Astellas Pharma Inc.
Online Meeting (Acquisition of Iveric Bio)

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Event Summary

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[Venue] Webcast

[Number of Speakers] 3
Naoki Okamura President and CEO
Jotaro Suzuki, Ph.D. Vice President, Primary Focus Lead, Blindness and Beyond
Hiromitsu Ikeda Head of Corporate Advocacy & Relations

[Participant Names] Hidemaru Yamaguchi Citigroup Global Markets
Kazuaki Hashiguchi Daiwa Securities
Seiji Wakao JPMorgan Securities
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Shinichiro Muraoka Morgan Stanley MUFG Securities
Kika Hyodo TOYO KEIZAI INC.
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Shinya Tsuzuki Mizuho Securities
Kasumi Haruta Credit Suisse Securities
Stephen Barker Jefferies
Yuino Yasukawa THE NIKKAN KOGYO SHIMBUN,LTD. (THE DAILY INDUSTRIAL NEWS)
Shunichi Okada Yomiuri shinbun
Presentation

Ikeda: Thank you for taking time out of your busy schedule to join us today for Astellas Pharma’s briefing session on the acquisition of Iveric Bio of the United States.

My name is Ikeda of the corporate advocacy and relations department. I will be your moderator today. Thank you for your cooperation in advance.

There are two ways to participate in this session, via Zoom webinar and live streaming. After our presentation, we will move on to the Q&A session, but we will only be accepting questions via Zoom webinar. Please note that the question will not be accepted from the live streaming.

Today’s attendees are Naoki Okamura, President, Representative Director, and CEO; Dr. Jotaro Suzuki, Primary Focus Lead, Blindness and Beyond.

Simultaneous interpretation will be provided between English and Japanese, including the Q&A session. Please note that we cannot guarantee the accuracy of the simultaneous interpretation. If you are attending from our Zoom webinar, please choose your preferred language from the menu on the Zoom screen. If you choose the original language, you will be able to listen to the original audio without simultaneous interpretation. Today’s explanation will be given in line with the presentation material posted on our website.

Let me read a cautionary notice. All statements in this presentation slides, other than statements of historical fact, are statements that could be deemed “forward-looking statements”.

This presentation slides contain “forward-looking statements” relating to, among other things, the proposed acquisition of Iveric Bio by Astellas and the objectives of such proposed acquisition, Astellas’ and Iveric Bio’s beliefs and expectations regarding the potential benefits sought to be achieved by Astellas’ proposed acquisition of Iveric Bio, the potential effects of the proposed acquisition on both Astellas and Iveric Bio, the expected benefits and success of Iveric Bio’s product candidates, the potential for and anticipated timing for approval of ACP, the anticipated financing of the proposed acquisition, and the anticipated timing of completion of the proposed acquisition, each of which involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

Astellas and Iveric Bio have based these forward-looking statements on their current expectations and projections about future events and trends that they believe may affect the financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs of Astellas and Iveric Bio, but they cannot guarantee future events, results, actions, levels of activity, performance or achievements, business and market conditions, the timing and results of biotechnology development and potential regulatory approval.

Next, I will read additional information and where to find it. In connection with the proposed acquisition, Iveric Bio will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed acquisition. This press release is not a substitute for the proxy statement or any other document which Iveric Bio may file with the SEC. The definitive proxy statement will be mailed to Iveric Bio’s stockholders in connection with the proposed acquisition. Before making any voting decision, Iveric Bio’s investors and the security holders are urged to read the preliminary and definitive proxy statements and any other documents to be filed with the SEC in connection with the proposed transaction or incorporated by reference in the proxy statement when they become available because they will contain important information about the proposed acquisition. Any vote in respect of resolutions to be proposed at Iveric Bio’s stockholder meeting to approve the proposed transaction or other responses in relation to the proposed...
transaction should be made only on the basis of the information contained in Iveric Bio’s proxy statement. Investors and security holders may obtain free copies of these documents when they are available and other related documents filed with the United States Securities and Exchange Commission, SEC at the SEC’s web site, and all documents filed by Iveric Bio with the SEC are available to all stockholders of Iveric Bio free of charge at its web site.

Next, I will read the participants in the solicitation, Iveric Bio, and its directors, executive officers and other members of management and certain other people may be deemed to be participants in the solicitation of proxies in connection with the proposed acquisition. Information about Iveric Bio’s directors and executive officers is included in the proxy statement for Iveric Bio’s annual meeting of stockholders for 2023, filed with the SEC on April 5, 2023. Additional information regarding these persons and their interests in the merger will be included in the proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents, when available, can be obtained free of charge from the sources indicated above.

Let me read the important additional information, and this does not continue. This communication is for informational purposes only and is not intended to and does not constitute, or form part of, an offer, invitation or the solicitation of an offer or invitation to purchase, otherwise acquire, subscribe for, sell or otherwise dispose of Iveric Bio common stock or any other securities, or the solicitation of any vote or approval in any jurisdiction, pursuant to the proposed acquisition or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law.

Let us start the presentation. Please start, Mr. Okamura.

