Astellas Pharma Inc.
R&D Meeting - New Research Organization Structure

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Event Summary

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[Number of Speakers] 3
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Document Notes

This document has been transcribed based on interpreted audio provided by the Company.
Presentation

Fujii: Everyone, thank you very much for your participation in this R&D meeting despite your busy schedule. I am Fujii from Corporate Investors Relations serving as moderator today.

For this meeting, you can participate either live streaming or by telephone. After the presentation from us, we will have the Q&A session. Questions will be accepted only via telephone. You cannot ask questions via live video streaming. On our website, there is material for this meeting, so please be ready with that if you are participating via telephone.

The participants who are here today are the Representative Director, Executive Vice President, CSO, CFO, and CBO, Naoki Okamura, and CSO, Yoshitsugu Shitaka. There are 2 participants.

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English and Japanese translation will be available for this, but accuracy of interpretation cannot be guaranteed.

Now we'll start the presentation. Okamura-san, please?

Okamura: Good afternoon, everyone. This is Okamura. I'm quite sure that you are all busy but thank you very much for your participation in this R&D meeting.

This October, our organization has changed, so today we would like to introduce our new research organization structure.

This is the caution statement for this meeting that Fujii already read. I would like to skip this.

AGENDA

1. Introduction
   Naoki Okamura
   Representative Director, Executive Vice President, CStO and CFO, CBO

2. New Research Organization
   Yoshitsugu Shitaka, Ph.D.
   Corporate Executive, CScO

Next slide, please. Agenda for today.

First, I will introduce the background of this reorganization and then Dr. Shitaka will explain the details.
Next slide, please.

In the CSP Corporate Strategy Plan 2021 that we announced in May this year, in order to show how Astellas will overcome the XTANDI patent cliff and achieve sustainable growth, we presented mid- to long-term goals that extend beyond 2027, when the patent expires, to 2030. As a result, we believe that our current vision for the next 10 years has been largely understood.

On the other hand, considering the uncertainties these days, and also with a longer-term perspective, Astellas must continue to grow sustainably in 2030 and beyond, converting scientific advances into value for patients. In order to achieve this, we need to implement and develop the focus approach and continue to create new and unique programs to constantly increase the value of our pipeline. In this process, this research organization plays an important role in creating a new Primary Focus as a source of future value. So, it’s quite important.
In this slide, I would like to talk about the background of the reorganization of the research organization structure in relation to the Focus Area approach and portfolio management.

Based on the strategy of the FA, Focus Area approach, we have been proactively acquiring innovative technologies and assets from outside of the Company rather than focusing only on our own technologies -- in order to supplement the elements necessary for strategy execution -- and have been executing a standard alliance with quick decision making. In addition, we have succeeded in acquiring several biotech ventures with the cutting-edge technologies, as shown on the slide. As a result, we have a variety of programs, as you find on the right bottom of our portfolio. It is well managed under the jurisdiction or the accountability of the CSTO in line with the strategy under the Primary Focus axis.

Into Primary Focus, prioritization is a matter of course, but also the very dynamism is well implemented. In fact, for example, ASIM, antigen specific immunomodulation, that is the Primary Focus. However, we believe that its role as to create programs has been completed and we define it as a new Primary Focus candidate, immune hemostasis, and are now working on it.

As for go/no go decision making for new modalities, actual decision-making is required. Instead of internally evaluating each project based on long-term preparation, we have developed a decision-making process for real-time project evaluation and portfolio management, depending on both internal and external evaluation, which has been named Kachi, that is value in Japanese globally, and we will start its operation in 2022.
Also, on the left bottom, while maintaining autonomous program creation activities of each organization, that was taken at the time of acquisition, it has become necessary to comprehensively manage the research phase.

Therefore, in April, we established a new CScO and appointed Dr. Shitaka, and in October we started a new research organization structure. So, today, Chief Scientific Officer, Dr. Shitaka, will explain the details from here. Dr. Shitaka, please.

MY JOURNEY TO CHIEF SCIENTIFIC OFFICER

Yoshitsugu SHITAKA, Ph.D.
Corporate Executive, Chief Scientific Officer (CScO)

Brief history:

<table>
<thead>
<tr>
<th>Year</th>
<th>Position/Role</th>
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<tbody>
<tr>
<td>1996</td>
<td>Joined the Company</td>
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<tr>
<td>2012</td>
<td>Head of Frontier Disease Research, Pharmacology Research Labs</td>
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<tr>
<td>2015</td>
<td>Head of New Product Science Strategy, Product &amp; Portfolio Strategy</td>
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<tr>
<td>2016</td>
<td>President, Astellas Institute for Regenerative Medicine (AIRM)</td>
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<td>2021</td>
<td>Present post</td>
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Shitaka: Today, I’m going to explain the new research organization. But before that, let me briefly introduce myself. Slide 8, please.

I joined the Company in 1996 as a researcher and was mainly engaged in the CNS program for Alzheimer’s disease and dementia. In 2012, I felt that there was a limit to continuity of the global category leader, or GCL model, and launched the Frontier Disease Research Unit. I believe that the research approach I had in mind at the time became the model for the current Focus Area approach. At that time, we began to focus on ophthalmology and muscle in the disease area, gene therapy and modality, and the mitochondria in the biology area. These have led to our current Primary Focus.

After the acquisition of Ocata in 2016, I served as the President of AIRM for 5 years. During that time, I was also involved in the acquisition of Universal Cells and Xyphos the development and execution of the cell medicine strategy in Astellas.
In April 2021, I became Chief Scientific Officer, and my first task was to reorganize the Astellas research organization. Today, I would like to talk about the outline and concept of the reorganization, and then I would like to introduce some actual examples about the collaboration and the development internally.
Slide 10.

