
Ingenious Brain
InnoSep 2024
Monthly Life Science & Healthcare Insights

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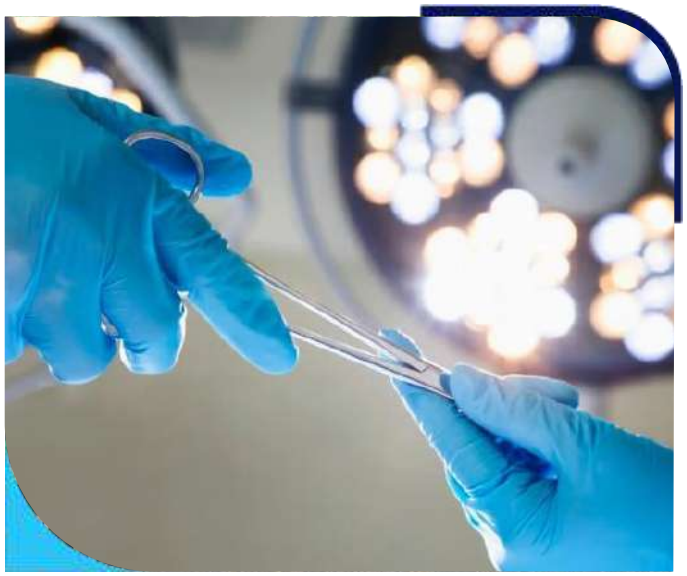
PepsiCo is set to acquire Siete Foods for $1.2 billion

PepsiCo, Inc. has agreed to acquire Siete Foods, owned by Garza Food Ventures LLC, in a deal valued at $1.2 billion, announced recently. The acquisition will broaden PepsiCo's portfolio by incorporating a well-known Mexican-American brand, aligning with its focus on healthier food options. Siete Foods, known for its flavorful, health-focused offerings, will add a unique cultural element to PepsiCo's expanding range of products. By integrating Siete, PepsiCo aims to enhance its multicultural offerings, providing consumers with a wider variety of delicious, authentic foods that contribute to meaningful dining experiences. This acquisition demonstrates PepsiCo's dedication to catering to diverse consumer tastes and preferences with innovative and inclusive food choices, ultimately enhancing the consumer experience.

Stryker makes another move with the acquisition of brain surgery device maker Nico

Stryker, a global leader in medical technologies, has completed its acquisition of Nico Corporation, an Indianapolis-based company specializing in brain surgery devices. This marks Stryker's seventh deal of the year, aligning with CEO Kevin Lobo's earlier commitment to a "bullish" M&A strategy. The strategic significance of this acquisition lies in Nico's innovative tools for minimally invasive parafascicular surgery (MIPS), which enables surgeons to navigate the brain's natural folds to treat severe strokes, remove brain tumors, and address other neurological conditions. Key technologies include BrainPath and Myriad, designed for treating intracerebral hemorrhages and cavernous malformations, along with tumor resections and biopsies. Earlier this year, Nico launched the Spectra system, which offers guided illumination and tissue removal for both minimally invasive and traditional craniotomy procedures.



Spain's Asabys Partners has closed a €180M ($200M) fund to invest in 12-15 biopharma and medtech

Spain-based Asabys Partners has closed its second fund, raising €180 million ($200 million) to invest in 12 to 15 life science companies across biopharma and medtech. Five companies have already received investments, including Barcelona's Orikine Bio and Belgium's Augustine Therapeutics. The fund, Sabadell Asabys Health Innovation Investments II (SAHII II), had its first close in January 2023, following the firm's initial €117 million fund in 2022. Asabys targets companies in biopharma, medical devices, and digital health focused on addressing unmet medical needs.

AzurBio Pharma launches service offerings to accelerate European market entry for biopharma companies

AzurBio Pharma has officially launched, with a strong focus on accelerating European market entry for biopharma companies targeting rare and serious diseases with unmet needs. Headquartered in Paris with a presence in Europe and the US, the company offers strategic partnerships and, importantly, flexible solutions that can be tailored to the specific needs of each client for EU market access, from registration to commercialization. Their turnkey solution fast-tracks time-to-market in France, leveraging the country's unique pathway for early access to medicines and potential reimbursement. Led by CEO Corinne Schmitz, founder of BlueReg and PharmaBlue, and supported by a strategic committee of biopharma experts, AzurBio aims to streamline market entry for North American companies.

