

PRESS RELEASE · SEPTEMBER 9, 2026

Lotus Neuro Launches to Deliver the Next Generation of Therapies Across the Blood-Brain Barrier

Clinical-stage biotech unveils a modality-agnostic platform and partnership-first model pairing focused ultrasound with medicines for brain cancer, neurodegeneration and other focal neurologic disease.

MIAMI, SEPT. 9, 2026 - Lotus Neuro, a clinical-stage biotechnology company pairing focused ultrasound with leading therapeutic modalities to treat focal neurologic disease, today announced its public launch. Spun out in December 2025 from Insightec, the global leader in incisionless focused ultrasound, Lotus Neuro is built on a clinically validated platform for precision modulation of the blood-brain barrier (BBB) and is dedicated to solving the delivery problem that has stalled decades of promising neuroscience.

The blood-brain barrier protects the brain, but it also keeps the vast majority of drugs from reaching it in effective concentrations. Many therapies that should work in the brain never get the chance, and a delivery failure is often read as a failure of biology. Lotus Neuro's platform uses the most clinically validated focused ultrasound technology in combination with circulating microbubbles to modulate the barrier across precisely targeted brain volumes, from a few millimeters to a large hemispheric region, in combination with therapeutic administration. The drug itself does not require modification, which makes the approach modality-agnostic: small molecules,



antibodies and antibody-drug conjugates, enzymes, gene therapies, oligonucleotides and cell therapies can all be paired with the technology.

The platform has been used in approximately 600 treatment sessions across brain tumors, Alzheimer's disease, Parkinson's disease and ALS, including delivery across four classes of therapeutics. In glioblastoma, a multicenter phase 1/2 trial published in *The Lancet Oncology* in 2025 reported median overall survival of 31.3 months when the barrier was opened during standard chemotherapy, versus 19.3 months in a matched control cohort, with no treatment-related deaths. In Alzheimer's disease, a study published in *The New England Journal of Medicine* in 2024 found greater amyloid plaque reduction in regions where the barrier was opened alongside aducanumab than in the matching untreated regions. In Parkinson's disease, a phase 1 study delivered an enzyme replacement therapy repeatedly to the putamen (*Movement Disorders*, 2022), and in HER2-positive brain metastases a radiolabeled antibody roughly doubled its uptake in sonicated lesions (*Science Translational Medicine*, 2021). Gene therapy vectors and oligonucleotides have been delivered to targeted brain regions in non-human primates, and the barrier has been opened safely over the motor cortex in ALS.

"Lotus Neuro exists because science is not the problem, delivery is. Brain disease is complex and variable, demanding an answer that is both personalized and precise. Through extensive pre-clinical and clinical testing, a global network of the leading neuroscience centers has demonstrated that focused ultrasound can safely pair with therapeutics and reach anywhere in the brain, delivering medicines where and when they are needed most."

ARJUN "JJ" DESAI, MD · FOUNDER AND CHIEF EXECUTIVE OFFICER, LOTUS NEURO

PARTNERING ACROSS FOCAL NEUROLOGIC DISEASE

Lotus Neuro is launching with a partnership-first strategy, working with pharmaceutical and biotechnology companies and with academic centers to bring promising therapeutics precisely to their brain targets. With a globally established clinical network and leading technology safety profile, Lotus Neuro is focused on near-term clinical development, using advances in blood, tissue and imaging analysis to characterize the most promising combination therapies.

Through its Proof of Pharmacology (POP) Challenge, launched in June 2026, Lotus Neuro is funding investigators at leading neuroscience institutions to add focused ultrasound study arms to existing investigational drug programs, generating clinical evidence of drug delivery and target engagement in the brain.

"Too many CNS drug trials have failed without first confirming that the therapy reached its intended target in the brain at a meaningful concentration. Without that evidence, a negative result cannot distinguish between an ineffective target and inadequate drug delivery. Focused ultrasound enables us to address this question with precision, tailoring blood-brain barrier modulation to a specific brain region and neurological indication. This approach allows us to assess earlier, directly in patients, whether a promising therapy is reaching its target and producing the intended biological effect."

AJAY VERMA, MD, PHD · FOUNDING SCIENTIST, LOTUS NEURO

"Because we don't alter the drug, we can move at the speed of our partners' science, whether that is a small molecule, an antibody, an enzyme or a gene therapy. Our work is to ensure that targeted delivery to the brain is as rigorous and repeatable as the medicines it carries."

JUNGHAE SUH, PHD · CHIEF TECHNOLOGY OFFICER, LOTUS NEURO

FROM DEVICE TO THERAPY

Insightec continues to advance and commercialize the core focused ultrasound platform, while Lotus Neuro applies it to new therapeutic frontiers in the brain, supported by shared translational data and close scientific collaboration across the two organizations.

"Brain health is the last frontier in medicine, and for a long time the tools simply weren't there. Insightec proved that focused ultrasound could safely and precisely reach the brain without a single incision. Lotus Neuro is the natural next chapter: taking that platform from treating symptoms to delivering the medicines that can change the course of disease, across brain cancer and neurodegeneration alike. Together we've built a complete ecosystem, from device to drug delivery, and JJ Desai is exactly the person to lead it."

MAURICE R. FERRÉ, MD · CHAIRMAN AND CEO, INSIGHTEC; MEMBER, LOTUS NEURO BOARD OF DIRECTORS

"The best companies are built at the intersection of a validated technology, a clear unmet need and a team with a track record of getting results. Lotus Neuro has all three. The platform has an expanding evidence base, the need across brain cancer and neurodegeneration could not be more urgent, and this team knows how to deliver. I joined this board because I believe this technology offers exciting potential to advance therapeutic options that have not been previously possible."

SCOTT RAKESTRAW, PHD · INDEPENDENT DIRECTOR, LOTUS NEURO

LAUNCH

Alongside the announcement, Lotus Neuro is unveiling its brand identity and website at lotusneuro.com, including a short film, *The Lotus Neuro Story*, featuring the company's founders, scientific leadership and advisors.

ABOUT LOTUS NEURO

Lotus Neuro is a clinical-stage biotechnology company advancing brain-targeted therapeutics through precision, low-frequency focused ultrasound. Spun out of Insightec in December 2025, the company pairs a clinically validated platform for opening the blood-brain barrier with medicines of any modality, opening the barrier only where the disease is and letting it close again. Its initial clinical focus is neuro-oncology, with programs and partnerships in neurodegeneration and other focal neurologic disease. Lotus Neuro is headquartered in Miami. Where Barriers Fall. Learn more at lotusneuro.com.

MEDIA CONTACT

Todd Ransick

Brand and Marketing Communications, Lotus Neuro, Inc.

press@lotusneuro.com

This press release contains forward-looking statements about Lotus Neuro, Inc.'s technology and development plans that are subject to risks and uncertainties, and actual results may differ. Lotus Neuro's technology is investigational and has not been cleared or approved by the FDA.

###