MERIT-WINGS Entrepreneurial Practice Report

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■ How I obtained the credit of Entrepreneurial Practice?

I completed the framework of this entrepreneurial challenge by taking a course called “Deep Tech Entrepreneurial Practice Exercise,” which is a lecture at the University of Tokyo. This course is coordinated at a level that is considered to be at the high end of entrepreneurship lectures at the University of Tokyo, and is so well organized that students who complete the course and excel are eligible to participate in the “DICE” and to be sent abroad. DICE stands for Deeptech Innovation Community for Entrepreneurs and refers to an entrepreneurship training community where voluntary study groups, entrepreneurship consultations, and overseas dispatches are planned and held by students who are struggling as researchers. For more information, please refer to https://entredu.t.u-tokyo.ac.jp/community/. In this course, the students were required to develop a feasible business plan and verify it by utilizing the high level of science and technology (deep tech). In the final presentation, only four selected teams were allowed to present in front of President Fujii, and our team was one of the four selected to present.

■ What kind of project proposal did we prepare?

First of all, we focused on surgery and chemotherapy, which are considered to be the four main types of treatment: surgery, radiation therapy, chemotherapy, and immunotherapy. We named the phenomenon “treatment dilemma,” in which the more surgery or medication is performed to remove the affected part, the more the patient loses functions that he or she does not want to damage, and set a vision to solve the “treatment dilemma” from the chemotherapy perspective. The first disease to be addressed in this process is “glioblastoma (grade 4 brain tumor),” and we are trying to develop a drug creation business that uses 10 nm and 30 nm drug delivery systems to deliver anticancer drugs to brain tumors with higher efficiency and lower side effects than conventional drugs. To achieve this, we envision a business model in which our platform technology is loaded with an anticancer drug, and after a Proof of Concept is demonstrated in disease-mimicking animals, the license is sold to a major pharmaceutical company. We envision a business growth model in which this business model is repeated for each disease and each drug to be used, with the aim of achieving an IPO.