First of all, I would like to explain the concept of this organization reorganization. In the past, DDR, our drug discovery research, was operated as a hierarchical function-based organization under the accountability of the DDR head. In the past 5 to 6 years, we have acquired several overseas bio-ventures, which are mainly under the accountability of the CEO as a separate organization from the DDR. While this has the advantage of allowing us to conduct our activities while maintaining autonomy, it also meant that Astellas research organization as a whole lacked a clear strategy, and it was difficult for the research organizations to collaborate with each other.

As for the patterning function, there were 2 functions in charge of early-stage and late-stage projects and the department in charge of early-stage projects was located in the DDR. In this reorganization, the DDR was dissolved, and all research organizations were consolidated under the CScO, and all product creation functions were ununified as agile in-house bio-ventures. About half of the personnel of the former DDR were cut out and placed in multiple internal bio-ventures, creating an environment in which each of them can operate with autonomy, just like the acquired bio-ventures.

In addition, we have established a new business department to oversee overall research strategy and a system that allows the internal bio-ventures to support partnering and maximize the use of core pharmaceutical capabilities.

In addition, we have decided to integrate the partnering function, which had been divided into 2 departments, into a single department.
Slide 11, please.

This is the new organizational chart. So, this is a new organization.

The agile in-house bio-ventures that are responsible for product creation are shown in blue. The core pharmaceutical capabilities that support these are shown in green. Partnering is in orange. The new organization that integrates strategies and drives synergy is shown in red. The stars show the internal ventures carved out from the old research, or DDR.
Slide 12, please.

Today, I will explain about these 4 groups in detail. But before that, I would like to give you a general overview of the roles and collaboration of the 4 groups.

First, the group responsible for product creation in blue. Again, this is a collection of internal bio-ventures. As for the organizational structure, we will adapt a so-called agile model and adopt a growth mechanism that mimics the ecosystem of external bio-ventures. AIRM, where I spent 5 years, was a bio-venture-derived organization, and it was an agile organization where various experts made decisions quickly on-site through repeated trial and error. This is very effective in moving forward with the program of cellular medicine, a new modality.

In addition to sales, we are working on new modalities and new biology in the Focus Area approach. We thought that integrating the Product Creation Units, including the former DDR into such an agile organization would be the key to success, and increase the productivity of the entire research organization. The gray group below shows the core capabilities that we have developed as a pharmaceutical company.

The development and research in green on the previous slide includes leading platform technologies, regulatory sciences, translational sciences, and such. The manufacturing functions are also our important core capabilities. In-house ventures make the most of these capabilities to accelerate programs, encourage the probability of success, and maximize value.
The role of the partnering group in orange is to quickly fill the technology and pipeline gaps of the internal ventures. The external network is made use of here.

The part at the bottom, these top 3 groups are integrated. They formulate the overall research strategy, then integrate our 4 driving synergies among the various organizations.

Slide 13. Now, let me explain each of the color-coded groups.

First, the production creation units that I'd like to talk about.
Slide 14, please.

First, I would like to explain 2 issues in the function-led hierarchical organization that was adopted by the former DDR. First, I will explain the 2. Blue, green, and yellow are the functional organizations such as pharmacology, pharmacokinetics, and safety in the drug discovery stage and the functional groups such as initial process development, process and formulation improvement, and GMP manufacturing in the manufacturing stage.

The first issue is hierarchical decision-making. For example, drug discovery research is carried out by the lowest layer, but there is no delegation of authority and decisions on teaming policies require approval within each department, which, in some cases, takes a long time to make. In addition, when challenging new modalities and various biology or diseases in the future, there may be cases where the manager or the department does not have the expertise, which makes it difficult to make appropriate decisions.

The second is business procedures, sequential procedures. In the case of established modalities such as low-molecular weight compounds and experienced disease areas, the waterfall model worked well, where each function executes assigned tasks individually and moves to the next process when the predetermined criteria are met. On the other hand, in the case of new modalities, it’s difficult to foresee all the risks in advance and to set advanced product requirements to be met by each function, or there are cases where unknown issues are faced in the back-end process, and we are back to square 1.
Slide 15, please.

This is why we have integrated the organizational structure of the Product Creation Unit into the agile style of bio-venture. The center of the slide shows the schematics of the agile model. Taking AIRM as an example on the right, stem scientists with expertise in cell differentiation and researchers with expertise in process development, manufacturing, safety, etc., are gathered here. In this way, the necessary experts are gathered according to the modalities and biology to be handled in each department, and the aim is to conduct research while making decisions autonomously within this group.

In this model, people with the various backgrounds and specialties are brought together according to the characteristics of the program, and the solutions to new problems are continuously refined through the process of trial and error. In this case, decision-making authority is delegated to the units in the field, allowing them to carry their activities quickly and autonomously. In addition, as a result of autonomous activities, we expect to strengthen the organic connection between internal bio-ventures by mutually combining their advanced elemental technologies.
Each Product Creation Unit follows a growth mechanism mimicking bio-venture ecosystems. The research organization in the middle of this page represents how it grows. From incubation/start-up to venture unit, each PCU is within the Discovery Accelerator, and it grows into an independent research engine.

As is described beneath, along with its growth, research goals of each unit will shift from research platform establishment to lead program creation and then to pipeline building, including clinical development candidates. In line with the growth of each unit, its headcount, the number of programs, and the authority will expand. For example, selection of product candidates will be done as an important decision delegated to each research engine head.

