

# On a mission to enhance the diagnosis of 100 million hearts

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CEO

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**We all deserve to know immediately if our chest pain is related to heart disease or not**



# More than 90% of patients with chest pain undergo multiple diagnostic tests – for no reason

**Every day, approximately 1 million patients** seek medical attention for chest pain related symptoms.<sup>1</sup>

**Common symptoms affecting 20-40%** of the population with chest pains at some point during their life time.<sup>2-5</sup>

**However, less than 1 out of 10 assessed have coronary artery disease (CAD)**

It is important to identify those unnecessary patient examinations and prevent significant cost burden on healthcare systems.<sup>6-10</sup>

1. Epidemiology of coronary heart disease and acute coronary syndrome, [Ann Transl Med.](#) 2016 Jul; 4(13): 256
2. Lifetime risk of developing coronary heart disease, *Lancet*, 1999 Jan 9;353(9147):89-92
3. Therning, C. et al. Low Diagnostic Yield of Non-Invasive Testing in Patients with Suspected Coronary Artery Disease: Results From a Large Unselected Hospital-Based Sample. *Eur Heart J – Qual Care Clin Outcomes* 2018; 4, 301-308
4. Winther, S. et al. Diagnostic performance of an acoustic-based system for coronary artery disease risk stratification. *Heart* 2018; 104, 928-935
5. Douglas PM et al. Outcomes of anatomical versus functional testing for coronary artery disease. *N Engl J Med* 2015; 372, 1291-1300



**90-94%**  
patients undergoing  
noninvasive testing  
do not suffer  
from CAD <sup>1,2</sup>

# Acarix uses innovative acoustics and AI to rule out heart disease in minutes

## Rule-out of CAD in less than 10 min with 96% confidence

The novel CADScor® System enables non-invasive, AI-based rule-out of suspected CAD in patients with chest pain or shortness of breath

## Used on >8,000 patients with suspected CAD

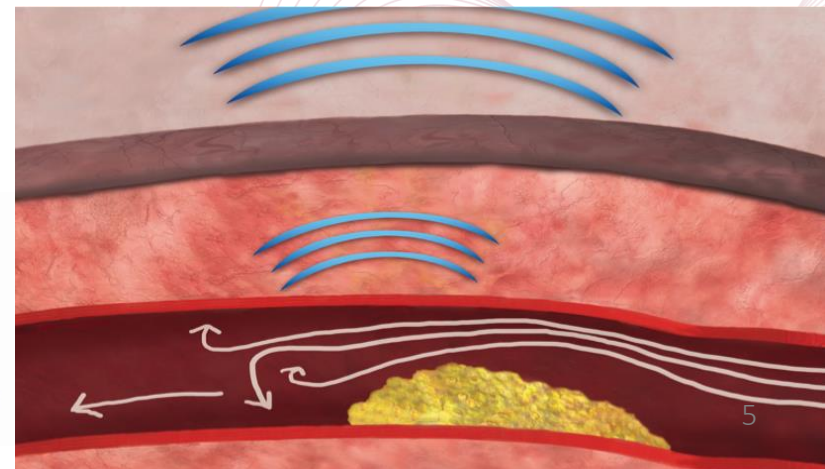
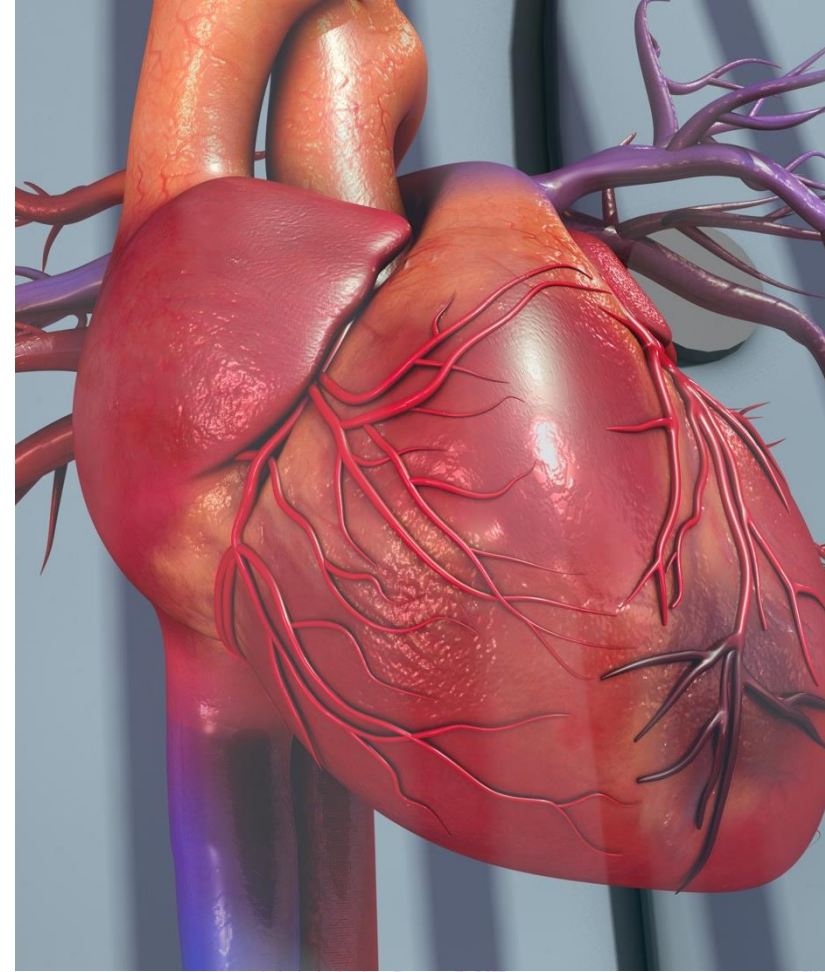
Unique CE- and FDA De Novo cleared AI technology based on more than 15 years of R&D in the Nordics and more than 45 patents