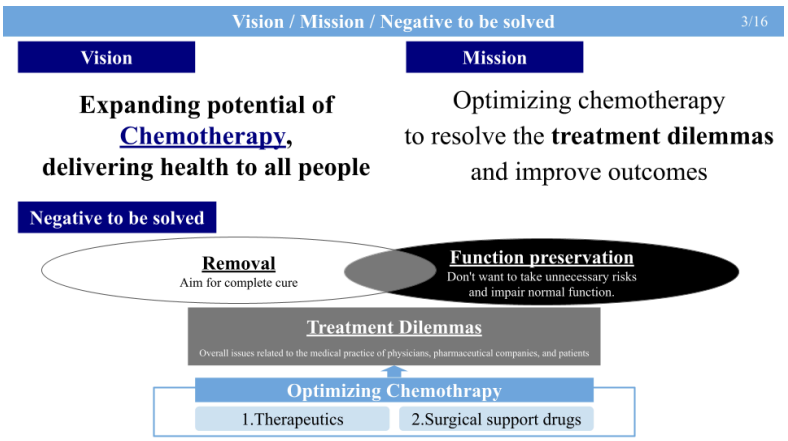

Figure 1: Vision, Mission, and Therapeutic Dilemma

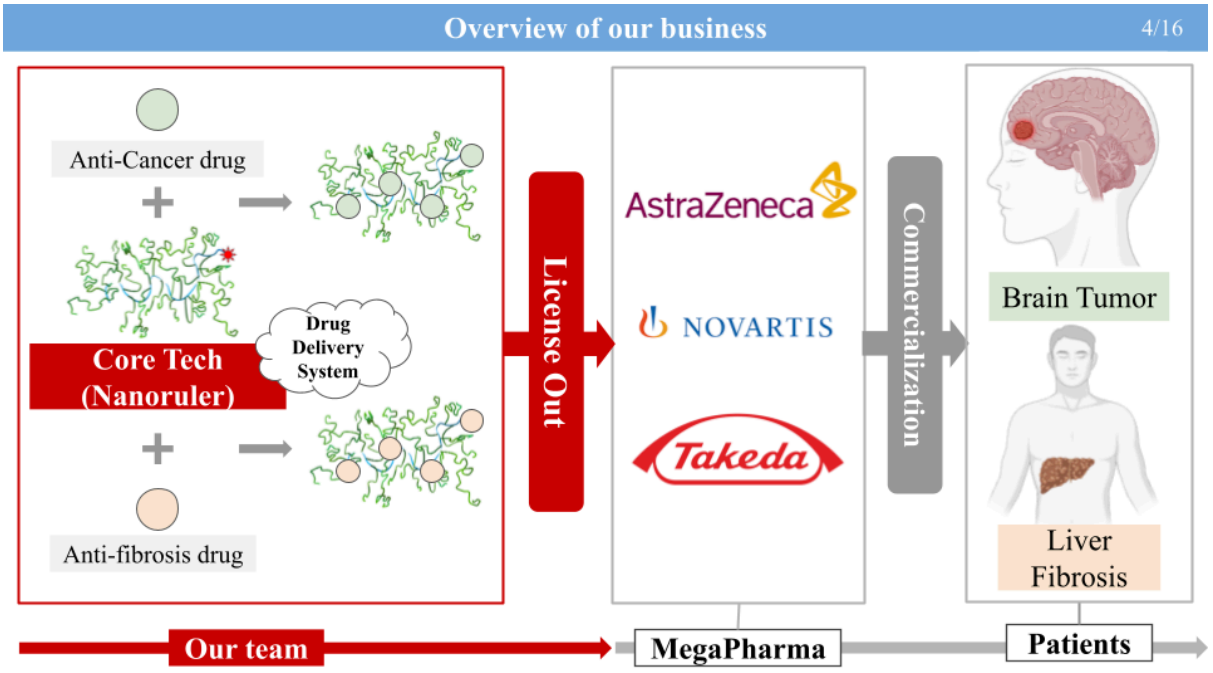

Figure 2: Business Schematic (MegaPharma is an example of a potential license)

■ Confirmation and exploration of needs for this project

Regarding the “treatment dilemma” defined above, we proceeded to confirm it through interviews with several neurosurgeons. We heard firsthand that glioblastoma has an abnormally high recurrence rate even when treated, and the five-year survival rate is low, making the disease a cause of tears not only for patients but also for doctors. On the other hand, we conducted interviews with professors at the University of Tokyo's Graduate Schools of Medicine and Engineering regarding the effectiveness and feasibility of the platform technology used to create the project proposal.

■ The effectiveness of this platform technology

This platform technology is a drug delivery system with a precise size control range of 8-30 nm, named “nano-ruler” in Miyata Laboratory, to which Yonekura (myself) belongs, and has been used to improve drug concentration in target areas in orthotopic mouse models of Duchenne muscular dystrophy and glioblastoma. The technology has been used to date to improve drug accumulation in target areas in orthotopic mouse models of Duchenne muscular dystrophy and glioblastoma. The improvement in accumulation in brain tumors is particularly remarkable, and we are considering building a lead pipeline of business models in anticipation of the high potential of this technology. [Y. Ishibashi, K. Miyata, et al., Size-dependent glioblastoma targeting by polymeric nanoruler with prolonged blood circulation. Bioconjugate Chem. Bioconjugate Chem. 35(8) 1154-1159 (2024)]

In this paper, we found that 10 nm nanoruler and 30 nm nanoruler have different accumulation profiles in brain tumors, so we decided to use the 10 nm nanoruler, which reaches deeper into the brain tumor, with more anticancer drugs for

therapeutic effect and the 30 nm nanoruler with a smaller amount of anticancer drugs and drugs that make brain tumors less likely to spread, simultaneously. The 30 nm nano-ruler is equipped with a small amount of anticancer drug and a drug that prevents the spread of brain tumors, and the new drug delivery platform technology enables the simultaneous administration of these drugs to improve therapeutic efficacy and reduce side effects.