Okamura: Hello, everyone. I’m Naoki Okamura from Astellas Pharma Inc. Thank you very much for joining us today in spite of a short notice. We will explain our acquisition of Iveric Bio Inc., which we announced this morning at 8:00 AM, JST.
On pages two and three, our cautionary notice and information. This was explained by Ikeda earlier, I’m not going to read these pages.
Page four is the agenda for today. I will explain the transaction summary and overview of Iveric Bio and then strategic rationales for this acquisition. I will also touch on financial considerations for this transaction as well.

TRANSACTION SUMMARY

<table>
<thead>
<tr>
<th>Party</th>
<th>IVERIC bio, Inc. (New Jersey; listed on NASDAQ)</th>
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<tbody>
<tr>
<td>Purchase Price</td>
<td>• US$40.00 per share in cash</td>
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<tr>
<td></td>
<td>• Premium of 64% to Iveric Bio’s unaffected closing share price of US$24.33 as of March 31, 2023</td>
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<tr>
<td></td>
<td>• Premium of 75% to Iveric Bio’s 30 trading day volume weighted average price as of March 31, 2023</td>
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<td></td>
<td>• Acquisition amount: approximately US$5.9 billion*</td>
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<td>Acquisition Method</td>
<td>• A wholly-owned subsidiary of Astellas US Holding, Inc. (Berry Merger Sub, Inc.) will acquire 100% of the outstanding shares of Iveric Bio</td>
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<tr>
<td>Timing for Closure</td>
<td>• The acquisition is expected to close during Q2 FY2023, subject to approval by Iveric Bio’s stockholders and other customary closing conditions</td>
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*Acquisition amount includes the full amount required to purchase all outstanding options and restricted stock units.

On page five, I will explain the transaction summary. Purchase price is USD40 per share in cash. The purchase price represents a premium of 64% to Iveric Bio’s unaffected closing share price as of March 31, 2023, and a premium of 75% to Iveric Bio’s 30 trading day volume weighted average price as of March 31, 2023. The acquisition amount is about USD5.9 billion in total. As for acquisition method, a wholly owned subsidiary of Astellas US Holding, Inc. will acquire 100% of the outstanding shares of Iveric Bio. Iveric Bio will become an indirectly wholly owned subsidiary of Astellas. This acquisition is expected to close during Q2 of FY2023.
subject to approval by Iveric Bio’s stockholders and other customary closing conditions, including receipt of required antitrust regulatory approval. The impact of this acquisition on our financial results is not reflected in our full-year consolidated financial forecast we announced on April 27, 2023. We are reviewing the impact, and we promptly announce any event data to be public reported.

On page six, I will introduce an overview of Iveric Bio. Iveric Bio is a biopharmaceutical company headquartered in New Jersey in the United States. It focuses on the discovery and development of therapeutic drugs in the field of ophthalmology with high unmet medical needs. The number of employees is about 260 in total. About 60 of them are engaging in R&D. The company has a commercial team of about 90 people. It’s preparing to establish a commercial foundation in the United States for sales and marketing activities of its lead program, avacincaptad pegol, hereinafter called ACP, after obtaining marketing approval. In its current pipeline, the company filed NDA for ACP with USFDA for geographic atrophy, secondary to age-related macular degeneration. It’s also considering a rare disease called Stargardt disease as an additional indication as well. In addition, a small molecule program as well as multiple gene therapy programs using adeno-associated virus for retinal diseases are in research stage.
Turning to page seven. We think there are two major strategic rationales for this acquisition, which I’m going to explain. First, the acquisition of its lead program, ACP. ACP has potential to become a standard of care in the geographic atrophy market with large patient population and significant unmet medical needs. If the acquisition of ACP and its approval and launch is successful in line with the expectations, ACP can serve as a new revenue-generating pillar to make sure of the achievement of our FY2025 revenue targets set in CSP2021. Also, ACP is anticipated to help compensate for the decline in sales after XTANDI LOE. Second, we can establish foundational ophthalmology capabilities, which will lead to the future development of one of our Primary Focuses, Blindness and Regeneration. We hope that we can further promote our programs by incorporating Iveric Bio’s strength in commercial, medical, and R&D areas in ophthalmology.
AVACINCAPTAD PEGOL (ACP) OVERVIEW

ACP has the potential to be an innovative medicine to address significant unmet medical needs in ophthalmology

| MOA | Complement C5 inhibitor: Suppresses activity of complement system that causes retinal cell degeneration, leading to a decrease in the rate of geographic atrophy (GA) progression |
| Modality | Pegylated RNA aptamer (Chemically synthesized) |
| Administration method | Monthly or bi-monthly* intravitreal injections |
| Target disease | Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) |
| | Stargardt disease |
| Regulatory status | Breakthrough Therapy designation granted by FDA (November 2022) |
| | NDA filed (PDUFA date: August 19, 2023, under Priority Review) |

*Bi-monthly regimen is under investigation.

