

The Berke Report

First Half of March 2023 CDMO & Manufacturing

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- 03.17.23 Samsung Biologics Expands Capacity with Fifth Plant (contractpharma)
 - Samsung Biologics, a CDMO, will begin construction of a fifth plant as part of its strategic expansion in response to increased market demand. The company plans to begin construction in the 1Hof 2023 and commence operations in 2025. As part of Samsung Biologics' second Bio Campus, Plant 5 will have manufacturing capacity of 180,000 liters, expanding the company's total site capacity to 784,000 liters upon its completion. Samsung Biologics will invest over South Korean Won 1.9 trillion in the facility, fulfilling its strategic commitment to continuous capacity expansion. The company's existing Plants 1 through 3 are under near-full utilization and its Plant 4, which started partial operations in October last year, is expected to commence full operations by mid-year.
- 03.16.23 LG Chem nets \$200M contract to manufacture several vaccines (endpts)
 - The S. Korean chemical and life science producer LG Chem has secured a manufacturing contract worth \$200 million for UNICEF to produce its polio vaccine called Eupolio and the pentavalent vaccine Eupenta, which is designed to prevent diphtheria, tetanus, hepatitis B, meningitis and pertussis. LGC will produce \$100 million-worth of its polio vaccine for two years, from 2024 through 2025. The contract for Eupenta will produce \$100 million-worth of the vaccine for the next five years, starting this year through 2027. While no exact production amounts were given, LGC estimates 80 million children globally.
- 03.15.23 Bristol Myers blasts off with SpaceX to study biomanufacturing in space (endpts)
 - The launch of SpaceX's Dragon spacecraft from Cape Canaveral had a new BMS project to study the crystallization of biotherapeutic compounds in microgravity is one of about 20 research projects on board, according to a press release from the International Space Station National Laboratory. The BMS research will investigate how the crystallization process could improve biomanufacturing and eventually provide delivery of higher doses of proteins.
- 03.15.23 Catalent and Grünenthal Announce Successful Collaboration to Facilitate Expedited Clinical Development Timelines (<u>lskh</u>)
 - Catalent, and Grünenthal, an international pharma company and a global leader in pain research and management, announced their successful formulation design and clinical-phase manufacturing collaboration for an orally dosed small molecule in Grünenthal's pipeline. Positive preclinical results from the molecule have allowed Grünenthal to progress its development program to first-in-human studies. In this phase, Catalent supported Grünenthal with the development of a bioavailability enhanced formulation, which, moving forward, enables expedited clinical development timelines. The two companies have been working together on this program since 2021. Catalent has assisted Grünenthal in reformulating the molecule using a lipid-based drug delivery system formulated in softgel technology to improve its bioavailability.
- 03.13.23 Evergreen Theragnostics Completes \$15M Series B, Launches Discovery Unit, and Prepares Ga-68 DOTATOC Supply Chain (PR)
 - Evergreen Theragnostics, a clinical stage CDMO who is developing radiopharmaceuticals for cancer therapy, today announced the completion of a \$15M Series B capital raise. The round was primarily subscribed by existing shareholders exercising their rights of first refusal. Leveraging the capital raise, Evergreen is launching a new business unit, Evergreen Discovery, which is focused on developing novel radiopharmaceuticals for cancer therapy. To support its new business unit, Evergreen has recruited Dr. Thomas Reiner as their Chief Scientific Officer. Prior to this, Dr. Reiner served as Head of Radioligand Therapy Drug Discovery on the Executive Leadership Team of AAA (Advanced Accelerator Applications, a Novartis Company). He is a former Laboratory Head, Associate Professor and Member of the Chemical Biology Program at Memorial Sloan Kettering Cancer Center. Evergreen Discovery will be based in a new research facility near Princeton, NJ, opening in Q3'2023. The company will also use funds from the recent capital raise to prepare for the launch of Ga-68 DOTATOC, if approved. Activities will include building our commercial capabilities and staffing, as well as inventory build. The product is planned to be available through Evergreen's radiopharmacy partners around the country.
- 03.14.23 PCI Pharma Services Expands with New CoE Facility in Rockford, IL (contractpharma)
 - PCI Pharma Services is investing \$50 million in a new 200,000-square-foot to enhance capacity in injectable drug-device combination product assembly of biologics and small molecules. The new facility is the second expansion building, based on the success in Philadelphia, and will house over 20 dedicated customer suites with multiformat machines for the assembly and packaging of vials, pre-filled syringes, auto-injectors, and pen-cartridge combinations. This machinery can be used for the glucagon-like peptide 1 agonists (GLP-1) class of drugs prescribed to treat diabetes and obesity, as well as those needed for oncology treatment and autoimmune diseases. The site will have on-site cold storage, high-speed vial labeling, assembly, and packaging of multiformat autoinjectors, serialization, testing, and drug product release.