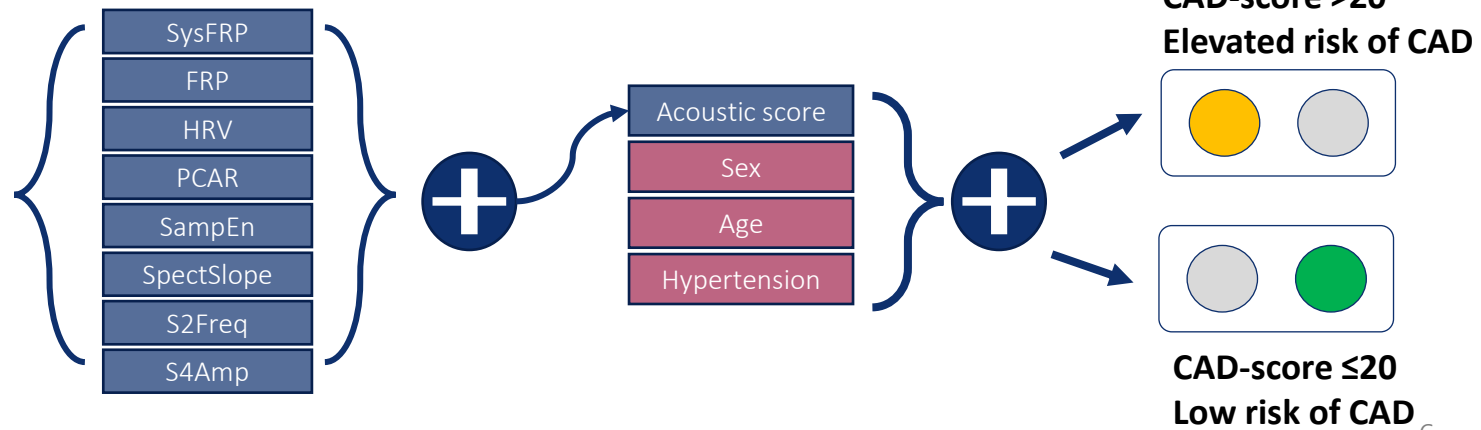
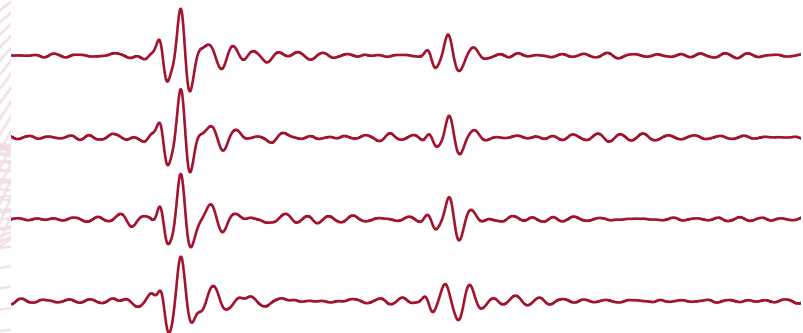
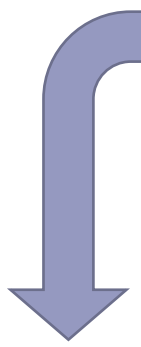
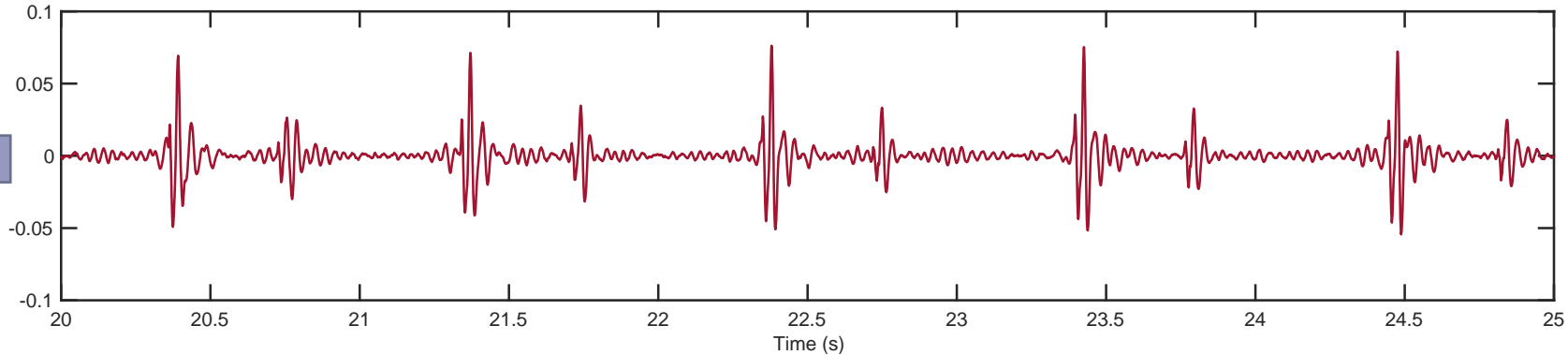
# The NOVEL CADScor<sup>®</sup> System for acoustic AI-based cardiac assessments

