Ramping Up Biomanufacturing Capacity

Capital Investments in Biomanufacturing Continues to Be an Active Area for CDMOs/CMOs

Biomanufacturing for both traditional biologics and new modalities, such as cell and gene therapies, continues to be an active area of investment for CDMOs/CMOS. Some of the major investments by the larger CMDOs/CMOs are outlined below.

Fujifilm Diosynth Biotechnologies

In October 2021, Fujifilm Diosynth Biotechnologies broke ground on a new, $2-billion, large-scale cell-culture biomanufacturing facility in Holly Springs, North Carolina. The company had announced the investment in January 2021. The facility is expected to be operational by the spring of 2025.

The new facility is one of several biomanufacturing investments announced or proceeding by Fujifilm Diosynth. In December 2021, the company announced plans to invest £400 million ($533 million) to expand its site in Billingham, Teesside, UK, with the addition of a viral gene-therapy facility and a mammalian cell-culture facility. The new facilities are expected to be operational by late 2023. The investment is part of a 90 billion Yen ($797 million) global capital investment package initially outlined by the company in June 2021. In addition to the gene-therapy and cell-culture manufacturing expansion in the UK, the investment includes doubling cell-culture production for recombinant vaccines in the US and doubling microbial fermentation capacity at an existing UK facility.

In addition, the company is investing 100 billion Yen ($928 million) at its site in Hillerød, Denmark, near Copenhagen, to double drug-substance biomanufacturing capacity, expand its capabilities to include fill–finish, and enhance its current assembly, labeling, and packaging services. Fujifilm Diosynth acquired the facility from Biogen in 2019 for approximately $890 million. The investment will expand production lines for bulk drug substances with the addition of six mammalian-cell bioreactors, which would bring the total capacity to 12 x 20,000-liter bioreactors by the fall of 2023.

The company is investing to expand its advanced therapy manufacturing capabilities. Earlier this year (2022), Fujifilm Diosynth announced a $300-million expansion of its single-use manufacturing campus in College Station, Texas, through the addition of a new production facility that will double the company's advanced therapy and vaccine manufacturing capacity in the US. The investment is part of the company's previously announced global capital investment package initially outlined by Fujifilm in June 2021. This new facility, expected to be operational by 2024, will add approximately 138,000 sq. ft. to the existing campus and grow the site to 300,000 sq. ft.

Also, earlier this year (2022), Fujifilm agreed to acquire a cell-therapy manufacturing facility in Thousand Oaks, California, from Atara Biotherapeutics, a South San Francisco, California-based biopharmaceutical company, for $100 million. The facility can produce both clinical and commercial cell therapies, including allogeneic T-cell and CAR T immunotherapies. The acquisition is expected to be completed in April 2022. Fujifilm Diosynth is also expanding its viral vector and gene therapy offerings in Darlington, UK, with process development laboratories and manufacturing capabilities for early-stage gene therapies. The process development laboratories are operational with manufacturing services starting in the spring of 2022.

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Samsung Biologics

One of the largest expansions announced or ongoing expansions by CDMOs/CMOs is Samsung Biologics' KWR 2-trillion ($1.7-billion) investment for a new biomanufacturing plant, the company's fourth, in Incheon, South Korea, and for a second bio complex. The company broke ground on the new facility in November 2020, which, upon completion, will provide 256,000 liters in total biomanufacturing capacity. The plant will have a modular design that will allow flexibility for certain parts of the plant to begin manufacturing activities by the end of 2022, with the goal to commence full operations in 2023.

In January 2022, Samsung Biologics, announced plans to start construction of a new manufacturing facility for multi-modal products, including cell and gene therapies and vaccines using mRNA, pDNA, and viral vectors, all at a single site. This facility will be in addition to the mRNA vaccine drug-substance manufacturing suite the company is adding to its existing facility in Songdo, South Korea.

The company says it is also venturing into securing additional sites within Songdo for the construction of a sixth manufacturing facility and innovation center, and also overseas in multiple locations to maximize its manufacturing capacity to produce large-scale biologics.

