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In 2024, Op2Lysis made significant progress in addressing the unmet medical needs of hemorrhagic stroke. By achieving regulatory milestones and validating the safety of our drug, fostering collaborations and advancing hematoma modeling, we have strengthened our position as innovators in this field. Major advances such as the results of the ENRICH and INTERACT 4 trials underline the importance of reducing hematoma size for better patient outcomes.

The following sections describe the company's progress in 2024.



A new regulatory milestone achieved



In 2024, our regulatory program successfully **met health agency expectations** following pre-IND consultations and Protocol Assistance. We initiated our **first toxicology study in rats, which included both acute and repeated local administrations.** The results showed no significant clinical signs, even at the highest concentrations tested. This reassures us about the safety of our product and its potential for use at optimal therapeutic doses.

A robust CMC process allowing stable productions



Ensuring the stability and sterility of our drug remains a key priority, and we have made great progress. We achieved **12 months of stability** for our molecule. Our particle production system has now been validated with seven consecutive batches, demonstrating reproducibility. We demonstrated the **viral clearance** over the complete process. Over 90% of the required analytical tests have been developed, with a strong focus in 2024 on **potency testing and methodologies for endotoxin monitoring and molecule detection.**

Increased recognition of scientific expertise and know-how



Our expertise in human hematoma reproduction is now widely recognized and has enabled us to collaborate on impactful projects. These include a hospital-university research project led by Lille University Hospital (principal investigator: Prof. Charlotte Cordonnier), and regional project research with Inserm U1237 to improve clot models for ischemic stroke treatment (principal investigator: Prof. Denis Vivien). We have also advanced the evaluation of thrombolysis conditions, successfully treating over 250 hematomas with our candidate drug to date. A new study is currently being evaluated for publication.

The dawn of a new era



The ICH field is evolving rapidly, supported by significant developments. Results from the ENRICH trial and INTERACT 4 confirmed the importance of reducing hematoma size to improve outcomes for ICH patients, aligning with the Stroke Action Plan for Europe. The concept of "surrogate markers" such as reducing hematoma size to below 15ml, is gaining traction. Additionally, the acquisition of Nico Corporation by Stryker (NYSE: SYK) in September 2024, a few months after ENRICH publication highlights growing interest and investment in innovative solutions for cerebral hemorrhages, promising a bright future for the field

