Ultra sensitive and intelligent AI-powered diagnostic aid, rooted in strong internationally renowned Danish audio engineering and academia



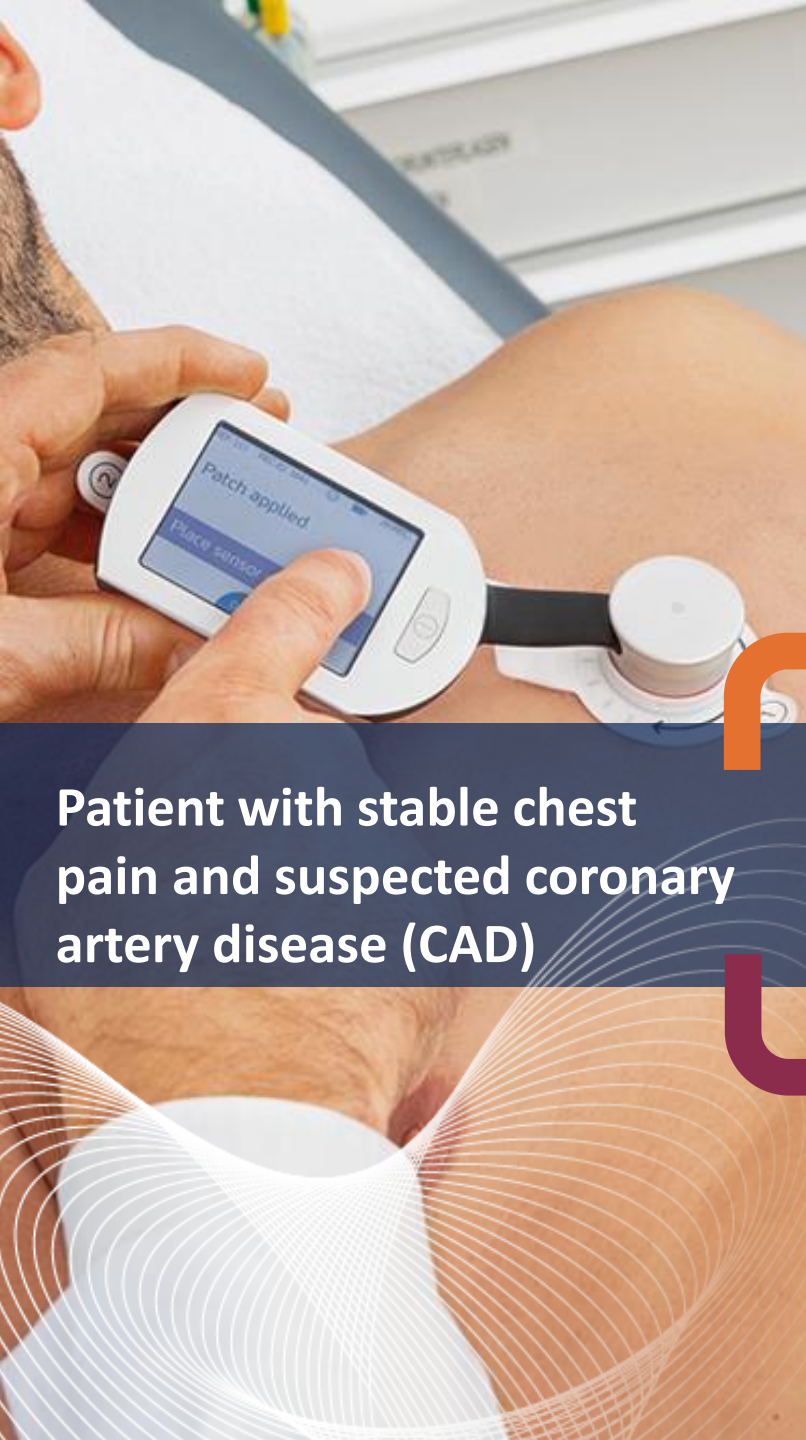
AALBORG UNIVERSITET

# The Acarix AI-powered unique algorithm for rapid detection of CAD



**+45 patents in 8 patent families + 2 pending**

# CADScor<sup>®</sup> System should be used early for maximum impact



Patient with stable chest pain and suspected coronary artery disease (CAD)

Do CADScor<sup>®</sup> System first for early rule-out



ECG Stress Test via treadmill

CCTA -Stress  
Echo MPI Nuclear Imaging



Invasive  
Coronary  
Angiography



Invasive  
Treatment  
(PCI etc)



