The Berke Report

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- 03.01.23 - Spark Therapeutics broke ground on its 500K-square-foot Gene Therapy Innovation Center (technical.ly)
  - City and state officials gathered at 30th and Chestnut streets Tuesday for the groundbreaking of one of Philadelphia's largest life science centers to date. The company at the center of the project, Spark Therapeutics, is a history maker for the region, too: It was acquired by Roche for $4.8 billion in 2019, Philly's largest-ever VC backed exit. At the time, the acquisition was a signal that the growing life sciences industry in Philadelphia was to be taken very, very seriously. Now, Spark's 500,000 square foot, six-story cell and gene therapy center will serve as the Philadelphia-based global center for Roche, and is one of many projects to bring more lab space to the region. The cell and gene therapy center, slated to be completed in 2026, will provide in-house manufacturing for Spark, but will also allow for "cross-functional teams and partners to come together and work side by side to realize the full potential of gene therapy," per a company statement. Spark's lease for the land is for 99 years, it said in 2021. The center is being built on Drexel University's Lot F — a purposeful move by Spark, then-CEO Jeff Marrazzo told Technical.ly in 2021, because Spark will partner with the university with the goal of advancing life sciences workforce development for the region. (Marrazzo left the company in spring 2022. His successor is former COO Ron Philip.) The facility will sit across the street from Spark's existing University City building, and will allow for hands-on learning experiences and R&D.
- 02.28.23 - RoslinCT And Lykan Bioscience Announce The Addition Of Six CGMP Suites To Meet Growing Demand (PR)
  - RoslinCT and Lykan Bioscience, a leader in Contract Development and Manufacturing for cell therapies, announced the addition of six new cGMP processing suites to their facility in Hopkinton, Massachusetts, in response to industry demand. The completion of the expansion brings the global capacity to 22 cGMP suites with 14 in Hopkinton, MA, and another eight in Edinburgh, Scotland. The new processing suites will range from 105 to 525 square feet, including specific suites designed to meet both US and EU regulatory requirements for clinical and commercial manufacturing. As part of the expansion, an automated processing room was included and will be capable of accommodating a range of manufacturing platforms as well as allogeneic and autologous-based products.
- 02.27.23 - Virginia to invest $66.7M in biomanufacturing projects (manufacturingdive)
  - Virginia will award $66.7 million in grants to fund four biotech, life sciences and pharmaceutical manufacturing projects, and a pharmaceutical manufacturing cluster, according to a Feb. 14 press release. The projects aim to bring new jobs to the state as it looks to become a leader in biomanufacturing, Virginia Gov. Glenn Youngkin said in the release. "Each of these projects will bring jobs and opportunity across the Commonwealth and further our position as a national leader in these business sectors," he said in a statement.
    - UVA Institute of Biotech - $36 million - The funds will help accelerate genomics/gene therapies and drug delivery technologies through incentives designed to attract 150 research scientists, who will operate out of a new biomanufacturing research facility.
    - City of Roanoke, Virginia - $15.7 million - Funding will establish an advanced laboratory incubator to develop new biotechnology companies throughout southwestern Virginia.
    - The Virginia Biotechnology Research Partnership Authority - $15 million - Funds will be used to construct a life sciences laboratory building in the Virginia Biotech Park in Richmond, Virginia. It will also go towards improving manufacturing pharmaceutical manufacturing capabilities in the Richmond-Petersburg region of the state.
- 02.23.23 - PackGene Biotech Inc. Breaks Ground on cGMP Biomanufacturing and Process Development Facility in Houston (PR)
  - The 25,000-square-foot facility will be located just outside Houston's inner loop at 9310 Kirby Drive. The facility will include process and analytical laboratories, cGMP manufacturing cleanrooms and support areas, quality control laboratories, a warehouse, and office space. This represents an expansion of the existing operations, which include some process and analytical development, and laboratory space, employing approximately 20 people. PackGene plans to nearly triple its Houston-area workforce to about 60 by the end of 2023 when the new facility is expected to be complete. Founded in Massachusetts, USA, PackGene has additional operations in Guangzhou, Shanghai, and Boston. The company works with customers to support gene therapy programs from early-stage research & development and preclinical development to IND-enabling (Investigational New Drug) studies. PackGene aims to accelerate gene therapy product development by providing a fully integrated one-stop solution including plasmid, viral vector, fill-finish, and quality control analytical services for the gene therapy industry.