On the next page, I will explain the details of each strategic rationale. On page eight, I will explain an overview of the lead program, ACP. ACP is a pegylated single-strand RNA aptamer with action to inhibit complement factor C5 targeting diseases, such as geographic atrophy secondary to age-related macular degeneration. Overactivity of the complement system is expected to cause the degeneration of retinal cells and affect the onset and deterioration of geographic atrophy and vision loss. By inhibiting complement factor C5, ACP prevents the progression of geographic atrophy as was demonstrated in clinical studies. As for ACP’s mechanism action in detail, please refer to page 19 in the appendix. Based on these data, ACP is currently the only drug granted with breakthrough therapy designation for this disease by US FDA. In February this year, the NDA filing was accepted by FDA with designation for priority review. PDUFA date is set for August 19 this year. We are hoping that ACP will be approved as an innovative treatment for ocular diseases with very high unmet medical needs.
On page nine, I will explain the pathogenesis of geographic atrophy secondary to age-related macular degeneration, a target disease for ACP. From here, we are going to use abbreviations, GA for geographic atrophy, and AMD for age-related macular degeneration. AMD is one of the main reasons for moderate to severe vision loss in aging adults. The macula is a small area in the center of the retina responsible for central vision. As AMD progresses, the loss of retinal epithelial cells and underlying blood vessels in the macula results in macular thinning and/or atrophy of retinal tissue. AMD has two types, wet and dry AMD. Wet AMD is caused by abnormal angiogenesis, while dry AMD is caused by the atrophy of macular tissues. For wet AMD, effective drugs, such as anti-VEGF therapies, have been launched. In dry AMD, which accounts for majority of AMD, with disease progression, it will develop a GA. GA leads to irreversible loss of vision in patients, about 40% of the eyes with GA are blinded. In the United States, at least about 1.6 million people are estimated to have GA, but currently, there is only one approved treatment. This is a disease with significant unmet medical needs on the longstanding need for effective treatment.
On page 10, we summarize the product pipeline for the target disease of GA by clinical phase. They are also arranged by modality from top to bottom, small molecules, nucleic acids and antibodies, genes, and cells. As the first therapeutic agent, Apellas SYFOVRE, complement factor C3 inhibitor was approved by the US FDA in February 2023. NDA has been submitted for ACP as the second therapeutic agent for GA. We expect that ACP will be a frontrunner in this disease for which there has been no treatment until now and that it will provide value to many GA patients. In addition, as you know, ASP7317 is our lead program in cell therapy, for which Phase I trial is currently ongoing. We believe that the addition of ACP to ASP7317 will provide therapeutic options for patients with GA with various degrees of severity and will help us build a strong product portfolio going forward.
On page 11, from here, I will discuss the two pivotal trials, GATHER1 and GATHER2. These studies evaluated the efficacy and safety of intravitreal ACP in patients with GA secondary to AMD. The primary endpoint was the change in the area of GA lesions measured by fundus autofluorescence at 12 months from baseline three doses of 1 mg, 2 mg, and 4 mg were studied in GATHER1, and the number of patients was increased with 2 mg, which was determined to be optimal and further studied in GATHER2.

Page 12, the results of the primary endpoints of both studies are described. GA area can be measured by analysis of fundus autofluorescence images. It is known that the expansion of the lesion is closely related to visual loss and is considered an important endpoint in verifying treatment efficacy. In both the GATHER1 and
GATHER2 studies, changes in GA area were compared before and 12 months after the treatment. In GATHER1, the mean change in GA area from baseline to month 12 was reduced by 27.4% with ACP compared to the sham group. In GATHER2, the number of patients is further expanded. Similarly, a 14.3% reduction was observed compared to the sham group.

Page 13. Data on the effect on vision loss are shown here. The results for GATHER1 and GATHER2 are combined in the post hoc time-to-event analysis, counting the number of subjects with significant vision loss from baseline. As shown in the graph, in the sham group, over 8% of patients had significant vision loss after 12 months. In contrast, fewer than 4% of subjects in the ACP group experienced vision loss for a hazard ratio of 0.44 or a 56% reduction in risk of vision loss. These results suggest the promising efficacy of ACP, which could be of great value to patients with GA for which effective treatment options have been limited.
On page 14, we discuss the safety data. There are no clear differences in the incidence of adverse events, including serious ones between the ACP-treated and the sham groups in either of the studies. Regarding choroidal neovascularization, or CNV, a comprehensive CNV surveillance program ensures a consistent safety profile. In addition, the risk of infection is a concern because complement factors are involved in protection against infection. As shown at the bottom of the table, no infectious endophthalmitis was identified. Based on these results, we believe ACP has a favorable safety profile.

On page 15, we present the medium-term revenue for illustrative purposes for our key products following this acquisition. We believe that ACP’s successful approval and growth will better ensure that we achieve our...
sales targets for FY2025 as set forth in our CSP2021. We expect ACP to continue to grow further in late 2020’s, becoming, along with fezolinetant and PADCEV, the third pillar of our business that will compensate for the decline in sales due to LOE of XTANDI while reducing our dependence on specific products.

