

On a mission to enhance the diagnosis of 100 million hearts

Capital Markets Day
Helen Ljungdahl Round
CEO

February 2022



ACARIX Capital Markets Day

Feb 18, 2022

- ➔ **1. Introduction to Acarix**
- 2. Technology Overview**
- 3. Clinical Experience**
- 4. US Expansion**
- 5. 2021 Financials, Outlook and Plans**
- 6. Q&A**

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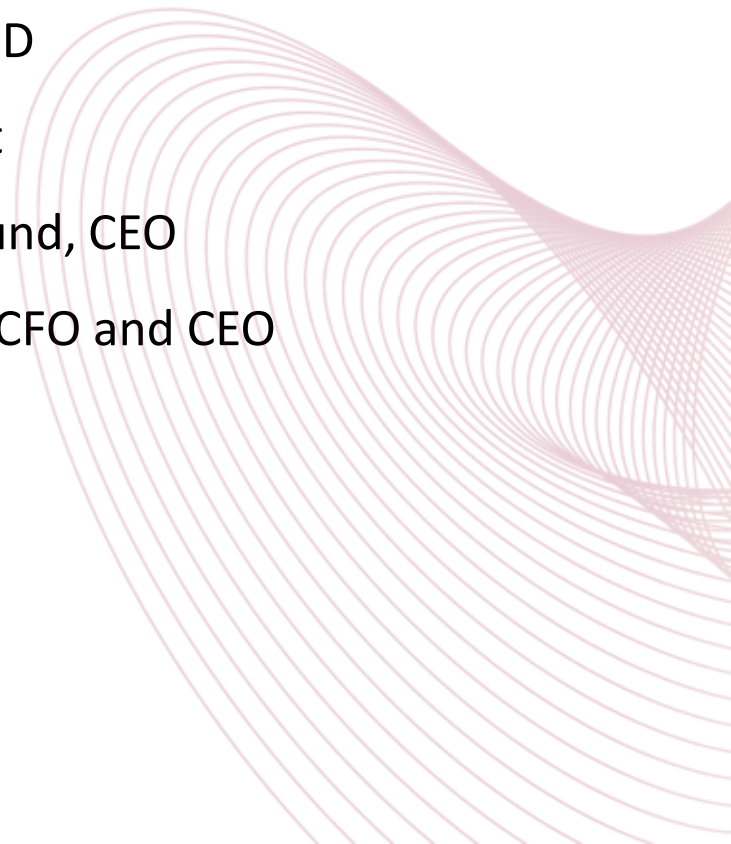
Samuel Schmidt, R&D

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We all deserve to immediately know 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 consult emergency or primary care for chest pain related symptoms ¹

Common symptoms affecting 20 - 40% of the population with chest pains at some point during their life time ²

However, only 1 person out of 10 with stable symptoms have Coronary Artery Disease (CAD)

It is important to identify those unnecessary patient examinations and prevent significant cost burden on healthcare systems ³⁻⁵

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

Acarix Leads Paradigm Shift to AI-powered Assessment of CAD

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

The CADScor® System enables non-invasive rule-out of patients with suspected Coronary Artery Disease (CAD)

Used on >8,000 patients with suspected CAD

With a unique CE- and FDA cleared AI technology based on over 15 years of research and development in the Nordics and protected by more than 45 patents

Razor / Razor Blade business model

Attractive model with installed CADScor® System and innovative single-use patches for every patient assessment



Coronary Artery Disease Assessment in Less than 10 Minutes



Patient with stable chest pain and suspected CAD
General examination

CADScor[®]
Rule-out 35%¹



Intended use ¹

The intended use of CADScor[®] System is to record heart sounds, i.e., murmurs and vibration for calculation of a patient specific score, the CAD-score, indicating the risk of coronary stenosis, as an aid in cardiac analysis and diagnosis.



Radiation equivalent of 500-1,000x ordinary x-ray¹⁴.

1. US user manual v.12.5, prevalence 10,7%, algorithm version US3.2
 2. ESC 2019 guideline does not recommend if other diagnostic tools are available

Now Rapidly Expanding to US, Following Early EU Commercial Validation

100+ CADScor® Systems in commercial use

CE and FDA De Novo cleared, used in 7 markets including Germany, UK and Sweden, with recurring sales and 85% Gross Margin