Remedee Labs' Wristband Therapy for Fibromyalgia Approved in Europe

Paris-based startup Remedee Labs has received European approval for its millimeter-wave wristband to treat chronic fibromyalgia pain. The non-invasive device uses low-energy electromagnetic pulses to stimulate endorphin release via the nervous system to relieve pain. A clinical study involving 170 participants—mostly women—demonstrated that three daily 30-minute sessions, combined with coaching, reduced pain, fatigue, anxiety, and improved sleep. After three months, 55% of participants showed reduced fibromyalgia impact scores, and 53% reported pain decreasing from severe to moderate. Remedee's wristband is the first device to receive CE mark approval, specifically for fibromyalgia treatment.

Mendaera has raised $73 million for its handheld, needle-based robotic system

Mendaera has raised $73 million in venture capital to advance its handheld robotics platform for needle-based percutaneous procedures, including biopsies, vascular access, and pain management. The Silicon Valley startup, with a mission to address growing demand and healthcare provider shortages, is bringing robotic precision to routine yet complex procedures beyond major surgeries. Founder and CEO Josh DeFonzo highlighted the potential of robotics and AI to improve care across the healthcare system. Mendaera combines real-time imaging with robotic guidance and has partnered with Butterfly Network to integrate its semiconductor-based ultrasound technology into its platform.

Roche has launched a 12-virus diagnostic test in Europe

Roche is launching a new infectious disease diagnostic in Europe that can screen for up to 12 common respiratory viruses in a single test. Using temperature-activated signal generation (TAGS) technology, the test merges PCR testing with fluorescent color analysis and other data. While most multiplex molecular diagnostics detect around four genomic targets—such as COVID-19, RSV, and flu strains—Roche's TAGS technology can track up to 15 pathogens with one kit. Moreover, it is compatible with existing equipment, requiring no hardware or software upgrades, further boosting confidence in its advanced technology.

GE HealthCare secures FDA clearance for its amyloid imaging software for Alzheimer's diagnosis

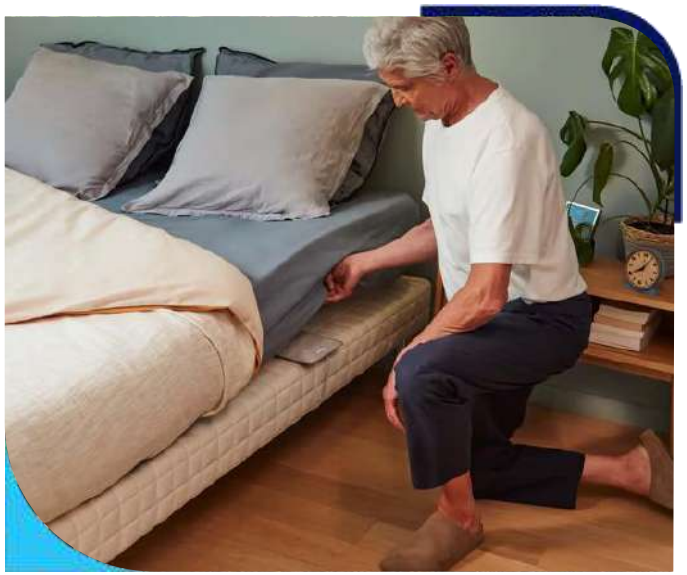
GE HealthCare's MIM Software division has received FDA clearance for its MIMneuro program, designed to quantify amyloid plaque density in Alzheimer's patients. The tool analyzes PET scans using radioactive tracers, providing standardized measurements of amyloid buildup, a key factor in Alzheimer's pathology. Utilizing the Centiloid scale, the program offers consistent readings across different scanners, with scores ranging from 0 (no amyloid) to 100 (typical Alzheimer's patient). With recent approvals of Alzheimer's treatments like Leqembi and Kisunla, GE HealthCare aims to support diagnostics essential for treatment decisions.

FDA has cleared Senseonics' Eversense CGM implant, designed for a 365-day wear

After collecting green lights for 90- and 180-day versions, the FDA has approved the latest version of the Eversense continuous glucose monitoring (CGM) system, which only needs to be swapped out once a year. Developed by Senseonics and Ascensia Diabetes Care, the Eversense 365 implant got the go-ahead for adults with Type 1 or Type 2 diabetes. The system features a rice-sized sensor implanted under the skin, which transmits blood sugar data to a wearable transmitter. The Eversense 365 is also cleared as an integrated CGM, compatible with insulin pumps and other diabetes devices. Ascensia plans to launch the sensor commercially in late 2024.

Withings' contactless sleep apnea mattress mat earns FDA approval

Withings has received FDA clearance for its Sleep Rx mat, the first contactless device to help diagnose obstructive sleep apnea without the need for wearables, wires, or masks. Placed under a mattress, the mat monitors heart rate, breathing, body movement, sleep quality, and respiratory disturbances over several nights. Traditionally, diagnosing sleep apnea requires an overnight sleep lab stay with multiple sensors, which can be costly and uncomfortable. Withings highlights that 80% of the estimated 30 million U.S. sleep apnea cases remain undiagnosed, increasing risks for cardiovascular and metabolic diseases if untreated.