ESTABLISHING FOUNDATIONAL OPHTHALMOLOGY CAPABILITIES

The acquisition of Iveric Bio is expected to provide capabilities as a leader at the forefront of ophthalmology field

**Commercial and Market Access**
- Enhance commercial capabilities in ophthalmology to maximize ACP’s value
- Advance market access proficiencies with payers
- Build a foundation to support the future launch and commercialization of PF-BR assets

**Medical and R&D**
- Access to network of ophthalmology experts and medical institutes
- Acquire the know-how that succeeded in clinical development in GA
- Acquire research platform and assets in retinal gene therapy

On page 16, let me explain the second strategic rationale, which is to establish foundational ophthalmology capabilities, roughly dividing it into two parts. First, the enhanced commercial capabilities and the market access proficiencies in ophthalmology will build a foundation to support the future launch and commercialization of Primary Focus drive assets, including ASP7317. In addition, the Company will gain access to Iveric Bio’s network of ophthalmology experts and medical institutions, know-how from successful clinical development in GA, and the talent and assets related to retinal gene therapy. Through the acquisition of these foundational capabilities, we aim to establish a position as a leader at the forefront of ophthalmology field, an area with high unmet medical needs.
On page 17, in addition to cash on hand, we plan to procure a total of approximately JPY800 billion through short-term loans and CPs to fund this acquisition. Subsequently, the Company expects to raise funds through the issuance of corporate bonds and long-term loans and to make the funds permanent as soon as possible. The new debt created by the acquisition can be repaid within the next five to seven years through robust cash flow. There will be no change in the capital allocation policy described on the right side of the slide after this acquisition. We will continue to diligently control our financial structure to allow for future opportunistic investments. We also plan to pay dividends in accordance with CSP2021.

This concludes my presentation. Thank you very much for your attention.
Question & Answer

Ikeda [M]: Thank you very much.

Next, we are going to entertain questions from the audience. You can ask questions on the Zoom webinar. You cannot ask questions from the live streaming. If you have a question, please press the raise-hand button at the bottom of the Zoom screen. If you’re joining from your smartphone, if you tap the details, raise-hand bottom will be displayed, so please press it. The emcee will name you one by one. So please unmute yourself on your screen. Please mention your name and affiliation before asking your question. Now, the floor is open to questions. Thank you very much.

First, Mr. Yamaguchi from Citigroup Securities, please.

Yamaguchi [Q]: Thank you very much. I have a few questions. First of all, Apellis product and the differentiation from Apellis product. I understand the unmet medical news in the differentiation from the Apellis product at 24 months. There was a reduction by 17 or 20. The data between the two studies was different from ACP. What’s the differentiating point compared to this Apellis product?

Okamura [A]: Thank you for your question. There is no head-to-head comparative study. With a different reduction rate, what is the differentiation? I think it’s too early to discuss that. In terms of the mode of action, related to the complement system, Apellis product is to inhibit C3 more upstream in the system. According to our expectations, C5 is more downstream closer to the disease conditions, which may contribute to safety. We cannot rule it out, but based on the clinical studies in a small sample size, it’s too early to discuss that point. As of now, which is superior or inferior, it’s difficult to say. Having said so, we are going to be either a second drug in this market, but we don’t think we are inferior to the leading product.

Yamaguchi [Q]: My second question is regarding the impact on the medium-term management plan. I think that there are various factors to be considered. The third blockbuster candidate as you mentioned, I know that it is too early to mention, but I think that there will be a potentially big opportunity for this. if you have any projection regarding the potential sale side or revenue and going forward, if you can provide such information when it becomes available.

Okamura [A]: Understood. Thank you very much for your question. Today, we would like to refrain from giving you any specific number. If you look at page 15, fezolinetant and PADCEV, and following the two, we believe that this is going to be the third pillar. Please understand this perception.

Yamaguchi [Q]: ASP7317 is your existing product. The indication is similar. You have not made a lot of progress in the development of what is going to be the expected synergy, including the acceleration of the development. If there is anything you can share, that would be highly appreciated.

Okamura [A]: As you pointed out, the clinical studies have not a lot of progress, so we are frustrated. Iveric, regarding retinal diseases, has a high level of specialty in their R&D. They have an R&D team with lots of expertise, and also, they have R&D facilities. They have a network with them. We struggled, and the progress was slow for 7317, but this can be a favorable win for us. According to expectations regarding the indications, ACP, in the development of GA, its progression is going to be slowed according to the MOA. ASP7317 is to transplant RPE cells so that they can function. That’s our expectation. Up to vision loss patients may be very severe, but they would be able to recover their vision to a certain extent. The indications are going to be slightly different between the two.

Yamaguchi [M]: Thank you very much. That’s all for me.
Ikeda [M]: Thank you very much.

Next, from Daiwa Securities, Mr. Hashiguchi, the floor is yours. Mr. Hashiguchi, please unmute yourself.

Hashiguchi [Q]: This is Hashiguchi of Daiwa Securities. Thank you for this opportunity.

On page seven, there are two strategic rationales for this acquisition. USD5.9 billion value to be divided into these two strategic rationales. What could be your allocation in terms of valuation at this acquisition that you are expecting? What value will be generated in these two segments with the strategic rationale roughly speaking, please?

Okamura [A]: Yes, thank you for your question. In the end, after closing of the deal, the purchase price allocation will be made, and then that will clarify which will be in the goodwill and in-process R&D and so forth. At such timing, this is where we turned into the intangible assets because we are approaching the time of the launch, but we are not able to give you any excuse based upon that. At least so far, in the process of valuation based on our gut feel, the value of ACP, we’ll carry the majority of the portion of the variation. I mean, number two here, the tailwind effect for number two, for our products and pipeline, it will be very difficult to quantify that. I believe that’s the portion to be allocated to number one in terms of the strategic rationale number one financially, at least. Thank you very much.

