

Q. How will the settle down of COVID affect the performance of the second half of the fiscal year?

⇒ We expect sales to be affected by approximately 10 billion yen and profits by 3-4 billion yen in the second half of the fiscal year with the COVID settling down. In addition, the revision of compensation levels in the second half of the fiscal year in order to strengthen the workforce in the CRO business has also had an impact, pushing down profit margins. From FY24 onward, the company will secure new business in healthcare, including that related to municipalities, and in the CRO business, it will secure more orders, especially international projects, by securing new resources and recovering profit margins.

Q. With the shortage of generic products in the market, I think there are increasing expectations and requests for CMIC CDMO business. Will you establish a one-stop generic production system including China, Korea, and India through the alliance with DNP?

⇒ Generic drug manufacturers launch new products every year, and CMIC, after consulting with generic manufacturers, determines the target new generic products, negotiates with API manufacturers in India and Taiwan for their development and supply, imports APIs or intermediates stably and at the lowest cost, and manages the imported API for purification at DNP Group API plants for commercialization. We will create a model in which we procure the API, develop formulation and manufacture finished dosage forms of the target generic products, and supply them to the generic manufacturers. Currently, we are not considering China or other APIs procurement routes, but we may consider them in the future.

Q. Are you currently working on specific projects with major generic manufacturers? Also, will the existing plants in Japan shift to the bulk pharmaceuticals business?

⇒ We are actually discussing with about 5 generic manufacturers. We will not shift our focus to APIs, but rather build an integrated manufacturing platform from API to generic formulation development and manufacturing, and create an ecosystem for the development and manufacturing supply of generic products in collaboration with our plants in Japan and other CMOs. We need to be flexible in terms of manufacturing capacity, but we will build an integrated manufacturing platform and make it a model that we will manage the entire process.

Q. The CRO business seems to be growing organically. How does this compare to market growth and what differentiates you from other companies?

⇒The CRO is doing well, as clinical trials, once halted due to the COVID pandemic, have resumed and medical institutions have increased their activities. The same applies to other companies, but CMIC is currently growing at a faster pace than before the COVID outbreak. CMIC is receiving orders for clinical trial monitoring, DM, and other services as a package, and this is the same trend not only for domestic projects but also for international projects.

Q. I would like to know the background behind the active recruitment in the second half of the year.

⇒In addition to the oncology, CNS, and cardiovascular fields, development projects in the primary care field are expected in the future, and we are in the process of filling vacancies to prepare for the next fiscal year.

Q. Regarding the potential of the PVC model, are there other companies that are willing to enter the pharmaceutical industry, such as Taiyo Holdings' new entry into the pharmaceutical industry?

⇒As for support under the PVC model, overseas ventures have a strong desire to enter the market, and support for the introduction of new drugs through CAN-UNIT has begun. Some companies like Taiyo Holdings are entering the market from different industries, but there are also existing pharmaceutical companies that wish to reform themselves, and CMIC believes that we can help them navigate through this process. As many new drugs are being introduced overseas, we would like to propose support for their entry into the Japanese market and work to eliminate the drug lag.

Q. The order backlog for healthcare is high, but what is the likelihood that it will be booked as sales in the revised forecast?

⇒The order backlog related to COVID will decrease as sales are booked in Q3, but the SMO business has a backlog due to strong orders. The clinical trial period will last 2-3 years, so sales will be booked in phases.

Q. What is the current status of the CRO business? I assume that inquiries from bio-ventures are active, but what is your outlook for the future? I understand that CMIC is strong in this area. Also, is there a risk that competition for orders from bio-ventures will intensify in the future?

⇒We have been active as a full-function CRO for 30 years and have established a well-established system. We are particularly proud of our very strong capabilities in regulatory

consultation, and have gained the trust of overseas bio ventures as our competitive advantage in PMDA consultation and strategy development. We have built a strong position in clinical, PM, and pharmacovigilance, and our full-functional clinical services are being utilized. In response to the competition for orders, we have received many inquiries from overseas bio-ventures, and we will continue to leverage our competitive advantage and view this as a positive opportunity to win projects.

Q. We see the alliance with DNP as a very good alliance, but we have the impression that the industry is becoming increasingly difficult to secure stable profits. If it becomes difficult to secure profits in the long term, is there a contingency plan to sell off CMIC's stake?

⇒CDMO has been a focus of CMIC's business for some time, and we see growth opportunities for the future. We have decided to partner with DNP as a long-term business partner because of the high demand for funds for internationalization, acquisition of new technologies, and capital investment, etc. CDMO is a stable business that can ensure a certain profit margin, and we consider it an essential business for Japan, and we have no plans to sell our stake in the company. We would like to continue the business in order to resolve the instability on the supply side in Japan.