PNC PHARMA & LIFE SCIENCES

Monthly News Brief

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2023: The Year of Re-Alignment, Yet All Data Points to Green Shoots Ahead for 2024 *(Contract Pharma)*
Despite current softness, the underlying demand drivers remain strong for the CRO & CDMO sectors with 2023 and 2024 viewed as a period of re-calibration. Key drivers of demand include R&D pipeline activity, emerging biotech funding levels, large pharma M&A activity, IRA drug pricing regulations, onshoring, FTC's increased M&A scrutiny, and CRO/CDMO M&A

FDA Approves First Interchangeable High-Concentration, Citrate-Free Biosimilar to Humira *(Contract Pharma)*
The FDA approved SIMLANDI, the first high-concentration, citrate-free biosimilar with interchangeability status to AbbVie's Humira. An interchangeable biosimilar may be substituted at the pharmacy without consulting the prescriber, much like generic drugs are routinely substituted for brand name drugs. In 2023, Humira was one of the highest-grossing pharmaceuticals in the world, with US sales of $12.2B

Invitae Files for Chapter 11 Bankruptcy *(MedTech Dive)*
Invitae filed for Chapter 11 protection to keep the genetic testing firm running as it pays down debt and assesses strategic alternatives. The company took several steps to pay down expenses before filing for bankruptcy, having sold its reproductive health assets to Natera and reducing its workforce by more than 1,200 employees. The bankruptcy filing will allow the company to safeguard its business, customers, patients and employees while working through a sale overseen by the court

Biotech IPOs are the Industry's Lifeflood *(BioPharma Dive)*
Initial public offerings (IPO) make the biotechnology industry tick, with stock listings providing young companies the funding they need to develop their next generation of drugs. IPO activity reached a peak in 2021, when more than 100 biotechs priced an initial offering and together raised nearly $15B. But that momentum came to a halt in 2022 and stock prices of newly public companies plummeted amid a sector-wide downturn. The pace of IPOs stalled since and in 2023 only 19 drugmakers priced IPOs

4 Heart Device Trends Shaping the MedTech Sector in 2024 *(MedTech Dive)*
Medical technology companies are launching devices that address cardiac care in two areas affecting millions of patients where drugs are not enough: high blood pressure and atrial fibrillation (AFib). The emerging market for pulsed field ablation (PFA), a treatment for Afib, is expected to help the global AFib ablation market to more than double to $11 billion by 2028, with PFA growing to 60% of procedures, from under 5% today. Due to increased innovation, the market for left atrial appendage treatments is predicted to quadruple to more than $6B by 2030

FDA Clears AI-Powered Digital Cytology Platform for Cervical Cancer *(Diagnostic Imaging)*
The FDA granted 510(k) clearance to an artificial intelligence (AI)-enabled digital cytology platform that facilitates enhanced sensitivity for early diagnosis of cervical cancer. The system facilitates digital image review of samples and alerts clinicians to suspicious cells for further review, resulting in a 28% reduction in false negatives for certain cervical cancer indications

AbbVie's Cerevel Deal Hits an Uncommon Roadblock *(BioPharma Dive)*
AbbVie's multibillion-dollar bid to acquire Cerevel Therapeutics hit an unusual snag that could prevent the deal from closing for months. The FTC issued a second request for more information about the deal which typically pertains to the products and services the companies offer, or how the acquisition could affect market competition. Cerevel's most advanced programs are directed at Parkinson's and schizophrenia — two diseases for which AbbVie already has marketed products. The FTC, has taken a closer look at the drugmaking industry over the past couple of years, scrutinizing mergers as well as the use of patents to impeded competition

BioMarin Preaches Patience Amid Slow Sales for Hemophilia Gene Therapy *(BioPharma Dive)*
Commercial success of BioMarin's recently approved gene therapy for hemophilia is slower than anticipated. The drug only generated $3.5 million in revenue in 2023, compared to projected revenue of $50 to $150 million. Management is preaching patience with this being "very much at the early stage". The drug is another cautionary tale of the challenges drugmakers can face selling a pioneering new gene therapy

Reforming the Medical Device Recall Process – A Call for Accountability *(Health Affairs)*
The FDA issues recalls for thousands of medical devices yearly due to safety issues. In January 2024, the Government Accountability Office accepted a request from Congress to review FDA's oversight of device recalls given the number of serious device recalls and the volume of adverse reports have increased over the last decade