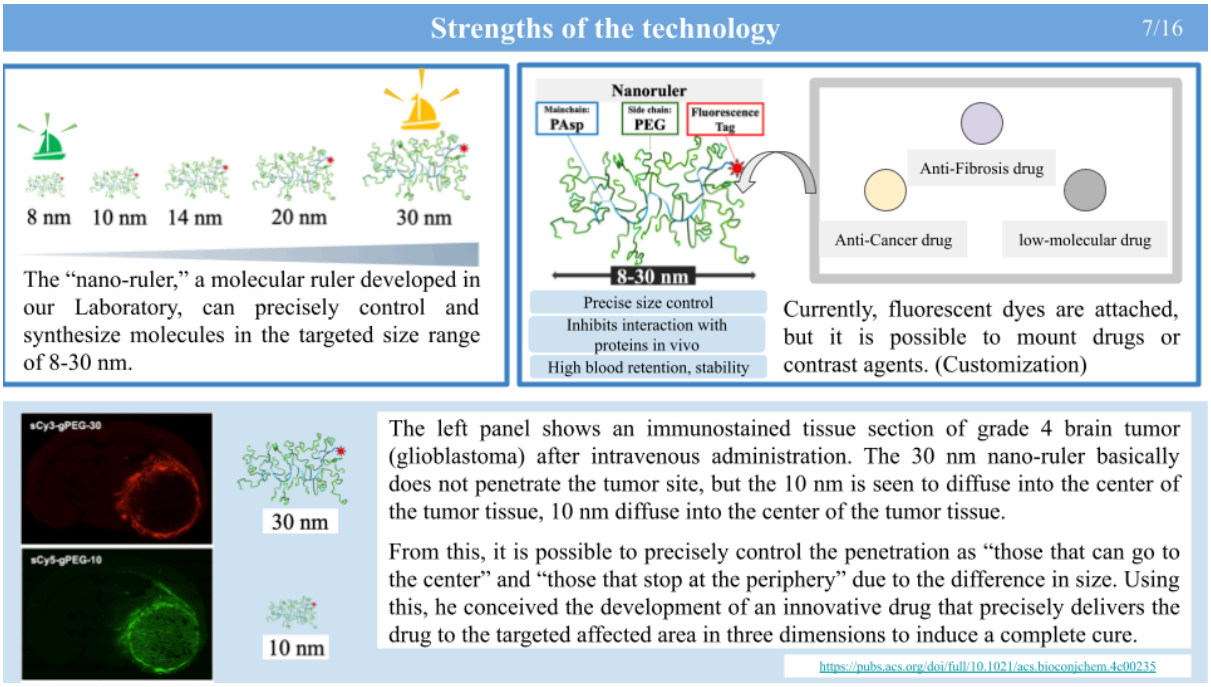

Figure 3: Overview of platform technology

■ About the envisioned pipeline

We believe that the true value of this platform technology will be demonstrated in disease systems where penetration changes depending on size, and with brain tumors, for which results are currently available, as the lead pipeline, we are also looking at "fibrosis-related diseases" as the next pipeline, where size may make a difference in the future.