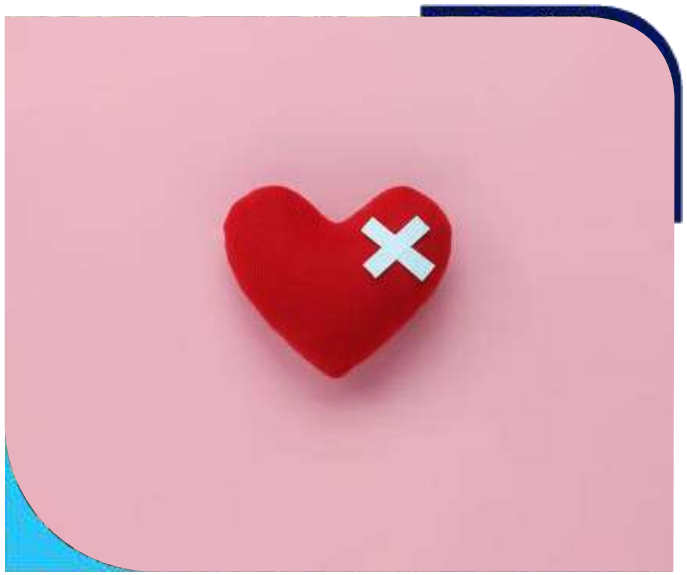


Embecta has received FDA clearance for its insulin patch pump for Type 1 and Type 2 diabetes

Embecta has received FDA clearance for its first wearable insulin patch pump, designed for individuals with Type 1 or Type 2 diabetes. The fully disposable device includes a 300-unit insulin reservoir, providing up to three days of insulin for most Type 2 users who rely on multiple daily injections. While 90% of diabetes patients have Type 2, many existing insulin delivery systems were originally designed for Type 1, which requires lower doses. Embecta's patch pump addresses this gap by offering a solution tailored to the needs of Type 2 diabetes patients.

FDA Approves Expandable Stent for Growing Children with Congenital Heart Defects

The FDA has approved Renata Medical's Minima stent, designed to treat infants and young children, including neonates with congenital heart defects. This re-expandable stent can grow in size as the child matures, addressing severe arterial narrowing, such as in the aorta or pulmonary vessels. Delivered via catheter in a minimally invasive procedure, the metal alloy stent starts at less than 2mm in diameter and can be expanded up to 24mm as needed. In clinical trials, it successfully opened blood vessels in 97.6% of cases, with no major complications reported for six months. Of the 41 children implanted, 12 have since undergone successful stent redilation. This approval marks a significant step in pediatric cardiovascular care.

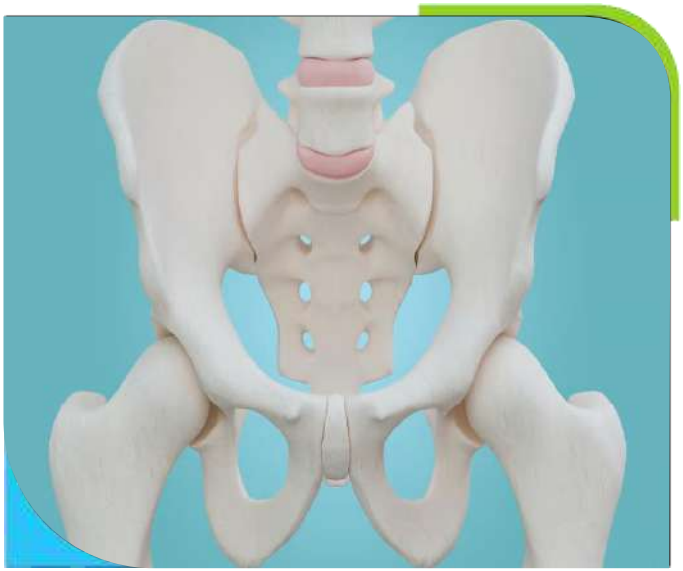


Abbott has launched a deep-brain stimulation trial for treatment-resistant depression

Abbott has launched a pivotal clinical trial to evaluate its deep-brain stimulation (DBS) technology for treatment-resistant depression. Previously approved for treating movement disorders like Parkinson's disease and essential tremor, the DBS system delivers electrical pulses to stimulate brain activity, similar to a pacemaker. The FDA granted Abbott a breakthrough designation to explore this technology for mood regulation. Prior studies showed 75% of patients experienced a 50% improvement in symptoms over several years. The new trial will enroll 100 participants who have not responded to at least four different antidepressant medications.

