PNC PHARMA & LIFE SCIENCES

Monthly News Brief

April 2025

Merck KGaA to Buy Biotech SpringWorks for $3.9B *(BioPharma Dive)*

Merck KGaA has agreed to buy biotechnology company SpringWorks Therapeutics in a deal valued at $3.9B. SpringWorks' portfolio includes two drugs that are approved in the U.S. to treat rare tumors. Merck KGaA, which provides bioprocessing services in addition to developing new drugs, has been hunting for deals as part of a strategy it rolled out last fall

PCI Pharma Services to Acquire Ajinomoto Althea *(Contract Pharma)*

PCI Pharma Services, a global contract development and manufacturing organization (CDMO) focused on innovative biopharma therapies, is acquiring an entire equity stake in Ajinomoto Althea (Althea), a U.S.-based sterile fill-finish CDMO. This acquisition creates a large-scale manufacturing hub in the San Diego region with aseptic facilities for prefilled syringes, cartridges and high potent formulations

Zimmer Biomet Completes Acquisition of Paragon 28 *(PR Newswire)*

Zimmer a medical technology company focused on musculoskeletal care, has acquired Paragon 28, Inc., a medical device company focused exclusively on the foot and ankle orthopedic space, for an undisclosed amount. Th acquisition will expand Zimmer's capabilities in the foot and ankle segment, one of the highest growth specialties in musculoskeletal care.

Top Republican Calls for 340B Reform in Long-Awaited Investigation *(BioPharma Dive)*

Senator Bill Cassidy, the chair of the Senate Health, Education, Labor and Pensions Committee, released a report calling for Congress to reform 340B drug discounts, citing concerns about the lack of transparency and oversight of the program. The 340B program, which was created more than 30 years ago, allows healthcare providers that serve large populations of low-income patients to buy certain drugs at a significantly reduced rate. The report found mixed evidence for how hospitals use 340B funds, with two health systems studied generating millions of dollars in 340B revenue but not passing those savings along to patients

FDA Plans to Phase Out Animal Testing for Some Drugs *(BioPharma Dive)*

The FDA aims to phase out animal toxicology testing for some experimental drugs, announcing a plan to reduce, revise or replace such requirements in favor of newer methods that are more "human relevant." By leveraging AI-based computational modeling, human organ model-based lab testing, and real-world human data, we can get safer treatments to patients faster and more reliably, while also reducing R&D costs and drug prices. The FDA will start by asking companies to submit data from these alternative approaches with Investigational New Drug applications, which are used to request permission to begin human testing. The FDA will also lower its "routine" requirement for six months of toxicology testing in primates for monoclonal antibody drugs

FDA Cuts Outlined in Draft HHS Budget *(BioPharma Dive)*

A draft budget document shows the Trump administration's plan to slash funding to the Department of Health and Human Services includes substantial cuts to the Food and Drug Administration. The preliminary budget sets a total of $2.9B in requested congressional appropriations for the FDA which is a ~18.6% decrease from $3.6B in budget authority the FDA received in its 2024 fiscal year

A Judge Blocked the FDA's Plan to Regulate LDTs. What Now? *(MedTech Dive)*

Following the ruling by a U.S. district court judge, the FDA's attempt to increase its regulatory scrutiny over Laboratory Developed Tests (LDTs) appears to be dead. In moving to expand its requirements for LDTs, the FDA argued that more active oversight was needed due to greater risks associated with modern versions of the tests. The grounds for the ruling cited high costs of complying with the rule, forcing labs to discontinue some test services to the detriment of patients. The more likely outcome is that the FDA won't appeal, and they will just let this die for now, until either activity from Congress or the next administration 4 years from now

Trump Takes another Stab at Lowering Drug Prices *(Axios)*

President Trump signed a wide-ranging executive order aimed at lowering pharmaceutical costs. The most noteworthy change asks HHS to work with Congress to fix what the administration calls a "distortion" in the IRA Medicare prescription drug negotiations provision for small-molecule drugs. Additionally, the law now exempts synthetic drugs from negotiation for nine years after they hit the market while giving more complex biologics 13 years