Lonza

Lonza is proceeding with expansions in the US, Europe, and Asia. In 2021, Lonza announced plans to invest approximately CHF 850 million ($935 million) to add two mammalian drug-substance manufacturing facilities at its sites in Visp, Switzerland, and Portsmouth, New Hampshire. The expansion in Visp will add a new 27,500-

m² large-scale mammalian drug-substance manufacturing facility. The facility is expected to be completed in 2024 with an investment of approximately CHF 650 million ($715 million).

In Portsmouth, New Hampshire, the company is adding a new biomanufacturing facility for small-to-mid-volume production. The CHF 200-million ($220-million) facility will add capacity for up to eight 2,000-L single-use bioreactors to support Phase III clinical and commercial small- to mid-volume products. The facility is expected to be completed in 2023. In addition, Lonza began operations in 2021 at its new 17,000-m² mammalian-cell biomanufacturing facility in Guangzhou, China.

Lonza is continuing to support its collaboration with Moderna for mRNA vaccine manufacture with a new mRNA line in Geleen, the Netherlands, as well as three new mRNA lines in Visp, making a total of eight mRNA commercial-scale lines the company has across Europe.

In addition, in November 2021, Lonza announced an investment to expand microbial development capacity at its facility in Visp, and in October 2021 announced plans to expand its biologics development services at its site in Tuas, Singapore.

Boehringer Ingelheim

In October (October 2021), Boehringer Ingelheim (BI) inaugurated a new €700-million ($780 million) large-scale, cell-culture biomanufacturing facility in Vienna, Austria. The facility has up to 150,000-liter manufacturing capacity for BI products and contract manufacturing activities. The company broke ground on the facility in 2017, and the facility adds to the company's biomanufacturing network in Biberach, Germany; Vienna, Austria; Fremont, California; and Shanghai, China.

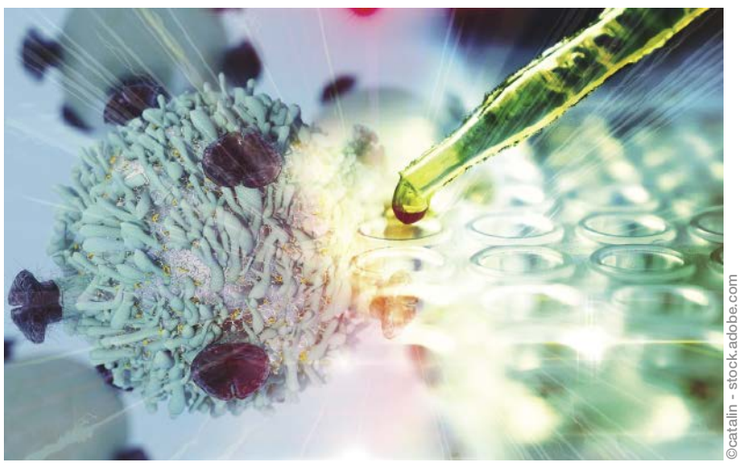
Thermo Fisher Scientific

Thermo Fisher made several moves to expand both cell- and gene-therapy manufacturing and traditional biomanufacturing. In 2021, the company added to its contract viral vector manufacturing services with the acquisition of Henogen, Novasep's viral vector manufacturing business, for approximately $875 million.

Also in 2021, Thermo Fisher Scientific opened a new pDNA manufacturing facility in Carlsbad, California.

Additionally, this year (2022), the company will launch mRNA synthesis capabilities at its site in Monza, Italy, to produce drug substance for vaccines and therapies.

The company is also moving forward with its partnership with the University of California, San Francisco (UCSF) for development and manufacturing of cell-based therapies. A new 44,000-sq-ft. cell-therapy development and cGMP manufacturing center at UCSF's Mission Bay campus is slated to open later this year (2022).