- 03.09.23 Sandoz to expand its presence in Slovenia with new \$400M plant (endpts)
 - Sandoz has agreed to build a new biologics plant in the town of Lendava, Slovenia, which is located about 125 miles east of Slovenia's capital of Ljubljana, near the border with Hungary. In an email to Endpoints News, a spokesperson said the plant will be used to manufacture biosimilars, but the company hasn't yet determined which ones. No other details, such as the size of the facility, have been disclosed, but Sandoz is anticipating the site will add around 300 jobs. Work on the site is expected to start sometime later this year, with the site becoming fully operational in 2026. As part of the terms of its proposed spinoff from Novartis, the Sandoz spokesperson said current biosimilar production and development will stay with Novartis, which will provide CDMO services to Sandoz while it builds out its network. The spinoff is on track for the second half of this year, Novartis said in its latest quarterly report.
- 03.07.23 Gilead plans to invest \$47M+ to boost its capacity in southern Ireland (endpts)
 - o The pharma is expanding its facilities located in the town of Carrigtwohill, Ireland, in County Cork in the south of the country. Gilead plans to sink €45 million (\$47.5 million) into the expansion which will be used to construct a 55,714-square-foot warehouse, according to a statement emailed to Endpoints News. The investment will result in a small increase in its employee headcount in Cork, a Gilead spokesperson said, but no other details were given beyond that. As reported by The Irish Times, Gilead aims to start construction in April and expects to be finished by November of next year. The warehouse will provide storage for both finished products and raw materials. The 366,000-square-foot manufacturing site in Cork is responsible for 30% of all of Gilead's solid oral drug development, with 24 of its products being produced or packaged at Carrigtwohill. The site, according to Gilead's website, is also responsible for production, quality control and packaging for the distribution of its products to the EU and other spots internationally.
- 03.08.23 Vitrian and The Howard Hughes Corporation Form Joint Venture to Develop Life Science Projects in The Woodlands, Texas (PR)
 - "Vitrian is excited to join The Howard Hughes Corporation in developing next-generation cGMP facilities in The Woodlands," said Scott Nudelman, co-founder and managing principal of Vitrian. "Our experience partnering with Cellipont Bioservices on their new headquarters and manufacturing site in The Woodlands' Research Forest—as well as our overall engagement in the Greater Houston region—has convinced us that we are in the early innings of growth in biomanufacturing. The dynamic environment and amenity base created and nurtured by Howard Hughes provides a unique place to attract and retain life science companies and their workforce."
- 03.09.23 Lonza adds Simris peptide payload to ADC toolbox (bioprocessintl)
 - Swedish biotech Simris Biolgics, previously known as Cyano Biotech, has entered a strategic partnership to make
 contract development and manufacturing organization (CDMO) Lonza its preferred partner for the commercialization of
 its ADC payload platform. Under terms of the deal, financials of which have not been divulged, Lonza will gain the
 exclusive right to offer the technology to customers seeking payloads to develop into ADCs, while Simris will promote
 Lonza as its exclusive partner for services using its technology.
- 03.09.23 Novo Nordisk is adding to its already considerable presence in Clayton, N.C. The Danish company has purchased 104 acres for \$6.8 million adjacent to its huge complex, where two plants pump out diabetes and obesity medicines (<u>fiercepharma</u>)
 - Novo Nordisk began operations in Clayton in 1993 with a plant that formulates and fills cartridges and vials, assembles
 pen devices and packages and labels the products. After several expansions of the 457,000-square-foot facility, which
 employs 1,000 people, Novo Nordisk built a \$2 billion plant next door that went online in 2021. It employs 700 people and
 is the company's first facility outside of Denmark to produce active pharmaceutical ingredients.
- 03.03.23 Samsung Biologics bags another Big Pharma with \$185m Pfizer deal (bioprocessintl)
 - Pfizer becomes the seventh top 10 pharma firm to ink a deal with Korean CDMO Samsung Biologics. According to a regulatory filing, contract development and manufacturing organization (CDMO) Samsung Biologics will supply biologics services for pharma giant Pfizer. The contract is worth KRW 241 billion (\$185 million) and is valid from February 2023 until the end of 2029. Further details have not been disclosed, but the contract is not an anomaly for the Korean CDMO, which has been inking manufacturing deals with Big Pharma firms ever since its inception in 2011. With Pfizer on board, the company can now name seven of the top 10 pharma firms on its books. Through its joint venture with Biogen Idec to form Samsung Bioepis (now fully owned by Samsung Biologics), the CDMO has been producing biosimilars marketed in some regions by Merck & Co.
- 03.06.23 Oligo Factory Opens New Manufacturing Facility (genengnews)
 - Oligo Factory is opening a new oligo manufacturing facility in Holliston, MA, that will serve as the company's new headquarters. With over 13,000 ft2 of combined bench space, offices, and labs for the company's next generation of synthesizers, the new facility increases manufacturing capacity by 12x, explains CEO Chris Boggess. Oligo Factory is opening its new facility after a recent growth capital investment that included Research Corporation Technologies and BroadOak Capital Partners. "The industry has a continuing need for more mid-scale production capacity," pointed out Bill Snider, a partner at BroadOak Capital Partners.