FINEHEART

One line pitch:
FineHeart is a medical device company focused on creating innovative technologies in the cardiovascular space.

Market Analysis:
Heart Failure (HF) is the second leading cause of death in the US and in Europe. It is a disease with high mortality rates, and repeated hospitalizations. Critical HF with short life expectancy affects 13% of the total HF population every year. For a 212 pmy population (9%), there is no performing therapy. 220,000 people are “left alone patients” today. FineHeart has developed the ICOMS, a minimally-invasive left ventricular pump, implantable on a beating heart in a closed chest, with no percutaneous electrical connection. Taking into account an average $100k unit price, related to our estimate of the present reimbursed devices – our revenue on an annual basis would be more than $4 Billion.

Value proposition:
FineHeart management has conducted a full survey of both current and emerging devices, and competitive patent filings, and has concluded that no other companies are pursuing technology similar to that of ICOMS. ICOMS is the only device in which the engine is placed through the wall of the heart, and the blood is accelerated into the heart, as opposed to “pumped” or “aspirated”. In addition, unlike the competition, ICOMS has the potential to treat a broad range of HF patients; the versatile device can provide partial support to Class III patients and full support for Class IV patients in a less invasive manner.

Business Model:
We allow for treatment of NYHA Class IV patients (similar to conventional LVADs today) as well as NYHA Class III patients due to the very small size, the simplicity of the surgical procedure and the absence of external battery connections. Our goal is to bring to the market by 2020 our therapeutic device. As all implantable active medical devices, Market release is conditioned to clinical proves and strategies. After a first in Man anticipated by end of 2018, clinical approach will be to first obtain CE mark and release authorization and reimbursement by comparing our ICOMS to traditional and already reimbursed cardiac pumps. FDA approval to penetrate US market is planned by end of 2021.

IP and Regulatory situation:
Our ICOMS is already patented in Europe, Japan and US, protecting FineHeart against any kind of propulsing cardiac pump synchronized to heart contraction. IP plan is to protect individually each key component of the ICOMS leading to about 20 patents before 2020. Quality Management System has been set up with an ISO 13485 certification planned by the end of 2017.