

Category

Best Startup

Product/Solution Name

Acorai

Date of Approval

2019-08-20

Indications

In 2018, there were 60 million heart failure (HF) patients globally. In the US alone, the HF-related costs are expected to be \$70 billion by 2030, with the number of HF-related hospital readmissions expected to reach \$11B. Only 1% of HF patients receive optimal treatment due to difficulties in assessing the condition, resulting in high readmissions (50% within 6 months) and mortality rates. The cost to the healthcare system is immense, reaching \$16,000 per patient readmission in the US. 75% of HF readmissions are preventable with intracardiac pressure monitoring (ICPM). Only implantable ICPM products exist on the market today costing up to \$20,000 per patient, thereby limiting the reach of care.

There is a need to develop the technology to lower the costs, reduce the risk to the patient during measurement, and provide safer and more accurate monitoring.

Therapeutic Categories

Cardiology

Background information and need for solution/product

Acorai is developing a device for heart failure management through non-invasive intracardiac pressure monitoring (ICPM), to help reduce hospitalizations and readmissions. Our product, The Acorai Heart Monitor, can monitor mean pulmonary artery pressure (mPAP) non-invasively through a machine learning analysis of pressure dynamics in acoustics, vibratory and waveform data. Our technology show compelling precision, has a low-risk clinical and regulatory pathway, a low dependence on reimbursement and a fast track to commercialization.

Our main competitors are invasive and implantable intracardiac pressure monitors. Acorai's advantage is that the product is non-invasive, more cost-effective and made for broader use. The product will help to reduce readmission penalties and enable treatment optimization and informed discharge planning. With better understanding of HF patient stability, a reduced length of stay will further lower the costs for the healthcare system.

History of the development of the solution/product

The Acorai Heart Monitor has been in R&D for over two years, focusing on noise cancellation,

robustness, and versatility, allowing Acorai to validate a novel use of AI-based voice recognition technology based on previous research on applied voice recognition within cardiology. This has led to 2 granted patents by the USPTO and 1 granted patent with the WIPO. Four additional patent family applications are currently pending.

Since February 2022 the validation-phase consists of a clinical pilot study at Sahlgrenska University Hospital and Skåne University Hospital in Sweden, including 100 patients.

An interim analysis of the study indicates:

- Accuracy in line with implantable devices currently on the market
- Superiority to standard of care in identifying congested patients
- Strong correlation across over 10 important vital signs (e.g. PVR, Cardiac Output): building blocks for future software product development

At the time of this writing our on-going clinical pilot study is almost finished. With promising results and a good conversion of the data into our proprietary AI and machine learning systems, we are in a good position to further develop our product. A continuation of the pilot study is planned, with the project starting in October 2022. The continuation will take place at two of Sweden's leading hospitals, as well as 6-7 additional hospitals across Sweden.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

Our main competitor is CardioMEMS, an invasive intracardiac pressure monitor. Despite data on good efficacy from the CHAMPION study, they offer invasive methods of ICPM, with high costs (\$20,000) and a lot of hospital resources required.

The competitors for Acorai are of four different categories:

- Implantable: CardioMEMS, Endotronic, Vectorious
- In-clinic HF patient monitoring: Sensydia, Vixiar
- At-home monitoring: Biofourmis, Cardiosense, VitalConnect, Volumetrix
- Pulmonary congestion: Donisi, Sensible Medical, Zoll

Acorai's advantage over these competitors is that the product is non-invasive, more cost-effective and made for broader use. Furthermore, the product will help to reduce readmission penalties and enabling treatment optimization and informed discharge planning. Through better understanding of HF patient stability, a reduced length of stay will further lower the costs for the healthcare system and the hospitals.

Our product, The Acorai Heart monitor, is a handheld medical device using multi-modal sensor technologies and a proprietary machine learning system based on unique insights into flow and pressure dynamics. The Acorai Heart Monitor will be distributed as medical device as a service. This includes the initial price of the device, together with a subscription-based price for the monitoring service.

Our R&D has allowed Acorai to validate a novel use of AI-based voice recognition technology based on previous research on applied voice recognition within cardiology. Together with the results from our clinical pilot study (discussed below), we have shown good accuracy, precision and correlation to both marketable devices and the clinical standard.

With further R&D and clinical trials, the accuracy is expected to improve with more data, further machine learning-pipeline development and ability to segment patient groups. The benefits for the marketplace will be improved quality and efficiency of care in the heart failure patient workflow. As a way to the market, our product has low risk clinical and regulatory pathways, is protected by proprietary IP and datasets, has a strong value proposition with shorter sales cycles and low dependence on reimbursement to drive revenue. Lastly, the distribution platform is built to be versatile, creating opportunities for future product offerings.

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In October 2022, a comprehensive continuation of our on-going pilot study is planned, including over 600 patients. The project will take place at 8-9 hospitals in Sweden. By the end of the project, we will be able to continue the development of the product, get 510(k) approval based on predicate device hardware and be able to further our plans for commercialization.

There is already on-going regulatory work being done. The team has experience from both the European and US regulatory pathways. In 2022 we are aiming for an FDA Breakthrough Device Application, the end of 2022 until mid-2023 entails an FDA 510(k) application, late 2023 we believe the Acorai Heart Monitor is ready for FDA 510(k) clearance and CE-marking and the whole of 2024 will be focused on SaMD De Novo submission and De Novo grant. Our aim is to ensure the comprehensive clinical study, which is the cornerstone for future regulatory work. We also believe that the project will help us to gain an EU Class IIa approval and a US class II medical device designation.

