



## Realheart development plan 2020

*Today, Realheart holds a stable position thanks to a number of milestones achieved last year. In 2019, Realheart focused on product development, laboratory tests and chronic animal trials. The company is pleased that great progress has been made in all three areas and ended the year with a successful animal trial where the sheep survived the first most critical 20 hours, which marks the end of the preparation phase within chronic animal trials.*

### Development Plan 2020

The three areas Realheart intends to work with during 2020 are: productization, supplier and partner collaborations for manufacturing, and FDA requirements specification.

#### productization

- Optimizing the mechanical properties of the pump
- Completing the design work to meet production requirements
- Initiating certification of the company according to ISO 13485 for medical technology companies

#### Supplier and partner collaborations for manufacturing

- Identifying suppliers and partners with experience in manufacturing high quality medical technology products
- Ensuring access to the most suitable suppliers for all critical components

#### FDA requirements specification

- Continued animal studies focusing on chronic animal trials and developing the surgery procedure
- Perform blood tests and flow studies using computerized programs and magnetic cameras
- Continuing the durability tests

"I am very proud of the work done by the team in 2019. It has prepared Realheart well for 2020 and onwards. Although it's a few years left until Realheart TAH reaches the market, our work is becoming more and more concrete. I feel that not least now when we are actively searching for production partners", says CEO and founder Azad Najjar.

#### For more information please contact:

Azad Najjar, CEO

Tel: +46(0)736-673 463

E-mail: [azad.najar@realheart.se](mailto:azad.najar@realheart.se)

*Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart TAH has a unique, patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atriums and two chambers) which provides the opportunity to generate a physiologically adapted blood flow that mimics the body's natural circulation. A unique concept in the medical technology world.*