Let me explain how to deal with this strategic stage. Each research engine is responsible for product creation and the current Primary Focus, while small- and medium-sized units within the Discovery Accelerator engage research activities that will lead to future Primary Focus. This growth mechanisms urge in-house bio-venture members to work on product creation with entrepreneurship and a strong sense of ownership.
Each Research Engine led by outstanding CSO and SAB members attracts competitive talent to grow.

**Universal Cells**
- President: Noboru Yamaji
- Immuno-Oncology, Immune Homeostasis

**Mitobridge**
- President: Mike Patane
- SAB: H. Robert Horvitz
- Ron Evans etc.
- Mitochondria Biology

**XYPHOS**
- President: Noboru Yamaji
- CSO: Gary Starling
- Immuno-Oncology

**AGT**
- Div. Head: Mathew Fletcher
- Genetic Regulation

**Immuo-Oncology**
- Div. Head: Taku Yoshida
- Immuno-Oncology

**AIRM**
- President: Hide Goto
- CSO: Robert Lanza
- Blindness & Regeneration, Mitochondria Biology, Immuno-Oncology, Immune Homeostasis

**PCU Headcount Growth**

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Page 17, please.

This page shows an overview of the current 6 research engines. They are doing autonomous activities at the sites on the map. You can see the Primary Focus they are dealing with in red. Outstanding researchers in each field belong to each research engine as a CSO or SAB members attracting top talent, and we are continuing to grow as an organization.

Ocata we acquired in 2016 and Audentes we acquired in 2019, increasing the number of researchers growing as AIRM and Astellas gene therapies, respectively. We have more than 700 researchers, in total, for the 6 units at present. The Discovery Accelerator has about 140 researchers right now. We will explain later.
Next, let me explain our structure for collaboration within divisions and with other divisions, which enables us to differentiate ourselves from external bio-ventures.

As was explained in the overview, collaboration among internal venture units and our pharma core capabilities can accelerate our programs, enhance the probability of success, maximize value, and also differentiate ourselves from external bio-ventures. 2 important pharmaco-capabilities are shown here. 1 is applied research and operations, and the other is pharmaceutical technology.

Today, due to limited time, I will explain our collaboration with manufacturing function in detail.
I’d like to use 2 pages to explain the importance of early collaboration between internal venture units and manufacturing function from the research stage, leading to our strength.

Let’s take cell therapy as an example. In the world of cell therapy, it is said that process is product to show its uniqueness. This means that changes in manufacturing process such as raw materials, culture methods, etc., drastically affect the product characteristics such as efficacy. This is a world different from small molecules.

In reality, when I was working at AIRM, I experienced a reduction in pharmacological activity of the cells when we changed from FDA-compliant materials to the ones based on PMDA’s standard, even though they were the same raw materials. Usually, for small molecule compounds, we use a waterfall model for collaboration between research, process and formulation development, and manufacturing functions. After handing over the process for manufacturing from research to manufacturing, various changes may possibly occur. But we can handle this as long as the structure is simple, like small molecules, and if you already have expertise and know-how for that modality.

On the other hand, in the case of advanced biological products such as allogeneic cell therapy products derived from pluripotent stem cells we are working on, the research team may optimize the process with efficacy as an indicator. But if we change manufacturing process, raw materials, and formulations in the middle of development, it can be very difficult to demonstrate comparability with what was produced before. We may have no other choice but to go back to the initial research stage, in some cases.
Therefore, in the case of advanced biological products, we take into account commercial production from research stage so that research and manufacturing can closely collaborate in the agile model organization and proceed with research and manufacturing process development at the same time. This is a key to success. By doing this, we can avoid returning to the initial step in case of issues after the process handover to manufacturing.

Also, in-house manufacturing capabilities enable flexible collaboration and know-how accumulation. We can accumulate capabilities in-house, which we cannot build just based on the model of outsourcing to CMO.

This is going to be an effective model also for future DDS integrated products such as gene therapies, messenger RNA and other products where formulation changes can lead to changes in product characteristics.

At AIRM, Universal Cells, and AGT, research and manufacturing functions are already co-located for collaboration as an agile organization. More than 70% of the personnel at AIRM and AGT are members of technical and operations who report to me.

Also at Tsukuba, mainly regarding DDS integrated products, we are strengthening collaboration with co-innovation, co-creation as a slogan or tagline for the past few years. Also in the new organization, the research and manufacturing collaboration will be further reinforced.
Next, let me talk about the integration between Early-Stage Partnering and business development department.
Challenges in External Partnership

- Two organizations operate side-by-side and lead early- and late-stage alliance/asset acquisition projects; respectively Early-Stage Partnering (ESP) and Business Development (BD), in order to better handle different types of deals.
- The increasing size and complexity of early-stage deals make them closer to late-stage deals.
- As a result, frequent project hand-over occurs, and more coordination is required between the two organizations.
- The drawbacks become more apparent than the advantages of operating the two organizations.

April 2022

ESP and BD will integrate into a new Business Development division, which will report to Chief Business Officer (CBO)

New BD

- Unified and consistent partnering capability and talent development through early to late stage
- Speedy decision making
- Clearer point of contact to external partners

Currently, there are 2 organizations in charge of partnering in our company. We divide the scope of responsibility by the stage of the projects. Early-Stage Partnering, ESP, is responsible for early-stage projects and late-stage projects are the responsibilities of business development, or BD. The strength of Early-Stage Partnering is the ability to identify great science. BD has strength in negotiations, deals and alliance management. However, the size and complexity of early-stage deals is increasing these days.

For example, in order to acquire research seeds in early stage, we access academia, for example. But once we begin negotiations, they want longer-term relationships, and we may have to negotiate economic conditions after commercialization in a lot of cases. So there is less difference compared to late-stage deals, and unnecessary processes may occur like the handover of the deals between the 2 organizations and coordination of the opinions, which is time consuming. This is different from the research and manufacturing organizations I mentioned before, but we began to see issues by having 2 organizations.

