EpiHeart

Cardiac Cell Therapy in Surgery

Information Memorandum
EpiHeart Oy

Content

EpiHeart

Introduction to the share issue

Company	Epiheart Oy
Industry	Medtech
Price per share	€6,20
Pre-money valuation (fully diluted)	€7 463 913 (€7 910 313)
Number of existing shares	1 203 857
Fully diluted shares	1 275 857
Managing Director	Kai Kronström
Business ID number	3107385-1
Founding year	2019
Head office	Helsinki, Finland
Website	www.epiheart.com
LinkedIn	www.linkedin.com/company/epiheart

EpiHeart funding round is open. Please find relevant information in this information memorandum. To join the round, please contact CEO Kai Kronström to discuss on details.

Kai Kronström
CEO, Co-founder

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Watch introductory video of EpiHeart from:
https://youtu.be/6Ltd8sU42lg

Subtitles available in

Company overview

EpiHeart Oy is a Finnish medtech company that enables **Cardiac Micrograft Therapy™** treatment with proprietary medical devices. The treatment aims to stimulate cardiac tissue recovery and improve heart function in individuals with heart disease.

No additional intervention is needed for the novel treatment, as it can be administered within regular cardiac surgical operations in the operating room with **EpiHeart's devices**.

EpiHeart's long term vision is to develop innovative medical devices that empower healthcare providers to deliver **personalized and optimized therapies** for patients with cardiovascular diseases.

6 devices CE marked

First-in-human studies completed (CABG, LVAD)

Study results published

Efficacy study ongoing (25+25 patients)

Advanced research in gene therapy

Adding value to existing cardiac operations

2 patents in PCT stage

European KOLs supporting

Market size 2,5B€

Product orders received

EpiHeart

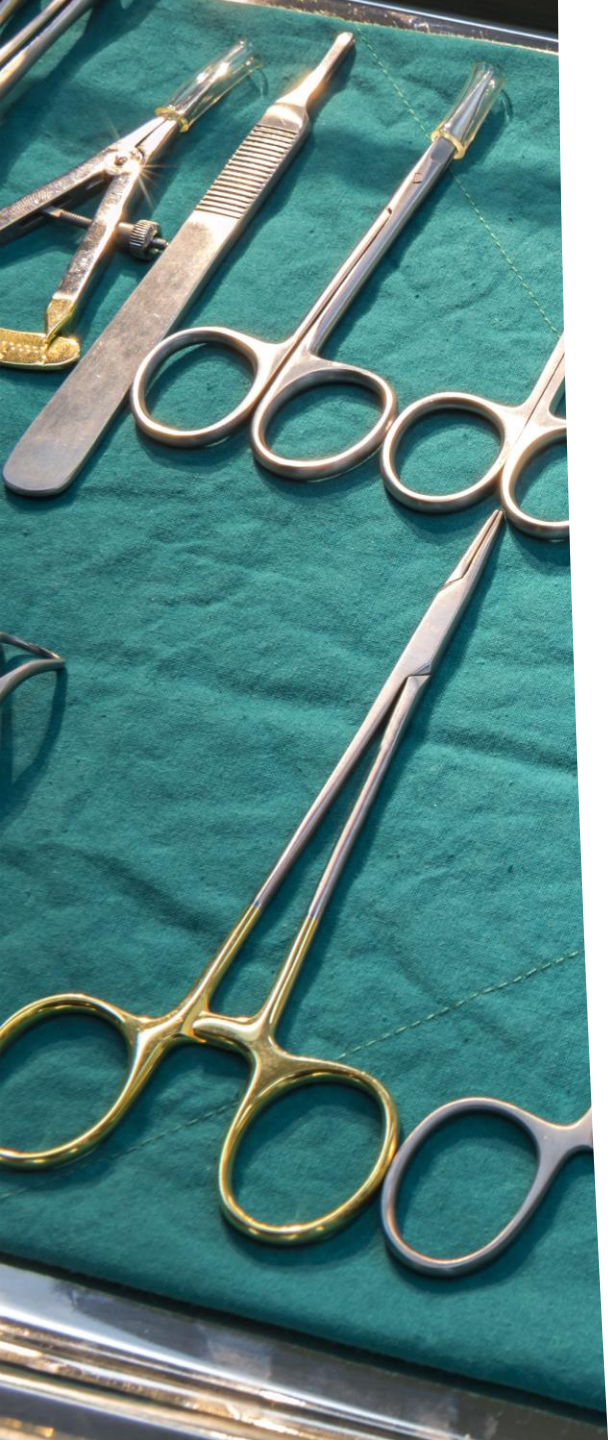
CEO’s statement

Cardiac Micrograft Therapy™ has potential to improve the structure and function of the failing heart; a major opportunity both economically, and for those who suffer from ischemic heart disease or heart failure.

EpiHeart enables efficient administration of this autologous cardiac cell therapy in the operating room. EpiHeart is well positioned to become a leader in this market, and we are now raising funds to continue our efficient execution and changing the practice of heart failure treatment.

Join us to enable cardiac cell therapy in surgery.

Kai Kronström, CEO



Key investment highlights

Large and globally unmet medical need

Over **200,000 patients** are diagnosed with heart disease annually in the EU. Cardiac Micrograft Therapy™ aims to regenerate and repair damaged heart tissue, hence improving its function. EpiHeart provides the devices and procedure for efficient and easy administration of this novel treatment.

Strategic partnerships

EpiHeart is part of a **consortium of research-oriented organizations** within the EU, dedicated to accumulating clinical evidence regarding the effectiveness of cardiac cell therapy. These consortium partners are actively engaged in the clinical market therefore offering a pathway for a swift adoption of cardiac cell therapy in clinics.

CE marked devices

EpiHeart's solution consists of **proprietary CE marked devices**, which make administering Cardiac Micrograft Therapy™ in the operating room easy and cost-efficient.

Treatment in clinical phase

The treatment has been studied academically for over a decade, and now the treatment is already at clinical study phase. **EpiHeart's devices are used** in ongoing efficacy study.

High margin business

The company's scalable business model is based on proprietary, high gross margin medical devices. Procedure kits sold for every patient create **recurring revenue** and a good basis for profitability.

Myocardial scarring and heart failure (HF)