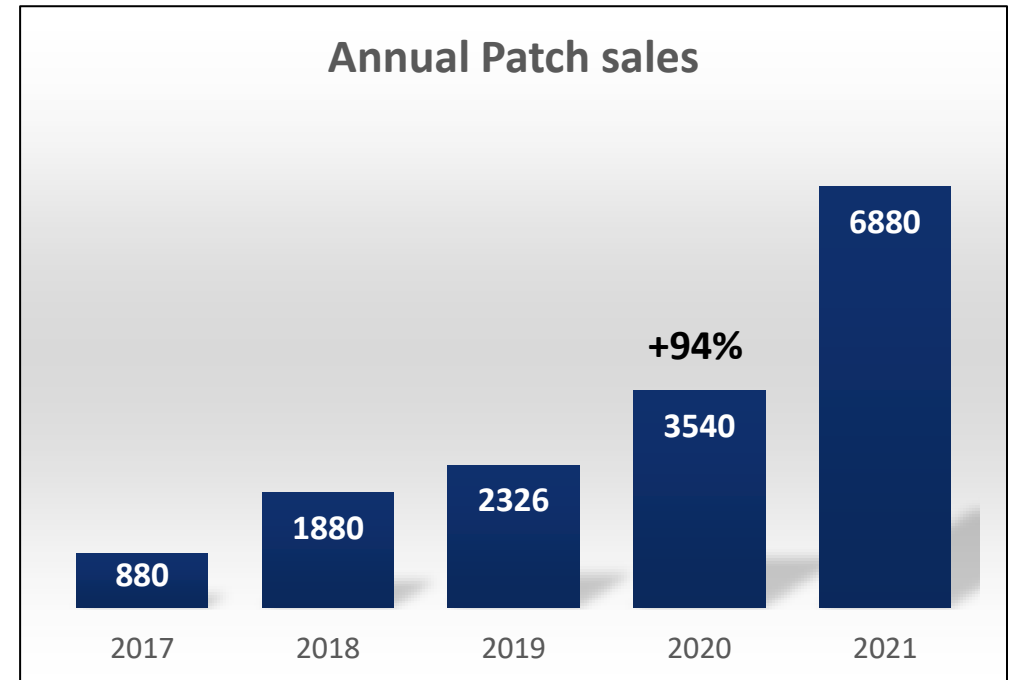
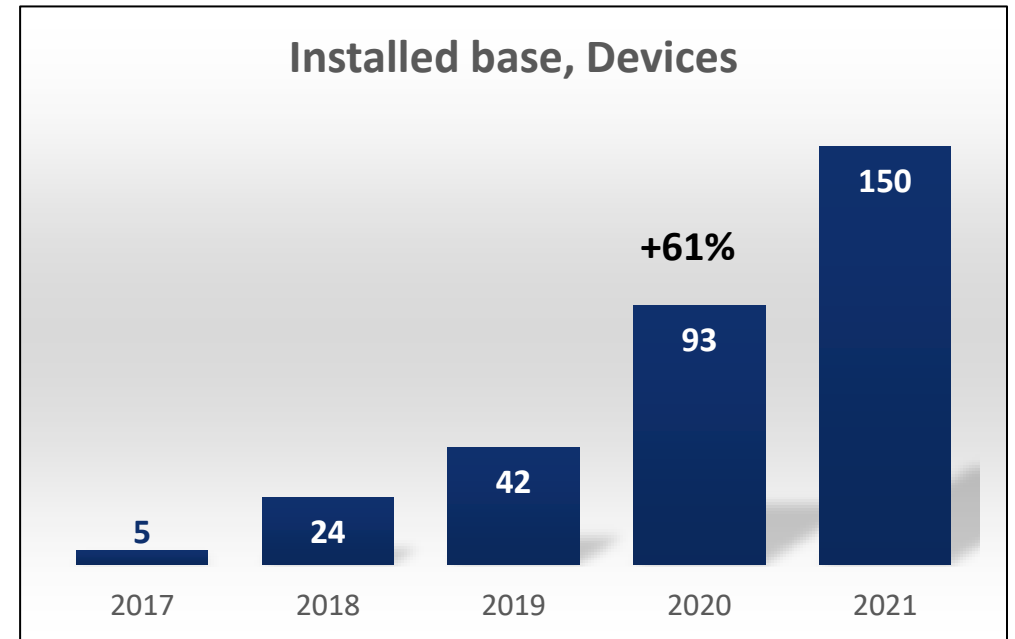
Recent funding of SEK 80+ million to support US expansion

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

With a mission to impact over 100 million lives

Market estimated at over USD 10 billion¹ per year, targeting primary care and cardiologists to optimize CAD diagnosis and clinical pathways

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



Strong Team with Global Experience To Make It All Happen



Helen Ljungdahl Round
President and CEO
Ex Merck, GN, Amnicell
> 25 yrs



Christian Lindholm
CFO
Ex TFS International, Doro
>25 yrs



Anders Krabbe
CSMO
Ex Novo Nordisk,
Ferring >25 yrs



Marianne Solhøj Nørskov
R&D, Clinical Development
Ex Novo Nordisk
>15 yrs



Tobias Fritz
CTO
Ex Dignitana, Sony Ericson
>15 yrs



Philip Siberg - Chair
Co-founder and ex-CEO
Coala Life. Chairman Senszime



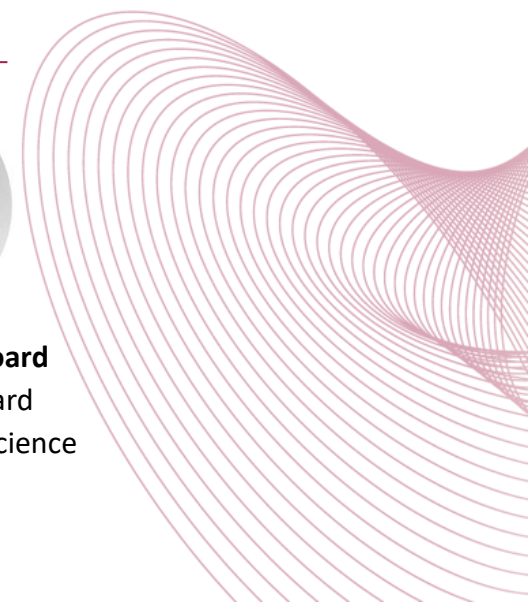
Marlou Janssen-Counotte - Board
Ex Medtronic, St Jude,
Biotronik