FDA has escalated three recalls involving Smiths Medical's ventilators and tracheostomy tubes

The FDA has upgraded three respiratory hardware recalls from Smiths Medical, including ventilators and tracheostomy tubes, to Class I, its most serious category. Smiths Medical, a division of ICU Medical, alerted healthcare providers in May and June to stop using affected devices, including all Pneupac ParaPAC P300 and P310 ventilator models. These gas-powered systems, used in patient transport, have been linked to one injury and one death due to a loose patient hose connector disrupting airflow. Additionally, the tidal volume setting knob may shift, potentially causing incorrect ventilation delivery.



Zimmer Biomet to phase out hip implant as FDA escalates recall

The FDA highlighted Zimmer Biomet's recall of its discontinued CPT Hip System Femoral Stem 12/14 Neck Taper due to its potential link to thigh bone fractures. In a July notice, Zimmer Biomet issued a field safety update, warning healthcare providers of an increased risk of femur fractures with the cobalt-chromium alloy implant compared to similar stainless-steel devices. The implant, which has been on the market for two decades, will be phased out by December. The recall doesn't require returning the implants but advises updated usage instructions.

FDA escalates Medtronic laryngoscope recall over battery explosion risk

The FDA has escalated a recall from Medtronic concerning McGrath MAC and MAC EMS video laryngoscopes due to battery packs that may overheat or explode. Initially notified in July, the recall was classified as Class I in August, the FDA's most serious level. The recall involves over 30,000 units worldwide; one injury has been reported, though no deaths. The FDA advises discontinuing use of older models and properly disposing of their batteries. At the same time, newer versions can remain in service if their batteries are undamaged, stored correctly, and within expiration.

Lilly and Novo Nordisk are investing billions to expand their obesity pipelines beyond GLP-1s

Novo Nordisk and Eli Lilly dominate the weight loss market, with Q2 sales of $1.7 billion for Novo's Wegovy and $1.2 billion for Lilly's Zepbound. According to a Pitchbook and Morning Star report, competitors like Terns Pharmaceuticals, Pfizer, and Amgen may challenge them by 2026, with the market expected to reach $200 billion annually by 2031. Novo and Lilly are preparing through acquisitions and partnerships, especially targeting new obesity treatments. Novo leads in business development with 37 partnerships, while Lilly invested $1.4 billion in business deals and $4.4 billion in R&D this year.

Medtronic unveils adaptive neurostimulation study for Parkinson's, pending FDA approval

Medtronic is conducting an at-home trial, ADAPT-PD, to test adaptive deep brain stimulation (aDBS) for Parkinson's disease, currently under FDA review. Published in *npj Parkinson's Disease*, the study explores how aDBS, which adjusts treatment based on brain activity, may improve the management of motor symptoms. The trial involved 68 patients with Medtronic's Percept PC neurostimulator, and adaptive stimulation was compared to continuous therapy. This marks the largest and longest real-world study of aDBS. Medtronic previously received FDA approval in 2021 for deep brain stimulation devices capable of sensing and recording brain activity.

Jury favors Axonics in Medtronic's long-standing neuromodulation patent lawsuit

A federal jury in California ruled in favor of Axonics, finding that its neurostimulators and leads for incontinence treatment did not infringe on three of Medtronic's patents. The case, one of several intellectual property disputes between the companies, began in 2019 but was delayed as the patents were reviewed. Earlier this year, the U.S. Patent Office upheld some of Medtronic's claims related to sacral nerve stimulation. However, the jury unanimously sided with Axonics, including the two patents reviewed and a third related to recharging implanted devices.

J&J hit with $1 billion penalty over Auris robotic surgery deal

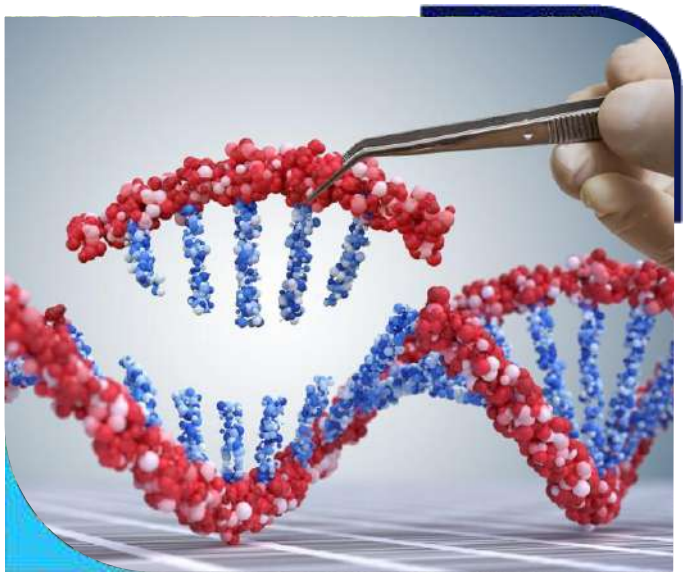
In 2019, Johnson & Johnson acquired Auris Health for $3.4 billion, with an additional $2.35 billion in milestone payments tied to the success of Auris' technologies. However, Auris' backers sued J&J, claiming the company failed to allocate resources to help meet the agreed milestones. This week, a Delaware judge ruled in favor of Auris, ordering J&J to pay over $1 billion in damages. The lawsuit centered on Auris' iPlatform robotic system, which competed against J&J's Verb Surgical robot, ultimately winning but facing challenges due to regulatory hurdles.