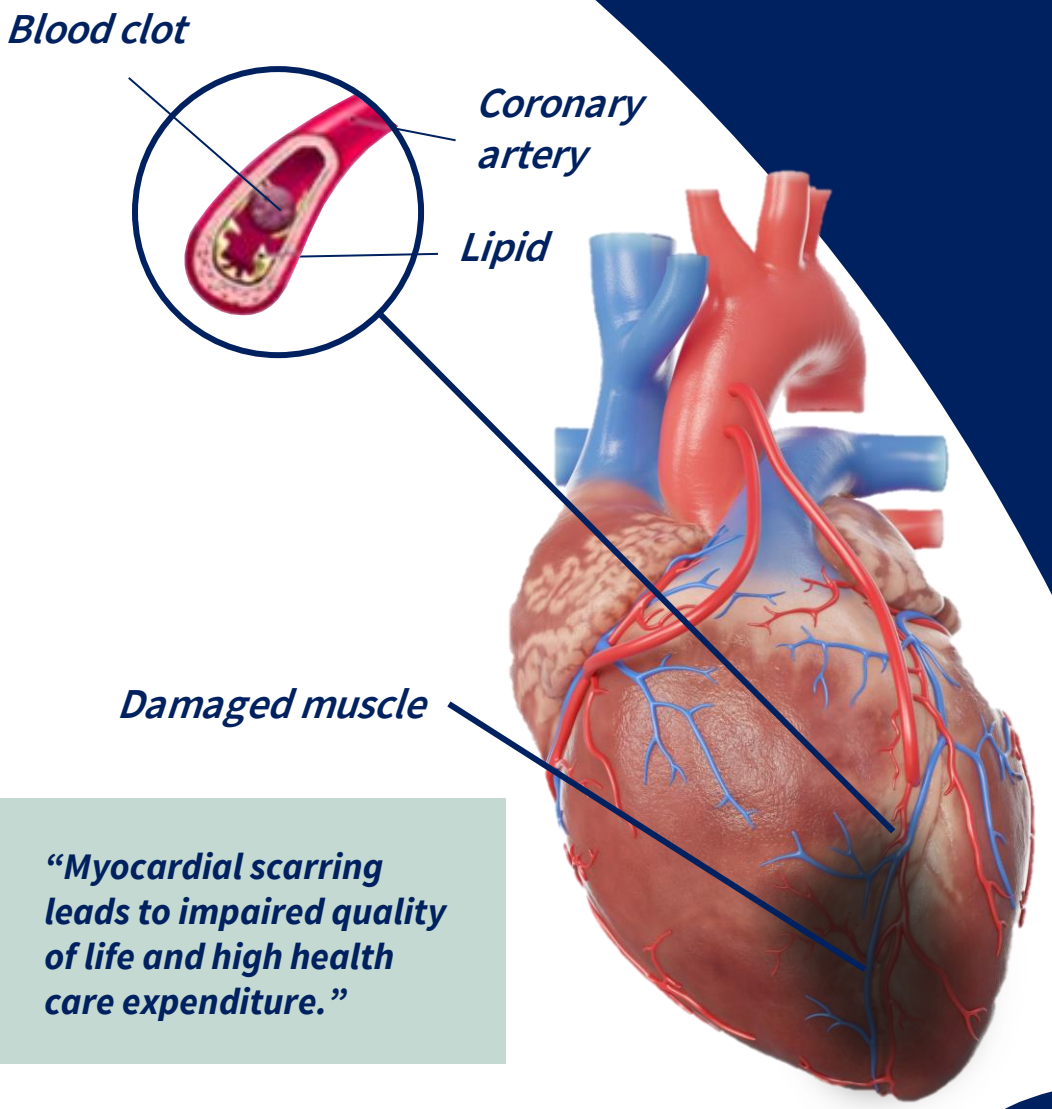
Myocardial scarring, a consequence of heart muscle damage, poses a significant burden on individuals by affecting their quality of life and imposes substantial economic costs on healthcare systems worldwide. When the heart muscle is injured, such as through a **heart attack** or prolonged ischemia, it can lead to the formation of scar tissue in the affected area. This scarring disrupts the normal functioning of the heart, impairs its ability to pump blood effectively, and can ultimately result in heart failure.[1,2]

Burden on individuals

For individuals, myocardial scarring can cause a range of debilitating symptoms, including shortness of breath, fatigue, and exercise intolerance. These symptoms significantly impact daily activities, reducing overall quality of life and restricting participation in work, social, and recreational activities. Individuals with myocardial scarring are also at **increased risk** of developing complications such as arrhythmias and further cardiovascular events, leading to a higher mortality rate.[1]

Burden on society

From a healthcare system perspective, myocardial scarring and subsequent heart failure requires long-term management, including **frequent hospitalizations**, medication regimens, and potentially invasive interventions such as cardiac surgeries or implantation of medical devices.[3] The economic costs associated with hospital admissions, diagnostic tests, medications, and interventions contribute to the overall burden on healthcare systems. Moreover, the increasing prevalence of cardiovascular diseases and the ageing population further exacerbate the burden, highlighting the urgent need for effective interventions and therapies to address myocardial scarring and its consequences.[4]



"Myocardial scarring leads to impaired quality of life and high health care expenditure."

Current approaches to managing HF

Due to advanced treatments and strategies, like heart support devices, medications, and quick restoration of blood flow to the heart, more people are surviving heart attacks, also known as acute myocardial infarction. However, the repair of the damaged cardiac tissue or the scarring of the heart muscle **is not addressed** by these interventions.

The current approach to managing myocardial scarring and heart failure involves a combination of pharmacological therapies, lifestyle modifications, and advanced medical interventions. Pharmacological therapies play a crucial role in reducing symptoms, improving heart function, and retarding disease progression. Medications such as angiotensin-converting enzyme inhibitors (ACE inhibitors), beta-blockers, and diuretics are commonly prescribed to manage heart failure symptoms and improve cardiac function.[5] Furthermore, in cases where the disease progresses to advanced stages, heart transplantation or ventricular assist devices (VADs) may be considered as a last resort treatment.[6] However, these **treatments are very costly** and for example donor hearts for transplantation are poorly available.

"Repair of the damaged cardiac tissue is not addressed by current interventions"

Added value for cardiac surgery

Advances in cardiac cell therapy and regenerative medicine hold promise for repairing and regenerating damaged heart tissue, potentially reducing or reversing myocardial scarring.[7] **Cardiac Micrograft Therapy™** uses autologous cardiac cells from the patient's right or left atrial appendage and only minimal processing. This approach has several unique benefits:

Done during surgery

Treatment can be administered concurrent with established surgical procedures such as coronary artery bypass grafting (CABG) or left ventricular assist device (LVAD) implantation **during the same surgery**. Possibility to adapt the treatment into less invasive cardiac operations.

Adding value

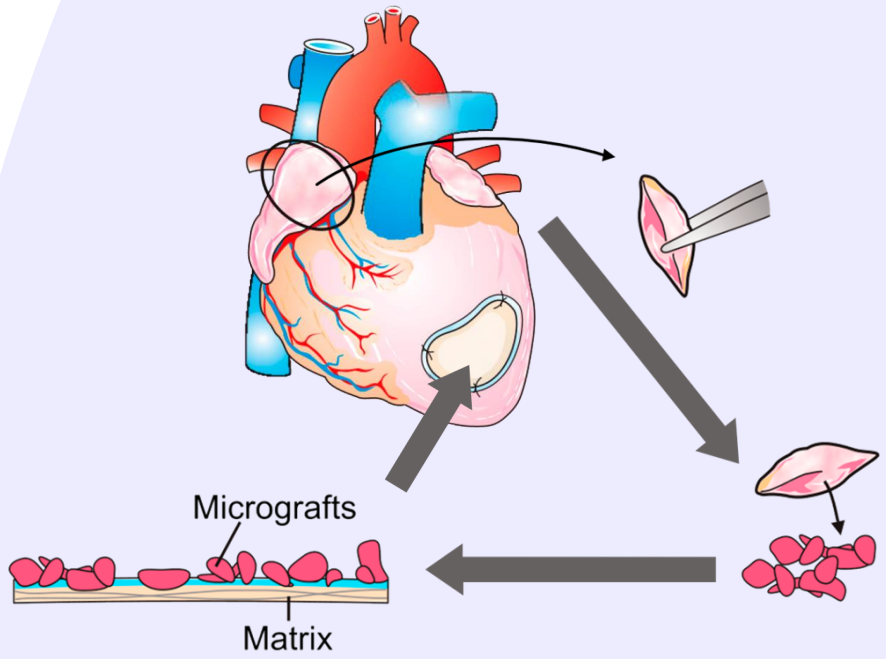
Cardiac Micrograft Therapy™ adds value to established surgical treatments and has a minimal impact on the duration or risk of the surgery. The clinical safety and feasibility studies done so far show **positive therapeutic effect** on the myocardium.

Treating damage

The tissue composition of the autologous atrial appendage, along with its secretion of soluble paracrine factors[9,10], contributes to heart healing. Cardiac Micrograft Therapy™ has been developed to enhance existing surgical treatments by utilizing **patient's own cardiac tissue** as a therapeutic graft for treating myocardial damage.

Regulatory simplicity

Using patient's own cardiac tissue and epicardial implantation of mechanically processed micrografts can enhance cardiac recovery and performance.[8] This approach also ensures **safety and simplicity** from a regulatory standpoint, as the treatment is not considered to be an ATMP treatment according to EU legislation.



"Cardiac Micrograft Therapy™ provides an integrated, value adding approach to treatment of heart failure patients."