Ulf Rosén - Board
Ex Seed Ventures.
CEO Lobsor



Fredrik Buch - Board
MD. Multiple Board
positions in life science



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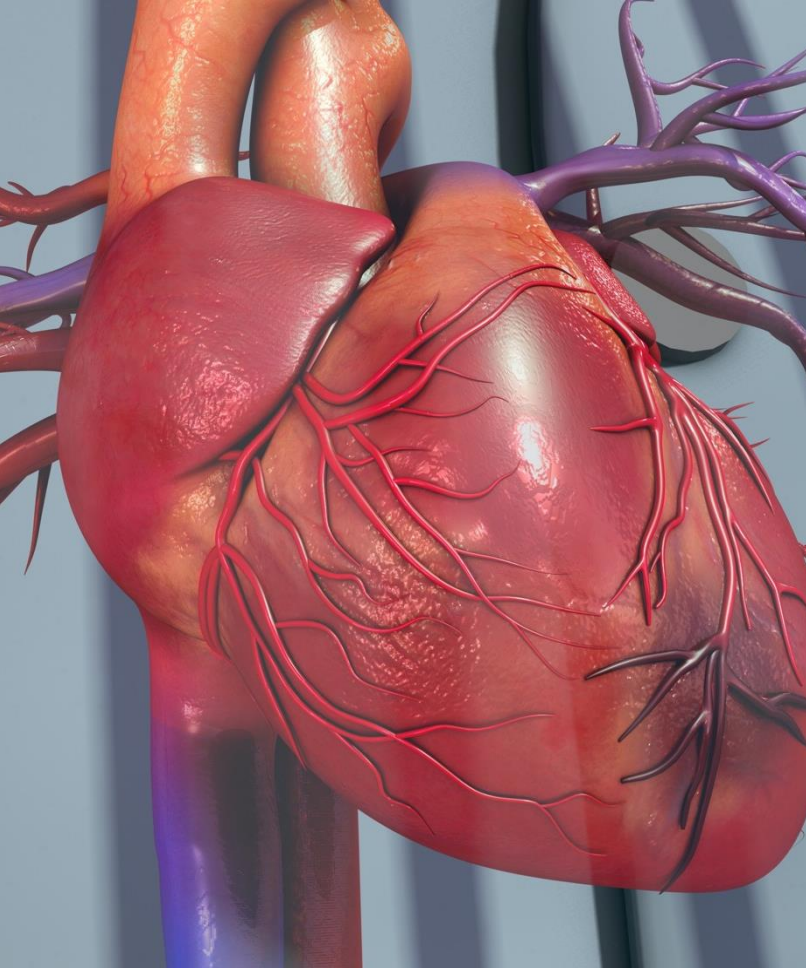
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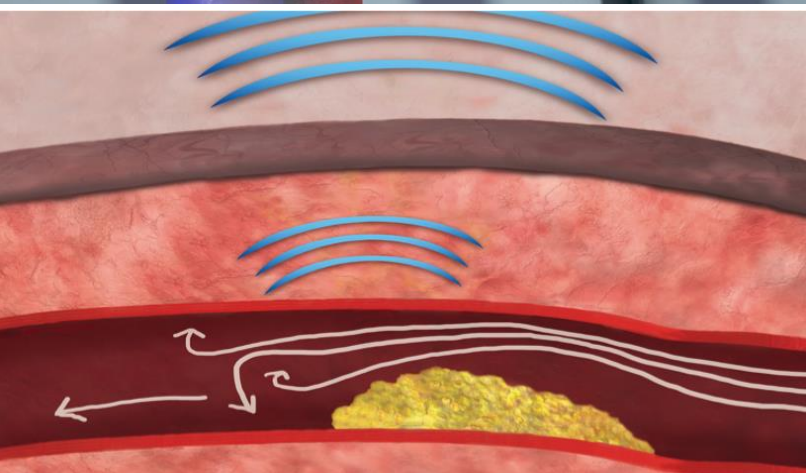
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The Idea Behind the CAD-Score

