



## OPLYSIS SAS

### One line pitch:

Op2Lysis develops the first medical treatment dedicated to the 1.5 million patients with a hemorrhagic stroke every year

### Market Analysis:

Intracerebral hemorrhage (ICH) is the most severe form of stroke, with up to 75% death or severe disability related to intracerebral hematoma. There is no approved treatment available. Our treatment is aimed at liquefying and evacuating the hematoma with one single intracerebral injection. Based on our expected benefits in ICH patients and cost-saving attributes, our hypothesis is a mean value worldwide of 10,000 € per treatment. Our conservative estimation is that 60% of ICH patients are eligible. Thus, with an estimate of 200,000 patients per year eligible for this therapeutic strategy in the 7 main pharmaceutical markets, the reachable market is 2 000 M€ per year.

### Value proposition:

The strategy of evacuation of the hematoma out of the brain with the local injection of rtPA (the class of product which we develop) through a minimally invasive surgery procedure shows promises, as suggested with alteplase in the MisTIE phase II clinical trial. However, alteplase in this strategy faces two major limitations for clinical benefit which offer major room for improvement with the product we develop: rtPA neurotoxicity, favoring PHE extension, and the short half-life, requiring multiple injections to achieve sufficient hematoma degradation. Our product is non-neurotoxic and its formulation is aimed at liquefying the hematoma with one single injection.

### Business Model:

Our business model is the one of a biotechnology company. Op2Lysis SAS, a spin-off from INSERM UMR\_S1237 Unit, develops a therapeutic option for ICH. Our aim is to safely liquefy and evacuate the hematoma out of the brain using an innovative lytic recombinant protein (rt-PA) in a sustained-release formulation suitable for intra-cerebral injection. Our development plan has been built to allow demonstration of the clinical proof of concept within 5 years, i.e. demonstration of efficacy in decreasing the hematoma volume under safe conditions. Exit strategies can apply at the term of our 5-year plan. The full development to registration/commercialisation will require 5 additional years.

### IP and Regulatory situation:

Product patent was applied in US, EU and Japan. US patent is now published. Op2Lysis has acquired the exclusive licence for development and commercialisation in two related indications of hemorrhagic stroke: ICH and intra-ventricular hemorrhage. Our development plan has been built to allow IND submission and initiation of the first-in-human study (which will be in patients and will allow assessment of the clinical proof of concept) within 3 years. The study will be initiated in EU, as well as potentially US and Japan if allowed by sufficient early funding.



### COMPANY PROFILE

- **Website:**  
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- **Field:**
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- **Founded in:** //04/2016
- **Employees:** 2
- **Financial information (€):**
  - **Company stage:**  
Proof Of Concept
  - **Capital raised to date:**  
173,175 €
  - **Monthly burn rate:**  
3000 €
  - **Capital seeking and date:**  
500 k€ by end 2017
- **Investors:**  
Christophe Gaudin , Jérôme  
Parcq , Jean-Claude Muller