



## Realheart's development plan 2021

*Despite the pandemic, during 2020 Realheart has achieved most of its previously communicated goals and milestones in the work of commercializing its artificial heart. In 2021, the company intends to focus on product development, animal studies and progress towards FDA requirements.*

In 2020, Realheart's development work focused on the areas of product development, supplier and collaboration agreements, as well as working towards FDA requirements. In light of the Corona pandemic, the company has succeeded in achieving most of the set goals. The new partner Berlin Heart - Europe's largest heart pump manufacturer, Realheart's newly established blood test laboratory, and new pressure sensors are three important milestones. However, chronic animal trials needed to be postponed due to the pandemic.

### Development plan 2021

The efforts towards future clinical trials continues. The three areas Realheart will focus its operations on in 2021 are: product development, animal studies, and work towards meeting FDA requirements.

#### *Product development*

Objective: Implement 2020's advances in design and create a fully functional prototype

- Carry out reliability tests
- Mount fully integrated sensors
- Fine-tune the algorithm in the automatic control
- Optimise the mechanical properties of the pump

#### *Animal studies*

Objective: Carry out chronic animal trials

- Initiate remote animal studies and evaluate the method
- Carry out the first series of chronic animal trials in which the animal is meant to survive more than 24 hours. Evaluate results and adjust the intensive care phase and the aftercare
- When reaching positive results from the first series, work towards increasing the survival time

#### *FDA requirements specification*

Objective: Blood test and animal study methods that have passed FDA's review

- Carry out chronic animal trials (as above) and blood tests
- Submit a report to FDA for review of updated blood test and animal study methods

- When passing FDA's review, use the methods to test the final version of the pump and collect data prior to approval to begin clinical trials

"My ambition with this year is for Realheart to take giant steps forward on our journey towards launching the world's first four-chamber artificial heart. Initiating chronic animal trials in sheep will be such a step, and a long-awaited one. To take the company quickly and safely to clinical trials, which is the major milestone we are heading towards, requires a strong and enforced organisation. Last year we made several new recruitments, and my plan for the near future is that we will continue to expand the team", comments Ina Laura Perkins, Realheart's new CEO.

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*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.*