# PNC PHARMA & LIFE SCIENCES

## Monthly News Brief

January 2024

#### **5 Questions Facing Emerging Biotech in 2024** (BioPharma Dive)

Last year brought a six-year low in IPOs, mixed returns for those who did go public and a wave of layoffs at small and large companies alike. Only 19 biotechs went public in 2023, down slightly from 2022 and far below the 104 that priced in 2021. While a smaller sample size, last year's numbers suggest the roadmap to an IPO may be longer for young biotechs, forcing startups to lean more heavily on their existing investors for fundings

#### 5 Questions Facing Pharma in 2024 (BioPharma Dive)

The arrival of powerful new drugs for obesity has reshaped the pharmaceutical industry, transforming Eli Lilly and Novo Nordisk into the sector's most valuable companies and sending others scrambling to catch up. Drug pricing, Oncology, Alzheimer's and next generation manufacturing are expected to be a few of the major areas facing the pharmaceutical sector in 2024

#### **5 MedTech Trends to Watch in 2024** (MedTech Dive)

After 3-years of navigating the unpredictable and complex COVID-19 pandemic environment, medical device companies returned to some sense of normalcy in 2023. Analysts expect M&A to speed up this year after the recent slowdown, as MedTech companies debut new products or gain regulatory clearances and macroeconomic conditions improve. Challenges such as low procedure volumes, hospital staffing shortages and an unreliable supply chain either improved or companies implemented strategies to navigate them

### Novo Holdings to Buy Contract Drugmaker Catalent for \$16.5B (BioPharma Dive)

Novo Holdings, the controlling shareholder of drug maker Novo Nordisk, to acquire contract manufacturer Catalent for \$16.5B in a take-private deal. In a related transaction, Novo Nordisk agreed to pay its parent \$11 billion for 3 of Catalent's plants to expand production of its GLP-1 drugs Ozempic and Wegovy. Novo Nordisk states the acquisition complements the significant investments they are already making in active pharmaceutical ingredients facilities, and the sites will provide strategic flexibility to their existing supply network. Upon the deal's close, which is expected by the end of 2024, Novo Holdings will take possession of Catalent's more than 50 sites, which include production facilities for small-molecule pills, injectable biologics, as well as cell and gene therapies

#### **Biogen Quits Aduhelm, Handing Back Rights to Original Developer** (BioPharma Dive)

In 2021, the FDA approved Aduhelm as the first medicine meant to slow the progression of Alzheimer's disease and now less than three years since the approval, Biogen is fully giving up on the drug. Aduhelm never succeeded commercially, as the approval was highly controversial, as was the price tag Biogen initially set, giving insurers leverage to push back on coverage. Biogen said a "large portion" of the resources that had been dedicated to Aduhelm will be reinvested in the company's other Alzheimer's treatments

#### Philips Stops Selling Sleep, Respiratory Devices in US Due to FDA Consent Decree (MedTech Dive)

Philips has agreed to stop selling new sleep therapy devices or other respiratory care products in the U.S., more than two years after launching its massive recall of related products. The company agreed to the action as part of a consent decree it is entering into with the U.S. Department of Justice, representing the FDA. Philips recorded \$392MM in provisions related to the decree in 4Q23 and the decree reduced comparable sales growth for the full year from 7% to 6%

#### FDA Authorizes Record Number of New Devices in 2023 (MedTech Dive)

The FDA authorized 124 new medical devices last year, setting a record in the process. In 2009 and 2010, the FDA authorized 25 and 29 medical devices and since then the figure has never dropped below 51 with 2018 the pre-pandemic peak at 106

#### FDA, CMS Defend Plans to Increase Oversight of Laboratory Developed Tests (MedTech Dive)

The FDA and Centers for Medicare and Medicaid Services defended a proposed rule to increase oversight of laboratory-developed tests (LDTs) in the face of heavy opposition. According to the Centers for Disease Control and Prevention "roughly 70% of healthcare decisions depend on laboratory test results." LDTs have changed significantly since the agency established its policy 50 years ago ago, and the FDA is aware of LDTs that have led to patients receiving inappropriate treatment and incorrect diagnoses

#### FDA Orders New Cancer Warnings for CAR-T Therapies (BioPharma Dive)

The FDA announced that the makers of CAR-T cell therapies will need to warn about the risk of new blood cancer. While FDA officials have said they believe the benefits of these treatments, which are approved for lymphoma, leukemia and multiple myeloma, outweigh their risks, the new labeling calls out the possibility of secondary T cell malignancies

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