



On a mission to listen  
to millions of hearts



Acarix Q3 2022 Earnings Call  
November 16, 2022

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# 2022 3Q Operational Highlights

- **US Reimbursement Code (CPT III)** effective from **July 1, 2022**, with average reimbursement level USD 165 (USD 84 – USD 300), so far. Establishing the reimbursement levels for the new code affected Q3 revenues short-term
- Continued expansion of US sales efforts including **commission-based sales agents** which together with Acarix Sales Team results in **52% coverage** of chest pain market
- Strategic collaboration agreement with **American College of Cardiology (ACC)** to define guidelines-type clinical frameworks to accelerate US roll-out
- Positive momentum and market feedback leads to **Full Focus on US** market going forward, leading to approx. 25 MSEK in reduced OPEX in 2023.
- Patient enrollment in **FILTER-SCAD** randomized controlled multicenter trial completed



# 2022 Q1-Q3 Financial Highlights

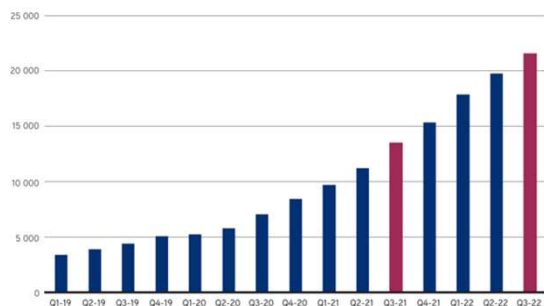
## Revenue:

- SEK 4,169 thousand (SEK 2,832) **+47% vs PY**
  - 48 (46) CADScor®System **+4% vs PY**
  - 6,252 (5,100) patches **+23% vs PY**

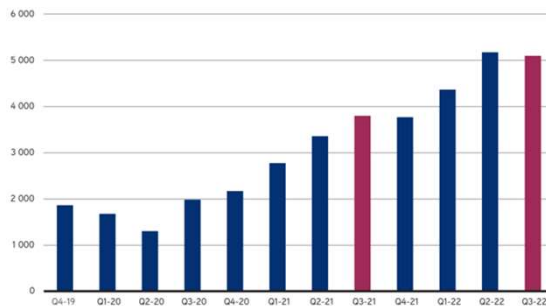
## Gross profit:

- SEK 3,292 thousand (SEK 2,098) **+57% vs PY**
- Increased Gross Margin of 79% (74%) **+7% vs PY**

Accumulated use of patches



Revenues rolling 12-months (kSEK)





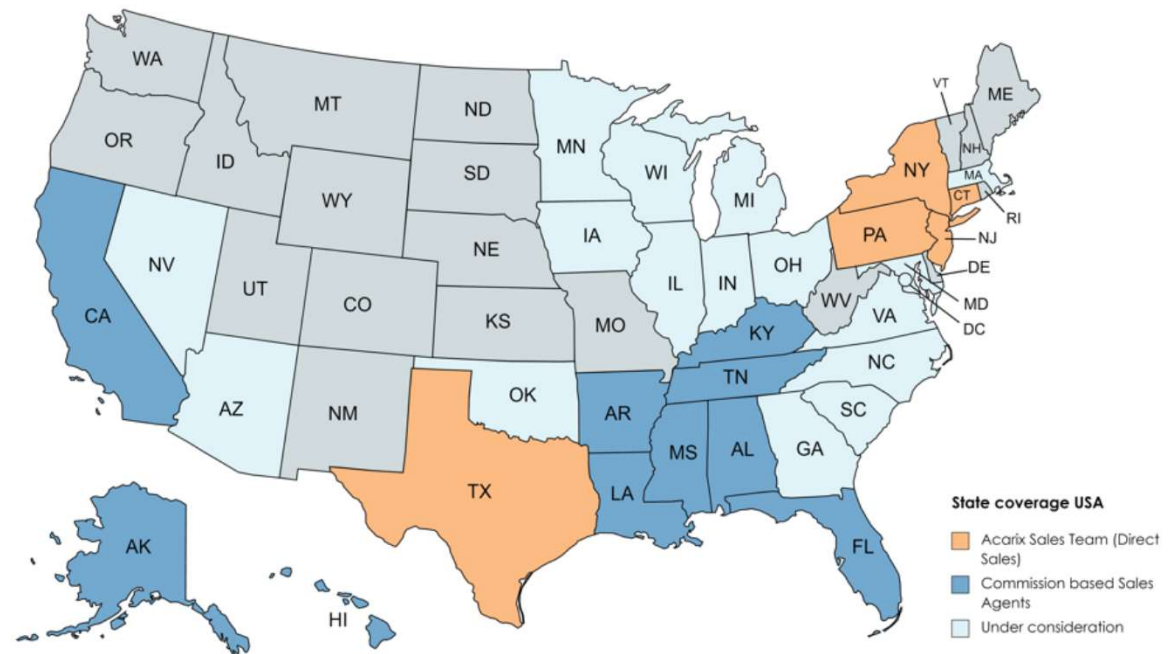
# Establishing and securing favorable reimbursement levels, paying up to USD 300 per CADScor®System assessment



