Bioindustry Dynamics

Exploring Innovations, Expansions, and Strategic Shifts

Driven by increased demand in biologic-based drugs, biologic drug substance manufacturing continues to be an active area of investment by contract development and manufacturing organizations/contract manufacturing organizations (CDMOs/CMOs), including several multi-billion large-scale biomanufacturing projects. What companies are expanding, and where do these expansions stand?

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Large-Scale Biomanufacturing Expansions Underway

Samsung Biologics. Samsung Biologics is proceeding with a multi-billion-dollar-plus investment to expand its biomanufacturing capacity, which includes the addition of a new biomanufacturing plant in South Korea. The expansion includes the addition of a fifth biomanufacturing plant and the expansion of its Bio Campus II, along with the establishment of a new stand-alone antibody-drug conjugate (ADC) facility in Songdo, South Korea. Plant 5, with a capacity of 180,000 L and spanning an area of 96,000 m², is slated for completion in April 2025, contributing to a significant increase in the company's overall biomanufacturing capacity, which will reach a total of 784,000 L upon Plant 5's completion.

The investment for Plant 5 amounts to KRW 1.9 trillion (~$1.46 billion). For the development of Bio Campus II, which will entail four plants (Plants 5–8) and an open innovation center, Samsung Biologics plans to allocate KRW 7.5 trillion (~$6 billion). Capacity expansion involves the construction of Bio Campus II, featuring four plants, each with a 180,000 L capacity. Combined with the company's Bio Campus I, the company aims to offer total capacity exceeding 1.3 million L by 2032.

Fujifilm Diosynth Biotechnologies. Fujifilm Diosynth Biotechnologies is proceeding with a multi-billion-dollar investment to expand large-scale cell-culture bulk drug substance and flexible single-use cell culture capacity, along with the addition of commercial-scale drug-product and finished goods capacity.

The company is proceeding with a $1.6-billion expansion of its large-scale cell-culture capacity at its site in Hillerød, Denmark. With mechanical completion achieved in January 2024, the first drug-substance expansion is set to come online later this year (2024). A new drug-product facility in Denmark is expected to be operational by early 2025, following a successful filling line test run in February 2024. The second drug-substance expansion is slated for online activation in 2026.

Earlier this year (April 2024), the company announced an additional investment of $1.2 billion in its large-scale cell culture biomanufacturing facility in Holly Springs, North Carolina, bringing the total investment in

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the facility to over $3.2 billion. The new investment will add 8 x 20,000 L mammalian cell-culture bioreactors by 2028, to the already planned 8 x 20,000 L bioreactors for bulk drug substances as part of the initial investment. The company was already investing $2 billion in its Holly Springs facility with the planned addition of large-scale cell-culture drug-substance suites in 2025.

In August (2024), Fujifilm Diosynth Biotechnologies opened a microbial fermentation manufacturing facility in Billingham, UK. The new facility triples existing microbial production throughput with the addition of a new production line equipped with 2 X 4,000 L fermenters, a primary separations suite, and a modular purification suite with an investment of over £100 million ($131 million). In addition, the company signaled in 2021, the company's intent to establish a flexible cell-culture facility at its Billingham site. A significant project scope change focused on applying modular principles, allowing lanes to mix 2,000 L and 5,000 L bioreactors. The facility is set to be operational by 2026.

Lonza. Lonza is making a large investment through its pending $1.2-billion acquisition of a large-scale biologics manufacturing site in Vacaville, California, from Roche's Genentech. Lonza plans to invest an additional CHF 500 million ($554 million) to upgrade the facility and enhance capabilities for producing mammalian biologic therapies. The products currently manufactured at the site by Roche will be supplied by Lonza, with committed volumes over the medium term and phasing out over time as the site transitions to serve alternative customers. The Vacaville facility currently has a total bioreactor capacity of approximately 330,000 L. Upon deal closing, approximately 750 Genentech employees at the Vacaville facility will be offered employment by Lonza. The transaction is expected to close in the fourth quarter 2024, subject to customary closing conditions. Upon closing, the Vacaville site will be integrated into Lonza's Biologics Division, joining a network of existing mammalian manufacturing sites in Visp, Switzerland; Slough, the UK; Tuas, Singapore; Portsmouth, New Hampshire; and Porriño, Spain.

Lotte Biologics. In July (2024), Lotte Biologics broke ground on its inaugural plant at its Songdo Bio Campus in Incheon International City, South Korea, the first plant of a $3.4 billion biocampus that the company is establishing. The company plans to build three biomanufacturing plants at its new biocampus in South Korea by 2030 that will provide total production capacity of 360,000 L, with each plant having 120,00 liters of production capacity. Lotte Biologics entered the CDMO market with the acquisition of a commercial scale biomanufacturing facility in Syracuse, New York, from Bristol-Myers Squibb in January 2023.

