Q&A Highlights: H.U. Group IR Day 2022 IVD Segment

Date: December 9, 2022

Q-1

- Regarding "CDMO: Total number of items", I think the number of items in manufacturing phase is important since it directly contributes to sales. What is the breakdown of the 52 items in FY2022? Also, please tell us when the 40 or so items start development in this fiscal year will step into manufacturing phase.

A-1

- Firstly, we expect it to take roughly 3 years from sign a deal to start manufacturing. If the item is for China, for example, it may take 4-5 years. In any case, it will vary depending on the regulatory and local conditions in the target country.
- As shown in the graph of test production volume on slide 18, the orange portion of the graph shows a gradual increase starting in FY2023. We assume that those items started development in FY2020 will step into manufacturing phase by the end of FY2022, and they will start contributing to sales around FY2023.

Q-2

- You have invested about 10 billion yen so far for capacity expansion of CDMO items. What is the timing of future capacity expansion and the amount of money for capital investment?

A-2

- Basically, we believe that major capital investments have been completed. There may be a shortage of some manufacturing equipment in the future, but we do not anticipate any major capital investments at this time.
- Even if the number of manufacturing items increases in the future, we believe that no major additional investment will be required.

Q-3

- My question is about how to proceed the CDMO business. You have stated that the key success factor is to "constantly expand portfolio of raw materials and technologies which other companies do not have." What are your initiatives to achieve this? Please tell us about the possibility of proactively acquiring

companies with unique technologies, such as ADx NeuroSciences, which you acquired this time.

A-3

- The source of our business competitiveness is to always have a firm hold on technologies what other companies do not have. The recent acquisitions of ADx NeuroSciences and Fluxus have expanded our portfolio, which is a positive factor.
- As for ADx NeuroSciences, we will have to commercialize what they have and then propose it to our customers to get them to adopt it, and as for Fluxus, we think they provide further opportunities to Fujirebio because they give us a wider choice of combinations of reagents detection instruments.
- Therefore, for the time being, rather than making new acquisitions, we will use the acquired technologies, including PeptiDream's, to achieve early commercialization and demonstrate their clinical value.

Q-4

- Could you please elaborate on the strengths of the ultra-high sensitivity detection technology of Fluxus?

A-4

- Fluxus is a company that originally specialized in optical technology. The company has been involved in various collaborations and is continuously experimenting with new developments.
- We have been in communication with Fluxus for a long time, and the detection technology they have developed is excellent, the idea is appealing, and we think it is very likely to be implemented.

Q-5

- I would like to discuss the relevance between "LUMIPULSE" and the ultra-high sensitivity detection technology. While continuing to develop items such as β-Amyloid as reagents dedicated to "LUMIPULSE", do you intend to launch the RUO (research use only) markers on the ultra-high sensitivity platform based on Fluxus' technology? Please let us know if there is any difference between them.

A-5

- First of all, we believe that the "LUMIPULSE" is a highly sensitive and stable instrument with little inter-instrument difference and good reproducibility. Therefore, we are currently developing various NEURO blood markers.

- However, some Alzheimer's-related items need to be confirmed with higher sensitivity. While the "LUMIPULSE" can detect to some extent, we would like to produce more accurate and precise values by ultra-high sensitivity technology.
- Currently, we have managed to ensure the sensitivity of various RUO reagents, in part because we have been able to secure high quality antibodies. However, it may be difficult to detect various blood markers for Alzheimer's disease in the future with the current chemiluminescence. Therefore, we are considering the development of the next target marker based on ultra-high sensitivity platform.

Q-6

- I understand that ADx NeuroSciences was acquired because they have various antibodies such as "pTau". On the other hand, Fluxus seems to have technology that has not been made into an IVD item so far, looking at their patents, and I am concerned about whether they can make an IVD item even if they can produce a RUO marker.

A-6

- While it is difficult to provide details of the Fluxus technology, we have evaluated it in comparison to other existing ultra-high sensitivity instruments or systems from other manufacturers and estimate that it could be implemented with equal or better performance. Therefore, we are proceeding with the study with confidence that it can be implemented.
- We acquired the technology with the aim of launching IVD items. We believe that results will be achieved based on our joint research to date, and we need to accelerate development.

Q-7

- What is the timeline for launching IVD products using Fluxus' technology? The business chance will be limited, if you launch RUO items only by high-sensitivity detection technology.

A-7

- Firstly, we will launch the RUO markers, and then we will work on the IVD plan. At this point, we do not have a definite plan yet, it will be 2025 or later from a medium-term perspective, not a short-term perspective.