Prestige BioPharma expects Solid Growth from COVID-19 Vaccine CMO business

[12 August 2021] / Prestige BioPharma Limited (PBP) specializing in the development of antibody therapeutics announced its unaudited FY2021 (from July 2020 to June 2021) results on August 12, 2021. Consolidated operating loss was KRW 18.78 billion due to an increase in operating expenses including R&D and personnel expenses which will be a future growth engine of PBP. The net loss for FY2021 reduced 48.7% from the previous fiscal year to KRW 7.69 billion due primarily to an increase in valuation gains on investment in its affiliate, Prestige Biologics' equity securities.

PBP has been laying a solid foundation for future growth for the last six years since its establishment in 2015, and the company was listed on the Korean stock exchange last February.

PBP is currently participating in the CMO consortium that will be producing Russia's Sputnik COVID-19 vaccines and its vaccine centre with 100,000 litres of final production capacity started a test operation this month. The commercial production of Sputnik vaccine is scheduled in the fourth quarter and a strong increase in sales and earnings is expected from the vaccine CMO business.

The company is also expecting a commercialisation of its biosimilar pipelines next year. PBP's Herceptin® biosimilar, HD201 has established the global distribution partnerships in the major regions of the world, and it is currently under EU EMA's review. The FDA bridging study of HD201 was published in the international journal of Pharmacology Research & Perspectives last July and the US submission to FDA is on target to complete this year. PBP's biosimilar to Avastin®, HD204 is in the process of the global Phase 3 clinical trial and PBP1502, biosimilar to Humira® is in the preparation of its Phase 1 clinical trial.

The Phase 1/2a clinical trial of PBP's first-in-class antibody treatment of pancreatic cancer, PBP1510 was approved in France in June this year. The European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) and Korean Ministry of Food and Drug Safety (MFDS) granted Orphan Drug Designation (ODD) to PBP1510 last year and ODD products' marketing authorisation application can be reviewed before Phase 3 clinical trial depending on the result of Phase 2 study.

Based on this fundamental strength, PBP will see a solid growth momentum from the fourth quarter this year.