EpiHeart

Cardiac Micrograft Therapy™

Watch case video of CMT treatment with EpiHeart devices in operating room:
https://www.youtube.com/watch?v=eG0hTB_WAZE

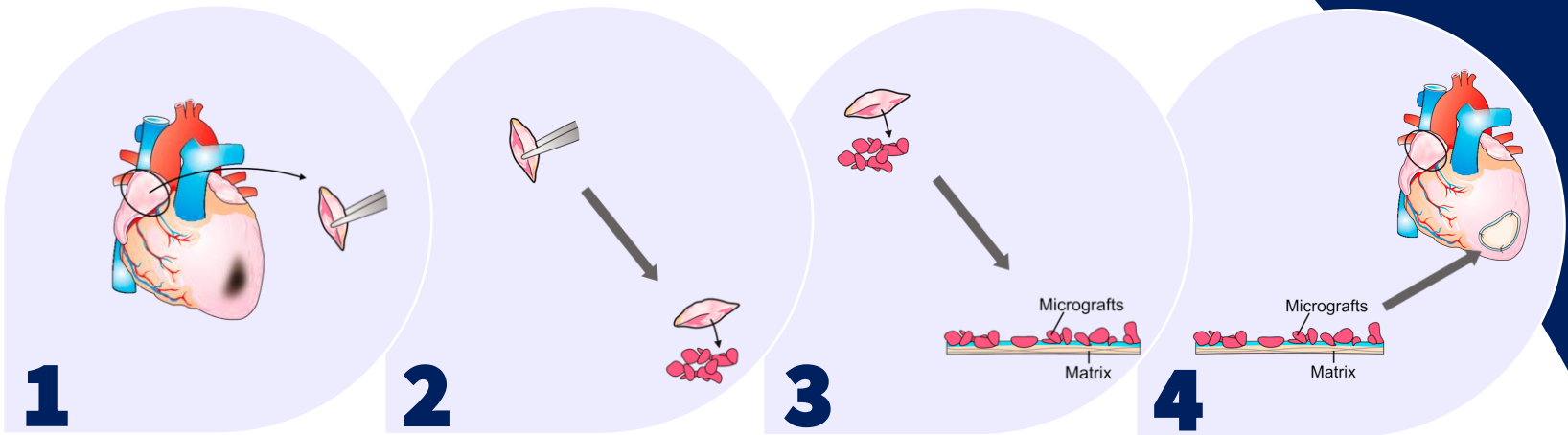
Integrated with surgery

Cardiac Micrograft Therapy™ is an innovative procedure that involves the transplantation of specialized cell clusters, known as micrografts, onto the damaged areas of the heart, aiming to stimulate tissue regeneration and improve heart function in individuals with heart disease. EpiHeart's solution enables the treatment to be carried out **inside operating room** easily while maintaining sterile workflow. Cell-transplant is created and applied inside the operating room while the open-heart surgery is ongoing, adding mere minutes to the duration of the surgery.

Optimal approach

After over 10 years of preclinical research and testing various cell types for cardiac treatments, the researchers at the University of Helsinki developed Cardiac Micrograft Therapy™ as an optimal approach to **cardiac regeneration**. With the treatment's safety and effectiveness established, EpiHeart is now leading the way in conducting efficacy studies and establishing it as the standard of care for cardiac treatment.

Cardiac Micrograft Therapy™ with EpiHeart technology



HARVESTING
Healthy heart tissue is harvested from patients' own atrial appendage

PROCESSING
The harvested tissue is processed into small micrografts.

ASSEMBLY
A cell-transplant is assembled from micrografts, cell-free connective tissue matrix and fibrin sealant.

APPLICATION
Transplant is applied epicardially on top of the damaged myocardium.

EpiHeart

Clinical evidence

First-in-human study

Clinical evidence forms the cornerstone of evidence-based medicine, ensuring that healthcare practices are grounded in **scientific evidence** and aimed at providing the best possible care to patients. Following extensive pre-clinical research at the Helsinki University, Cardiac Micrograft Therapy™ was performed in a first-in-human study at the Helsinki University Hospital.[11,12] This non-randomized study proved the safety and feasibility of the treatment and provided preliminary efficacy data. It also highlighted that dedicated equipment for carrying out the treament in the operating room was needed, which was the catalyst for founding EpiHeart.

AAMS2 study ongoing

Based on the success of the first pilot study, the clinical efficacy studies of Cardiac Micrograft Therapy™ are moving forward. Ethical and other permissions for the study named AAMS2 **have been granted** at Helsinki University Hospital (HUS). University of Oulu has joined the study, and patient recruitment starts from the beginning of 2024. Information can be found from clinicaltrials.gov (NCT05632432). The hospital has already ordered the first batch of devices from EpiHeart to carry out the study. The study is expected to be completed in December 2025.

"Epicardial transplantation of AAMs [autologous atrial micrografts] was safe and feasible to be performed during CABG surgery. CMRI [cardiac magnetic resonance imaging] demonstrated an increase in viable cardiac tissue at the infarct site in patients receiving AAMs treatment. Transplantation of AAMs shows good clinical applicability as performed during cardiac surgery, shows initial therapeutic effect on the myocardium and has the potential to serve as a delivery platform for cardiac gene therapies."

Nummi et al. 2021.

' Epicardial Transplantation of Autologous Cardiac Micrografts During Coronary Artery Bypass Surgery ', Frontiers in cardiovascular medicine, vol. 8, 726889

Clinical evidence

Multicenter approach

EpiHeart is engaging with 7 European surgical units (in Italy, Germany, Poland, Finland, and the Netherlands) to start further clinical efficacy trials. The multicenter approach will provide diverse patient populations with varying genetic backgrounds. This strengthens the validity and generalizability of the findings and enhances confidence in the **efficacy of the treatment**. A multicenter approach also allows for collaboration among experts in the field and encourages widespread adoption.

EpiHeart is leading this consortium of world class collaborators in applying for a multimillion EU Horizon grant to support the clinical efficacy studies. The application **passed the stage-1 evaluation**, and the full stage-2 proposal is due in April 2024.

EpiHeart devices

EpiHeart's devices have undergone clinical evaluation in compliance with European medical device regulations, demonstrating their **safety and excellent performance**. The devices have already been utilized in the world's first clinical use of the left atrial appendage (LAA) for epicardial micrograft transplantation during a left ventricular assist device (LVAD) implantation patient treatment of Cardiac Micrograft Therapy™ in Hannover, Germany.[13] Case video of this treatment can be seen through link https://www.youtube.com/watch?v=eG0hTB_WAZE

"Based on this successful case experience, a larger clinical study is being prepared. We are looking forward to a promising and continued collaboration between our team at MHH and EpiHeart."

Prof. Dr. Jan Schmitto

Director of the Mechanical Circulatory Support and Cardiac Transplantation Program at Hannover Medical School

EpiHeart products

EpiHeart solution

EpiHeart develops devices designed specifically for administration of cardiac cell therapy during surgery with minimal effect on the duration of the surgery.

EpiHeart's Cardiac Micrograft Therapy™ solution comprises CE marked **Operation Room Equipment**, CE marked single-use **Procedure Kits**, a treatment **protocol** and **training**; thus enabling clinicians to perform this potentially life-saving treatment. The company is utilizing valuable insights and best practices gathered from clinical studies and product development in the operating room to create the best solution for cardiac cell therapy.

Operation Room Equipment

EpiHeart Operation Room Equipment consists of EpiHeart Cooling Plate CP-42 and EpiHeart Operation Room Centrifuge ORC-40 products. These products are a one-off purchase for cardiac clinics, and, in the beginning, they can be rented to create a low threshold for adoption.

Operation Room Equipment

- One-off purchase for cardiac clinics
- The Cooling Plate provides an optimal temperature for cell survival, while supporting sterile workflow
- The Operation Room Centrifuge is easy to use in operating room environment
- Compatible with EpiHeart single-use products, supporting sterile tissue handling

EpiHeart ORC-40

EpiHeart CMT Core Kits

EpiHeart CP-42

EpiHeart products

Procedure Kit

EpiHeart **CMT Core Kit** (Core Kit) is a single-use procedure kit, which enables easy administration of Cardiac Micrograft Therapy™ in a sterile manner in the operating room.

