The Berke Report
CDMO & Manufacturing
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- 04.06.23 - Contract manufacturer Phlow raises $36M to build out services (endpts)
  - The Virginia-based manufacturer Phlow has pulled in $36 million into its latest funding round as it looks to augment its manufacturing services. According to a release, Phlow's latest funding raise will be going towards growing its CDMO program, dubbed cdmoX. Its CDMO program is designed to help customers achieve faster regulatory approvals as well. Phlow opened a new R&D lab last year, and its Petersburg, VA-based Kilo facility is on track to be finished sometime this year. By the end of 2023, Phlow will also finish the construction of its hybrid manufacturing facility, also in Petersburg. Phlow was looking to raise $50 million in funding, according to an SEC Form D filing, and by September of last year, had managed to pull in $24.2 million from 11 investors since the round kicked off in August. Phlow had a Series A round in 2021, pulling in $20 million to fund API R&D efforts and its commercial business team and create a data and analytics platform. However, the company has also seen massive contracts come in from the US government as well. In 2020, BARDA handed Phlow a $354 million contract (potentially worth up to more than $810 million) for the manufacturing of essential medicines that are at risk of shortage, including some Covid drugs like sedation meds for ventilator support, medicines for pain management and certain antibiotics.
- 04.06.23 - Catalent Commences Construction of New $20M Expansion to its Clinical Supply Facility in Schorndorf, Germany (PR)
  - The project will see the site's footprint increase by 32,000 square feet (3,000 square meters) to add capacity for the storage and handling of clinical trial supply materials at controlled room temperatures between 15 and 25 degrees Celsius, and creates space in the original building to accommodate the installation of a new, fully automatic bottle filling line, and a dedicated area for Catalent's FastChain® demand-led supply service. Work on the site is expected to be completed by June 2024.
- 04.05.23 - Sanofi breaks ground on BARDA-backed, $160M vaccine manufacturing site in Pennsylvania (endpts)
  - Sanofi has broken ground on a new formulation and filling facility at its site in the town of Swiftwater, PA, located halfway between Philadelphia and Scranton. The new 32,000-square-foot facility will cost an estimated $160 million, a Sanofi spokesperson told Endpoints News in an email. The site, according to a Sanofi release, will be a two-story building that will fill both syringes and vials. The site's opening will mark one of three investments made by BARDA to Sanofi to boost the domestic production of influenza pandemic vaccines. The Sanofi spokesperson said that BARDA will be reimbursing Sanofi for the cost of the project, and in exchange, the French manufacturer will make the new filling line available to the US government during any health emergency. Sanofi does plan to increase the headcount on the back of this move, but no details were immediately given on how many. Sanofi is also planning for construction to be finished in Q4 of next year and will eventually start operations in the latter half of 2026. The spokesperson said that the site will initially fill influenza vaccines, then followed by Sanofi vaccines or other injectables. The Swiftwater manufacturing site already produces other vaccines in Sanofi's portfolio and employs around 2,500 people.
- 04.05.23 - Forecyte Bio, a CGT CDMO, Hosted a Grand Opening for Its Brand-New GMP Facility in Shanghai, Just Two Months After Its Sister Site in the U.S. (PR)
  - Forecyte Bio held its opening ceremony for its brand-new, state-of-the-art Cell and Gene Therapy GMP facility in Shanghai, China, marking an important milestone after the successful opening of its United States facility in January. The new facility totals 140,000 sq ft, with a total investment of nearly 40 million USD. It offers multiple GMP production lines for plasmids, viral vectors, and cell therapies. The dual sites in the US and China offer advantages to CGT companies, especially those with the intention of filing internationally. Both facilities offer high-quality production capacities operated by industry veterans and an executive team experienced in CGT CMC manufacturing.
- 04.05.23 - Longboard Pharma Selects Societal CDMO to Support Clinical Development of LP352 (contractpharma)
  - Societal CDMO, Inc. has been selected by Longboard Pharmaceuticals, Inc. to provide CDMO services, including technology transfer and analytical method validation activities to support Longboard's lead asset, LP352, a 5-HT2C receptor superagonist. LP352 is currently being evaluated in a Phase 1b/2a basket trial in participants with developmental and epileptic encephalopathies or DEEs, such as Dravet syndrome, Lennox-Gastaut syndrome, tuberous sclerosis complex, CDKL5 deficiency disorder, SCN2A-related disorders, among others.
- 04.04.23 - Avid Bioservices Unveils Completed Mammalian Cell Facilities Expansion Providing Significantly Increased Capacity for Existing and Future Customers (PR)
  - The company has already launched analytical and process development capabilities at this viral vector facility and remains on track to launch the CGMP manufacturing suites by the end of the third quarter of calendar 2023.The newly expanded manufacturing capacity includes both upstream and downstream CGMP manufacturing suites and serves as complement to Avid's existing Myford facility, providing increased capacity to address the needs of both existing and future mammalian cell business customers. The addition of the capacity provided by the new manufacturing suites within the Myford facility has the potential to generate approximately an additional $100 million in annual revenue.
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- 04.01.23 - Celltrion eyes US biomanufacturing plant on back of Biden's Executive Order (bioprocessintl)
    - With the US Government pushing a domestic biomanufacturing policy, Korean drugmaker Celltrion says it assessing building a facility in the country. Like fellow Korea-based drugmaker Samsung Biologics, Celltrion has built up its biologics production network within its home city of Songdo, Incheon. The firm has two biologics plant with 190,000 L of bioreactor capacity operational, while a third manufacturing plant was announced in November 2020 at a cost of KRW 500 billion ($383 million). Plans for a fourth and even fifth facility in Songdo were also mooted as the firm eyed a total capacity of 600,000 L of capacity by 2030. The US concept is not the first time Celltrion has looked outside of Korea to grow its network. The firm signed a construction agreement with Wuhan city and the provincial government of Hubei Province for the construction of a 120,000 L biosimilars plant in China in January 2020. However, weeks later the idea was put on ice as the full emergency of COVID-19 made itself clear.
- 04.01.23 - Thomas Jefferson University to Expand Jefferson Institute for Bioprocessing (JIB) Facilities and Offer Early Phase cGMP Clinical Production with Cell and Gene Therapy Focus (PR)
    - By increasing production area to include four additional clean room suites, this milestone effort is expected to see cGMP production capacity active by early summer 2023. With a focus on cell and gene therapy and expanded analytical capabilities, the project aligns with clients' needs. The expansion will provide Current Good Manufacturing Practices (cGMP) capabilities, which will allow for phase I/II clinical production. The new expansion area is designed with suites capable of cGMP production of cell therapies, gene therapies, viral vectors and plasmid DNA. It will also include expanded analytical and quality control service areas to support internal programs as well as for external client contract work.
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