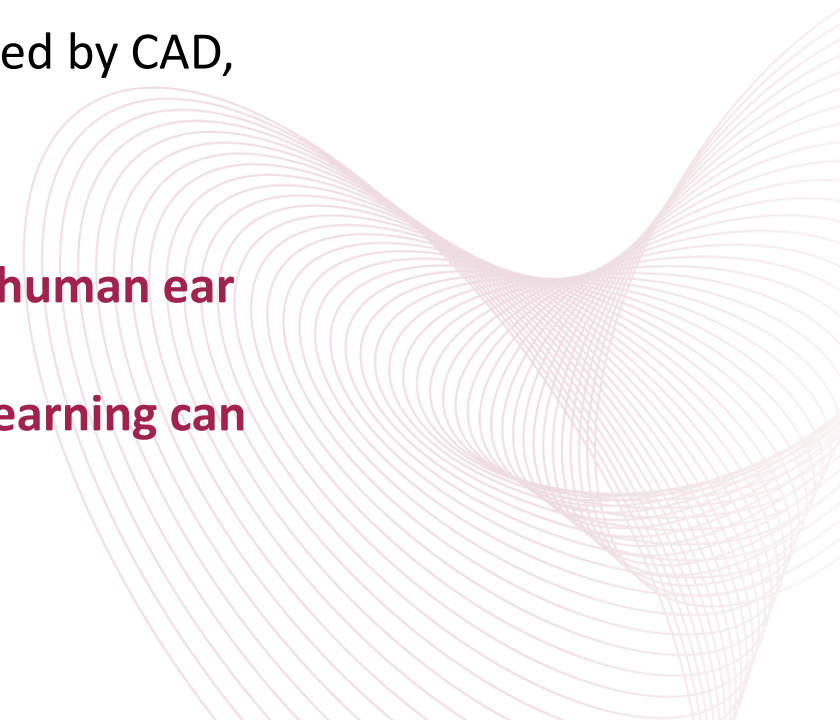
Coronary artery disease (CAD) causes weak alterations in the heart sounds

- Narrowing's caused by plaque build up will produce turbulent blood flow, which makes a weak noise
- The relaxation of the heart is altered by CAD, which changes the heart sounds