IP and production

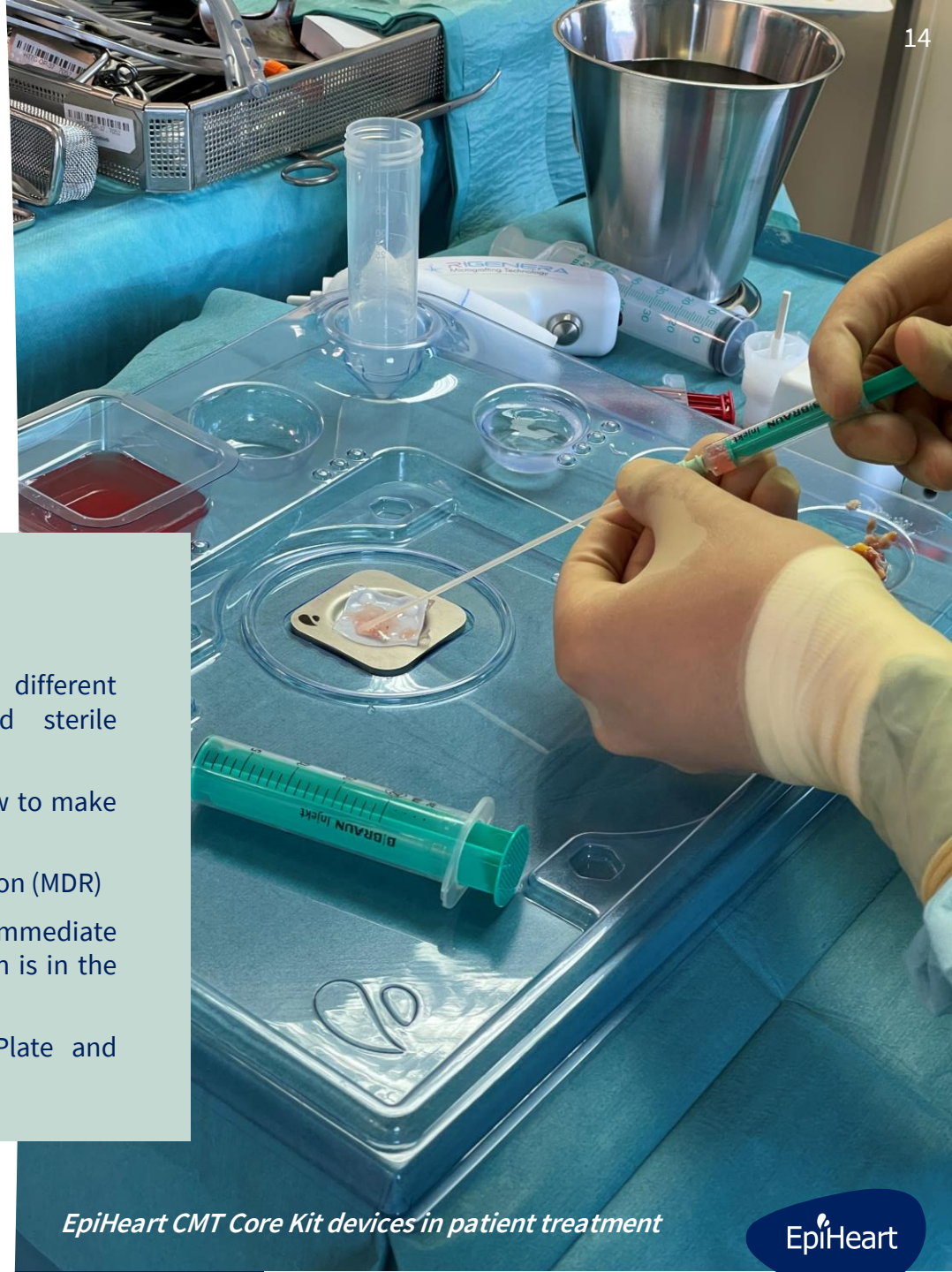
The interoperability and the sterile working field created by EpiHeart Cooling Plate and CMT Core Kit has a pending patent that is positively assessed by European Patent Office. Another patent application addresses a novel tissue processing device under development. This device will further improve the cell therapy workflow in operating room.

Europaisches Patentamt
European Patent Office
Office européen des brevets

All critical manufacturing and assembly operations of EpiHeart devices are done by the company at its own production facilities.

CMT Core Kit

- Single-use procedure kit containing 4 different medical devices for easy, quick and sterile preparation of the micrograft transplant
- Designed according to the nurse's workflow to make the learning of the operation easy
- Conforms to the EU Medical Device Regulation (MDR)
- Delivered in a sterilization wrapping for immediate sterilization at site (sterile-delivered version is in the product development roadmap)
- Compatible with the EpiHeart Cooling Plate and Operation Room Centrifuge



EpiHeart CMT Core Kit devices in patient treatment

Business model

Revenue from every surgery

The company's scalable business model is based on proprietary, high gross margin medical devices. Procedure kits used for every patient create stable recurring revenue and a good basis for profitable long-term growth. The company targets cardiac surgery units, starting in Europe and expanding globally, within a **well-defined customer segment** in which best practices tend to spread fast.

Creation of efficacy evidence

The cardiac surgery field is potent for innovation and added value. However, the field can be considered conservative, and value of new treatments need to be established scientifically. This means that EpiHeart needs to focus on clinical research and studies to establish the proof of benefits and achieve clinical acceptance. Research is also necessary to obtain specific reimbursement codes in different countries (e.g. German NUB). Over the next few years, the company's primary focus will be on these clinical studies, which are crucial for **driving future business growth**. EpiHeart is well-positioned for these studies and opportunities for potential grants. Initial revenue will also come from the studies, and the company has already received such an order for the efficacy study.

Defensible solution to dominate the market

EpiHeart positions itself as a solution provider for Cardiac Micrograft Therapy™. The company ensures the functionality, safety, performance, and interoperability of the devices. By establishing a standard best practice and patenting device interoperability, EpiHeart aims to achieve a sustainable and defensible **competitive advantage** in the market.

Scalable operations

EpiHeart has established its supplier network, has own facilities and processes for **in-house assembly and quality assurance**. While customers are currently approached directly, once demand grows, dedicated distributors will be utilized to support scaling.

"The company's scalable business model is based on proprietary, high gross margin medical devices."

Further business opportunities

New market segments with less invasive operations

Although open-heart surgeries are very common globally, less invasive approaches have been developed for e.g. ablations, revascularization and valve operations. Same development from initial open-heart surgery to less invasive treatment approach is expected to take place in field of **cardiac cell therapies**. EpiHeart is well positioned to lead this development and has already build understanding on suitable approaches. This development grows the potential market massively.

Tools beyond cardiac cell therapy

The devices developed by EpiHeart may potentially be used in non-cardiac cell therapy medical applications. The decision will be made per each opportunity, but there has already been early verification of **synergic 3rd party demand** for certain EpiHeart technology through a pilot order.

Outside Europe

Regarding expansion beyond Europe, the US market is seen as a significant opportunity. The timing and approach for entering the **US market** will be carefully considered, as it requires substantial resources and focused efforts.

Opportunities through advanced research

EpiHeart and the University of Edinburgh's Centre for Cardiovascular Science, a world leader in cardiovascular gene therapy research, have entered into a collaboration to develop advanced therapies for the treatment of heart failure. The multi-year collaboration is supported by Medical Research Scotland. Advanced gene therapies offer the ultimate potential to repair damaged hearts by **targeting cell signalling and protein production**. Combined with EpiHeart's epicardial approach, the treatment enables unique features, such as precise dosing, local administration and reduced systemic exposure.

"I believe this collaboration with EpiHeart not only supports basic science, but also has the potential to reduce the burden of transitioning from laboratory into clinical research."