We decided to integrate the 2 organizations as 1 partnering team from April 2022 to launch a new Business Development division. We hope that the internal process will be enhanced, and the partnering speed will be further enhanced into the future more than now.
Page 23.

This page shows the network we have built in order to access potential partners in various stages. Through our 4 sites, shown on the map, we have established a strategic network with academia, incubators, and venture capitals globally. We have also made strategic investments in start-ups and biotech companies.

As you can see on the right, we have successfully acquired assets and platform technologies in line with our strategy from research seeds to M&A by now. We hope that we can further leverage the network we have established under the new structure.
Last but not least, I'd like to explain our structure to manage these organizations to drive synergies.
In the previous research management, the overall strategy was the near sum of the strategies of individual organizations, lacking flexibility in resource allocations in some cases. In other words, we have felt a great potential among different organizations, but we couldn't drive the synergies successfully.

In terms of modalities, we have small molecules, antibodies, cell therapy, and gene therapy, and we have world-leading research engines in the respective fields. We think there is some room for further improvement of productivity by driving their synergy.

Due to a lack of sufficient information transmission, sometimes it was difficult to understand the status of our activities from outside. Bio-ventures used to transmit information actively, but no more information transmission once they were acquired by Astellas in some cases. Of course, we may not be able to talk in a timely fashion about negotiations with the regulatory authorities, for example, but we think there is also some room for improvement here.

Furthermore, it took time for the acquired organizations to enhance their value within Astellas. We wanted them to work at their full speed after acquisition. But due to factors such as integration work after acquisition, there was some slowdown in some cases. Therefore, to resolve these issues, we have established an appropriate decision-making system and new office functions.

As for strategies and resource allocation, we have established a new decision-making system called Research Leadership Summit. It consists of research division leaders who discuss the strategies of the entire research
organization, collaboration among different functions, portfolio management, and resource allocation. I chair this summit for decision-making.

As for information transmission, particularly in research areas, we will enhance our communication so that we will be a company of choice for potential partners and great talent. Affiliate management function will support the integration and activities of newly joining research organizations. We have also established research architect lead to drive the overall research transformation activities. Through these initiatives, we have established a structure to maintain our autonomous activities by internal venture units with lots of diversity, and to enhance synergistic value as a whole at the same time.

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**TODAY’S AGENDA**

1. **OUTLINE, CONCEPT, AND AIM OF RESEARCH REORGANIZATION**

2. **DEVELOPING AND OPERATING PRODUCT CREATION UNITS**
   - CREATE VALUE FROM THE COMBINATION OF CUTTING-EDGE TECHNOLOGIES: CAR-NK FAMILY
   - GROWTH OF VENTURE UNIT: PROTACs

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Page 26.

From here, I’d like to give you 2 examples of developing and operating internal venture units working in collaboration.
CREATE VALUE FROM COMBINATION OF CUTTING-EDGE TECHNOLOGIES: CAR-NK FAMILY

Creating VALUE that our competitors cannot follow from the combination of cutting-edge technologies

CAR-NK (PF: Immuno-oncology)

- Though the pharmaceutical efficacy of CAR-NK in B-cell tumor is being confirmed, there are many challenges for the current developed products.
- We aim to overcome these challenges with products differentiated from allogeneic pluripotent stem cells and aim to expand indications especially for solid tumor.
- As this requires multiple advanced technology elements, many divisions in Research and Manufacturing are collaborating.

Page 27, please.

The first example is the collaboration in the CAR-NK family program. The pharmaceutical efficacy of CAR-NK is being confirmed in B-cell tumors, but there are issues with the products other companies are developing right now. We aim to overcome these challenges with our allogeneic pluripotent and stem cell products and aim to expand indications for solid tumor.

In order to deliver the value, we are aiming for, multiple advanced element technologies are necessary. You can see different technologies in different colors. First, clinical grade pluripotent stem cells at AIRM would be turned into universal donor cells in order to avoid immune rejection. Here, Universal Cells precise gene-editing technology using AAV vector would be necessary.

Xyphos’ convertible CAR technology can target multiple cancer antigens, and this is used to integrate genes into UDCs. By using UCells gene editing technologies, we established a process to differentiate the sales into NK cells, and technology is transferred to AIRM, Astellas cell processing center, to enable GMP manufacturing of the target cells, CAR-UDC-NK. And we have MicAbody to target cancer antigens. This is produced at Tsukuba.

By combining the cutting edge technologies from the respective units, we can create values that a single bio-venture cannot follow. We have Universal Cells, Xyphos, and others to be linked together to realize this.

The second example is the growth of venture units. Right now, we have 6 venture units generated at our research laboratories or research centers in Tsukuba. 2 of them, tumor-directed inhibition and specific Treg,
are PF candidates. In terms of the strategic stage Primary Focus candidates, we are promoting research so that these units can be Primary Focus in the near future.

At the bottom of the slide, you can see the PROTAC protein degrader, the Tumor-directed Inhibition venture unit is working on. Let me briefly explain its features. PROTACs have a structure to cross-link through a linker, POI binder and E3 ligase binder. The target protein, which could not have been a drug target or druggable target for the conventional inhibitor approach, can be turned into ubiquitin by E3 ligase for degradation by proteosome not inhibition, in order to block signaling and demonstrate efficacy.

This internal venture unit has shown great performance internally over the past few years and is growing. I talked about ecosystems, making external bio-ventures and this is 1 of the units where we are reinforcing our internal investments.