These sound are not audible by the human ear





But signal processing and machine learning can detect these

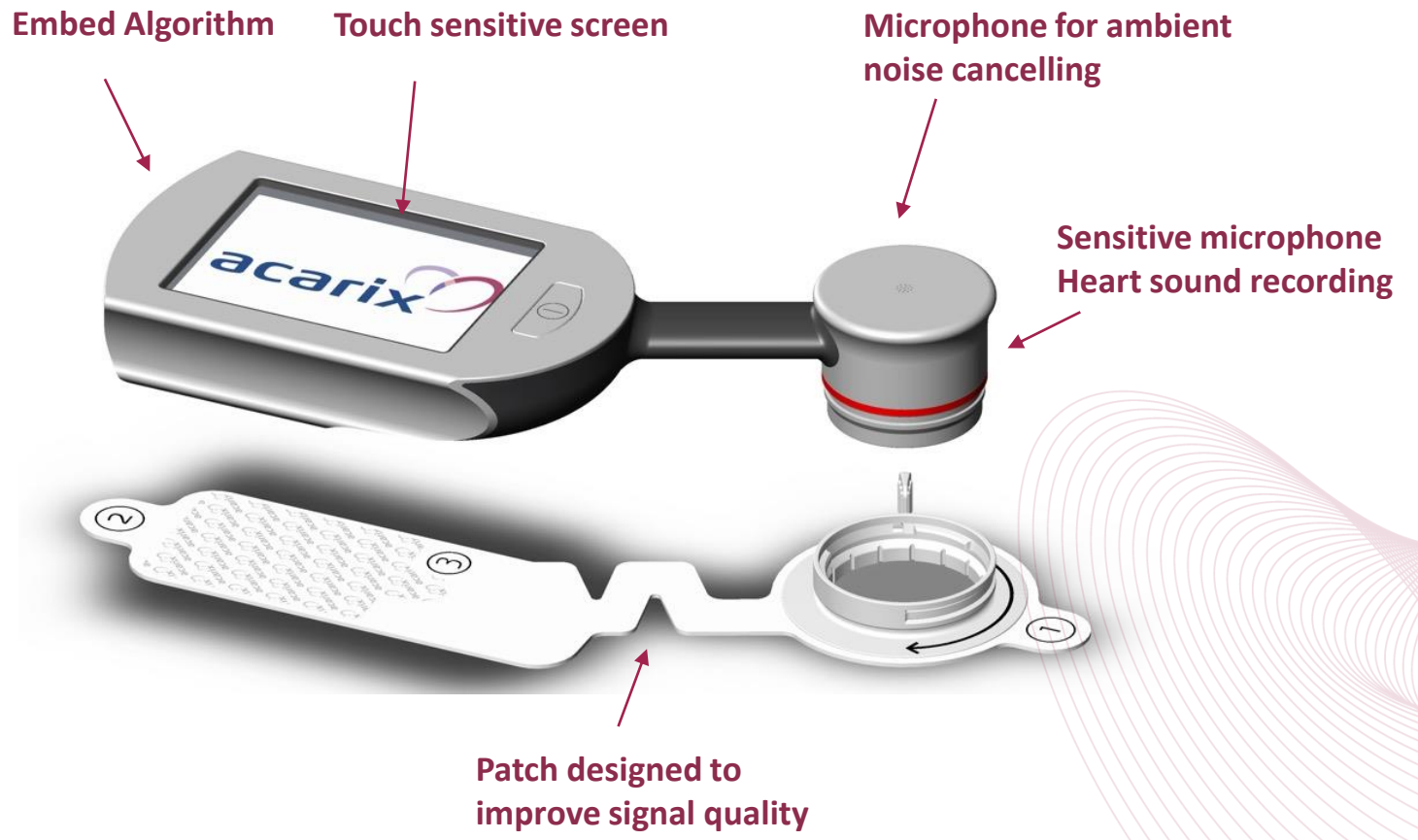


The NOVEL CADScor[®] System

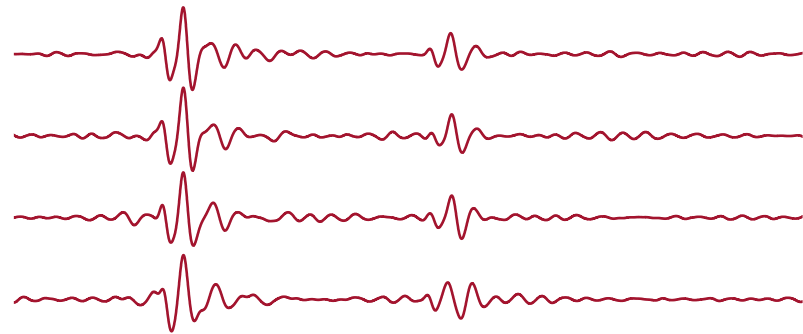
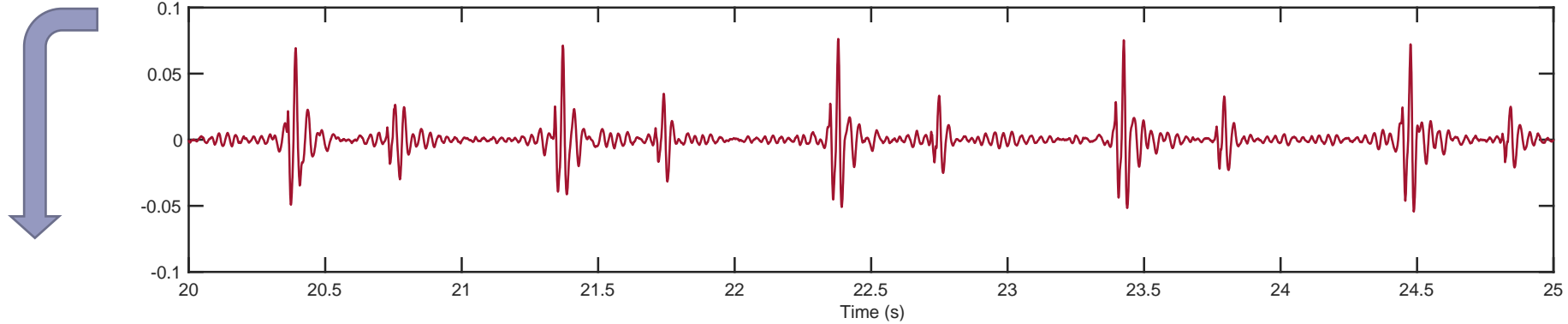
Ultra sensitive and intelligent AI-powered diagnostic aid, rooted in strong Danish audio industry and academia



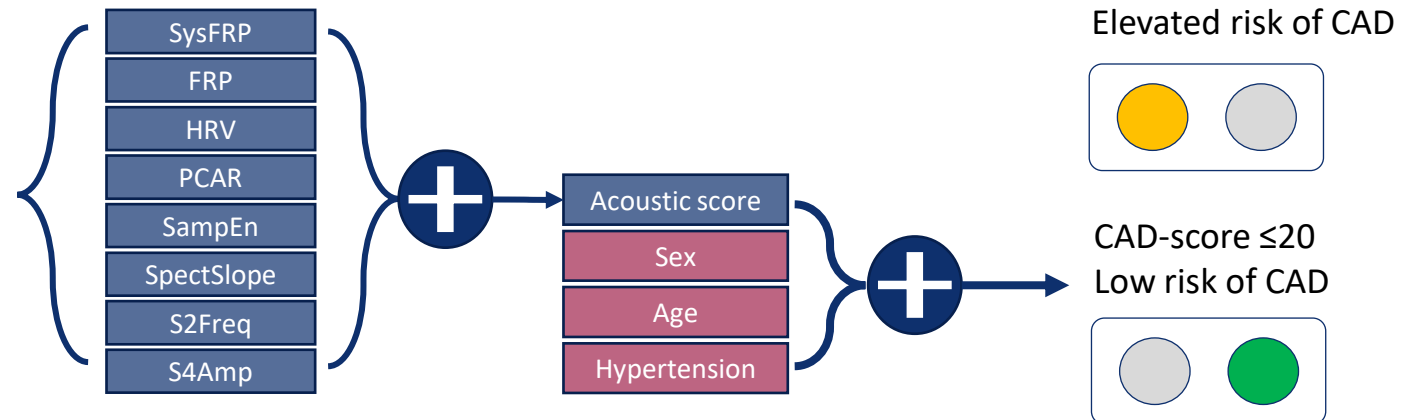
CAD-score ≤ 20 Low risk of CAD	CAD-score > 20 Elevated risk of CAD
 	 



AI Algorithm for Detection of CAD



+45 patents in 8 patent families + 2 pending



The need for rule-out

Low diagnostic yield of current diagnostic methods

Current noninvasive testing includes:

- Cardiac CT
- Stress ECG
- SPECT

Current noninvasive testing is

- Costly
- Depends on specialized equipment located at hospitals

90-94%
patients undergoing
noninvasive testing
do not suffer
from CAD ^{1,2}

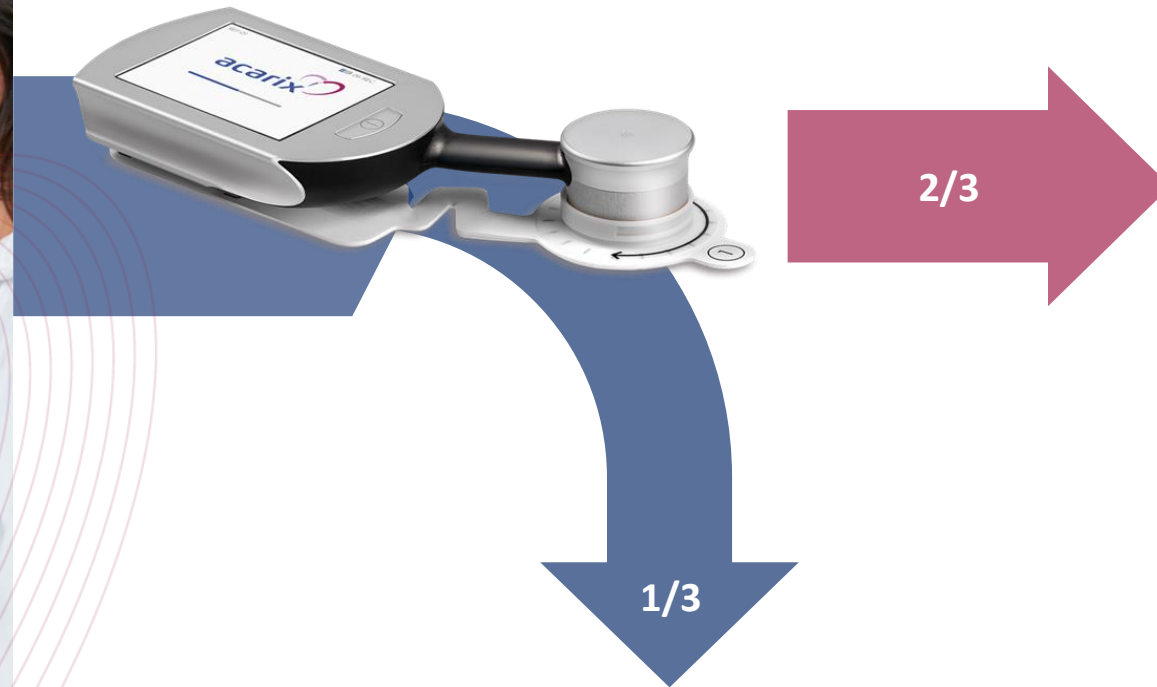
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2 Winther, Simon, et al. "Diagnostic performance of an acoustic-based system for coronary artery disease risk stratification." Heart (2017): heartjnl-2017



Rule-out Capacity of CADScor® System

The point-of-care CADScor® System can safely rule out more than one third of patients referred for non-invasive testing with at least 96% certainty



Non-invasive testing

No further assessment for CAD

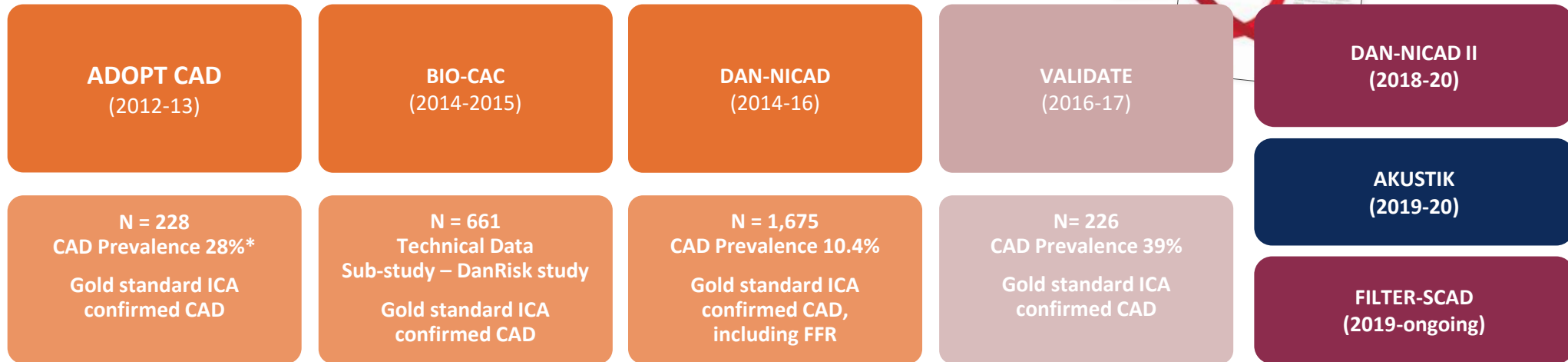
A Clinical Powerhouse and Continued Clinical Development

Patients included:

- Reported studies: 2,790
- Ongoing studies: ~3,800



Clinical trial overview



Continuous Algorithm Optimization



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

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Testimonials



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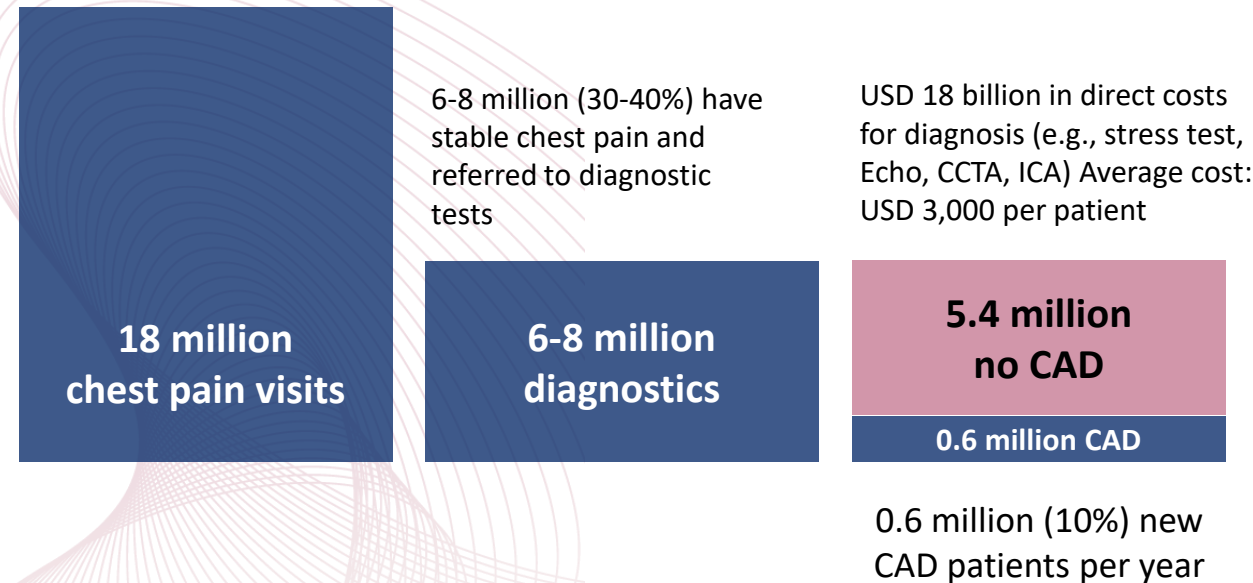
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The Timing is Right for Acarix to Expand to World's Largest Market



18 million chest pain visits to ER / Ambulatory Care annually



US Market Fundamentals

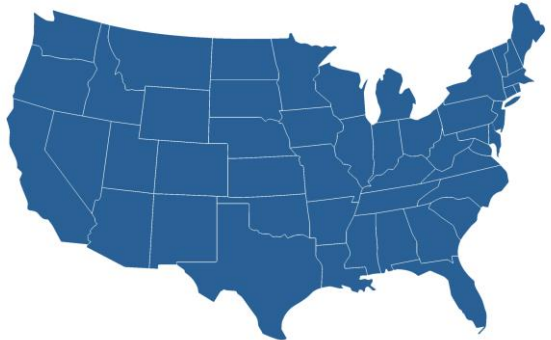
- US healthcare driving towards **Value-based Health Care** and cost reduction solutions
- **New Chest Pain Guidelines:** Any patient with a pre-test probability of less than 15%, do not proceed with diagnostic procedures

US Expansion Off to a Good Start

Sales: Hybrid sales model with direct sales team and commercial partners targeting key states, Integrated Delivery Networks (IDN's) and Self funded employers' segment

Targeting: Primary Care, Internists, and General Cardiologists to enable early diagnostic pathways

Structured approach:



Expansion Into Heart Failure

CAD is most common reason for developing Heart Failure

Ability to expand use of CADScor® System to address a broader market

More than 60 million have HF; Millions more remain undiagnosed

Current methods are difficult to read or too expensive for monitoring

Seismo has potential to be used as diagnostic for HF, detecting early disease progression in 5min

Application for FDA Breakthrough Submission filed Feb 2022

Successful approval opens door to US market with initial procedural CPT billing code

The rationale

- A substantial need for a simple and reliable tool to guide early evaluation of patients with impaired myocardial performance
- Only 1/3 of patients referred for suspicion of HF had the diagnosis confirmed¹

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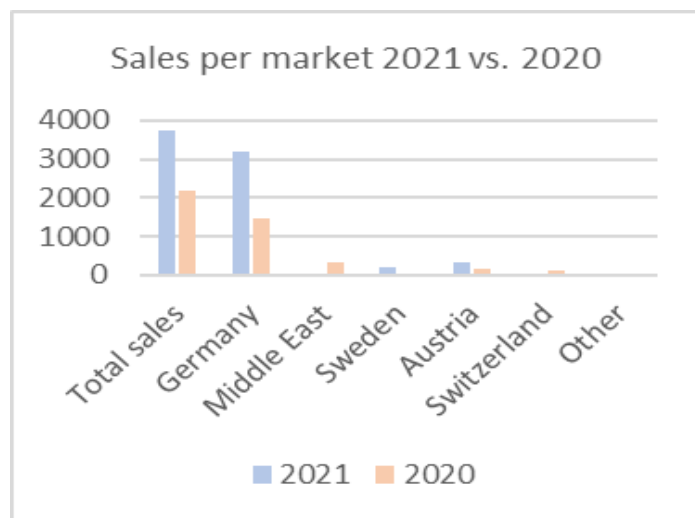
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Income Statement