Prof. Andrew Baker

Head of the Centre for Cardiovascular Science at the University of Edinburgh

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EpiHeart

Market

Emerging large market

The cardiac cell therapy market is an emerging field with vast potential. Globally numerous clinical studies utilizing different types of cells to treat damaged heart muscles are underway. Clinical application of cardiac cell therapy is expected to increase the quality and duration of lives of human beings suffering from heart failure.[14] Currently, most cardiac cell therapies in clinical studies use stem cells that are grown and manipulated externally, and this comes with a high price tag. Cardiac Micrograft Therapy™ undercuts costs thanks to its application being completely intraoperative. Product pricing can be tailored based on market characteristics, nevertheless maintaining **healthy margins**.

Cardiac Micrograft Therapy™ is not a stand-alone treatment. It is conducted during existing open-heart surgeries like coronary artery bypass grafting (CABG) and left ventricular assistive device (LVAD) implantation, with minimal impact on the surgery duration. There are currently about **200,000 such surgeries** annually in Europe alone with numbers expected to rise as the rate of heart diseases increase.[15,16]

Pricing

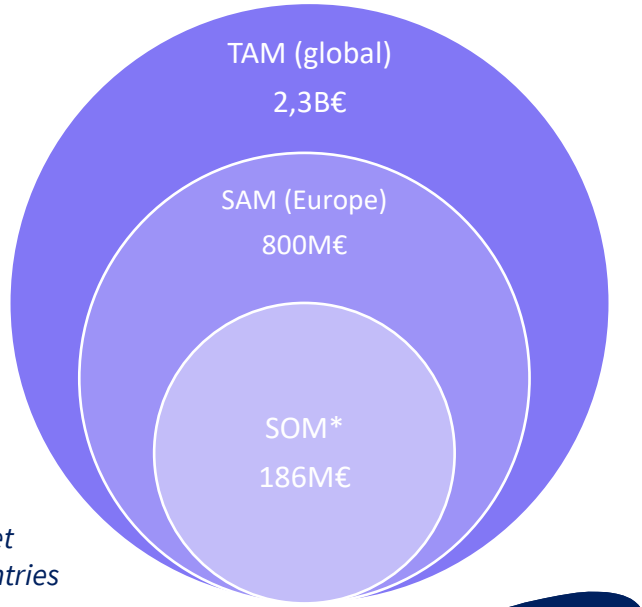
EpiHeart provides the medical devices to enable Cardiac Micrograft Therapy™. The commercial pricing of EpiHeart's CMT Core Kit is projected at **4000€ per patient**. This is based on market feedback from different European countries and current reimbursement practices of related treatments.

Market size

The market size for cardiac cell therapy is difficult to estimate precisely as there is no established market yet. However, the global market for regenerative medicine, which includes cardiac cell therapy, is projected to reach **several billion dollars** by 2025. The market is driven by factors such as the increasing prevalence of cardiovascular diseases, advancements in stem cell research, and the growing demand for innovative treatments for heart conditions.

The market size of cardiac cell therapy can be determined by the number of relevant surgeries annually. On a global scale, **over 500,000 such surgeries** are done making the Total Achievable Market (TAM) about 2,3B€. Within Europe, about 200,000 such surgical operations equates to 800M€ from the serviceable Achievable Market (SAM). EpiHeart's estimated market share of the Serviceable Obtainable Market (SOM) is estimated at 186M€ assuming the company can reach 60% of the market within the first 5 years of commercialization. These numbers are based on the commercial pricing of EpiHeart's CMT Core Kit at 4000€ per patient treated.

"Cardiac Micrograft Therapy™ undercuts costs thanks to its application being completely intraoperative."



**Estimated market share in 5 EU countries*

Competition

Heart failure can be treated with various approaches including pharmacological, mechanical support, heart transplantation and cell therapies. The cell therapy approach is promising as it has potential to **treat root causes** of the conditions. Cardiac Micrograft Therapy™ provides a unique cost-effective approach that utilizes the patient's own tissues to create micrografts that are then administered concurrent to an open-heart surgical operation. EpiHeart has the ability to develop proprietary solutions and is the only company that provides procedure kits and medical devices optimized for this treatment. The table below illustrates EpiHeart's competitive landscape.

Treatment options for heart failure

Medication
- Treating only symptoms
- New drug discovery ongoing

Cardiac cell therapy
- Treating the root cause
- Administered on its own or during other surgery

Heart transplantation
- Last-resort treatment for end-stage heart failure
- Poor availability of transplants

Mechanical support
- Pump installation to support heart in severe cases
- Limited and costly therapy

FEATURES	EPIHEART	METCELA	CELL PROTHERA	BIOCARDIA	CARDIOCELL	MESOBLAST	PROCELLA THERAPEUTICS
Cardiac cell therapy	✓	✓	✓	✓	✓	✓	✓
Autologous cells	✓	✓	✓	✓	✗	✗	✗
Cells of cardiac origin	✓	✓	✗	✗	✗	✗	✓
Multiple cell types	✓	✗	✗	✗	✗	✗	✗
Cell types	atrial tissue micrografts (cardiomyocytes, iendothelial cells and fibroblasts).	specific cardiac fibroblast cells	CD34+ stem cells	bone marrow cells	itMSC* stem cells	mesenchymal lineage cells	cardiac stem cells
On-site processing	✓	✗	✗	✗	✗	✗	✗
Mode of administration	epicardial patch	catheter based-cells	intramyocardial injection	catheter based procedure	intravenous injection	injection into the heart muscle	-
CE-mark	✓	✗	✗	✗	✗	✗	✗
Medical device	✓	✗ ATMP	✗ ATMP	✗ ATMP	✗ ATMP	✗ ATMP	✗ ATMP

*ischemia-tolerant mesenchymal stem cells

Key performance indicators

The following key performance indicators are used to monitor the progress of the company. These indicators will direct the company towards accelerated market adoption that is expected to happen with the accumulation of clinical efficacy data of the Cardiac Micrograft Therapy™ .

- Number of clinical efficacy studies in preparation
- Number of clinical efficacy studies recruiting
- Number of patients treated
- Maturity of the solution, including production costs, potential for profitability
- Quality and quantity of the study results, including the number of publications
- Quality and quantity of partnerships

Team

Kai Kronström
CEO, Co-founder
Board Member

With a Master's degree in industrial engineering and management, Kai has launched **multiple medical device start-ups** and has CEO experience in effectively steering these businesses to success. His drive stems from a combination of curiosity, constantly seeking to create something new, and a sense of responsibility. He has over 15 years of experience in the medical device industry both in managerial positions and as a CEO.

Esko Kankuri
Head of science,
Co-founder
Chairman of the Board

As an Adjunct Professor (MD, PhD) at the pharmacological department of Helsinki University, Esko is an experienced researcher of various regenerative treatments, including cellular therapies. He has supervised numerous Ph.D dissertations in biomedicine and drug research and **has over 120 publications**. Esko is the group leader of Cardiovascular and Regenerative Pharmacology at the Faculty of Medicine, Department of Pharmacology. Helsinki University. His scientific research has led to the development of Cardiac Micrograft Therapy™ aimed at repairing the damaged parts of the heart after heart failure.

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UNIVERSITY OF HELSINKI

Aleksi Kuuva
Chief Engineer, Partner

With a Master's degree In Mechatronics, robotics and automation engineering, Aleksi is a multi-talented engineer who has experience in **product development projects**. His work on the optimization and development of operating room workflow and device kits for a novel cardiac treatment is the foundation on which EpiHeart's medical devices are based and is the foundation on which the Cardiac Micrograft Therapy™ protocol is designed.

Linda Dinda
Clinical Specialist

With a Master's degree in Health Technology, specializing in documentation, and with over five years of experience of working as a registered nurse and nursing instructor, Linda is able to fluently discuss medicine and business. She has been building the **international network of cardiac professionals** and creating the protocols for the starting clinical efficacy studies.

Jouko Vallikari
Director, Partnering
Board Member

M.Sc. in mechanical engineering with about 40 years of experience in developing international high-tech, b-to-b businesses, products and processes in fields ranging from the aeronautical industry through medical technology to laser welding. Among his achievements, Jouko has successfully developed **distribution channels globally** for several medtech companies, and performed strategy reviews and other corporate development projects.

