



Transcatheter Mitral Valve Implantation

Company Fact Sheet

President & CEO : **Georg Börtlein**

Inception : **2010**

Funding : **M€ 20, privately held**

Sector : **Medical devices**

Cardiac valves

THE MANAGEMENT

Georg Börtlein, age 50, engineer, President and CEO of HighLife SAS.

Previously co-founder and COO of **CoreValve**, the pioneer of trans-femoral Transcatheter Aortic Valve Implantation (TAVI), which was acquired by Medtronic in 2009 for M\$ 700+. Also co-founder of *Devax*, *Stentys* (innovative coronary stent solutions), *Tripelay* (Endovascular Abdominal Aortic Aneurysm treatment) and *Baccata*, a medtech incubator.



THE COMPANY

HIGHLIFE SAS was incorporated in 2010 and is headquartered in Paris, France. It was founded with the ambition to offer less invasive treatments to patient suffering from heart valve diseases. It has been funded since its inception with over M€ 20. It has scientific backing from world renowned experts in heart valve treatment :

- **Professor Rüdiger Lange**, age 64, chief of cardiac surgery at German Heart Center in Munich, Germany.
- **Dr Nicolo Piazza**, age 40, interventional cardiologist at the Royal Victoria Hospital in Montreal, Canada.

THE DISEASE

Mitral regurgitation (MR) refers to the lack of competence of the mitral valve (one of the four heart valves) leading to blood flowing back towards the lungs with every heart beat instead of the normal forward motion supplying the organs with oxygenated blood.

It is a severe cardiac disease with progressively increasing symptoms starting with shortness of breath and reaching, if untreated, congestive heart failure and death. The gold standard treatment when symptoms have reached a severe degree is open heart surgery. This well controlled yet invasive and costly procedure leaves the **inoperable patients without treatment option**. Also the frail patient population reveals at high risk of mortality when receiving surgery.

This disease is progressively more prevalent with age (19% of the population has mild MR over 54 years of age). It is estimated that over 4 million patients currently suffer from mitral regurgitation in western countries.

THE MARKET OPPORTUNITY

The approximately 100,000 patients in Europe and USA who are at too high risk for open chest surgery, would benefit from a beating heart treatment option if it were available today. This unmet clinical need represents a **\$ 2 billion market potential** readily available. With the aging population and additional geographical markets, the market potential could exceed **\$ 7 billion worldwide** in the coming years.

THE TECHNOLOGY

The company's **strong patent portfolio** is covering very complementary aspects of beating heart mitral valve treatment. The key features of the company technology are :

- Beating heart procedure with multiple access options (trans-apical, trans-septal, trans-atrial)
- Proprietary anchoring technology
- Enhanced delivery ease with self-centering features
- Innovative valve design enabling large patient size coverage

THE CLINICAL RESULTS

The **Clinical Proof of Concept** has been reached with multiple successful implantations within clinical studies and under compassionate use in Europe. The technical success along with the good follow-up data support the safety and efficacy of the products.