



### Developing the first medical treatment dedicated to 1.5 million patients with a hemorrhagic stroke every year

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# Reachable Population of Intracerebral Hemorrhage > 200,000 patients every year



# INTRACEREBRAL ADMINISTRATION OF A THROMBOLYTIC AGENT (minimally invasive surgery) CAN LIQUEFY THE HEMATOMA and DECREASE HEMATOMA VOLUME\*

BUT...

**Neurotoxicity** 

**Pharmacokinetic limitations** 

- Multiple injections needed

\*MisTIE academic NIH-funded program, coordinated by BIOS at Johns Hopkins, Baltimore, MD, USA





#### ΙP

- EU Patent 2011
- International extension (PCT) 2012
- Granted in US and JP 2017, soon in EU
- Exclusive licence to Op2Lysis

### Op2Lysis O2L-001



## A MUTANT OF rt-PA DESIGNED FOR INTRACEREBRAL ADMINISTRATION

Local drug administration and blood elimination through a thin catheter (minimally invasive procedure)

Ability to achieve better/faster hematoma liquefaction with a unique injection (sustained release formulation)

**Safer** with an adjusted quantity of a **non-proneurotoxic** lytic agent

#### **DEVELOPMENT STAGE**

- ✓ Preclinical proof of concept in vitro and in vivo with *Drug Substance*
- ✓ Feasability of production and purification
- ✓ Feasibility of sustained release formulation
- ✓ Cell line identification
- ✓ Market analysis

# Superiority to Projects Currently in Development in Acute Hemorrhagic Stroke Patients



#### **Stop bleeding**

Facteur VII (biologic)

Nicardipine (chemical)

tPA S481A (biologic)

None of the tested options was substantially effective

#### **Evacuate the hematoma**

Alteplase (rtPA, biologic)

Brainpath<sup>™</sup> NICO Corporation (device)

Artemis<sup>™</sup> system, Penumbra (device)

Op2Lysis O2L-001

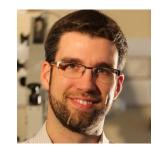
Best-in-Class\*

<sup>\*</sup> Optimal benefit - risk ratio and facilitated implementation/use with reduced costs at hospital level (enhanced market access)

### ✓ A Complementary Team Dedicated to Op2Lysis Growth



Christophe
Gaudin, MD
Co-Founder
20 yr. Cardiovascular and
Thrombosis Drug Dev.



Jérôme Parcq, PhD Co-Founder 10 yr. in Neurosciences Engineer in Agronomy, Challenge + (HEC)



Jean-Claude
Müller, PhD
Advisor
20 yr. Pharm and
Business Dev.

- ✓ A core operational team 3 employees in 2018 adjusted to project needs
- ✓ A strong international network
  - Strategic Committee

Patrick Cassagne, Christophe Gaudin, Philippe Monteyne, Jean-Claude Muller, Jérôme Parcq, Thierry Sempere

- International Scientific Experts
  - Prof. Denis Vivien and Prof. Emmanuel Touzé (Caen, France)
  - Prof. Javier Romero (Boston, US)
  - Prof. Daniel Hanley (Baltimore, US)
- Academic collaborative support (incl. US investigators involved in the MisTIE clinical study)

# Biotech Business Model based on product valorization in 4 years 18 M€ needed to get a product ready for Phase 3 development

Fundraising in 2018

640 k€ in equity + 815 k€ in non-dilutive grants

2018 - 2022
O2L-001 Lead Product production
and validation of clinical
POC\*/Phase 1-2 accomplished
(18 M€\*\*)

Early international plan (EU/US/JP) is Key for highest value



2022 – 2027
Validation of clinical
efficacy and O2L-001
fast-track registration\*\*\*

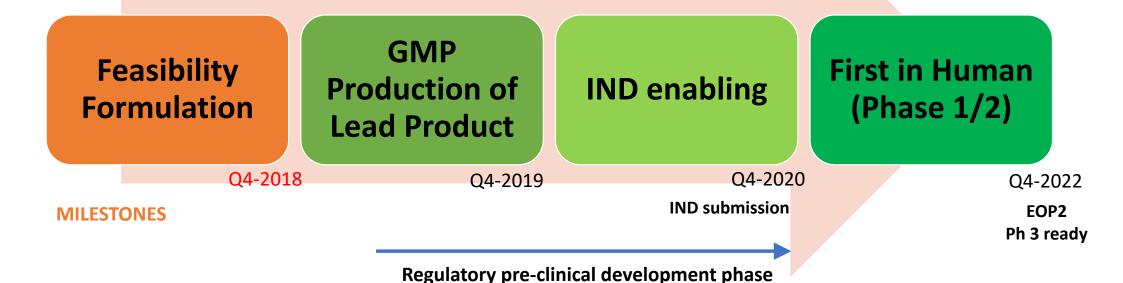
<sup>\*</sup> Clinical Proof of Concept (decreased intracerebral hematoma volume on MRI/CT-Scan)

<sup>\*\*</sup> Equity and non-dilutive, to allow POC demonstration both in EU and US and production ready for Phase 3

<sup>\*\*\*</sup> Potential for Orphan Drug Designation in US

### Milestones of O2L-001 Development Plan





### Proof of success

**April 2018** 

Laureate **Big Booster** Class of 2018

Aide à l'Innovation PIA3 (0,5 M€ **Grant)** 

Nov 2017

**SME Stage I** 

Seal of **July 2017** 

**Excellence** 

**May 2017** Laureate

**Concours i-LAB** 

Laureate **April 2017** (225 k€ Grant) **NETVA Boston** 

#### **BIOVISION**

THE CATALYZER **SELECTION COMMITTEE** SPECIAL AWARD

Jan 2017 **Special Jury** 

price Convention

d'Affaires

**Dec 2016** 

Scientipôle

incubator

Label EIP - Pôle de Compétitivité

Medicen

Integrated in

NormandInnov

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**May 2018** 

**First fundraising** 640 k€

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