The Berke Report

CDMO & Manufacturing

Contact Carl Berke For More Information @ Carl@Berkesearch.com

- 01.24.23 - Eli Lilly to pour $450M more into diabetes drug plant in North Carolina, add 100 jobs (fiercepharma)
  - Even though Eli Lilly has yet to begin manufacturing at its ballyhooed plant at Research Triangle Park in North Carolina, it now has plans to expand it to the tune of an additional $450 million.That's how much more Lilly says it will pour into the facility, along with an increase of at least 100 more employees, to help meet an expected surge in demand for new Type 2 diabetes treatment Mounjaro, which the company anticipates will soon be approved to treat obesity.The expansion will bump up the site's capacity for device assembly, filling and packaging, Lilly said. It comes on top of other expansion plans for the site, bringing the total earmarked for the facility to $1.7 billion, the company added. In 2020, Lilly unveiled plans to spend $474 million to build the plant, which would house 462 employees and produce the company's diabetes medicines including Trulicity, which racked up sales of $6.5 billion in 2021 and $5.5 billion in the first three quarters of last year.
- 01.17.23 - Pfizer to Acquire Sanford, North Carolina Manufacturing Site from Abzena (PR)
  - Pfizer Inc. and Abzena today announced that the companies have entered into an agreement under which Pfizer will acquire Abzena's manufacturing facility in Sanford, North Carolina. Upon completion of the construction, the state-of-the-art facility will have extensive capabilities for producing biologics drug substance and provides additional manufacturing capacity allowing Pfizer to help accelerate its innovative pipeline. In addition, Abzena and Pfizer's CentreOne contract manufacturing organization will seek to collaborate to advance complex biologic products to market. The new Sanford, North Carolina site is expected to employ approximately 300 employees by 2025, including the current staff of approximately 100 employees, which is expected to bring Pfizer's total workforce in North Carolina to more than 4,500 employees. The site will employ experts in both biological pharmaceutical sciences and biological manufacturing, enabling Pfizer to offer a comprehensive co-development capability. Since 2017, Pfizer has invested more than $5 billion to support the ongoing growth of its manufacturing footprint in the U.S., with $1.4 billion invested in North Carolina.
- 01.16.23 - Lonza Completes Expansion to Solid Form Services Facility at Bend (US) Site (PR)
  - The offering complements Lonza's API development services and first-in-human services, aimed at the rapid advancement of small molecules. New facility is based at Lonza's Bend, Oregon (US) site, a Center of Excellence for bioavailability enhancement.Lonza today announces the completion of a planned expansion to its Solid Form Services (SFS) offering for small molecule drugs. The expanded facility in Bend, Oregon (US) became fully operational in Q4 2022, enhancing Lonza's capabilities in meeting accelerated timelines for increasingly complex molecules. The expanded facility includes remodeled and dedicated laboratory space which is primarily being used to support biotech and midsize pharma companies in developing early-stage compounds. It can support all aspects of solid form screening and characterization of small molecule APIs, alongside selection and early crystallization process development. Effective screening and selection are critical for early-stage and late-stage development to reduce risk and strengthen intellectual property claims.
- 01.11.23 - Contract manufacturer nets capital investment to expand its physical space and install a new fill-finish line (endpts)
  - Jon Lenihan, the SVP of commercial at Argonaut, said that while the company won't disclose the size of the investment. the funds will be going toward installing a new fill-finish line and acquiring more space for the company. Lenihan stated that the company is already moving forward with this and has taken steps to purchase the equipment. For boosting the size of its footprint, Argonaut will either acquire or lease a building next to or near its current 100,000-square-foot facility in Carlsbad, CA, and plans to tack on another 25,000 to 30,000 square-feet of space in total. Lenihan noted that this can help the company have more room to install a third fill-finish line in the future. The California-based CMO Argonaut Manufacturing Services has roped in some cash to start the year in an effort to make a significant expansion to its business. "Our focus area is those types of projects that are kind of orphan or ultra-orphan type, commercialization size products, 15-to-20,000-unit batches. This new line will double that size and scale," Lenihan said.
- 01.10.23 - Resilience Announces Equity Investment from Mubadala and Funding of New Biopharma Manufacturing Facility in the United Arab Emirates (PR)
  - Under the agreement, Mubadala will establish the new manufacturing facility, which will be operated by Resilience, to manufacture certain biopharmaceutical-related products in the UAE. The facility will include a range of therapeutics for complex diseases such as cancer, infectious diseases, and inflammatory and autoimmune disorders, as well as vaccines. As part of the collaboration, Resilience has agreed to provide manufacturing, technology, and operational expertise for the Abu Dhabi-based facility and integrate the site as a node within its global network. The facility would be the first Good Manufacturing Practice (GMP) biopharma facility in the region based in Abu Dhabi to manufacture essential life sciences products for advanced therapies.