Hashiguchi [Q]: ACP originator is a different company in my view. What is the right relationship? Because of early licensing gain, can we assume that it’s going to be very profitable? Regarding the timeline of the development in the United States, you talked about it. What about other regions such as Europe?

Okamura [A]: Thank you for your question.

First, about your second question, I’d like to respond. Then, regarding the rights, Primary Focus lead, Jotaro Suzuki, is going to respond.

First, about your second question. In principle, Iveric does not have capabilities or organization outside of the United States. There’s development there. Finally, at the end of last month or last week, they started the discussions to exchange views with the European regulatory authorities. If we are to join together, we have a bigger geographical footprint compared to them. Outside of the United States, the development there, and also the discussions with the regulatory authorities, we can accelerate.

Going back to the first question, Jotaru Suzuki is going to respond.

Suzuki [A]: Thank you for the question. Regarding this product, before Archemix is a company, which licensed out this compound to Ophthotech, former Iveric, and the rights have been transferred to Iveric by now. Archemix relationship would not have a huge impact as of now.

Hashiguchi [Q]: Thank you very much. Well, the development status in Europe. In that sense, I mean the timeline, could you please elaborate on the timeline when you expect to launch this product? There will be wide-ranging scenarios that should be considered. Is this correct understanding?

Suzuki [A]: Regarding the development in EU, I would say as soon as possible, we would like to come up with policy in order to realize it, but as of today, we have not come up with any accurate or precise time schedule.

Hashiguchi [M]: Thank you very much.

Ikeda [M]: Thank you very much.

From JPMorgan Securities, Mr. Wakao, the floor is yours.
Wakao [Q]: Yes, this is Wakao speaking. I am from JPMorgan.

I have several questions. First question is on page 12. GATHER1 and GATHER2 data, what is the difference generated from the data between the two studies? I believe that the patient profile is almost similar between the two studies. What is the difference in the data?

Suzuki [A]: Thank you for your question. Well, we are not quite sure actually about the difference. In both studies, there has been a clinically significant difference that has been demonstrated. That is for sure.

Wakao [Q]: Also, the impact on your financial results, I have a question on that. Particularly on P&L, SG&A cost, and R&D expenditure by Iveric Bio would be included in your statements. According to your presentation today, R&D, sales and marketing, you think you have found value there. I thought that you can bring it into your P&L. I have that question to ask.

Okamura [A]: PDUFA is August. What we have to avoid the most is that Iveric has prepared a lot by now. That should not be coming to a standstill. We have to avoid the standstill. What to do will be decided by the two companies through discussions. Right after the closing, the organization right after the closing will be preserved unless something unnecessary would be found. Iveric will be preserved as is in principle.

Wakao [Q]: Understood. Thank you.

Lastly, we are approaching the PDUFA target date, so PDUFA day and the closing. What will be the timing of these two dates?

Okamura [A]: Getting approval or when are we expected to get approval, that is not included as the condition for closing. For us, the shareholders of the other parties’ approval need to be obtained and also clearance from regulatory authorities. In this type of M&A agreement, a closing condition, commonly accepted closing conditions, will be met over time. The approval from shareholders of Iveric as well as the clearance of the antitrust law-related conditions, these two must be met.

Wakao [M]: Thank you very much.

Ikeda [M]: Next, Schroder Investment Management. Ms. Sato, please.

Sato [Q]: Thank you very much.

Regarding this compound for Stagardt disease, what is the progress of the development of this compound in that indication?

Suzuki [A]: Regarding Stargardt disease, it’s still in Phase II. We don’t have the results yet, but Iveric conducted preclinical studies for Stagardt disease, we think we can expect efficacy as well, so we are supporting that.

Sato [Q]: What is the timing of the end of Phase II studies?

Okamura [A]: As of now, we don’t have the accurate information, so we would check and come back to you later.

Sato [Q]: Then, after 13 injections and the frequency of administration is lowered, but still, the progression of the disease can be suppressed. That effect has not declined?

Suzuki [A]: While GATHER2, after 13 administrations, yes, in this study, we believe it is a very important study. Up until the first year, monthly administration was tested and studied. From year two onwards, this has been changed by monthly administration. By this, the frequency of administration interval could be extended to
reduce the burden on the patients, and that was tested in the study. The results have not become available yet, and this will become available by the end of 2023.

Sato [Q]: So, after PDUFA date, is it correct?

Suzuki [A]: Very subtle timing though.

Sato [Q]: It’s understood.

Regarding the existing staff of Iveric, 90 of them are commercial staff members. Information provision about this product would be done by 90 people, is there going to be no need to hire additional people?

Okamura [A]: Well, it’s difficult to say. Of course, there are specialists in retinal diseases. The sales force with experience in ophthalmology were hired to create a team of 90. Market access and other things other than the field force, they would need a variety of staff members. From Iveric’s perspective, they may think this is going to suffice, but for the future, commercial organization members would also work together and discuss with them. We may suggest a reinforcement in some areas or staff members can be utilized, so there may be no need to hire additionally. Such kind of discussions will take place from now on.