Page 29, please. This is my last page.

This reorganization, we believe, will enable us to maximize value of the bio-ventures we worked on in the past, and we can generate a new Primary Focus and grow continuously our bio-ventures, and pursue synergy among organizations. In promoting a Focus Area approach, we can have a more effective organization.

That’s all about the explanation of the new research organizational structure. Thank you very much.
Question & Answer

Fujii: That’s all from us. Now we would like to entertain your questions.

From the Japanese line, Citigroup, Mr. Yamaguchi, would like to ask a question. Please start.

Yamaguchi: The first question is about valuation. In the case of venture, market, and such, including the stocks or share price are the indicators for the valuations. So mimicking those who are exposed to them, you increase the evaluation internally and in a sense, more competition base salary will be given to your employees. But once again, for that evaluation part, due to this reorganization, the valuation system or the ways of evaluating will be different greatly?

Shitaka: Evaluation of the employees or human resources that we have. I believe that’s your question.

First of all, convention system will be maintained from this October. But in the future, the overseas bio-venture mimicking type of the evaluation ways might be incorporated into our new organization.

Yamaguchi: The second question might be related to that. In the beginning, Okamura-san mentioned about Kachi, where real-time evaluation would take place. With this change and project value change and evaluation of the project, those are all connected?

Okamura: Thank you for the question. They have to be all linked or connected. Otherwise, it’s going to be meaningless. For example, the clinical trials started and the clinical trial POC was established. That is happening in the earlier phase. Seeing the project in other phases is impossible.

So the different departments would start to collect the information and if we achieve certain milestone, all the data are all combined to reevaluate. But each project or each project would do that with a different timing. When it comes to portfolio management that happens once in a year, twice in a year, 3 times in a year, that is the conventional way. But as you see, the technologies have been advanced quite quickly and also those with the superior technological platform can gain further to go ahead. In that case, the older method of spending 6 months of evaluation is not really quick enough. For each compound has each compound’s event, and each, at that kind of time, evaluation should be done.

For example, not only with the internal information, but if there is some news, including good and bad, for the outside products to be used for the factors of our evaluation, the evaluation of 1 project will be changed, then the portfolio priority will be changed. If they are to be changed, then the resource and investment allocation will be different. That is going to be always turning around. That’s what we are aiming at.

Yamaguchi: Understood. I have 1 more question. As 1 example, you talked about CAR-NK. As you said, in this field you have technologies at different locations and whether you can combine them to work together. Looking from outside, I was wondering when this can be integrated to be used? CAR-NK-UDC, you’re saying that you can realize this. In this field, CAR-NK, NK itself, this is some are in the clinical studies, Takeda, Helios, and others are also working in this field. So, to demonstrate your competitiveness in this field, it’s important to have clinical studies at an earlier timing. The progress of this project, when can you enter the clinical stage? When can we see? If possible, could you elaborate on the timing of the clinical stage?

Shitaka: In May, when we had a meeting for CSP2021, this program was included in there. In approximately FY2022 to FY2023, we can enter the clinical stage according to it. The situation has not changed.

Yamaguchi: Understood. Thank you very much.
Fujii: Next, from the Japanese line, Mr. Hashiguchi from Daiwa Securities.

Hashiguchi: Hashiguchi speaking. Thank you. There are several questions.

The first question, the Focus Area approach concept that you have currently, how long will it be continued to be included for the interpretation of your direction, including the current reorganization? There are 4 Primary Focuses, and each has a triangle. There is a Primary Focus lead for each 4, and it has delegation to do the activities. I believe that’s your explanation. But now Product Creation Unit, I don't know if there are 6 or 7 of them, but each has its organization. It seems Primary Focus is not linked to a 1-to-1 relationship with this new Product Creation Unit. As for cell therapy, I had an understanding that it is a common foundation covering multiple units. But it seems the positioning of this cell therapy is now discussed outside. For example, AIRM and Universal Cells, you have 2 separated organizations. So, to what extent of your conventional explanation should be reset and introduce this new idea? Could you reorganize those?

Okamura: Focus Area-approach-wise, there’s no change to it. Focus Area approach has biology, modality, and medical needs, creating 1 triangle. The foundation of those triangle modalities needs modalities, biologies. So those factors are considered. That is a selected triangle with those perspectives and if the triangle is made, that is considered as a Primary Focus.

Primary Focus Lead, the role of that is that each program becomes each program candidate, to the clinical that is covered by the Lead. Primary Focus itself has triangles and there might be same biology, but the modality might be different. So within 1 Primary Focus, there are multiple programs.

The benefits or beauty of the Primary Focus is that if the flagship makes success, then there are followers. From there, multiple programs will emerge. Considering that, Primary Focus Leads, a certain triangle combination of Primary Focus becomes the candidate as a first compound, and that achieves the clinical proof of concept. Then, that goes to other hands, but there will be another program coming from the source. So the role of the lead is going to continue for a longer time.

Details will be explained by Dr. Shitaka, but for example, within accelerators, there are some senior units, meaning that the Primary Focus are already established. And there, following triangles to try to be identified or if you have already established triangles, then the followers will be generated.

Would you please show the slide with all boxes? What I’m talking about is AIRM to Mitobridge. I’m talking about these 6. On the very right of the blue that Discovery Accelerator that looks like 1 unit, but there are many start-up types of units. They are looking for each top point of each triangle for the focus. So that’s what the Discovery Accelerator would basically do. Trying to identify those components.

Ocata was acquired and AIRM got started for cell therapy. At that time, we consider that smallest organ outside access is possible, and we have the immune patent, so ophthalmology is what we've started, then Universal Cells was acquired and off-the-shelf product became available. We expanded the scope outside of ophthalmology.