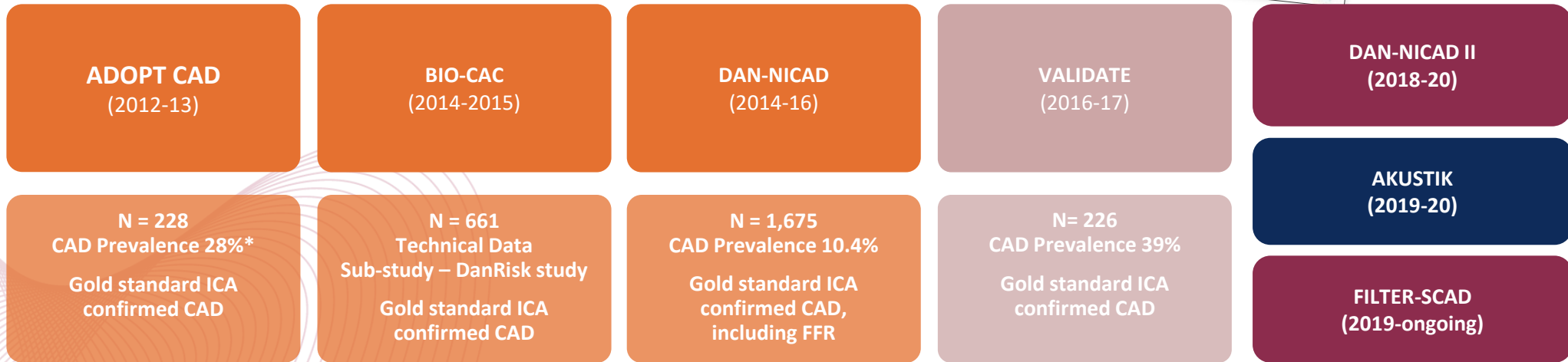
Radiation equivalent of 500-1,000x ordinary x-ray<sup>14</sup>.



# A clinical powerhouse in CAD detection with continued clinical development



## Clinical trials overview (>8,000 patients)



## Continuous Algorithm Optimization



➔ Current CE-mark and FDA clearance   
 ➔ Pending Publication   
 ➔ Key Studies: Ongoing/Reporting Phase