Roche's weight-loss drug candidate raises concerns over side effects

Roche Holding AG downplayed concerns over side effects from its weight-loss shot CT-388, which caused a 4.5% share drop after trial details leaked. Hans Clevers, head of pharma research at Roche, said they were "not alarmed" by the results, as no patients halted treatment. He also highlighted the potential of their pill, CT-966, as "best in class." Despite the recent dip, Roche shares have risen 10% this year, as the obesity drug market is forecast to hit $130 billion by decade's end.

Pfizer’s Oxbryta Exit Disrupts Sickle Cell Care, Alarms Investors

Pfizer's sudden withdrawal of Oxbryta, a sickle cell therapy once projected to reach $750 million in sales by the decade's end, has left patients and providers with limited options and raised concerns among investors. The decision followed a European Medicines Agency (EMA) review citing an imbalance of fatalities, including increased cases of vaso-occlusive crisis. Pfizer halted clinical trials earlier this year over similar safety concerns. Approved in 2019, Oxbryta’s removal marks a major setback for the sickle cell community, already underserved by newer therapies, according to analysts and advocates.



EU High Court Rules in Favor of Illumina in Grail Case

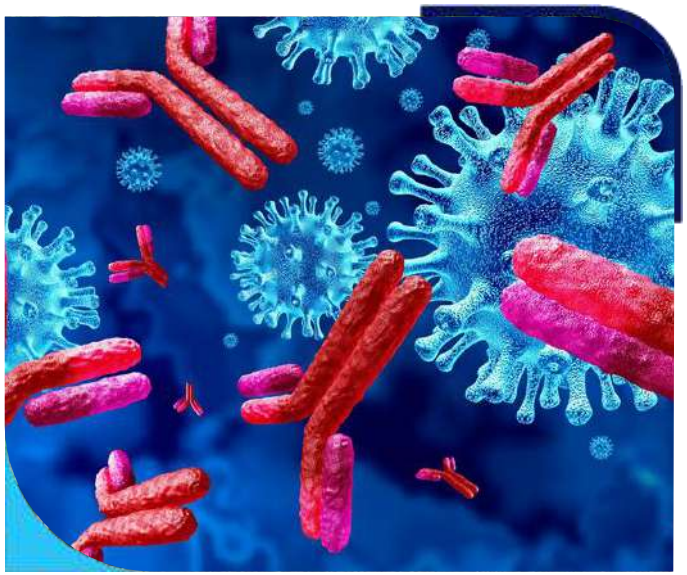
After Illumina's sale of Grail this summer, following clashes with antitrust regulators and heavy fines, the EU's highest court has ruled in favor of Illumina's appeal. The European Court of Justice found that the European Commission lacked jurisdiction to block Illumina's acquisition of Grail, a cancer blood test developer, as Grail had no business operations in Europe at the time. The case began after several national regulators referred it to the EC. The ruling counters earlier conclusions from both the EC and the U.S. FTC, which cited competition concerns.

Medtronic, Siemens Healthineers unite to transform spine surgery with cutting-edge imaging tech

Medtronic and Siemens Healthineers, two of the top 10 medtech companies renowned for their expertise, are partnering on robotic head and spine surgeries. Announced at the North American Spine Society meeting, the collaboration aims to integrate Medtronic's AiBLE platform—featuring the StealthStation navigation system, Mazor robotic guides, and AI-driven implant design—with Siemens' pre- and post-op imaging expertise. Siemens will add its Multitom Rax robotic X-ray scanner to the partnership, and both companies plan to co-market the ceiling-mounted system, enhancing precision and efficiency in spinal procedures through advanced imaging and robotics integration. With these two industry leaders at the helm, the future of medical technology looks promising and secure.