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These expansions build on the company's continued investment in cell- and gene-therapy manufacturing facilities, including: (1) viral vector facilities in Cambridge, Lexington, and Plainville, Massachusetts, and Alachua, Florida; (2) a new cell-therapy manufacturing facility in Princeton, New Jersey; and, (3) a new dedicated cryocenter in Weil am Rhein, Germany, to provide specialized cryogenic and cold-chain supply-chain services to support clinical trials across Europe and globally. The new commercial manufacturing site in Plainville, Massachusetts for viral vector capacity for gene therapies and vaccines is slated to be completed later this year (2022).

Also, later this year (2022), Thermo Fisher will begin operations at a new biologics manufacturing site in Lengnau, Switzerland. The company had earlier formed a strategic partnership with CSL Limited, a Melbourne, Australia-based biopharmaceutical company, to operate the site, for both CSL and other customer projects. Thermo Fisher is also expanding operations at its biologic drug-substance manufacturing facility in St. Louis, Missouri, and is expanding in Asia-Pacific with an integrated biologics drug-substance and sterile drug-product manufacturing facility in Hangzhou, China.

Catalent

Catalent is investing to increase biologics drug-substance manufacturing and cell- and gene-therapy manufacturing. In July 2021, Catalent announced that it will begin the first phase of a planned $100-million expansion at its facility in Anagni, Italy, to add biologics drug-substance manufacturing. The initial expansion is expected to be commissioned and operational for customer projects in April 2023. Catalent's Anagni site now provides aseptic filling, secondary packaging, and oral dose manufacturing for late-stage and commercial product launches. Since Catalent acquired the facility in January 2020, it has become a European hub for Covid-19 vaccine manufacturing as well.

Also, on the biologics drug-substance side, in 2021, Catalent completed the expansion of two new suites at its biologics drug-substance development and manufacturing facility in Madison, Wisconsin. The expansion increased the number of manufacturing suites at the site to five, which more than doubled its overall cGMP-scale capacity.

In cell and gene therapies, in 2021, Catalent acquired RheinCell Therapeutics, a Langenfeld, Germany-based developer and manufacturer of human induced pluripotent stem cells, which became part of Catalent's Cell & Gene Therapy business. In May 2021, Catalent acquired Promethera Biosciences' cell-therapy manufacturing subsidiary, Hepatic Cell Therapy Support SA (HCTS), including its 32,400-square-foot facility in Gosselies, Belgium. The facility will accommodate Catalent's commercial-scale pDNA manufacturing and is located on Catalent's existing campus in Gosselies, adjacent to the Delphi Genetics building. Catalent announced the acquisition of Delphi Genetics in 2021, a spinoff from the Université libre de Bruxelles and a bioproduction CDMO with capabilities in pDNA development and cGMP manufacturing. Catalent gained its facilities in Gosselies, Belgium, with its $315-million acquisition of MaSTherCell, a provider of cell- and gene-therapy development and manufacturing services in 2020.

In addition, in October 2021, Catalent announced a $230-million expansion project to add three commercial-scale viral-vector manufacturing suites and associated support facilities and services at its gene-therapy campus in Harmans, Maryland, which brings its total investment at the site to $360 million. A second facility is under construction following an initial $130-million to add five new manufacturing suites. When completed at the end of 2022, the campus will house a total of 18 viral-vector manufacturing suites.

WuXi Biologics

Last November (November 2021), WuXi Biologics completed the first GMP production of a new 24,000-L line of its drug-substance facility (MFG) in WuXi, China. This followed the initial GMP operations of the 36,000-L biomanufacturing line at the facility earlier in 2021. The facility has a total of 60,000 L of biomanufacturing capacity to support late-phase and commercial projects across multiple modalities, such as monoclonal antibodies, bispecifics, and fusion proteins, providing the company with total biomanufacturing capacity of approximately 150,000 L.

Also, in 2021, the company completed three acquisitions to increase its production capacity: a drug-substance facility in Wuppertal, Germany, from Bayer; drug-substance/drug-product facilities in Hangzhou, China, from Pfizer; and the Chinese CDMO CMAB Biopharma.

Note: Currency conversions at time of announced investments.

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