Other Biomanufacturing Expansions

AGC Biologics. In June (2024), AGC Biologics completed a new $200 million biomanufacturing building at its Copenhagen, Denmark, campus. The building doubles the site's single-use bioreactor capacity for mammalian services and allows the company to produce 150 more batches of drug product each year. The expansion adds 19,000 m^2 of space in a building that houses a manufacturing floor, expanded quality control and process development lab space, utilities to support all operations, and a dedicated warehouse to serve the entire AGC Biologics Copenhagen campus.

In addition, in January (2024), AGC Biologics announced an investment of JPY 50 billion ($350 million) to construct a new biomanufacturing facility at its Yokohama Technical Center in Japan. The new facility will offer preclinical through commercial services for mammalian-based protein biologics, cell therapies, and mRNA. The site will house multiple 2,000-liter single-use bioreactors and several 4,000 L or larger reactors for mammalian cell-culture products. The facility is expected to be operational in 2026. The company currently operates one site in the region, in Chiba, Japan, which provides mammalian expression and microbial fermentation services.

MilliporeSigma. MilliporeSigma, the life science business of Merck KGaA, is investing more than €300 million ($326 million) for biomanufacturing support through a new bioprocessing production center in Daejeon, South Korea, to provide products such as dry-powder cell-culture media, process liquids, pre-GMP small-scale manufacturing, and sterile sampling systems. Covering an area of 43,000 m^2, the facility will include production capacities, a distribution center, and an automated warehouse. The investment is expected to create approximately 300 additional jobs by the end of 2028.

Wacker Biotech. In June (2024), Wacker Biotech, a CDMO of biologics and a subsidiary of Wacker Chemie AG, opened an mRNA Competence Center at its biotech site in Halle (Saale), Germany, with an investment of over €100 million ($107 million). The new facility enables the large-scale production of active ingredients based on messenger ribonucleic acid (mRNA). Four new production lines have more than tripled the site's capacity. Some of the new capacity will be made available to the German government as part of its pandemic-preparedness plan to supply Germany with vaccines as and when required.

Just Evotec Biologics. Just-Evotec Biologics, a subsidiary of Evotec, is investing in a new facility for continuous biomanufacturing in Toulouse, France. The facility applies the company's J.POD design featuring a single-use continuous cell-culture manufacturing platform set inside production-on-demand modules within a ballroom manufacturing space. In this way, it replicates the design of the company's J.POD facility in Redmond, Washington.

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The investment of approximately €150 million ($163 million) was announced in April 2021, and the company broke ground in September 2022. Last October (2023), the building shell was completed, and the autonomous cleanroom POD installation occurred at the beginning of this year (2024). The facility is set to be operational by the second half of 2024 and will contain two continuous cell-culture manufacturing streams. J.POD Toulouse will manufacture both clinical and commercial material and will have capacity to produce up to 2000 kg of antibody per year.

Aurigene Pharmaceutical Services. In June (2024), Aurigene Pharmaceutical Services, a Dr. Reddy's Laboratories' company, opened a biologics facility spread across 70,000 sq ft in Hyderabad, India. The facility provides process and analytical development and small-scale manufacturing of antibodies and other recombinant proteins for preclinical and early-phase clinical requirements. The process and analytical development laboratories are now operational while the commissioning of manufacturing capacity will be completed later in 2024.

Enzene Biosciences. Enzene Biosciences, a Pune, India-based CDMO, is adding a new facility for continuous biomanufacturing in the US via its US entity, Enzene Inc. The company is building a new GMP manufacturing facility in New Jersey, built around the company's proprietary EnzeneX technology. The company has successfully identified, leased, and set up this inaugural manufacturing plant. The facility is 54,000 sq ft and will be launched in three phases, with the Phase I launch date slated for the third quarter of 2024. The full expansion will also include a drug-product manufacturing suite with formulation and small-volume filling equipment. The facility will also include a quality control lab, development lab, warehouse, freezer rooms, and a cell-bank store.

Aragen Life Sciences. Aragen Life Sciences, a CDMO of small molecules and biologics, is proceeding with a biomanufacturing expansion by investing $30 million for a cell-culture biomanufacturing facility in Bengaluru (Banagalore), India. The process development laboratory has been operational since December 2023. The first manufacturing suite is scheduled to be operational by December 2024.

Note: investment amounts and currency conversions are as of time of news announcement.

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