

BIOTEM implements new industrial unit dedicated to development and production of immunoassays

Leader in development of high-quality custom antibodies, BIOTEM is boosting expertise in immunoassays and increasing kit production capacity tenfold

Project partly supported by French government through *France Relance* economic initiative

Apprieu, near Grenoble, France, June 20, 2022 – BIOTEM, a hybrid Contract Research Organization (CRO) and Contract Manufacturing Organization (CMO) focusing on high added-value services in the development/production of custom monoclonal antibodies and immunoassays, today announces the implementation of a new industrial site in Colombe, Isère, located just over a mile (2km) from its current site. This new site will be fully dedicated to immunoassay production, which will enable BIOTEM to improve the quality and quantity of its offering to meet the requirements of the *In Vitro* Diagnostic Medical Devices (IVDMD) market.

The new 900 m² (~ 9,600 ft²) facility will complement the company's 2,000 m² (~ 21,500 ft²) of antibody production platform already in operation. It will focus specifically on ELISA (Enzyme Linked ImmunoSorbent Assay) and LFIA (Lateral Flow ImmunoAssay) tests, manufacturing them to the highest current standards. The site will be equipped with humidity-controlled dry rooms, an ISO 5 standard room (equivalent to a cleanroom), a biosafety 2 confinement laboratory, cold storage, packaging and assembly facilities, and warehousing. BIOTEM's boosted capacity will allow it to meet the demand for immunoassays, which has been growing rapidly, particularly against the backdrop of the healthcare situation of recent years.

The company has benefited from a €300k (\$314k) grant awarded by the French government as part of its *France Relance* economic initiative. Together with two loans from its historic banking partners (BNP Paribas and Crédit Agricole Centre-Est), this grant will support BIOTEM in strengthening its position as a domestic producer of biological tests and help to reduce the country's dependence on suppliers that are either physically or strategically distant, the importance of which was put in stark relief by the covid-19 pandemic.

With this boost to its capacity, BIOTEM has upped its projections and now expects growth of 20–30% over the next three to five years. Alongside these developments, the company is planning to step up recruitment by hiring around 20 new staff in the coming months and intends to double the size of its immunoassay team, also within the next three to five years. BIOTEM is seeking to consolidate its quality assurance and regulatory divisions to extend the scope of support it can offer its customers.

"We're delighted to be able to provide a better immunoassay offering to our clients. This additional infrastructure will allow us to meet more stringent quality requirements in the field of IVDMDs while retaining our flexibility," explained Clarence Deffaud, co-manager and CSO at BIOTEM. "Our ambition has always been to provide a quick and efficient response to the requirements of the international market. These new facilities will enable us to further stake our position within the sector. We are also planning to deepen our partnerships with large groups within the human health, veterinary and environmental sectors."

BIOTEM is the only company in France offering a one stop service, all the way from the development of 100% fee-for-service proprietary antibodies to production of CE-marked IVDMDs under its ISO 13485 certification; in compliance with the European Regulation (EU) 2017/746. The company provides customized support, starting from the R&D stage, through to industrial production. Its platform - processes, capacities and so on - can be tailored to clients' needs. BIOTEM has even signed contracts with international customers; its portfolio of clients includes [Rhythm Biosciences](#) and [Proteomics International](#).

The new facility will be operational in Q3, 2022, once the equipment has been validated and certified for use. The company is not ruling out additional future investments to further enhance its readiness for new partnerships; it has an adjoining building plot available at its disposal to expand its facilities for this purpose.

The world immunoassay market (sales to end clients) was measured at [\\$21.8 billion \(€20.9bn\) in 2018, with a CAGR forecast of 6-8% up until 2027](#). Meanwhile the immunoassay [R&D market represents about \\$7.72bn \(€7.34bn\)](#) (estimated figure for 2023). The market has experienced sustained growth since its recent expansion driven by the Covid-19 pandemic.

About BIOTEM

BIOTEM is a CRO/CMO that supplies high added-value services in bespoke development and production of antibodies and immunoassays (both ELISA and LFIA). Thanks to its unparalleled knowledge and experience and its quality offers, backed by ISO 9001:2015 and ISO 13485:2016 certifications, BIOTEM is the preferred partner of almost 500 private and academic laboratories for their basic research projects, development of biological diagnostics and the discovery of therapeutic tools.

From the creation of unique monoclonal antibodies□ - produced via lymphocyte hybridization and/or phage display techniques□ - through production, characterization and development of immunoassays up to fine-tuning them for their intended purpose, BIOTEM offers its clients a wide range of services tailored to each individual project.

Founded in 1980, BIOTEM is based in Apprieu, near Grenoble, France, and has around 50 staff.

www.biotem-antibody.com

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