementation.

Yamaguchi: Thank you for your time today.