Then we acquired Xyphos acquired. In oncology cell therapy is possible to be used. Also, just has been press released, mitochondria biology is also where that cell therapy is used for the program. Such a program is under consideration.

So, the cell is 1 of the modalities. The Focus Area approach triangle includes the cell as just a part of it. With that, to what extent and what way the unmet needs are contributed to. With that, we can find various possibilities. AIRM and Universal Cells, they produce cells for Xyphos. In the process, gene editing is conducted by Universal Cells. That’s what it will be. Any additional comment?
Shitaka: As Okamura said, there is no change in our Focus Area approach. As you can see on page 16, the strategic stage and research organization are on this page. Regarding the strategic stage, within the Primary Focus Area, strategy development and implementation would be done by PFL. As for the execution to produce product, research engines, and venture units are responsible. It’s not 1-on-1, as was mentioned.

Gradually, for example, on page 17, AIRM has entered the areas from ophthalmology to cell therapy. Initially, blindness Focus Area, it was almost 1-on-1 relationship before. But using this as a cell platform is expanding internally, mitochondrial, cell therapy is an area of interest. Immuno-oncology also would like to handle this. So it’s no longer 1-on-1 anymore, but rather this is something we take positively. The internal platform is being leveraged among multiple PF areas. So we think this is a good direction. That’s all from me.

Hashiguchi: Thank you very much. 1 more point. On page 17, at the right bottom, you can see the PCU headcount growth. Gene therapy unit has a lot of members followed by AIRM in terms of the headcount. This headcount composition, do you think it is already optimized? At the time of the acquisition to the acquired company, how many people were they? By adding them up, I think there is a great impact from that addition. Into the future, you’d like to increase the headcount strategically in some areas, and you may consider reducing the headcount in some areas. If any, please share such details.

Shitaka: For example, former Ocata, the predecessor of AIRM, when we acquired it, a little more than 30 people existed in the organization. Now we have more than 200 people. This is based on our needs and the number of programs in-house. Accordingly, we are increasing the headcount. We don’t have extra people or people in excess, but in line with the program, we are increasing the headcount there.

The same is true with gene therapy. In principle, after the acquisition, instead of reducing headcount, depending on the number of programs and the utilization of the programs, the headcount is increasing accordingly.

Hashiguchi: Thank you so much. That’s all.

Fujii: Thank you. Next, please, from the Japanese line, Credit Suisse Securities, Mr. Sakai, please.

Sakai: Sakai from Credit Suisse. There are 2 questions.

First of all, Product Creation Unit. Several years ago, a company in Koishikawa proposed this type of organization. At that time, they considered that the unit should be depending on the therapeutic areas, low-molecule weights, so the CNS and oncology. Organizations are vertically created. From there, drug discovery to development throughout. Without any changes, the development will take place.

But this time, your PCUs, each are individual, but at the same time, they merge together to create something. What about the development afterwards? Because of the time constraints, you might have skipped it. But Okamura-san, as you mentioned at the very beginning, new modality, cell genes and process, if you say process is a product, I think mostly it will be completed within PCU, but in that sense, will the development be changed? Is that understanding you correctly?

Shitaka: This reorganization, we considered our internal needs and also the status, and we decided this way will be the best for us. That’s why we decided to do this reorganization. Our current unit situation is considered. We have the research and manufacturing gather together in most of the cases. But with the expansion of the pipeline, some units are needed to conduct their business. And for them, how the agile aspect is incorporated will be future discussion.

Sakai: That means, as a result, that the development part is not reorganized or not changed at all?
Shitaka: Right. This reorganization does not include development.

Sakai: Okay, thank you. This may offend you, but in your case, among your mainstay products, licensing products have become very large. This is true. Maybe in other words, you have been able to identify great products. But in terms of in-house drug discovery, it's not satisfactory, at least for me, according to my judgment. But you're acquiring bio-ventures and you started new modalities, and you're incorporating this in-house. From here, you will have your own internal drug discovery and your in-house development product to lead to enhancement of the product manufacturing. Is that the view of the management?

Shitaka: Yes, you're right.

Sakai: Understood. Thank you very much.

Fujii: Next, from the Japanese line, Mr. Ueda from Goldman Sachs Securities, please.

Ueda: I'm Ueda from Goldman Sachs Securities. My first question is as follows. Regarding the environment and the mindset of the researchers, what about the changes? What's your view on this? Right now, you are changing the organizational structure as you explained today to be practical. The working environment and the mindsets are important. You talked about KPIs and the assessment and evaluation are not going to change is what you said. But on page 15, as you can see here, there are a lot of overlaps. Per person, how many hats does 1 person have to wear? Without synergy, you may not be able to afford to do this. Do you have a sufficient number of people who can drive synergy? Otherwise, as you can see on page 25, you cannot leave the previous model of just the near sum of individual strategies. What's your view on this?

Shitaka: Thank you very much. There is no overlapping among units. Each individual belongs to 1 unit, dedicating themselves 100% in principle. As for the overall mindset, with this reorganization, the biggest change was in the organization of research at Tsukuba in Japan. We had a hierarchical or function-based model changing to an agile model. So, the mindset is expected to change as well. A stronger ownership and commitment and entrepreneurship are expected. Vis-a-vis external bio-ventures, we shouldn't be defeated in terms of quality and speed. We have to change the mindset in that direction. Such change is already occurring, and we'd like to promote these further into the future.

Ueda: Thank you. For such changes, are you going to think about the reformation of your hiring strategies system?