AstraZeneca Expands AI-Powered Immuno-Oncology R&D Alliance with Immunai

AstraZeneca is expanding its collaboration with Immunai in a multiyear deal to integrate Immunai's AI-powered immune cell atlas into the design of AstraZeneca's cancer immunotherapy clinical trials. The two companies previously worked together on research for inflammatory bowel disease using cell-by-cell immune system analyses. Immunai's multi-omics technology also contributed to the development of AstraZeneca's bispecific antibody volrustomig, now in phase 3 trials for lung, cervical, and head and neck cancers. Founded by MIT, Harvard, and Stanford researchers, Immunai has built a digital map of the immune system to explore disease interactions.

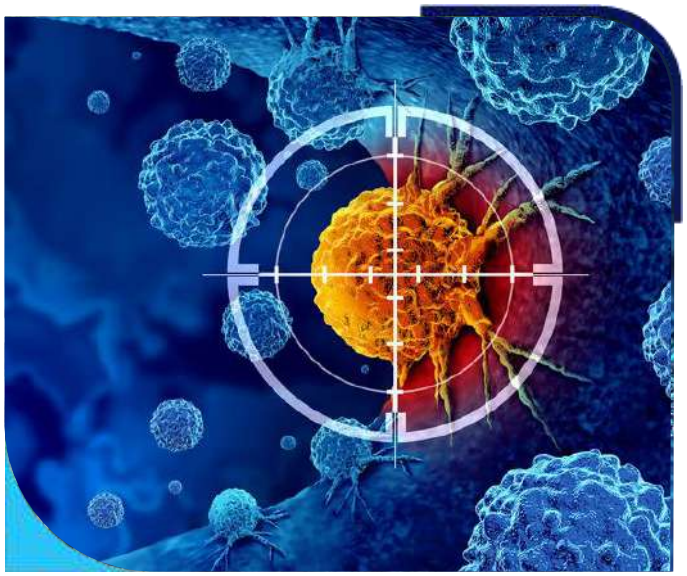


Merck secures rights to Evaxion's AI vaccines, balancing modest upfront with high backend gains

Merck & Co. has secured options on two AI-designed vaccine candidates from Evaxion Biotech, paying $3.2 million upfront with potential milestones exceeding $1 billion. The deal covers a gonorrhea vaccine, EVX-B2, and a vaccine targeting an undisclosed infectious agent, both derived from Evaxion's EDEN platform, which uses AI to identify antigens that trigger strong immune responses. Merck holds the option to license these vaccines for $10 million next year, with Evaxion eligible for up to $592 million per product if Merck exercises the option and development milestones are met.

Flagship anticipates biotechs leveraging Mirai's algorithmic tech to advance genetic therapies

Flagship Pioneering has launched Mirai Bio, a new venture backed by a $50 million commitment to help biotechs enhance the precision of genetic medicines. Mirai's AI-driven platform is designed to improve and accelerate the development of gene therapies across various therapeutic areas. The platform optimizes the delivery of therapies to specific tissues and cell types while also refining the therapeutic "cargo." Additionally, it aims to streamline key manufacturing steps and accelerate clinical transitions. Flagship describes Mirai as the biotech industry's first open, end-to-end platform for fully optimized genetic medicine co-creation.

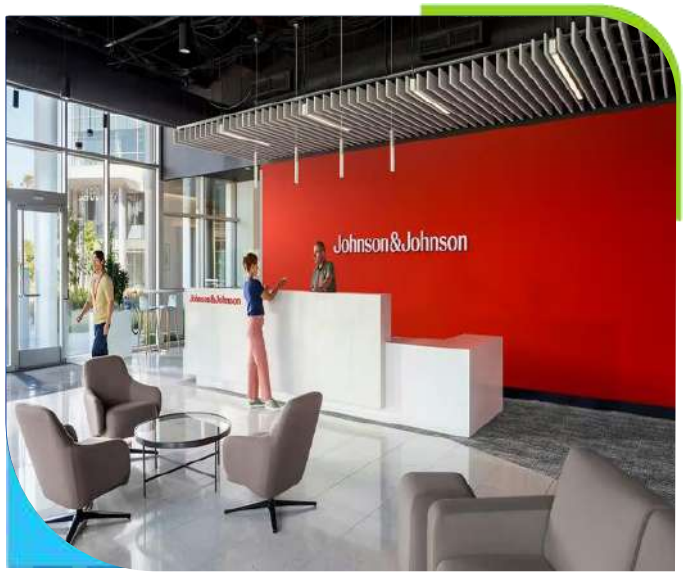


Finnish biotech Orion FI taps Aitia's 'Digital Twin' tech to drive new cancer drug discoveries

Finnish biotech Orion has partnered with Aitia to leverage its "digital twin" technology for cancer drug development. Aitia's Gemini Digital Twins uses multi-omic patient data, AI, and simulations to model diseases, uncover hidden pathways, and accelerate drug discovery. Orion will contribute clinical data to Aitia's platform with the goal of developing oncology candidates. Orion holds an exclusive option to license resulting drugs, while Aitia could earn over $10 million per target in milestone payments and royalties. This collaboration follows a broader trend of using digital twins in drug development and clinical trials.

