

PNC PHARMA & LIFE SCIENCES

Monthly News Brief

September 2026



CMS Expands ACCESS Pilot to Boost Use of Digital Health Tech *(MedTech Dive)*

The Centers for Medicare & Medicaid Services (CMS) is expanding its ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) pilot program to encourage greater adoption of digital health technologies for chronic disease management. Beginning in 2027, the program will add coverage for heart failure, chronic obstructive pulmonary disease (COPD), substance use disorders and tobacco cessation, while extending support for certain musculoskeletal conditions. Participating healthcare organizations receive outcome-based monthly payments for using digital tools to manage chronic illnesses.

CMS Sets Preliminary Cuts to Medicare Lab Reimbursement Rates *(MedTech Dive)*

CMS released preliminary 2027 Medicare Clinical Laboratory Fee Schedule rates that would reduce reimbursement for many laboratory tests after determining Medicare has been paying ~16% more than private insurers for comparable services. The proposed rates would reduce payments for ~1,200 tests, including 775 tests that would face the maximum 15% cut in 2027, followed by more reductions in 2028 and 2029. The changes could save the government ~\$1 billion annually. The American Clinical Laboratory Association argues the cuts could threaten patient access to diagnostic testing and innovation.

FDA Launches Pilot Program to Speed Up Early U.S. Drug Research *(BioPharma Dive)*

The U.S. Food and Drug Administration launched the Expedited Investigational New Drug Pilot, a new initiative under “Operation Trialblazer” aimed at accelerating early-stage drug development and encouraging companies to conduct first-in-human studies in the United States versus in countries like China and Australia, which have friendlier regulatory environments. The program will pair drug developers with up to 10 specialized research institutions and allow rolling FDA reviews of application components as they are submitted. Regulators hope the approach will reduce delays, streamline trial preparation, and improve predictability in the clinical development process.

FDA Clears First Generic Radioligand Drug *(BioPharma Dive)*

The FDA approved Curium’s Bexlutry, the first generic radioligand therapy and a copycat version of Novartis’ Lutathera for certain neuroendocrine tumors. Like Lutathera, Bexlutry delivers radioactive lutetium to a protein, “SSTR,” found on the surface of certain neuroendocrine tumors. It’s now the first generic “radioligand therapy,” or targeted radiopharmaceutical for cancer.

Autoimmune CAR-T Faces Tough Questions After Novartis, Bristol Myers Study Halts *(BioPharma Dive)*

The autoimmune CAR-T therapy sector faced increased scrutiny after Novartis and Bristol Myers Squibb paused multiple autoimmune disease trials due to safety concerns. Novartis reported three patient deaths linked to a severe immune reaction, while Bristol Myers cited reversible inflammatory events. The developments raised concerns about the broader autoimmune CAR-T landscape. However, the safety issues may be tied to compressed production times and speedier approaches to grow modified cells, rather than the entire treatment class.

mRNA Cancer Vaccines’ Biggest Barriers to Market *(BioPharma Dive)*

The strong Phase 3 results for Merck and Moderna’s personalized mRNA melanoma vaccine highlighted the promise of individualized cancer vaccines, but significant commercialization challenges remain. Unlike traditional medicines, each vaccine must be custom designed from a patient’s tumor, requiring complex manufacturing, extensive computational analysis, strict chain-of-identity tracking, and rapid production timelines. Industry experts believe cost, scalability, and the ability to manufacture thousands of patient-specific batches efficiently will be critical hurdles, along with clinical challenges also persisting.

RNAi Drug Specialist ADARx Raises \$446M IPO *(BioPharma Dive)*

ADARx Pharmaceuticals, a biotechnology company focused on RNA interference (RNAi) therapies, raised ~\$446 million through an upsized initial public offering. The offering marks the first U.S. IPO by an RNAi-focused biotech in more than a decade. The bulk of the 22 drug companies to price IPOs in 2026 have been small molecule or biologics developers. ADARx is developing RNAi treatments for hereditary angioedema, kidney diseases, geographic atrophy, blood disorders, obesity, and neurological conditions.

Enveda, an AI Drugmaker, Banks \$311M in Venture Funding *(BioPharma Dive)*

Enveda Biosciences raised \$311 million in a Series E financing round to advance its pipeline of AI-discovered drug candidates. The company uses AI to identify and analyze molecules from plants and microbes, ranks the molecules by their drug potential, and then Enveda’s chemists turn the most promising ones into drug prospects.

Novo Looks to Anthropic’s AI Models to ‘Supercharge’ Drug Development *(BioPharma Dive)*

Novo announced a partnership with AI company Anthropic to use advanced artificial intelligence models across drug discovery and development. The collaboration will help Novo analyze scientific data, identify potential drug targets, streamline research workflows, and support decision-making throughout the development process. The initiative is a way to “supercharge” innovation by combining AI capabilities with Novo’s scientific expertise. The deal reflects a broader pharmaceutical industry trend of integrating generative AI into R&D operations in hopes of reducing development timelines and improving the efficiency of bringing new therapies to patients.

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