Shitaka: First of all, internal bio-venture. If we have, then we need to have somebody who can lead it, not only from the scientific perspective, but considering the future business model as well. The person who can lead, like an EIR type of the human resource of the position. We might have to hire somebody from outside or start-up level unit so that it can be vertically set up. Outside scientists who serve as principal investigators may be dedicated role or might not be dedicated. But anyhow, such a leader class is currently why we have already started our approach.

Ueda: About slide 12, that is the value enhancement with utilizing your own facility of the manufacturing, and you talk about the advanced element technologies. What's your view about that? What do you think about it from the perspective of global competitiveness?

Shitaka: There are many. For example, using AI and compound metabolism prediction, efficacy prediction, and antibody designing. That is where there is the scale merit benefit with the amount of venture units that can utilize such kind of technology. That's why we can invest. That's 1 of the examples. There are also robotics bioinformatics. So those are included within this advanced element technologies.

Ueda: Understood. Thank you very much. That's all for me.
Fujii: Thank you very much. Next, from the Japanese line, Mr. Kohtani from Nomura Securities.

Kohtani: Kohtani from Nomura Securities. First, reorganization concept. I’d like to ask a fundamental question. I haven’t thought about organizational theories. In Japanese companies mostly, they have the conventional method after reorganization. Bio-ventures formed independently, and various functions are easy to use. What I’d like to understand is, compared to US companies, how novel is this kind of organization structure? This will lead to the future acquisition of bio-ventures? That’s the most important, not just obtain money, you cannot beat Merck or Pfizer. So a Japanese company must be selected, and in such a case, you have to consider ways. As Okamura-san said before, you have to solicit companies who want to be acquired by a Japanese company. To do so by venture acquisition, and then you can grow together, you have to create such a mechanism. Is my understanding correct that this reorganization will contribute in that respect?

Shitaka: As for the US companies, in general, and their general benchmark, I don’t have such data myself, but at least in our industry right now, the number of drugs approved by US FDA in terms of the performance, more than half is from bio-ventures. It may be about 70%, depending on how you count. Such early discovery competitors are bio-ventures in our view. What’s good about them can be incorporated in our structure. That’s 1 background.

Whether this will lead to the next acquisition into the future, if you can see our organizational chart, you can tell. Very new companies can be added easily for the blue part in the slide; we can add the company we acquire to the blue part. Then you can automatically be a member of our group, according to this structure. Also Affiliate Engagement has been newly established. So, regarding new acquisitions, it’s very easy to handle according to this new organization. Also, acquisition, triggering our next new acquisition, we have such an experience. We acquired the company in cell therapy already. Those who would like to work with AIRM at the time of the acquisition of Universal Cells, that was 1 motivation of the other party, Xyphos. Because of AIRM and UCells, they would like to work with us.

There is the first level, second level and third level in technologies, and the sequence is important. That is why we acquired Audentes for gene therapy. We will need the second level and third level technologies in the future. And also, Dyno, we announced would be the technology on the second level. So this can induce a very good cycle for us.

Okamura: Mr. Kohtani, please, Okamura speaking. Let me add 2 points.

First of all, today, Chief Scientific Officer Shitaka and I are talking about the reorganization of the research organization under Shitaka as Chief Scientific Officer. If other ventures want to work with Astellas or not, it’s not just a matter of the research organization. Development, pharmaceutical technology and others would be involved. Intellectual properties, legal are necessary as well, various functions, which a small organization cannot handle. Who we’d like to partner with will be decided based on this. Just looking at this page to see whether the next collaboration or next M&A will come, that may be a little more biased.

Another point is as follows. After the acquisition of a company, it’s independent from our research organization, and it’s under the CEO. If you acquire and if it incorporated and absorbed into the original organization, you wanted to get it and you acquired it. It’s incorporated into the order of the organization. There is an immune reaction and it’s gone somewhere.

After the acquisition of the company, you have to maximize and leverage the company we acquired and we have to find the optimal point somewhere between completely independent and completely absorbed. In this acquisition, around here, in between, in this case, we have to go through trials and errors to accumulate our know-how, then we can have synergy from the acquisition to demonstrate value. So it’s not so simple. We cannot generalize in a simple fashion. That’s what I thought when listening to your comments.
**Kohtani:** Understood. My intention of the question might not be really straightforward, but the point is, this may be also a bit off the track of this announcement. But in oncology, what is hot is rather than CAR-NK, PROTAC, is collecting more attention. Arvinas is the originator for clinical development of this. And the thalidomide drug is analyzed as a result. E3 Binder is ligated nearby, and we will be getting degradation for the protein that is considered to remove older proteins.

Recently, Pfizer and Arvinas worked together for the development of ARV-471. This is a very hot area; more than a dozen are in clinical development currently. Androgen receptor, estrogen receptors, it seems that currently they are working for such an existing mechanism.

If the area is already peaked and crowded in this way, you have to add something unique. So against the already known mechanism, is E3 Binder is attached? Or rather, you would like to find a new novel target for further development of this?

**Shitaka:** The ordinary inhibitor approach, if that is sufficient for the certain targets, yes, we may do that. Conventional inhibitor approach, if that is not sufficient to make a drug, and if the target is not targeted with the convention drug, then PROTAC is used. There are targets that is to a certain extent validated, but still undruggable. So that will be the target of our priority. Did I answer your question?

**Kohtani:** ARV-110 already developed, the structure is disclosed, and it looks like Darolutamid, that is where E3 Binder is added in terms of the structure. The binding pocket has to be there as a protein. So, in a word, it seems like the extension of the conventional inhibitor. With this, for example, RAS or K-RAS, there are no further pockets, so I think it's impossible. What do you think about this way of thinking?