Gilead strikes $35M partnership with AI drug discovery firm Genesis

Genesis Therapeutics has secured a $35 million partnership with Gilead Sciences to leverage its AI drug discovery platform, GEMS. This marks Genesis' third collaboration with a major pharma company. Gilead will pay upfront for AI-driven research on three undisclosed targets, with the option to nominate more for additional fees. Gilead gains development and commercialization rights to any compounds discovered, while Genesis stands to receive milestone payments and tiered royalties. CEO Evan Feinberg highlighted GEMS' ability to tackle challenging protein targets, where conventional machine learning struggles due to limited training data.

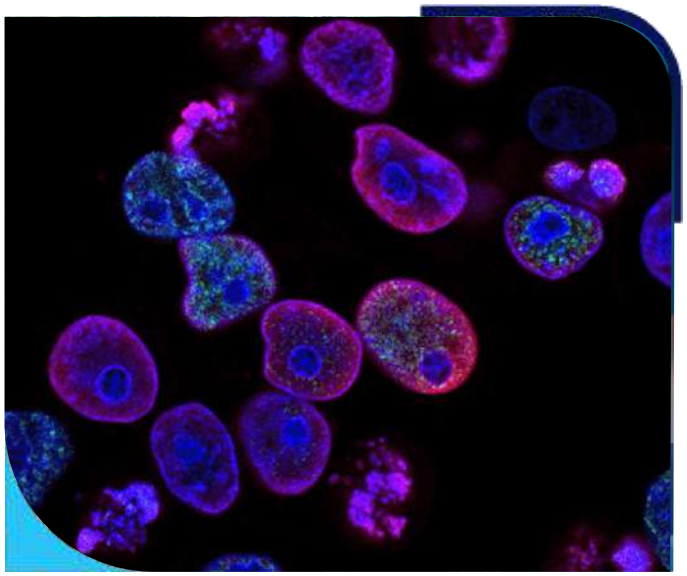


J&J consolidates its medtech brands under a single banner

Johnson & Johnson is uniting its medtech brands—Ethicon, DePuy Synthes, Biosense Webster, Abiomed, and Cerenovus—under the single banner of Johnson & Johnson MedTech. This rebranding aims to simplify the company's presentation without altering any product portfolios. The move follows J&J's broader marketing updates last year, including a modernized logo and the planned renaming of its Janssen pharmaceutical group to Johnson & Johnson Innovative Medicine. This shift builds on a 2022 decision to streamline references to its medical device division as Johnson & Johnson MedTech.

Eli Lilly is diving deeper into AI with a $409 million deal for Genetic Leap

Eli Lilly has entered a partnership with RNA specialist Genetic Leap in a deal worth up to $409 million in upfront and milestone payments. Genetic Leap, known for its AI-driven platform targeting RNA, will use its technology to discover oligonucleotide drugs against selected targets for Lilly in high-priority areas. This partnership adds Lilly to Genetic Leap's growing list of collaborators, including Astellas. The move follows Lilly's recent $700 million investment in a Boston-based nucleic acid R&D center, furthering its focus on advancing RNA and DNA therapies for conditions like neurodegeneration, diabetes, and obesity.



Rakovina strengthens AI push in cancer research targeting DNA-damage kinases

Five months after pivoting to AI, Rakovina Therapeutics has partnered with Variational AI to develop cancer therapies targeting DNA-damage response (DDR) kinases. Using its Enki platform, Variational AI will identify novel DDR inhibitors, providing Rakovina with potential drug candidates. Rakovina will evaluate these candidates over 12-18 months in its University of British Columbia labs. Financial terms include a “low upfront fee” and potential milestone payments. This collaboration complements Rakovina’s existing AI-driven research on PARP-resistant cancers, expanding its pipeline beyond next-gen PARP inhibitors with a focus on DDR targets.

Exact Sciences has presented early data on its blood test for colorectal cancer

Exact Sciences has presented promising clinical data on its blood-based colorectal cancer test at the European Society for Medical Oncology meeting. Findings from the ongoing BLUE-C study of over 26,000 participants showed the test achieved 88.3% sensitivity for malignant colorectal cancer and 31.2% for precancerous lesions, with a false-positive rate of 9.9%. The study also finalized an algorithm using DNA methylation patterns and a new marker class. The test’s performance may match the fecal immunochemical test (FIT) in detecting advanced polyps, offering a non-invasive screening option for colorectal cancer.