Existing solutions are invasive and implantable intracardiac pressure monitors or non-invasive solutions that typically lack intracardiac pressure insights and focus on remote monitoring. Implanted sensor solutions require surgery, are bulky and cost up to \$20,000 per patient. Non-invasive solutions does not deliver enough data for accurate measurement.

Acorai's advantage is that the product is non-invasive, more cost-effective and made for broader use. Furthermore, our competitive edge is that the Acorai Heart Monitor has a versatile hardware solution enabling future software distribution channels, clinically proven heart failure vital sign that is non-invasive and cost-efficient and a clear product clinical workflow fit with shorter sales cycles and low dependence on reimbursement policies.

Please provide appropriate references (ie Pubmed links)

Filip Peters – CEO & Co-founder

Responsibilities: IP, machine learning & hardware development

Kasper Bourdette – Head of Growth & Co-founder

Responsibilities: Strategy, commercialization and marketing

Jakob Gelberg – Product & software development, Co-Founder

Responsibilities: Front and backend infrastructure development

Niklas Lidströmer - Chief Medical Officer
Responsibilities: Brand building

Alessandra Stella - Head of Regulatory
Responsibilities: Regulatory strategy

Henri Coste - Head of Machine Learning
Responsibilities: Machine learning development

Fatima Boumares - Head of Clinical Operations
Responsibilities: Clinical strategy and operations

Chris Stokely - Cardiology physicist
Responsibilities: Product and IP development team

Matthew Mace - Commercialization
Responsibilities: Commercialization team

Tiffany Adde - Finance Manager
Responsibilities: Accounting, Payroll and Financial planning.

Dan Vikström - Finance Assistant
Responsibilities: Accounting assistance, finance, financial research, administration of back-end data room and social media admin.

Professor Martin Cowie
Chief physician scientist at AstraZeneca and Chair of the Digital Health Committee of the European society of Cardiology. Martin's relationship with Acorai is as an advisory member to help us understand what clinical evidence to generate to convince various stakeholders and advisory bodies on the efficacy of Acorai's product.

Dr. Goran Radegran
Head of Lund Hemodynamic lab as well as a professor in Cardiology at Lund University. Dr Radegran provides insights on pulmonary hypertension.

Dr. Niklas Bergh
An associate professor in experimental cardiology at the Sahlgrenska University Hospital. Dr Bergh helps Acorai to understand the clinical workflows of heart transplants.

Dr. Oscar Braun
An associate professor of heart Failure at Skane University Hospital. Dr Braun provides Acorai with information on heart failure.

Dr. Nihar Desai
Associate professor at Yale School of Medicine, Section of Cardiovascular Medicine.

Part of Acorai's US clinical advisory board.

Dr. Shaline Rao

Associate Professor at NYU Langone Health, with specialties in Heart Failure and Cardiology. Part of Acorai's US clinical advisory board.

Dr. Alanna Morris

Associate Professor at Emory University School of Medicine, with specialties in Heart Failure Therapy. Part of Acorai's US clinical advisory board.

Patrick Schnegelsberg

Former COO at Occultech and is currently the managing director at the Venture Office. Patrick has 20+ years of life science experience in executive, operational, financial, and consulting roles. He has subsequently successfully launched products and led/played key roles in M&A, licensing, business development, and financial deals. Patrick is part of the board of directors of Acorai.

Tim Kovac

Currently part of Business Development at the SMILE incubator as well as CEO of Medzinita Innovation. Medzinita innovation provides transactional, management and diligence consulting to the life science industry. Tim's relationship with Acorai is currently as a Life science consultant.

Steven Laken

Currently the president of Cephos LLC, in which they specialise in developing scientific discoveries, breakthroughs and concepts into established business enterprises. Steven also acts as a strategic business consultant for Advice Connect Inspire and as strategic lead for the German Accelerator. Steven's relationship with Acorai is currently as a Life science consultant.

Annick Bay

Currently works as a Gold Track program director for advice Connect Inspire. At ACI she provides tailored, strategic guidance to emerging European life-science companies to create a customised roadmap to succeed in the global marketplace. Annick's relationship with Acorai is currently as a Life science consultant.

Nadeem Ishaque

Has 30+ years as chief innovation officer for GE healthcare imaging. Dr Nadeem has extensive experience in developing new products and solutions from inception to commercialisation including hardware, data analytics, assays, and systems.

Acorai has since the start in 2019 grown to six full time employees with over 12 part-time and consultant workers. We have employed and engaged people from multiple countries, sectors, sexes, and educational levels. Acorai has also been the place for academic research, including the place for two master thesis, one in Management and economics of innovation and the other in Industrial Engineering.

By being involved in the clinical trials, the CEO of Acorai, Filip Peters, have been the first recipient of the transfer of knowledge. The knowledge transfer is also being provided to the rest of the Acorai team, with a select group that will gain in-depth knowledge. Providing a broad understanding within Acorai

of the procedures of the clinical- and regulatory work during project, will increase the competences over time. Selecting a group for in-depth understanding will make Acorai less dependent on the project manager and outside expertise and cement the knowledge within the company.

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With a team with more than 50 years of industry experience, we can help heart failure patients live longer, healthier, and less uncertain lives.