

CHALLENGER Naoki Shinohara

***I want to contribute to the advancement of medicine through the development and marketing of biopharmaceuticals.***

Biopharmaceuticals are manufactured by applying cell culture, genetic recombination, and other methods. Biopharmaceuticals also have follow-on products that are released after the patent has expired. While generic drugs can be produced using the same recipe as the original drug, it is difficult to produce identical products for biopharmaceuticals because the active ingredients, such as hormones, enzymes, and antibodies, have large molecular weights and complex structures. Subsequent products are called "biosimilars" as they use the same active ingredients as the original drug. They are required to demonstrate equivalence and homogeneity with the branded drug in terms of quality and safety, and require the same testing as the new drug in order to pass the review. Biopharmaceuticals and biosimilars such as insulin, etanercept, interferon, and antibodies are essential for the treatment of cancer and immunological diseases, but most of these drugs used in Japan are foreign products. "While South Korea and other countries were quick to take the initiative in acquiring manufacturing technology and building facilities, Japan has lagged behind in development, and such drugs are extremely expensive. Japan's social security costs continue to increase, and in an environment of an aging society and increasingly sophisticated medical technology, the economic burden of medical costs will continue to weigh heavily on the next generation. I would like to contribute to the reduction of medical costs by producing biosimilars in Japan," said Naoki Shinohara, President and CEO of Japan Biotechno Pharma, Co., Ltd. Founded in 2016, the company is working to produce antibody drugs at its San Francisco lab, as well as developing in vitro diagnostic test kits to predict the onset of Alzheimer's and Parkinson's diseases, and kits to measure drug and protein levels in the blood. "Alzheimer's disease is a very difficult disease to treat. Alzheimer's disease is one of the most difficult diseases to treat, but risk factors that increase the likelihood of developing the disease have been identified, and preventive medication can be used to reduce the incidence of the disease in those who have it. If we can take preventive action against dementia with the help of test kits, we can extend healthy life expectancy, which will also help reduce social security costs." If we can reduce the cost of drugs, which account for a large portion of medical expenses, we can increase the remuneration of medical service providers while also improving the quality of medical care. "People tend to think that doctors make a lot of money, but that's not always the case when you consider the balance with working hours. Among them, I feel that the field of surgery is facing a major obstacle in terms of education system and labor force processing. There are some cardiac surgeons in Japan who are called upon 24 hours a day to perform difficult surgeries,

but are paid less than one-tenth of what they are paid overseas. In addition, Japanese doctors in the field of surgery are aging as a whole, and if this trend continues, Japanese patients may eventually have to travel overseas for surgery." In order to contribute to Japanese healthcare beyond pharmaceuticals, Shinohara established Next Innovation

Partners Co., Ltd.

The company provides consulting services for pharmaceuticals and medical devices, management of academic societies, and preparation of materials for negotiating NHI prices for new drugs. "I will continue to work on various projects to materialize 'what I wish I had' for the future of medicine, such as the project to train the next generation of cardiac surgeons." When he was a student, Mr. Shinohara was devoted to theater and ran his own theater company. When he was job hunting, he wanted to work in the mass media industry. "However, I didn't get any job offers, and one of my seniors suggested that a foreign pharmaceutical company might be interesting because of its future potential. That's how I got into the industry," he says. At the foreign pharmaceutical company, Mr. Shinohara was mainly involved in sales and marketing, and his career progressed steadily. "However, although I felt that my work was worthwhile, I began to ask myself, 'Is it enough to just sell medicines like this?' and 'Am I helping medicine and patients?' At that time, a scientist acquaintance of mine asked me, 'Don't you think about manufacturing biotechnology products in Japan?' Certainly, I was also concerned about various issues in Japanese medicine, such as the lagging biopharmaceutical industry. However, it was first of all impossible to do so in a foreign company due to the policy of the home country. So, I had no choice but to start my own company," he said. "When I started the company, some people admonished me for being reckless. On the other hand, the aforementioned scientist and many other university doctors with whom he had deepened relationships while working at the company backed him up. One of them said, 'I cannot be in a position to start a company, so I would like to entrust my dream to you indirectly.' After the establishment of our company, many people who retired from pharmaceutical companies came to us with an interest in our company and became involved on a freelance basis. Five years have passed since our establishment, and our recognition has increased, and we are finally in a position to approach the medical administration. I would like to continue to propose and implement useful things for the sake of Japanese healthcare."

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