- 02.22.23 - Eli Lilly: Capacity and access key to launching Mounjaro outside US (bioprocessintl)
  - Eli Lilly expects to double incretin capacity by the end of 2023, driving the launch of once-weekly type 2 diabetes medication Mounjaro (tirzepatide) beyond the US. Type 2 diabetes medication Mounjaro received US Food and Drug Administration in May 2022 and pulled in $187M in its first full quarter, and a further $279.2 in Lilly's Q4.The once-weekly drug consisting of incretin hormones GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) is an expected blockbuster so long as Lilly can ensure supply keeps up with demand, both in the US and globally. With major CAPEX projects in Research Triangle Park and Concord (both North Carolina) underway, and additional investments in Indiana and Ireland.

- 02.21.23 - Updated: Resilience to cut most staff, suspend operations at Massachusetts manufacturing plant (endpts)
  - National Resilience, a biotech manufacturing startup funded with more than $2 billion since its launch in July 2020, has sent notices to employees that it will cut jobs at a Massachusetts manufacturing site that it bought just two years ago, citing reduced demand. Multiple people whose LinkedIn profiles said they had been employees at the plant posted over the weekend saying they were told the site will shut down. In a follow-up interview, CEO Rahul Singhvi told Endpoints News that Resilience is keeping the facility in a "state of readiness" as it seeks new customer[s]. The company has put $150 million to $200 million into the site since acquiring it. A Resilience spokesperson said the site is finishing up a run of manufacturing on biologic and vaccine products and will transition production to another undisclosed site, and some employees have been kept on board during a "suspension of operations." A WARN notice filed with Massachusetts last week says the terminations will affect about 213 employees, with 50 to 80 staying on for a limited time "to continue to assist with certain tasks."
- 02.21.23 - Oxford Properties Group acquires Resilience site for $125m (bioprocessintl)
  - Oxford will acquire National Resilience's manufacturing facility in Marlborough, Massachusetts and then lease the property back to the CDMO. Global real estate investor Oxford Properties Group (Oxford) says the purchase and lease back of the 120,000 square-foot biomanufacturing facility from and to contract development manufacturing organization (CDMO) Resilience will expand its North American footprint while raising proceeds for the CDMO.The facility, which is close to completion, will be leased to Resilience for up to 30 years and the firm will use the site to carry out its day-to-day business operations. Once fully operational, the Marlborough plant – around 34 miles from Boston – will be Resilience's flagship site in the US and has been designed to be compatible with various modality manufacturing capabilities. The site includes production suites, offices, and warehouse space.
- 02.16.23 - LIfT BioSciences and Minaris Regenerative Medicine Enter into a Manufacturing Partnership (PR)
  - Under the terms of the agreement, Minaris, in conjunction with LIfT Biosciences are confident they can develop a Good Manufacturing Practice (GMP)-compliant manufacturing process to supply LIfT's clinical trial programmes in Europe, currently anticipated to start in Q1 2024. N-LIfT is made from Immunomodulatory Alpha Neutrophils committed myeloid progenitors (IMANp) that are manufactured ex vivo from hematopoietic stem cells (HSCs) of healthy donors who exhibit exceptional innate cancer killing properties. The unique mechanism of action of N-LIfT allows the product to work effectively through the innate immune pathway as well as activating multiple other factors of the adaptive immune system.
- 02.15.23 - Nexcella Enters into U.S. GMP Manufacturing Agreement to Expand NXC-201 Phase 1b/2 Clinical Trial (contractpharma)
  - Nexcella, Inc., a biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, has entered into a manufacturing agreement with a well-known United States Good Manufacturing Practice (GMP) cell therapy manufacturer that will supply a US Phase 1b/2 clinical trial of NXC-201 in relapsed/refractory multiple myeloma and AL amyloidosis.With plans to expand the ongoing Israel trial to the U.S., Nexella says that it is necessary to demonstrate that clinical trial drug supply has been secured when submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA).The company believes recently reported Phase 1b clinical data from the ongoing clinical trial in Israel supports expanding the NXC-201 trial to the U.S.