Annu Nummi
Cardiac Surgeon, Co-founder

As an MD, PhD, and cardiac surgeon, Annu has been a key member of the research team involved in ground-breaking pre-clinical and **first-in-human studies** conducted at Helsinki University Hospital and the University of Helsinki.

HUS

''It is truly inspiring to be at the forefront of developing and implementing groundbreaking solutions that have the potential to reshape the future of cardiac care."

Linda Dinda, Clinical Specialist

EpiHeart

Professional network

Antti Siltanen
Business advisor, Board Member

Antti holds a Ph.D. in biomedicine and expertise in cardiac tissue engineering and cell transplantation. Antti also has a background in molecular sciences and is currently working as a life science equity analyst, bringing valuable **business knowledge** to the team.

Jani Virtanen
Regulatory and quality advisor, Partner

Jani is a D.Sc. in Engineering with expertise in medical device regulation and in the development of new cardiac devices, sharing **regulatory and technical know-how** for the company

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Clinical network

Prof. Dr. Jan Schmitto
Director MCS and Cardiac Transplantation Program
Hannover Medical University Hospital
Germany

Prof. Dr. Jolanda Kluin
Head of Cardio-Thoracic Surgery
Erasmus University Medical Center
The Netherlands

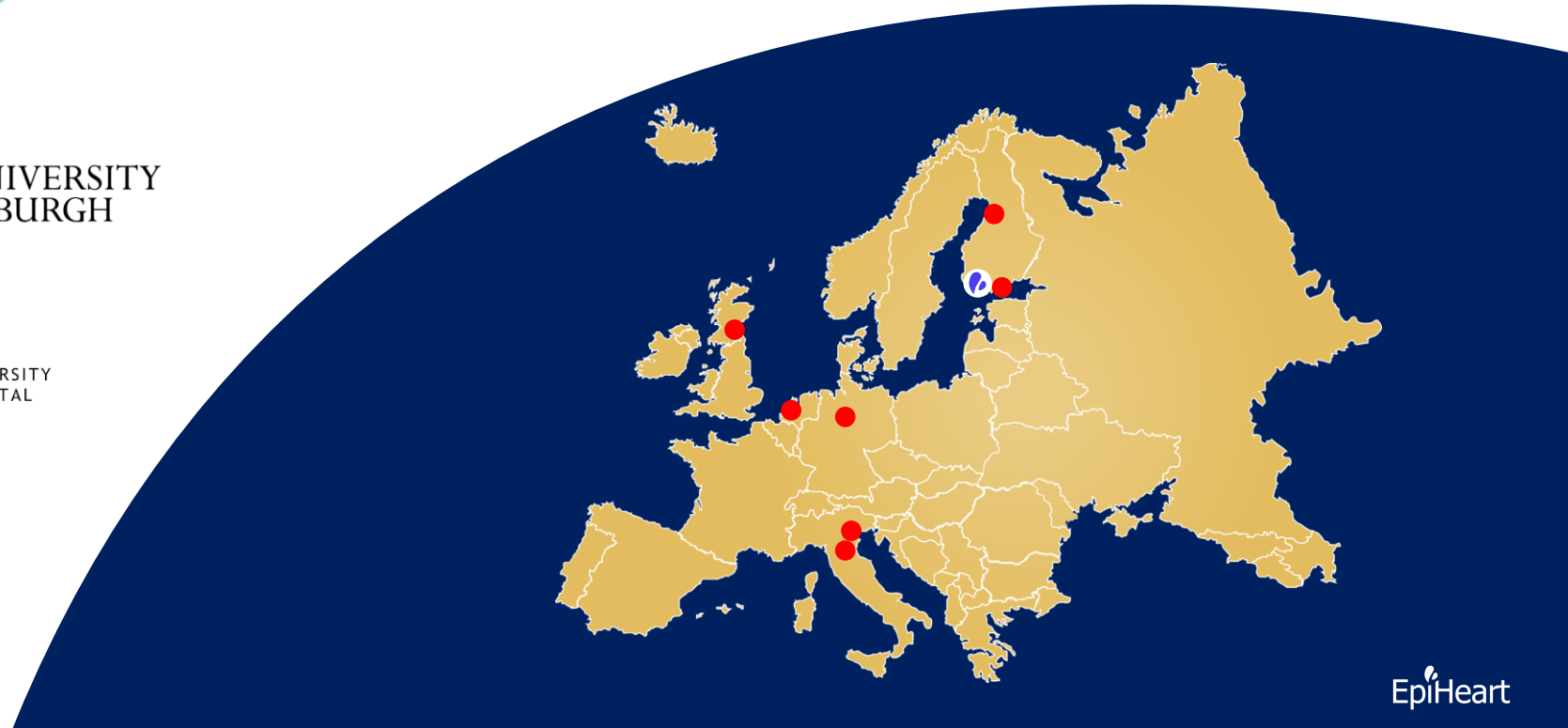
Prof. Andrew Baker
Head of Centre for Cardiovascular Science
University of Edinburgh
United Kingdom

Dr. Kari Kervinen
Cardiologist
Oulu University Hospital
Finland

Dr. Annu Nummi
Cardiac surgeon
Helsinki University Hospital
Finland

Prof. Dr. Gino Gerosa
Director of Cardiac Surgery
Padova University Hospital
Italy

Prof. Dr. Davide Pacini
Chief of Cardiac Surgery
University of Bologna – S. Orsola Hospital
Italy



EpiHeart

Key achievements

EpiHeart has built the current foundation in a cost-efficient manner. The funding has included sweat, grants, <1M€ equity investments and loans <0,5M€. With these funds, the company has managed to reach the following milestones.

- **Six (6) CE marked devices in use in Cardiac Micrograft Therapy™.**
- **First patient treated with EpiHeart's devices in Hannover, Germany.**
- **Case article of the Hannover treatment published in *Frontiers in Cardiovascular Medicine*[13]**
- **EpiHeart's products to be used in the starting clinical efficacy studies (AAMS2)**
- **EpiHeart has two separate patent families pending in PCT stage.***
- **Established connections with key opinion leaders within Europe. This supports go-to-market activities as well as clinical evidence acquisition.**
- **New product development underway with excellent preliminary test results**
- **Two product orders received, to be delivered in 1Q2024**

*Patent numbers: WO2022223523, WO2022090848. Patent applications indicated by the European Patent Office to contain novelty and inventive step and thus patents are estimated to be granted.

Interdisciplinary Heart-Team at MHH, Hannover, after successful LVAD + Cardiac Micrograft Therapy™ surgery

Use of funds

The funds collected in this financing round will be used for strengthening the foundation for the company's growth. The main focus will be in the **clinical studies and evidence gathering** to create demand for the company's products. EpiHeart's product offering will be further enhanced through product development. To advance clinical evidence gathering, strategic research and other collaboration, partnerships will be developed.

The planned use of funds is divided as follows:

- Clinical studies 35 %
- Product development 25 %
- Growing organization to support partnerships, sales and customer training 20%
- Collaboration with hospitals and research institutes 20%

The efficacy study ongoing in Helsinki and Oulu is producing clinical evidence independently of the company. This means that some **important milestones will be achieved** without major investments. Further clinical studies can be orchestrated with reasonable investments.

Key milestones achievable in 18 months

- Drive clinical efficacy studies on an optimal scale: 50 patients recruited, studies ongoing and initial evidence obtained
- Enhance product offering, including needed efforts to get higher regulatory class devices through the European regulation
- Strengthen the collaboration with cardiac professionals
- Apply for non-dilutive funding
- Create a plan for US market entry

Industry leader

EpiHeart has the position to be the **leader in the emerging cardiac cell therapy market**. With sufficient funding, the clinical efficacy studies can be conducted in a rapid phase enabling fast market adoption. However, the company can operate with different cost levels, meaning that the investments in above-mentioned targets can be tuned according the available funds and still achieve meaningful milestones. In any scenario, the company is eligible for significant non-dilutive funding opportunities and there's possibility to obtain early revenue through study collaboration.