SEK K	FY 2021	FY 2020	Change (%)
Revenue	3 760	2 170	73%
Gross margin	75%	73%	3%
OPEX	54 519	43 025	27%
EBIT	-51 696	-41 431	25%
Number of Systems sold	57	51	12%
Number of Patches sold	6 880	3 540	94%
Ongoing customer evaluations	12	5	140%
Repurchase Patches	55%	47%	17%



Key Take-aways

Revenues increased with 73% for the year

Gross margin increase from 73% to 75%

Number of ongoing customer evaluation increases during the end of 2021

Sales mainly on German market

Gradual increase in repurchase of Patches from our existing customers.

Operating expenses increase related to entry into the US market

Financial Position and Cashflow

SEK K	FY 2021	FY 2020	Change (%)
Total assets	118 601	89 948	32%
Equity	100 545	70 124	43%
Cash and cash equivalents	15 860	64 113	-75%
Cash flow for the period	-48 214	10 663	-
Completed rights issue	-	47 536	-
Ongoing rights issue	83 195	-	-
Costs related to ongoing rights issue	-13 860	-	-
Rights issue excluding related costs	69 335	-	-

Key Take-aways

Increase in total assets and equity driven by ongoing rights issue

Cash position December 2021 amounts to SEK 15,8m compared to SEK 64,1m in December 2020

Payment from rights issue executed during January 2022, net proceed SEK 69m

Cash sufficient to run operation until first quarter 2023

Investor Relations (Holding per Jan 31)

10 largest shareholders	# Shares	Holdings (%)	Market value
FÖRSÄKRINGSAKTIEBOLAGET, AVANZA PENSION	22 091 397	8,93%	16 789
FORMUE NORD MARKEDSNEUTRAL A/S	6 644 909	2,69%	5 050
BNY MELLON SA/NV (FORMER BNY), W8IMY	6 524 705	2,64%	4 959
CARNEGIE INVESTMENT BANK FILIAL AF	5 860 000	2,37%	4 454
SYDBANK A/S	4 814 502	1,95%	3 659
NORDNET PENSIONS FÖRSÄKRING AB	4 576 999	1,85%	3 479
ÖBRINK, ANDERS	3 109 786	1,26%	2 363
XINCHANG PUHUA-JINGXIN-GUZHOU HE	2 654 259	1,07%	2 017
KADER, MOHAMAD	2 639 099	1,07%	2 006
BERGVALL, LEIF HARALD	2 625 000	1,06%	1 995
10 largest shareholders	61 540 656	24,87%	46 771
Other	185 868 418	75,13%	141 260
As of January 31, 2022	247 409 074	100,00%	188 031

Location	# Shareholders	(%)	Holding	Holding (%)	Market cap
Swedish residents	4 678	85,02%	181 084 155	73,19%	135 624
Other Nordics	768	13,96%	39 679 255	16,04%	29 814
Other Europé	41	0,75%	21 920 751	8,86%	16 639
USA	2	0,04%	1 806 099	0,73%	1 372
other world	13	0,24%	2 918 814	1,18%	2 213
As of January 31, 2022	5 502	100,00%	247 409 074	100,00%	185 662
New shareholders in Jan	537				
Discontinued shareholders Jan	-182				

Key Take-aways

10 largest shareholders represent 25%

Largest shareholder Avanza Pension 8,9%

85% of shareholders are Swedish residents, representing 73% of holding

During January 537 new and 182 discontinued shareholders

Total 5 502 shareholders as of January 31, 2022 (5 300 Dec 31 2020)

Compensation issue, approx. 5m shares, registered in February 2022.

Growth Plans and Objectives 2024

Strong foundation

- Technology, evidence, FDA and CE
- > 10,000 patients diagnosed with CADScor® to date
- 45 global patents

Timing is right

- US healthcare moving towards value-based care and cost reducing solutions
- New AHA/ACC Guidelines supporting non-invasive methods

Large market opportunity

- focused approach combined with direct sales and commercial partnerships



Focus and plans

- Drive sales in **US market**. directly and with commercial partners
 - Health care professionals
 - INDs and VA
- Continued **EU expansion** in select markets
- **Reimbursement** approval in Germany and UK
- Expansion of portfolio with **Heart Failure** (US)
- Experienced and **strong team**

Milestones


- **Market leadership** in early AI-based CAD rule-out

2024:

- Installed base **3,000 CADScor® Systems**
- Target revenue above **SEK 200M**
- Gross Margin **above 80%**



Engage and Invest in Acarix

- 1. Solid R&D, patented technology, published clinical data, regulatory approvals**
Clinical work completed and published. Now ready to scale and drive impact for Acarix, health care providers and patients
 - 2. Strengthened EU position**
Strong increasing base and increased utilization of patches; ongoing work with G-BA and NICE
 - 3. US market opportunity**
Timing is ideal, FDA De Novo and CPT Code. New Guidelines. Significant unmet need with matching business model
 - 4. With a strong competent team to make it happen !**
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Q&A



Thank you!