Sato [Q]: A commercial team of 90 people?

Okamura [A]: That’s not necessarily 90 sales reps people, but market access people, reimbursement people included. Yes, commercial team.

Sato [Q]: How many sales reps do they have?

Okamura [A]: We don’t have the details at the time. We will check and come back to you if we can find it out.

Sato [M]: Thank you very much.

Ikeda [M]: Next, from Morgan Stanley MUFJ Securities, Muraoka-san, please.

Muraoka [Q]: Hello. This is Muraoka of Morgan Stanley. Thank you for this opportunity.

I think we have heard various discussions so far. This is a question for clarification. Borrowings will be made. Interest rate on borrowings. Is this going to be based upon the Japanese interest rate? Or should we assume interest rate in the United States to be applied?

Okamura [A]: Well, please consider Japanese interest rate.

Muraoka [Q]: Thank you very much.

Earlier, the closing date and the PDUFA date could be close. This is a question to clarify the potential risks. In case you cannot get approval at the PDUFA date or before closing, if there’s going to be any suspicion, no doubt, this deal can be canceled? In that case, how much money you need to pay? Such provisions exist, if you can share, please.

Okamura [A]: In an agreement like this, material adverse event, MAE clause, does exist. If it is, we can terminate the agreement from our side. If that close is met, if we are to terminate mutually, some portion of the agreed amount must be paid. That’s a general clause in an agreement like this in general. If approval cannot be achieved, does that constitute MAE? It can be a legal debate, so I’d like to refrain from answering this question here.
Muraoka [Q]: In terms of value or number, is there something that you are able to mention any numbers?

Okamura [A]: We would like to refrain from mentioning any specific numbers as well.

Muraoka [Q]: Understood. Thank you very much.

Earlier, the payments shall be made to the partner in the past from which licensing was done, and a single-digit amount of money shall be paid to Massachusetts University. In total, what percentage of the amount shall be paid to the outside parties for this drug?

Okamura [A]: We do not have the detailed data. If it is possible to disclose, we will do so.

Muraoka [Q]: So, it’s not going to be a significant figure?

Okamura [A]: That is our understanding.

Muraoka [M]: Understood. Thank you very much.

Ikeda [M]: Thank you very much.

Next, Toyo Keizai, Ms. Hyodo, please. Hyodo from Toyo Keizai, can you hear me?

Hyodo [Q]: I’d like to confirm this can be a third pillar. Based on the size of the revenue vis-a-vis fezolinetant and PADCEV?

Okamura [A]: Yes, your understanding is correct.

Hyodo [Q]: Also, regarding this acquisition from when you started, what is the background?

Okamura [A]: Thank you for your question. Regarding this compound, the ophthalmology field in the posterior eye segment targeting that area, we started discussing R&D, and we have been watching this compound for a long time. The clinical study data is becoming available. Initially, we thought this can be a licensing deal outside of the United States. That’s how we have been discussing with Iveric. At the beginning of March this year, from their side, the acquisition can be incorporated as a possibility, so we switch to the tie-up format to an acquisition resulting in this agreement to acquire the company.

Hyodo [Q]: When this was included as the primary focus, so how many years ago? Have you noticed that this company had also changed into the partnership?

Okamura [A]: That started in 2014 or 2015, we started to monitor and watch this company, and negotiation for licensing started from last year, I believe. In March this year, this has been switched to the consideration of the acquisition of the company itself.

Hyodo [Q]: Okay. That switch was made in March this year, understood.

Lastly, this is going to be a huge amount. At the Board of Directors meeting, there may be voices from members of the Board who have been cautious and careful about the acquisition. Are there any oppositions?

Okamura [A]: Of course, we asked. From the management team, we have responded to those questions at the Board, and then unanimously the Board has approved and supported this proposed acquisition.

Hyodo [M]: Understood. Thank you very much.
Ikeda [M]: Next, NHK, Ms. Enoshima.

Enoshima [Q]: Yes, I can hear you.

There may be some overlap with the previous questions and answers, but I would like to ask the President and CEO once again. The objective of this acquisition, and what are your expectations? Could you respond to this question once again?

Okamura [A]: Slide 7 was used to explain roughly. First of all, ACP lead program would be acquired first. Relatively speaking, we can expect the market launch in the near future. This can be expected to be a blockbuster in our CSP2021. We can make sure of the achievement of the FY2025 targets. Also, outside of the CSP, 40% of the revenue is from the XTANDI anti prostate cancer agent, which will result in LOE. We think this can help compensate for the decline in sales after LOE of XTANDI. Number two, as I said before, in the ophthalmology area, diseases in the posterior segment, gene therapies and cell therapies have been researched by us. Iveric has expertise, which can be a following win for our programs. That’s number two.

Enoshima [M]: Thank you very much.

Ikeda [M]: Thank you very much. Next, from Goldman Sachs Securities. Ueda-san, please. The floor is yours.

Ueda [Q]: Yes, this is Ueda speaking. I am from Goldman Sachs.