Financial figures

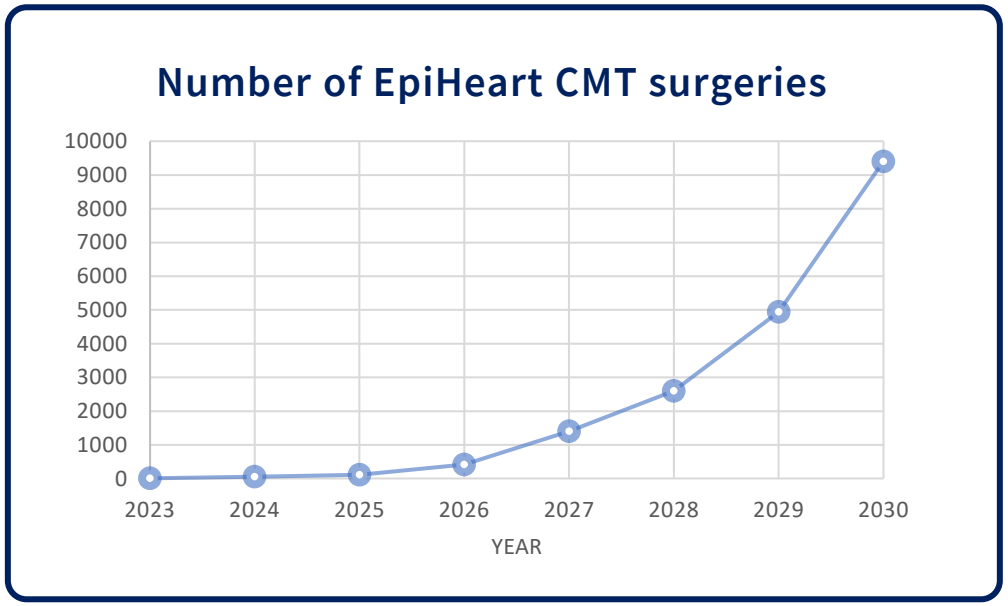
EpiHeart is essentially a pre-revenue company, although minor revenue is received e.g. from clinical study devices. During the next 3 years, early sales will generate modest revenue for the company. The revenue is expected to grow as the clinical evidence of the treatment efficacy accumulates. There is also **significant potential** to fund clinical studies through non-dilutive funding e.g. EU grants*.

The figures on the table reflect the expected development of the company, especially:

- Rapid growth is starting from 2026 onwards
- Company can be developed with relatively low level of capital investments as clinical studies can be funded partly through **non-dilutive funding**.
- Due to high margins sales contribute to the profitability from the beginning.

These figures are a scenario only and actual future figures may vary due to external conditions and decisions made by the company.

(In €)	2023	2024	2025	2026	2027	2028
Revenue	**5 200**	**32 400**	**64 800**	**1 350 000**	**5 792 000**	**10 262 000**
Gross Margin	**- 1 030**	**4 980**	**3 960**	**1 217 400**	**5 398 000**	**9 556 000**
Personnel expenses	248 996	327 180	550 620	813 960	2 394 000	3 231 900
Clinical study investments	-	80 000	80 000	80 000	200 000	-
R&D investments (excl. pers.)	12 000	120 000	144 000	144 000	360 000	840 000
Other fixed costs	72 300	93 000	167 400	252 000	835 000	1 195 000
EBIT/Cash flow	**- 310 326**	**- 615 200**	**- 938 060**	**- 72 560**	**1 609 000**	**4 289 100**
Number of employees	4	5	7	12	28	35



"Rapid growth is starting from 2026 onwards."

*EU application in progress: Comparative effectiveness research for healthcare interventions in areas of high public health need. TOPIC ID: HORIZON-HLTH-2024-DISEASE-03-08-two-stage

EpiHeart's consortium has passed the stage-1 evaluation, and full stage-2 proposal is due in April 2024. Total proposal sum is 6,75M€.

EU Horizon grant

Call

EpiHeart is part of an **excellent consortium** consisted of European clinical partners, which applied for EU Horizon grant named “Comparative effectiveness research for healthcare interventions in areas of high public health need”. In this application “Efficacy of autologous cardiac microtissue therapy in heart failure, comparative clinical research” it is presented how the effectiveness of cardiac cell therapy could be established. The sum asked for in the grant is 6,75 M€.

Accepted to stage-2

The application passed rigorous stage-1 evaluation of the European Health and Digital Executive Agency, and the consortium is to deliver the full stage-2 proposal due April. If the consortium is chosen to be eligible for funding, it means significant funding for the efficacy research of cardiac cell therapy and approximately **1M€ non-dilutive funding directly for EpiHeart**.

Clinical partners in application (stage-1)

- Hannover Medical School, Germany
- Erasmus University Medical Center, Rotterdam, The Netherlands
- University of Padua, Italy
- Jagiellonian University, Krakow, Poland
- University of Helsinki, Finland

European Commission

EpiHeart

Growth drivers

Rapid growth from research

EpiHeart's growth forecast is supported by the increasing studies in the field of cardiac muscle regeneration. The company is leveraging clinical efficacy studies that commenced in Helsinki. Clinical studies are expected to expand to other **European clinics in 2024**. Currently, the company is placing significant emphasis on product development, clinical studies, and data generation to stimulate market growth and secure future revenue. EpiHeart believes these efforts will result in rapid growth, and profitability during the go-to-market phase.

Efficient operations and high margins

The company is dedicated to establishing Cardiac Micrograft Therapy™ as a widely adopted procedure by obtaining clinical evidence and forming strategic partnerships with clinical units within Europe. The company will establish a network of distributors to locally increase market demand and generate sales. EpiHeart anticipates **substantial revenue and profits**, supported by a large global market, unique solution, and efficient operations. The CMT Core Kit's gross margin is projected to be 80%.

1 ***A large global market which is well addressable as best practices in the medical field tend to spread globally***

2 ***EpiHeart's solution is unique and protected with patents, first mover advantages and trade secrets***

3 ***The production and operations are already organized in an efficient way which supports high scalability and profitability***

Valuation

The valuation in current funding round for EpiHeart is 7,5M Euros, excluding options. This corresponds to a price per share of 6,20€. This valuation reflects the understanding of the Board of Directors and the majority shareholders of EpiHeart Oy of a fair value in the current market environment.

The main drivers for EpiHeart's valuation are the valuation in the financing round with Invesdor in 2021 (4,6 MEUR), the ability to **develop the product and meet key milestones** after the previous financing round. EpiHeart's management expects that successfully reaching the go-to-market phase will impact the valuation substantially.

Options

EpiHeart has an option program of 72 000 options out of which 18 900 are active options. Options are allocated to employees and other key stakeholders to align the incentives of the whole team and the shareholders.

Outstanding loans

EpiHeart has obtained a product development loan of 318,000 Euros from Business Finland, which carries an interest rate 3% lower than the base rate set by the Finnish Treasury, but at least 1%, and is guaranteed by the Finnish Treasury.

The Business Finland loan, originating in 2022 with a 7-year term and a 3-year amortization-free period, will commence loan amortizations in the fall of 2026, amounting to 79,500 Euros annually. With an estimated interest payment of 3,975 Euros per year based on current rates.

(In EUR)	**Capital**	**Interest**	**Total payable**
Total loans outstanding 12/2023	318 000		
Of which repayable within 12 months	-	3 975	3 975
Of which repayable within 24 months	-	3 975	3 975
Of which repayable within 36 months	79 500	3 975	83 475
Of which repayable within 48 months	79 500	3 000	82 500
Of which repayable within 60 months	79 500	2 000	81 500
Of which repayable within 72 months	79 500	1 000	80 500

Distribution of the company shares

	Shareholder	Shares	Votes
1	Kai Kronström	731 200	60,74 %
2	Esko Kankuri	200 200	16,63 %
3	Annu Nummi	60 000	4,98 %
4	6K Invest Oy	34 860	2,90 %
5	Aleksi Kuuva	15 250	1,27 %
6	Other shareholders (280)	162 347	13,49 %
	TOTAL	1 203 857	100,00 %

Epiheart Oy is an independent company and not a part of a group. The company has only one class of shares with each share carrying equal voting right.