# Early EU commercial validation completed – now in scale up phase

## 150 CADScor® Systems in commercial use

CE-marking and used in 7 markets with recurring sales and 75% gross margin

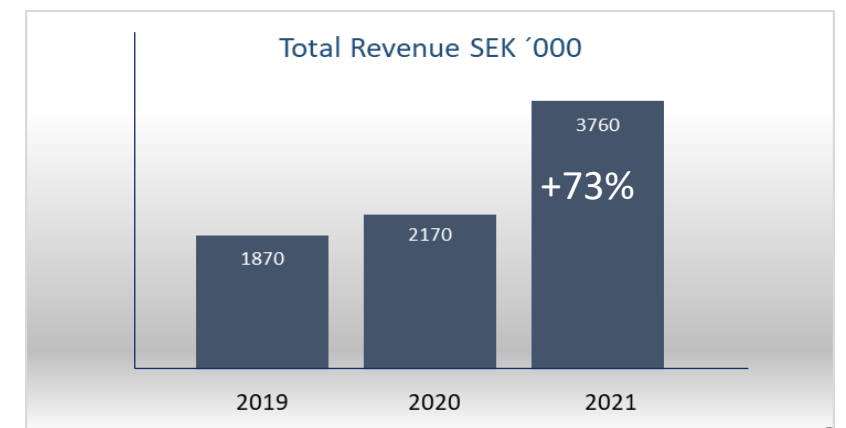
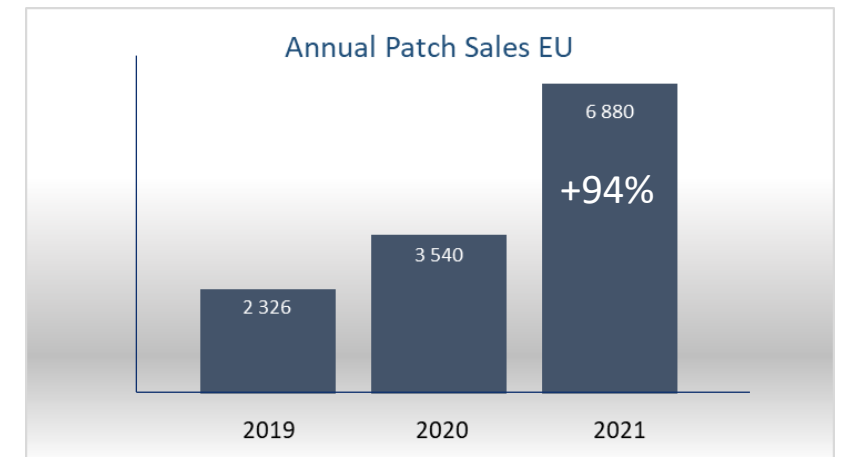
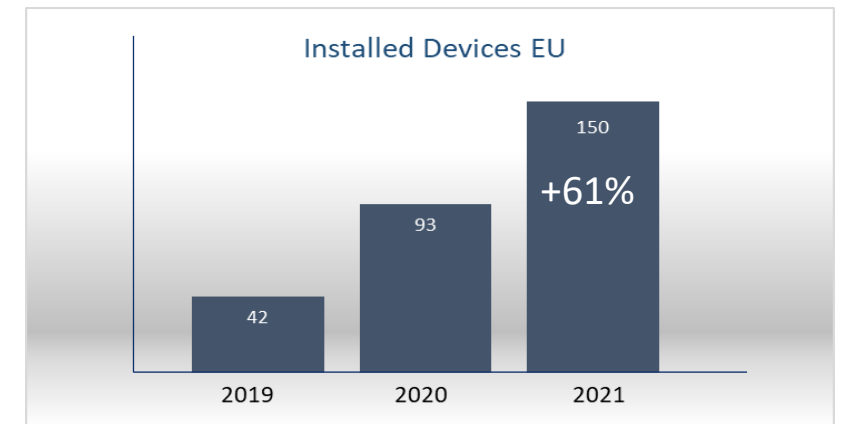
## Recent funding of net SEK 69 million to support US expansion

FDA De Novo clearance, approved CPT III Code and ideal timing to enter US market with direct sales team and commercial partners to maximize impact

## With a mission to impact over 100 million lives

Market estimated at USD 10 billion<sup>1</sup> per year, targeting primary care and cardiologists to optimize CAD diagnosis and clinical workflow

1. Estimated average cost of CAD diagnostic test @USD 1,000



# Attractive financial metrics



## More than 75% gross margin business model

Attractive business model with innovative personal single-use patches for each patient assessment

**Estimated Lifetime Value (LTV)** of one delivered CADScor® System over 3 years: including use of disposable patches:

- SEK 300,000 EU
- USD 73,400 estimated US

## High potential US market

- 20-40% lifetime prevalence of chest pain
- >10.5 million visits to ED and outpatient clinics
- 18 million CAD patients - leading cause of death
  
- 30,000 cardiologist
- 45,000 emergency medicine
- 120,000 internal medicine



# CADScor® System is ideal for US market, meeting a clearly defined medical need



## Reimbursement code covering CADScor® System

AMA granted CADScor® System CPT III code, which will be active in July 2022. In meantime, HCPs billing unspecified cardiac code with USD 200 payment



AMERICAN COLLEGE of CARDIOLOGY

## New chest pain guidelines opening new door

Any patient with pre-test probability (PTP) of less than 15%, should not proceed with current diagnostic procedures.

CADScor® System endorsed by the ACC



## Large, patient driven billion \$ US market

Driving towards value-based and cost-efficient care.