Regarding the background of the acquisition, I have a question. So far, you have been developing your own pipeline products in Phase I and others. Relatively speaking, early stages of clinical development, and it will take considerable time before launching, but this time, the products are in the later-stage development. Also leading to the acquisition of this compound and this candidate of Iveric other than ACP, I believe that the other candidates are in early stages of development. Other than launch of the products, there is a big gap between the launch of products as well as the candidates in the development. Could you please explain your view on this gap?

Okamura [A]: Understood. Thank you.

I have difficulty in answering your first question. So far, recently, products in early stages or the Primary Focus to be compensated or supported and augmented by the candidate products acquired from the external parties. Actually, in the case of Audentes, after acquisition, we didn’t take a lot of time before launching the products. We had such expectation. For example, in 2010, when we acquired OSI, which had the already launched products inclusive of the infrastructure for supporting that product. This is not quite a peculiar or a special case this time around based upon such past examples. However, CSP2021 is ongoing. From the project, the two POC in clinical stage cannot be obtained, and XTANDI is maturing. Also, the Lexiscan generic will be launched soon. Therefore, in order to achieve the management target under CSP2021, we needed to have the later-stage development candidates. We would not be able to make it. In order to explore the opportunities, considering these factors, we have been exploring various opportunities, and that has led to this acquisition of Iveric.

Ueda [Q]: Thank you very much. Also, in the ophthalmology field, any in-licensing of ophthalmology products into the future?

Okamura [A]: As you know, ophthalmology or urology, in principle, we are not thinking about expanding the business in that way. Among ophthalmological diseases, unmet medical needs may be high in the posterior segment eye diseases. We are not saying that there is no potential project. Jotaro Suzuki is working on a Primary Focus strategy. If there are promising compounds, there are already promising compounds and also more promising compounds into the future.
Ueda [Q]: Thank you. Second question is related to potential impact on the shareholder return. Capital allocation policy will not be affected by this acquisition you explained earlier. On the other hand, in the past, JPY300 billion to JPY400 billion are appropriate levels of cash. I believe that the share buyback has been conducted within that range. By funding for this, JPY300 billion to JPY400 billion cash on hand will be maintained, and the net cash, maybe situation may be changing. Could you please give us your take on these financials?

Okamura [A]: In principle, I said that the debt can be repaid in five to seven years. That means that we are expecting to see very strong robust cash inflow. The repayment plan shall be formulated, and we will run in line with the plan. If cash flow will remain exceeding that range and then whether or not that will be used for repaying earlier the debt, or are we going to utilize that cash or extra funds for returning to shareholders, this will be considered going forward. For now, we are borrowing money to acquire another company, so we will not be able to consider immediate share buyback tomorrow. Looking at the cash flow in and out and then if there is any extra cash available, and then we will consider what is the optimal policy. before making a decision on allocation of the cash.

Ueda [M]: Thank you. Understood. That is all I have. Thank you very much.

Ikeda [M]: Thank you very much. Next, Mizuho Securities. Mr. Tsuzuki, please.

Tsuzuki [Q]: Yes. Regarding the study results, I have a question about niche areas, Apellis compound. According to the packaging side, change from baseline at month 24, for your compound, GATHER2, the slope of the growth, the background is different. We shouldn’t make a direct comparison, but can we compare in that way? That’s my first question. After 12 months, if you inhibit the complement system, there’s going to be a bigger reduction by Apellis compound. Can your target also achieve this as a possibility? That’s all my questions.

Suzuki [A]: Thank you very much. Regarding Apellis, they have results up to month 24. We have results up to month 12.

This is quite hypothetical, and we cannot ask this question. What is going to happen after 12 months? Apellis compound and another compound, there’s going to be a strong inhibition of the complement system, so similar results could be achieved. That’s what we can imagine. As of now, we cannot say anything definitive yet as of now.

Tsuzuki [Q]: The rate of growth and should we compare the slope in terms of the change of the growth?

Okamura [A]: Yes, we are looking at the slope, so your understanding is correct.

Tsuzuki [M]: Thank you very much. Thank you.

Ikeda [M]: Thank you very much. Next, from Credit Suisse Securities. Haruta-san, please have the floor.

Haruta [Q]: Yes. This is Haruta speaking. I’m from Credit Suisse. My first question is from March 31, 2023, VWAP and the premium of 75% has been added recently. A premium should have been 20% or so. Of course, ACP, the current phase of development of ACP, is considered. Also, this can be considered to become the larger scale in sales. Could you please give us your take on the validity or appropriateness of this valuation?

Okamura [A]: Yes. Thank you very much. As we have been telling you, in March this year, we changed our consideration to acquisition of this company, and we conducted due diligence. At the end of March, I think, very last day of March, for the first time, we presented nonbinding conditions. As of March 31, a share price against wheat premium was added, and that premium compared to the share price of Iveric. This was the
original assumption of the premium. As of the end of March, over 30 days past the volume-weighted average price was used. That is the reason why we applied this. That means that for existing shareholders of the Iveric, that is the level of the premium we presented to those shareholders. From our shareholders, what is the true or the final variation with premiums should be added. For example, at the end of April, share price premium level can be considered or the 30-day trading day average volume-weighted average can be considered. They were significant. 22% and 47% were considered and calculated as a result of such considerations. Have I answered your question?

Haruta [Q]: Yes. Understood.