Abbott's MitraClip study demonstrates improvements in functional but leaky heart valves

A study by Abbott indicates that using its cardiac valve repair implant earlier in heart failure—when the mitral valve remains functional—could reduce hospitalizations and enhance quality of life. The results from the RESHAPE-HF2 trial contrast with earlier studies, MITRA-FR and COAPT, which focused on more severe cases and found mixed results regarding the MitraClip device's effectiveness. The RESHAPE-HF2 study primarily involved patients with moderate to severe functional mitral regurgitation, a condition caused by issues with the heart's surrounding structures rather than the valve itself. Current guidelines recommend intervention only during other surgical procedures.

Astrix joins Sapio Sciences Partner Program to enhance life science solutions

Sapio Sciences has announced that Astrix, a leader in delivering innovative strategies and solutions to the life science community, has joined its Partner Program to provide consulting and implementation services for life science and biotech customers. As a Sapio Services Partner, Astrix will support the deployment of the Sapio Platform, Sapio LIMS, and Sapio ELN. The partnership aims to enhance business, scientific, and medical outcomes by leveraging world-class processes and technologies. Through this collaboration, Astrix will offer its clients access to the fully configurable Sapio platform and other advanced technologies.

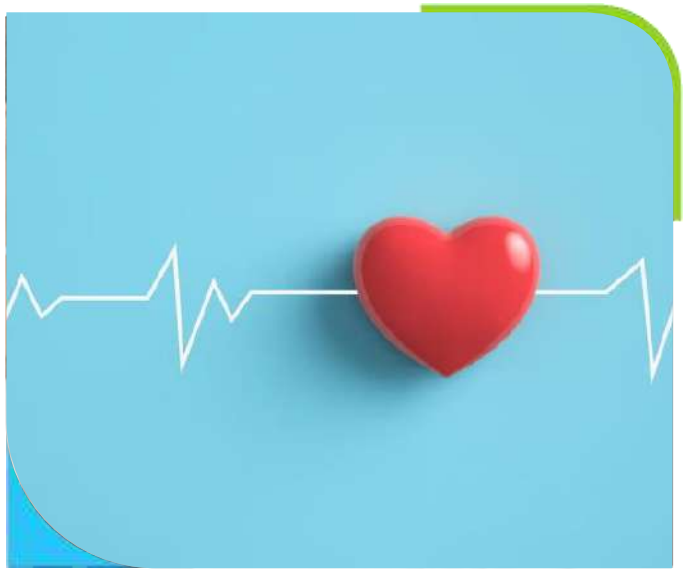
sapio sciences

Medtronic appoints new CMO for digital surgery and robotics division

Medtronic has appointed James Porter as the new chief medical officer for its digital and robotics teams, recognizing him as one of the top five robotic surgeons in the U.S. Currently the medical director of robotic surgery at Providence Swedish in Seattle, Porter has performed over 5,000 robotic procedures specializing in prostate and kidney cancer. As CMO, he will shape the division's clinical evidence development plans while continuing part-time practice. Porter is set to perform a live partial nephrectomy using Medtronic's Hugo robot at the European Robotic Urology Society meeting in Bordeaux, showcasing the system's capabilities.

Think Surgical gains approval for handheld knee replacement robot

Think Surgical has received its third FDA clearance in three months for a specialized version of its knee replacement system designed to work with Zimmer Biomet implants. The TMINI platform, which secured its first FDA approval in May 2023, features a wireless handheld tool that uses a 3D model from CT scans to guide surgeons in accurately placing bone pins and cutting guides. In July, the company also obtained a 510(k) update to enhance joint positioning and soft-tissue balance. Recent clearances include collaboration with Medacta International for its GMK Sphere and SpheriKA systems.



SpectraWAVE secures $50 million to advance imaging technology for clogged plaque-filled blood vessels

SpectraWAVE has raised $50 million to enhance its imaging technology for analyzing clogged, plaque-filled blood vessels. The Massachusetts-based company integrates optical coherence tomography and near-infrared spectroscopy into a catheter-based tool, enabling surgeons to assess coronary artery blockages from within. Its HyperVue system received two FDA clearances in 2023 and includes an AI-powered program that measures vessel plaques without contrast agents, aiding in precise stent placement during percutaneous coronary interventions. Johnson and Johnson Innovation led the Series B funding round, with support from various investors, including S3 Ventures and SV Health Investors.

Stay tuned for more such updates in the coming months!

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