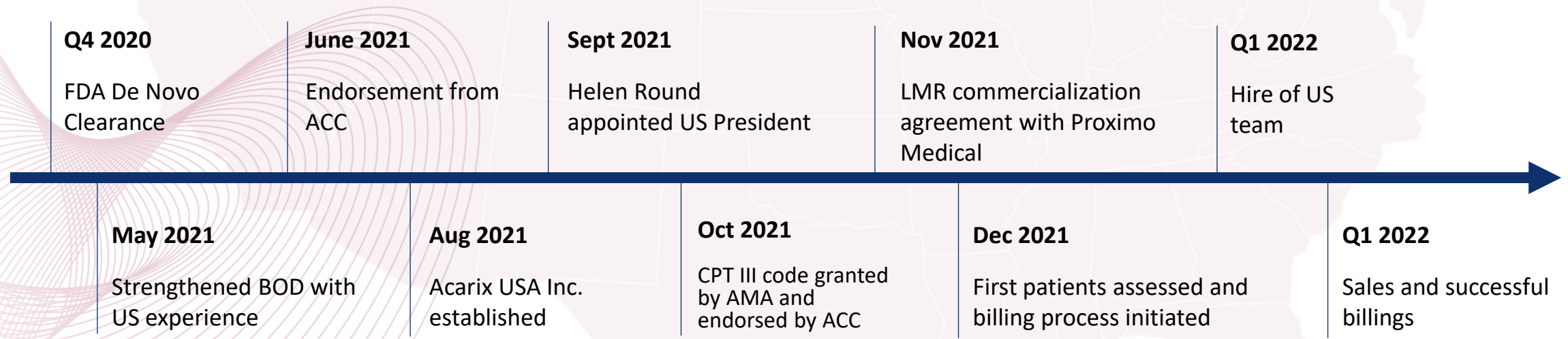
Patients requiring response to chest pain in clinics

Ideal timing and market conditions for launch in US market

# Structured US commercialization and expansion rapidly ongoing

**Sales execution** - Hybrid sales model including a direct sales team and sales agents in key regions, with IDNs, and VA. Sales partners targeting other channels and self funded employers' segment

**Positioning** – Targeting Primary Care, Internists, General Cardiologists and Emergency Medicine to enable early use in diagnostic pathway and workflow





# Creating shareholder value – 2024 financial and operational targets

## 2021/2022 Goals

- ✓ New CEO and expanded team
- ✓ US expansion
- ✓ Secured funding via new shares issue

## 2024 Goals

- Installed base of 3,000 CADScor<sup>®</sup> Systems with focus on US market
- Target revenue >SEK 200 M
- Gross margin >80%

## Focus and plans

- Drive sales in US market, directly and with commercial partners
- Continued EU expansion in select markets
- Reimbursement approval in DE and UK
- Expansion of portfolio with Heart Failure (US)
- Experienced and strong team

# A strong team with international experience to make it happen



**Thomas Lundstroem COO**  
Ex GN Hearing, Valcon, Accenture  
>15 yrs

**Anders Krabbe, CCO**  
Ex Novo Nordisk  
>25 years

**Helen Ljungdahl Round, CEO**  
Ex Merck, GN, Aminicell.  
>25 years

**Christian Lindholm, CFO**  
Ex TFS Int, Doro  
>25 years

**Marianne Solhøj Nørskov, CRO**  
Ex Novo Nordisk  
>15 years



**Philip Siberg, Chair**  
Co-founder/ex-CEO Coala  
Life, Chairman Senszime



**Marlou Jansen-Counotte, Board**  
Ex Medtronic, St Jude,  
Biotronik



**Ulf Rosén, Board**  
Ex Seed Ventures. CEO  
Lobsor



**Fredrik BuchM MD, Board**  
Multiple Board positions in  
life science



# Summary

## Why engage and invest in Acarix?

1. Solid R&D, strong IP, regulatory approvals in place and strong comprehensive clinical data
2. Commercial model proven in EU, now expanding with reimbursement coverage in the US, the largest market and potential
3. Compelling financial metrics and a world-class team in place to make it all happen!



# Thank you!

## Contact us

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