Secondly, GA. On page 10, you have shown us the pipeline, including GA. Your product on slide has a different position to inhibit the complement system in other disease states, various modalities and targets are shown. In this disease, why does a variety of development programs exist with the diversity? How are they going to be used differently for this disease condition? Could you give us an overview?

Okamura [A]: Thank you very much. Thank you for the great question. It’s a difficult question. Page 10 shows the pipeline of assets. You can see complement would draw your attention. ACP and also, SYFOVRE complement inhibitors and also Danicopan, and ANX and IONIS-FB-L are also complement inhibitors. AAV-based products are also complement-based. The majority is based on complement. The disease and also the cause is still unknown for this GA. There is a hereditary link. The complement system with the strongest inheritance link is where the drug discovery is concentrating using a variety of modalities. They try to approach this area. There are failures and successes. That’s the history in this area, showing the pipeline overview here. Tinlarebant also exists. Vitamin A cycle in the eye is going to be slowed. This is like a sunglasses-type drug. It’s a different type of drug. Using these agents, R&D is progressing. However, there is a focus on the complement ACP we are trying to acquire as well as SYFOVRE from Apellis frontliners among these assets. That’s the positioning.

Haruta [M]: Thank you very much. Understood.

Ikeda [M]: Thank you very much. Next, from Jefferies Securities. Mr. Barker, please.

Barker [Q]: This is Barker of Jefferies Securities. Thank you very much. Regarding financials, I have a question. The borrowings will be made JPY800 billion. Is this going to be made wholly in Japanese yen?

Okamura [A]: Yes, borrowings will be made in Japanese denomination. Yes.

Barker [M]: Thank you very much. That’s all I have. Thank you.

Ikeda [M]: Thank you very much. Next, Nikkan Kogyo Shimbun. Ms. Yasukawa, please. Can you hear me? We can’t hear you clearly. Could you be closer to the microphone?

Yasukawa [Q]: Thank you very much. I’m Yasukawa from Nikkan Kogyo Shimbun. Regarding ACP, I have a question. The market you’re targeting, you talked about the number of patients. What is going to be the size of the peak? What’s your development plan in Japan? If there’s anything you can tell, as of now, that would be highly appreciated.

Okamura [M]: Your first question is about the peak sales?
Yasukawa [M]: Yes.

Okamura [A]: We like to refrain from showing the specific figures. On slide 15, fezolinetant, PADCEV, and this can be a third pillar, so you can estimate the size, roughly speaking. We couldn’t catch your second question. Could you repeat it? Sorry, it was difficult to catch.

Yasukawa [Q]: Regarding ACP in Japan, do you have a development plan, if any?

Ikeda [A]: Development plan in Japan. Thank you for the question. We’re still examining the details. We don’t have any information to disclose as of now. Sorry for that.

Yasukawa [M]: Thank you very much. That’s all for that.

Ikeda [M]: Thank you very much. Now, the time is approaching to close. We like to take that one last question. from Yomiuri Shimbun, Okada-san, please.

Okada [M]: This is Okada speaking. I’m from Yomiuri Shimbun. Can you hear me?

Ikeda [M]: Yes.

Okada [Q]: I have a question for you, Mr. Okamura. Now, this is the acquisition of a venture company, start-up company. The R&D capabilities and the financial strength are held by you, Astellas. What have been the challenges that should be improved so far? What aspect of Iveric have you focused on in consideration of this acquisition?

Okamura [A]: Yes, thank you for your question. In this current world, you are not able to discern from large-sized companies to start-up companies. I think it is becoming less meaningful to discern in that money aspect. Innovation needs to be generated continuously in order to turn such into innovation into value. That is our stance as Astellas. We are exploring aggressively whatever is innovative for us. This time, such a compound in this clinical development stage is held by a company like this by paying this amount of money under the current management plan, CSP2021, for achieving the key metrics like in revenue, sales, and operating profit ratio in 2025. In order to achieve these challenges, we believe that this will pose one of the options that we are able to implement. That’s why we have come up to the decision to acquire this company.

Okada [Q]: As a follow-up question, I think at the beginning, you mentioned that it is less meaningful to discern between the large size of the company and the start-up companies. What do you mean by that?

Okamura [A]: Well, in the past, the pharmaceutical companies, how to value the critical mass in R&D as well as commercialization, there was a certain critical mass. The large companies were supposed to be stronger compared to the start-up companies in the past. From the end of the 20th century to the beginning of the 21st century, we started to think that it’s not anymore the time to consider such a start-up and large companies. Well, even with the start-up companies, if they have bold beliefs, as well as these excellent technologies, they will be able to create something that cannot be copied by large companies. Large companies try to develop many things on their own and try to sell everything by themselves. Getting rid of such concept, if there is anything excellent, we need to partner with the start-up companies to create together. This is not only limited to Astellas but also other big pharma in the West, the US and European market. I believe that everyone is having this attitude nowadays.

Okada [M]: Understood. Thank you very much.

Ikeda [M]: Thank you very much.
Some people are still waiting for their chance to ask questions, but time is up. We’d like to close today’s explanatory meeting.

Thank you very much for joining once again. Thank you very much.

[END]

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Document Notes

1. Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.
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