Exit scenarios

First North Helsinki listing

EpiHeart has a significant number of shareholders and listing the company through Nasdaq First North Helsinki will be considered. Although this is not a generic exit scenario as such, it would make the shares liquid and allow individual shareholders to exit. In addition, a listing would provide additional tools for fundraising to expand further clinical studies and to execute a US expansion strategy. In addition, having a clear market valuation with liquidity, would also support a possible M&A (both inbound and exit). Considering tentative discussions held with Nasdaq and various advisors this path is to be explored further.

Trade sale to a larger medical technology company

EpiHeart would be interesting to large companies selling medical devices in the cardiac surgery space. These companies include industry leaders, which tend to acquire proven growth companies fitting in their strategies.

Trade sale/merger as an outcome from collaboration

Although EpiHeart is well positioned in its own niche, there are some companies that have synergies beyond the sales channels. There are for example, companies focused on atrial appendage closure devices and cardiac patches (matrices). In addition, there are companies that may benefit from epicardial gene therapy / drug delivery capabilities. EpiHeart is looking for strategic collaboration, and successful strategic collaboration may lead to joining forces. Joining forces through a strategic collaboration could lead to a trade sale and offer an exit opportunity for EpiHeart's shareholders.

Risks

The board of EpiHeart has a plan in place for managing risks. However, various risk factors associated with investing in the company may be significant if realized. Many of the company's risk factors are part of the nature of its business and are typical for the industry. Each risk may have an essential effect on the company's business, profits, and the potential ability to achieve its financial objectives. The risks presented here are not ranked in order of importance nor does the order in which they are presented, reflect the likelihood of their occurrence.

Risks related to the share issue and the company's shares

- Various risk factors and circumstances may lead to a fall in the market price of a share, which may result in a partial or total loss of the invested capital.
- There may be no return on the investment at all.
- The company's shares are not publicly or multilaterally traded on any marketplace, so there is no active or liquid secondary market for the shares. There is a risk that the security may not be sold at the desired time or at all, or that the price offered may be lower than its subscription price or its actual value.
- The transferability of the shares is limited in a way that the transferee must enter into the company's Shareholders' Agreement.

Risks related to the company's business

- The most significant risk of the company is that the results gained from future clinical studies are not in line with the previous results. This is a genuine risk, but if this risk would be likely, the company would never have been established. Should this risk be realized against the expectations, turning the course of the company would need to be considered. In such a case, decisions would be made based on the best available information.
- The company's business plan is based on several assumptions of the future, including assumptions of the operations and the operating environment of its customers, cooperation partners, and other parties, and of the development of the company's financial situation. Creating a new growth company requires a certain amount of optimism, but based on the understanding of the company's management, it is realistic. However, predicting the future and assumptions always involve risks and uncertainties.
- The starting of the sales operations can be delayed for various reasons, and various risks are related to product development, product approval, clinical trials, and the delivery chain. It should also be noted that the risk classification of the company's own products, which are needed as part of the overall solution, is such that their introduction into the market can be implemented in a relatively risk-free manner during spring 2023.
- The sales often grow slowly at the beginning even when they are to accelerate later. This is a realistic risk that must be accepted. In practice, the company aims to continuously get a feel of the market and to recognize the reasons that slow down the sales and prevent the quick increase in the sales. One such reason is the scantiness of clinical evidence. However, no excessive investments will be made in the sales before the dynamics of the sales are understood and heavy investments in the sales operations are justified.
- The company is relatively confident as regards the implementation of its plans, but delays caused by internal or external factors or other hindrances cannot be completely ruled out.
- The company does not currently have an ongoing commercial business
- Patient safety is always a relevant threat for a medical device company. Patient safety is also a significant concern for the company's management. It is good news that based on the completed studies, the company's products do bring significant benefits to the patients and the safety profile of the treatment is excellent. The company develops, manufactures, and monitors its products in accordance with the regulations and best practices in the field. Risk management will be implemented in a manner instructed in the EU Medical Device Regulation and the ISO 14971 standard (Medical devices. Application of risk management to medical devices).

Risks related to management and staff

- The company employs only a small number of people, and their expertise is critical. The company has committed all the key persons to the company through ownership, and the conditions for the development and growth of the team are good. Several types of personnel risks, such as recruitment difficulties or situations where the key persons are no longer available to the company, are always risks.

Legal risks

- The company has not identified special legal risks. The company does not have any pending disputes or lawsuits. The realization of legal risks is, however, always possible, even though the risks are minimized through good management practices and carefully considered agreements.

Regulatory risks

- The company operates in a highly regulated sector and understands the significance of regulation. The company recognizes the product-specific requirements of the regulation in the product development process and has discussed regulation matters with the authorities. This does not mean that surprises cannot occur as regards the interpretation of regulations or unidentified regulations, in addition to which any future changes made to the applicable regulations can place new kinds of requirements or require additional measures. The company also uses products manufactured by other companies and subcontractors, which are also subject to similar regulations and therefore the same risks related to the identification and application of applicable regulations and measures required by possible changes to these regulations apply to them. Thus, the risks related to regulations can also be realized through the availability of subcontractors or products.

Financial risks

- The company's financial projections are subject to risks, as forward-looking estimates, targets, and other statements always involve uncertainty, and they are only predictions, not guarantees of the future.
- The company may require additional funding, but the funding of the company and the availability of the necessary funding are not something to be taken for granted in all situations. If the company succeeds at achieving its goals reasonably well, it can be expected to be an interesting subject of investment, meaning that the preconditions for the funding of the development and growth of the company in various situations will also be more diverse.

Macroeconomic risks

- Uncertainty in the global economy and financial markets may adversely affect the company's business and operating results.
- The risks listed above are not the only risk factors affecting operations of the company. Other risks and uncertainty factors that the company currently does not identify or currently considers to be irrelevant may also have an integral effect on the business operations, business result, and financial standing of the company.

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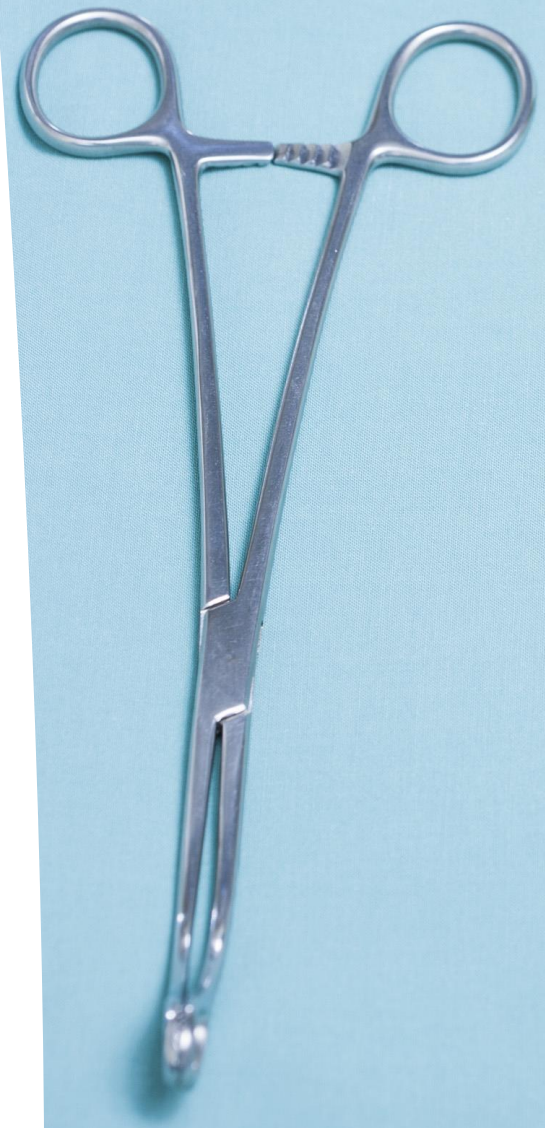

EpiHeart

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