M&A

Thermo Fisher Will Buy The Binding Site for $2.6B to Gain Specialty Diagnostics Portfolio (MedTech Dive)
Thermo Fisher agreed to acquire U.K. based diagnostics firm The Binding Site Group for $2.6B. The Binding Site makes two blood tests for multiple myeloma called Freelite and Heyelite. The deal will add to Thermo Fisher’s specialty diagnostics portfolio, which includes tests to monitor immunosuppressant drug levels in transplant patients and COVID-19 testing.

Bio-Rad, Qiagen are in Talks Over $10B Merger (MedTech Dive)
Bio-Rad Laboratories is in talks to merge with Qiagen in a deal that may be valued at more than $10B, although an agreement isn’t likely for a few weeks and may still fall through. The report of the potential acquisition comes amid a lull of MedTech M&A following a spending spree last year.

FDA Approvals

Roche Nets FDA Approval for HER2-low Breast Cancer Test Paired with AstraZeneca-Daiichi’s Enhertu (Fierce Biotech)
Roche has received the first FDA approval for a companion diagnostic to identify patients carrying the HER2-low status, a more precise characterization of breast tumors. Previously, metastatic breast cancer patients with a lower level of HER2 did not have targeted treatment options. Now they may be eligible for a HER2-targeted therapy, significantly increasing the number of patients who could have improved outcomes.

Abbott Lands FDA Emergency Authorization for First Commercial Monkeypox Test (MedTech Dive)
Abbott Laboratories has become the first company to win emergency use authorization (EUA) for a commercial monkeypox test kit. Quest Diagnostics received EUA for its monkeypox test last month, becoming the first company with an authorized test against the pathogen, but is not available commercially.

Vaccines

Pfizer Planning Steep Price Hike for COVID-19 Vaccine (BioPharma Dive)
Pfizer is considering raising the price of its COVID-19 vaccine by roughly 4x as it prepares for sales in the U.S. to shift from government contracts to the private market. The U.S. government has been paying ~$25 to $30 a dose and is targeting between $110 to $130 per dose from the private market.

GSK Sets High Bar with Trial Results for RSV Vaccine (BioPharma Dive)
GSK’s vaccine for respiratory syncytial virus “RSV” proved effective in a large Phase 3 trial in people 60 years and older by 83% compared to the placebo. The shot was effective in patients by severity, age group and health problems, with only mild sild effects which are common to other vaccines. GSK plans to ask the FDA to approve its vaccine by the end of 2022.

Merck Pays $250M to License Moderna Cancer Vaccine (BioPharma Dive)
Merck will pay Moderna $250M for joint rights to a personalized cancer vaccine under development by the two companies. The goal is to tailor treatments to specific tumor mutations so the body’s immune systems can better attack cancer cells. Under this agreement, Merck and Moderna will share costs and profits equally while collaborating on both the development and marketing.

Other News

MedTech Groups Praise MDUFA Passage as Legislators Plan to Include Reforms in End-of-Year Bill (MedTech Dive)
Congress passed the Medical Device User Fee Amendments (MDUFA), which will provide the FDA ~$1.9B over the next five years to fund its review of medical devices. Groups including the Medical Device Manufacturers Association said the agreement would support innovation in healthcare and patient access to new technologies.

Can Biosimilars, After Years of Limited Impact, Finally Make a Mark in the US? (BioPharma Dive)
The looming loss of patent protection on several lucrative branded biologics could give biosimilar makers a needed marketing opportunity. The anticipation moving forward is for the U.S. system to shift significantly as biosimilars enter the market.

Hospitals and Pharmacies Profit as 340B Drive Up Patients' Drug Costs (Bio News)
The federal 340B Drug Pricing Program is starting to get a great deal of attention for all of the wrong reasons. The program started in 1992 with the goal of allowing hospitals and clinics that work with underserved communities to provide outpatient prescription drugs to patients at deep discounts. The program has become a revenue generating source for hospitals and pharmacies that is ultimately not benefiting the patients it was created to serve, and the program is increasing the overall cost of healthcare spending.