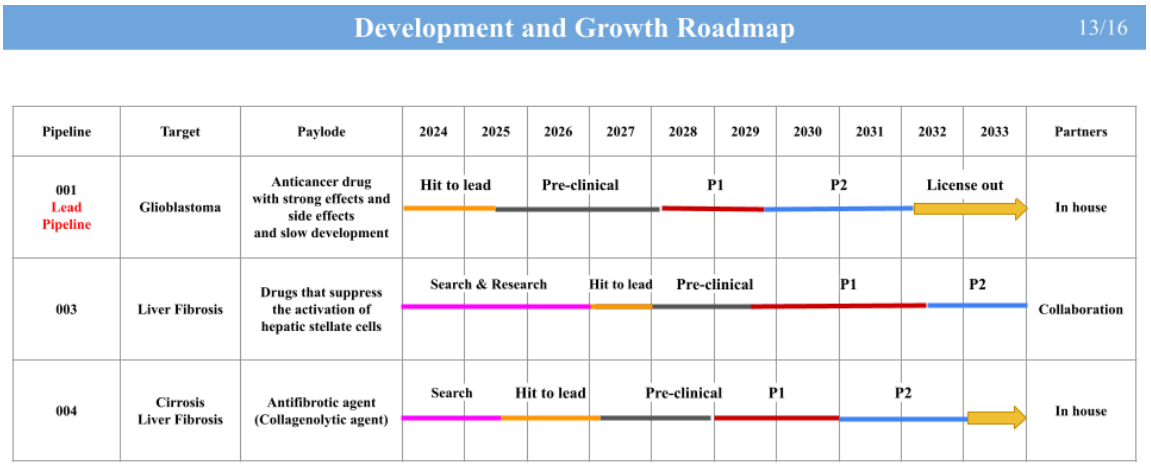

Figure 4: Schematic diagram of pipeline construction

■ Funding Calculation and Uses

Regarding funding, in the pre-seed and seed phases, the company will experiment with the anti-cancer drug as widely as possible while collecting grants, and will first proceed to obtain a PoC. Then, we hope to seek VC funding starting with Series A. We would like to proceed so that a major pharmaceutical company will shoulder the burden of actual manufacturing and clinical trials, but we would like to proceed without delaying development, using a CRO if necessary. By the time the Series B financing is completed, the company hopes to be in a position to generate milestone revenues from pharmaceutical companies and possibly out-licensing, and hopes to create a new pipeline and make progress in clinical trials as the situation allows. The plan was created with the hope that the company would be able to repeat multiple out-licensing transactions in this manner and go public as a company.

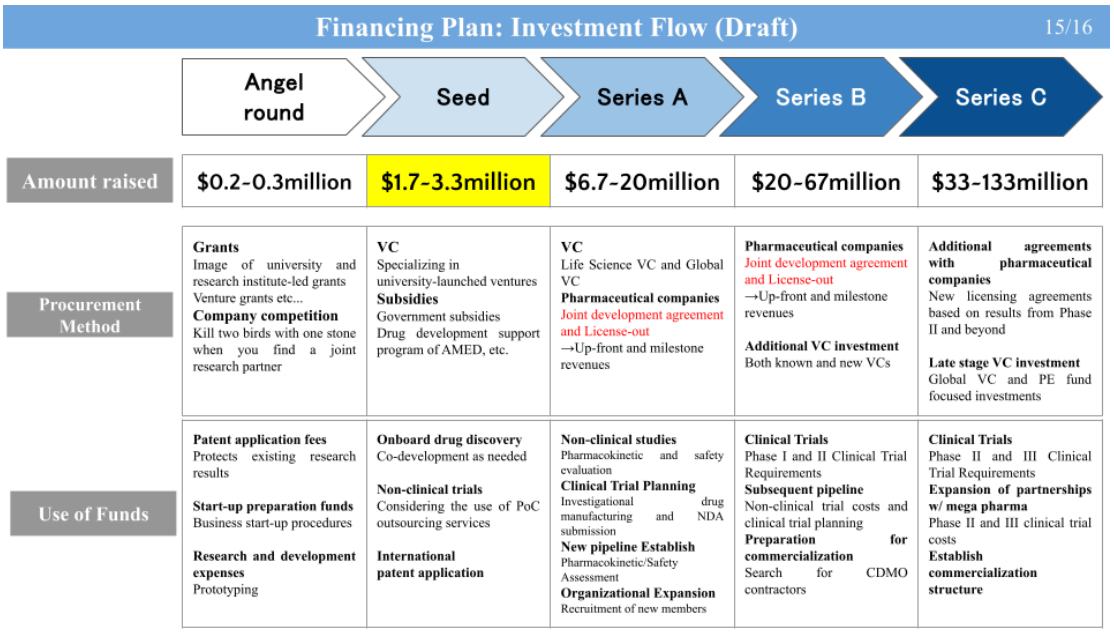

Figure 5: Discussion of funding and how it will be used

■ Future Prospects

Since it has been decided that interviews can be held with domestic pharmaceutical companies, we hope to discuss and tune the desire of each other with potential future sellers. We believe that our immediate goal is to build relationships that will generate milestone revenues as well as promote research and development.

■ Reflections on this lecture

I consider this lecture to have been a valuable time for me to rethink from a bird's eye view, covering both customer needs that I cannot see at the lab level on a daily basis and specific improvements that I can see because I have spent a lot of time in experiments at the lab level. I felt that by viewing this lecture as an engine for commercialization and research promotion, we will have a better chance of creating the seeds for drug discovery that society needs and of becoming a leader in the development of subsequent pharmaceuticals. I would like to continue to voluntarily work on deepening business proposals, promoting research, and establishing treatment methods that can address unmet medical needs. I would like to express my gratitude to all those who were involved in this lecture, and I hope that you will continue to make further efforts in the future.