- 01.10.23 - Kite Pharma Expands Cell Therapy Operations in Maryland.
  - announced an expansion to our cell therapy operations in Frederick, Maryland with a new, centralized raw materials warehouse that will serve Kite's global manufacturing network, bringing an additional 100 jobs to the area and deepening the company's investment in the local life sciences community.
- 01.10.23 - Sterling Completes Acquisition of API Manufacturing Facility in Ringaskiddy, Ireland (Chemicalknowledgehub)
  - The completion of its acquisition of an active pharmaceutical ingredient (API) manufacturing facility in Ringaskiddy, Ireland, from Novartis, in a deal that was initially announced in March 2022. The facility will provide additional capacity for Sterling's growing API manufacturing services, and the deal includes an ongoing supply agreement with Novartis to continue to manufacture a number of APIs for cardiovascular, immunology and oncology medicines at Ringaskiddy. No financial details of the deal have been disclosed. The 111-acre site, located near to Cork, includes multiple commercial-scale production buildings, with a total vessel capacity of 175 cubic metres across over 30 reactor trains, as well as a small-scale facility, and a development and support building housing 14 development and analytical laboratories. 350 staff at the site have now transferred to Sterling's employment.
- 01.10.23 - CordenPharma Signs Multi-Year Agreement for the Manufacturing of a Commercial Peptide (LSKH)
  - CordenPharma is pleased to announce the signing of a multi-year agreement commencing in 2023 for the contract manufacturing of a large-volume peptide at its CordenPharma Colorado facility. The manufacturing agreement will potentially cover a value of ca. USD 1 billion, depending on actual production over the term of the agreement, and will support the launch of an innovative peptide. The companies have agreed not to disclose additional details and respect customer confidentiality.
- 01.10.23 - Ajinomoto and Exelixis Enter Into a License Agreement to Discover and Develop Novel Antibody-Drug Conjugates for the Treatment of Cancer (PR)
  - As part of the license agreement, Exelixis will have the right to use the AJICAP technology to support its aim of advancing multiple ADCs with the potential for higher efficacy and lower toxicity than currently available options. Ajinomoto Co. is eligible to receive development, regulatory and commercial milestone payments as well as royalties on commercial sales.
- 01.05.23 - WuXi inks $1.5B GSK pact, a big biobuck bet but a blip in billions lost from US unverified list (Endpts)
  - Only $40 million of the GSK deal will initially go to the Shanghai-based contract research and manufacturing giant, but with a biobuck bet above $1 billion, the Big Pharma sees lots of potential. The pact is a boon to WuXi, which suffered a loss of billions in market value after being placed on the US Department of Commerce's unverified list last February. WuXi was removed from the list last month. Kicking off the deal is one preclinical bispecific antibody that targets a tumor-associated antigen on bad cells and CD3 expression on T cells, WuXi announced Thursday. CD3 is one branch of Amgen's Blincyto bispecific, and it's one part of the focus of Roche and Genentech's Lunsumio. FDA cleared the bispecific as a third-line treatment for adults with relapsed or refractory follicular lymphoma last month.