- 03.15.23 - ThermoGenesis Announces Roll Out of ReadyStart cGMP Suites for Early-Stage Cell and Gene Therapy Companies (PR)
  - ThermoGenesis Holdings, Inc. (Nasdaq: THMO), a market leader in automated cell processing tools and services in the cell and gene therapy field, today announced that the Company is rolling out a new facility in the Sacramento metro area, containing a total of 12, class-7, ReadyStart cGMP Suites available for lease by early-stage life science and cell gene therapy ("CGT") companies. The roll-out of the ReadyStart Suites is part of ThermoGenesis' previously announced plan to transform from a medical device company to a contract development and manufacturing organization ("CDMO") in the cell gene therapy field. The facility is expected to be available for customers in the second or third quarter of this year. If fully occupied, the facility is anticipated to generate an estimated $10-16 million in annual revenue. The ReadyStart Suites are located in a 35,500+ square foot cGMP facility that will meet the highest scientific, quality, and regulatory requirements. The designing, building and managing of a cleanroom requires a significant capital investment is extremely time consuming and can be draining on a company's resources. ThermoGenesis' ReadyStart cGMP cleanrooms are ideal for early-stage companies looking to jump-start their development efforts and/or scale up in the same facility, providing a turnkey solution. Further, the suites will eliminate a tremendous resource burden and greatly accelerate the development cycle by allowing the resident companies to focus on their core science.
- 03.14.23 - Catamaran Bio selects OmniaBio as partner to develop and manufacture allogeneic CAR-NK cell therapies (PR)
  - OmniaBio, along with its parent company CCRM, is developing Catamaran Bio's CAR-NK cell therapy process at their Toronto site, where the process development lab is co-located with good manufacturing practices (GMP)-compliant clean room suites to offer a seamless transition between rocess development and clinical manufacturing. The OmniaBio-CCRM partnership enables highly adaptable and flexible end-to-end support for therapeutics developers, such as Catamaran Bio, that need to move rapidly from development to the clinic and beyond
- 03.10.23 - Catalent Expands UpTempo AAV Platform to Accelerate Development of Gene Therapies (PR)
  - UpTempo platform process for the development and CGMP manufacturing of adeno-associated viral (AAV) vectors. The platform now includes an in-house, clonal HEK293 cell line, and off-the-shelf plasmids to support a robust supply chain for developing and manufacturing gene therapies, and the reduction of timelines to first-in-human clinical evaluation.
- 03.09.23 - Recipharm's Arranta Bio Expands Rna Process Development Capacity By 50 Per Cent To Meet Increased Customer Demand (PR)
  - This major development comes less than a year after the acquisition of Arranta Bio by Recipharm, demonstrating Recipharm's continued focus on the advanced therapeutics market. The expansion includes the fit out of approximately 2,000 ft2 of state-of-the-art laboratory space with flexible, modular small scale and pilot scale equipment to enable rapid development and scale up to GMP manufacturing. The Watertown facility is an 80,000 ft2 commercial-ready GMP manufacturing facility with Grade C production suites suitable for the end-to-end production of mRNA, lipid nanoparticle formulation, and automated sterile fill finish into vials or syringes within a gloveless, robotic isolator. The facility has capabilities for process and analytical development and GMP manufacturing for drug substance and drug product. Recipharm completed the acquisition of Arranta in April 2022, building on its presence in the biologics market, with a particular focus on drug substance manufacturing of novel ATMPs.
- 03.09.23 - Aldevron and Evanoa Sign Licensing Agreement (medtechalert)
  - Evanoa Bioscience, a cell line developer for biologics manufacturing, together with Aldevron, a global leader in the custom development and manufacture of plasmid DNA, RNA and proteins for the biotech industry, today announced the signing of a licensing agreement for two E. coli strains to be used in plasmid production. Evanoa is using its proprietary evolution-based platform to develop novel strains of E. coli that produce more plasmid per cell and are more stable under fermentation conditions. Strains developed by Evanoa have been shown to produce as much as two times more plasmid per cell and total plasmid titer per fermentation. Based on these current favorable data, Aldevron has licensed the strains to further explore their utility in different environments.
- 03.09.23 - Charles River Launches Helper Plasmid to Streamline Adeno-Associated Viral Vector Manufacturing (PR)
  - The addition of pHelper plasmids follows the launch of the eXpDNA™ plasmid manufacturing platform, established over decades of plasmid DNA CDMO scale-up experience, which significantly reduces plasmid production turnaround time for advanced therapy medical product (ATMP) and vaccine developers.
- 03.08.23 - Evonik opens new facility for pharmaceutical lipids at site in Hanau, Germany (PR)
  - The types of lipids that can be produced at Evonik's lipid launch facility will serve a broad range of RNA and gene therapies such as infectious disease control, cancer immunotherapy and protein replacement therapies. With particle engineering and purification capabilities, including chromatography, the lipid launch facility can support customers with production of all types of custom and proprietary lipids, including PEGylated lipids, phospholipids, and ionizable cationic lipids. The opening of the lipid launch facility is the latest in a series of investments by Evonik in lipid manufacturing for RNA and gene therapies. Last year, the company announced a triple-digit million-dollar joint investment with the U.S. Government to build a new lipid production facility at its U.S. site in Tippecanoe in Indiana.
- 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.