**Shitaka:** That might be the area where we may be able to get breakthrough. The pocket might be a bit shallow. However, PROTAC might be effective.

**Kohtani:** Understood, thank you.

**Fujii:** Thank you very much. From the Japanese line, JP Morgan Securities, Mr. Wakao, please.

**Wakao:** Wakao from JP Morgan. I'd like to ask a question about the Discovery Accelerator. By letting us know about this, when you have a new venture seeds program in the future, I think that they are going to grow into the future. As for the drug accelerator, 140 people belong to this organization, as was mentioned. The current number of the headcount, how this is going to increase into the future, what are the original themes for them? How are they going to come up with themes? And how are you going to refresh the drug discovery accelerator? In case of new ventures, you have funding. If you don't have money, I think they're going to die. So this kind of refreshment of the organization is going to be important. That's why I'm asking.

**Shitaka:** As for the drug Discovery Accelerator, according to this chart, the left 2/3, we have 40 people working here. On page 28, specific venture units are shown. There are 6. For individual venture units, going back to page 16, 10 to 30 people. In total, we have about 140 working within these 6 units.

As for the future metabolism of the organization for incubation startup, at that stage, research platforms will be established and not on a stand-alone. We think we can have multiple, then it's turned into a venture unit. As you can imagine, the earlier the probability of success is smaller. Incubation start-up has the quickest cycle followed by venture unit. In terms of the change of the contents inside, we are developing rules internally to manage this.

**Wakao:** On page 16, there are 1 to 2 programs. This is not the current number of the programs, right? How many start-ups are there right now?
Shitaka: I’m talking about the number of the programs. 1 incubation, or start-up, deals with the program, so the themes. That’s the number of the programs.

Wakao: What about the number of the incubations?

Shitaka: I cannot come up with a number from my mind, but there are about 30 people. The number of researchers is 1 to 5 per incubation. Number of incubations and start-ups are more than venture units.

Wakao: So 140 people, and the other members in Tsukuba, there are about 1,000 people working in Tsukuba. So, in the future, they would shift to the Discovery Accelerator? How are you considering the allocation of your resources, human resources?

Shitaka: When it comes to the organizational chart, by the way, we don’t have the organizational chart just for Tsukuba, but we don’t have 1,000 people there. In Tsukuba we have Applied Research, that is this green, that’s the biggest department. There are about 300 people. Also, we have accelerated immuno-oncology. Those blue units, there are a little more than 200. That’s the current situation.

Wakao: Understood. Discovery Accelerator and incorporation of external technologies, what’s your idea about this combination? When you have ventures in-house, they can become independent as a research engine. So, technologies based outside may not be necessary. On the other hand, depending on the themes, you may need external technologies. For the future, when you incorporate outside technologies, how do you do this considering your in-house ventures? From the management, when you need external technologies, are you going to do so? Or for projects and things, they can become independent and in-house technologies alone maybe enough to enter the clinical stage?

Shitaka: As we did before, we’d like to incorporate and bring in outside technologies. They can be big biotechs, smaller start-ups, or academia-level discovery seeds for joint research, of course. As I touched during my presentation, in every stage, from outside necessary fees and technologies will be incorporated, we’d like to consider these possibilities into the future as well. If you are to acquire a start-up, then internally, as we showed the growth mechanism through these processes, we’d like to grow them into a research engine. That’s what we are considering right now.

Wakao: Understood, thank you very much.

Fujii: Media people are participating. We would like to entertain questions from them. Also, because time is running out, we would like to make it the last question for this meeting, please.

From the Japanese line, Nikkei BP, Mr. Hashimoto, please.

Hashimoto: Nikkei BP Hashimoto. The evaluation of people was asked already. My question might be overlapping with that, but I’d like to ask, you acquired several companies so far. How to treat people, the way of hiring people amongst those companies, even though they are under Astellas, but such system hasn’t been really integrated or unified, or has this been touched upon? So, internal venture from Tsukuba originated from Tsukuba, for the time being the way to treat them or the way of hiring them will not be different?

Shitaka: We acquired overseas a variety of companies. After that, they followed the Japanese Astellas HR system. The same applies to AIRM and Universal Cells, as well. The same ladder, or grading, is applied. In that way they are managed. The new way of evaluation or the new ways of treating people will be the coming things. For example, some milestone is achieved, then a special bonus might be paid. We haven’t been really in the stage to execute such approaches. Basically, the research organization members regardless of their locations, they are all managed under Astellas HR system.

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Hashimoto: Understood. If so, again, including these internal ventures, including overseas companies, the human resource exchange amongst those ventures might not be hindered and smoothly conducted?

Shitaka: Your understanding is right.

Hashimoto: Another question. Depending on the progress of the projects, you may need more people, and the need for such people may be reduced in a flexible fashion within the system. Is there any place to pull extra people, or people in excess? Which is the department of revision where you can pull people?

Shitaka: In principle, we don’t have any people in excess. The Company is evolving all the time, and the capability we need is also changing every day. We have to refresh the necessary headcount and necessary capabilities. The matching of the people, or the talent, that should be a good match. So, an organization to pool excessive personnel, we are not planning to establish such an organization.

Hashimoto: As an image, incubation start-up, resources may concentrate there, correct?

Shitaka: For example, if we have a research engine, if we thought it’s going to be successful, we might increase the headcount. But unfortunately, it may not be working so well as expected, dozens of people might have nowhere to go. We cannot rule out such a possibility. Even in such a case, as with the case with external biotech ecosystem, they can find a job at other bio-ventures to demonstrate their capabilities there. So that’s the market principle and we might need to think about this in our organization.

Fujii: We’d like to close this meeting. Thank you very much for your participation today.

[END]
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