# High interest among physicians, as we are building a strong US footprint

## Focus on key states with hybrid sales strategy covering 52% of US Chest Pain market

- **Coverage:**
  - Acarix Sales Team covering 28% of market
  - Commission-based Sales Agents covering 24% of market
  - Additional states under consideration reaching 82% of market
- **Sales Channels:** Clinics, Hospitals, IDNs, VA with sales cycles from 2-24 months
- **Targets:** Cardiologists (30,000), Emergency Departments (6,000), Urgent Care (9,600), Primary Care (120,000)



Created with mapchart.net

The Acarix logo features the word "acarix" in a dark blue, lowercase sans-serif font. To the right of the text is a stylized heart icon composed of two overlapping loops, one in red and one in purple.

**AMERICAN  
COLLEGE of  
CARDIOLOGY®**

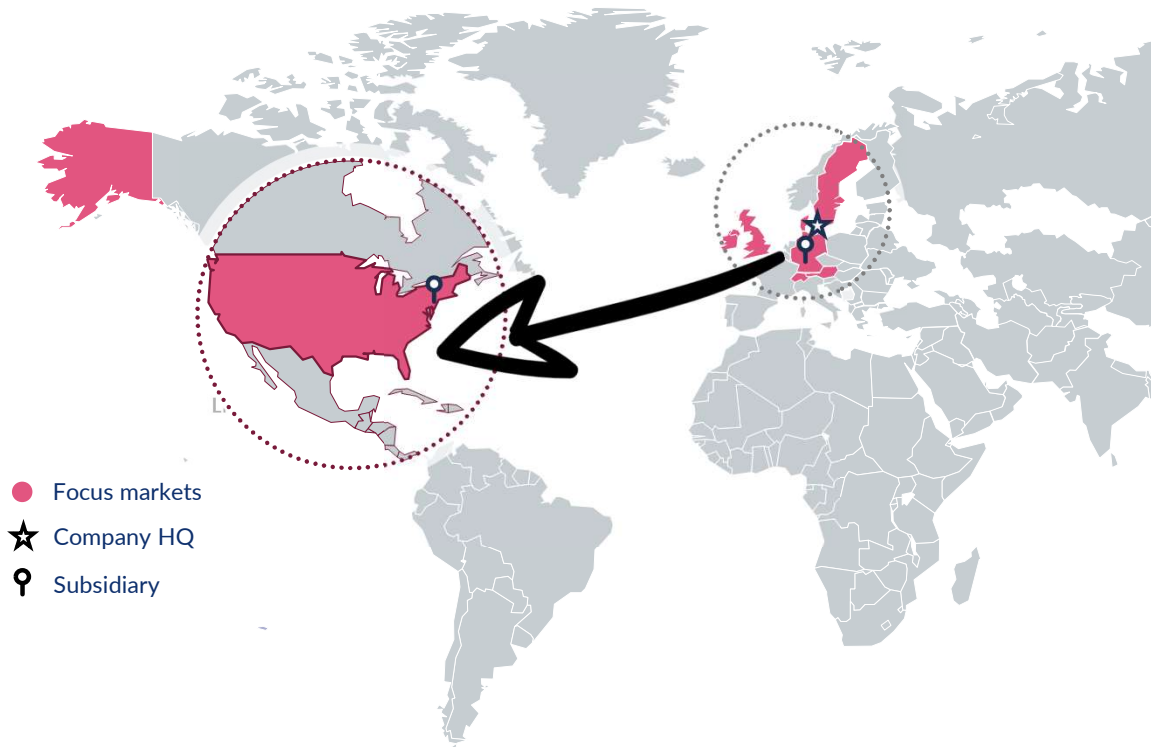
## **Acarix and American College of Cardiology (ACC) announce strategic collaboration**

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In September 2022, Acarix and ACC entered a strategic collaboration agreement to help accelerate the roll-out of products in the US market.

ACC will provide clinical and scientific expertise to Acarix and develop a clinical framework (guideline-type) for use of CADScor® System in upstream cardiac diagnostics.

# Going forward - Full focus on US market with key building blocks now in place



- Estimated active market value >USD 10 billion.
- Currently, 200 CADScor® Systems in markets and 20,000 assessments completed
- Increased FOCUS on US expansion – ideal timing with FDA De Novo clearance and CPT III Code, effective July 2022
- Positive momentum and market feedback leads to **Full Focus on US** market going forward, leading to approx. 25 MSEK in reduced OPEX in 2023.



# Acarix commercial focus is now on creating value in large US healthcare market



**18 million patients per year with chest pain – that want immediate results**

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Acarix offers a unique solution that quickly rules out CAD, addressing a large market of tens of thousands of clinics



**FDA De Novo clearance and CPT III reimbursement code for CADScor® System**

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Acarix offers a solution with attractive coverage and ROI for healthcare providers – with minimal cost to patient



**AMERICAN COLLEGE of CARDIOLOGY**

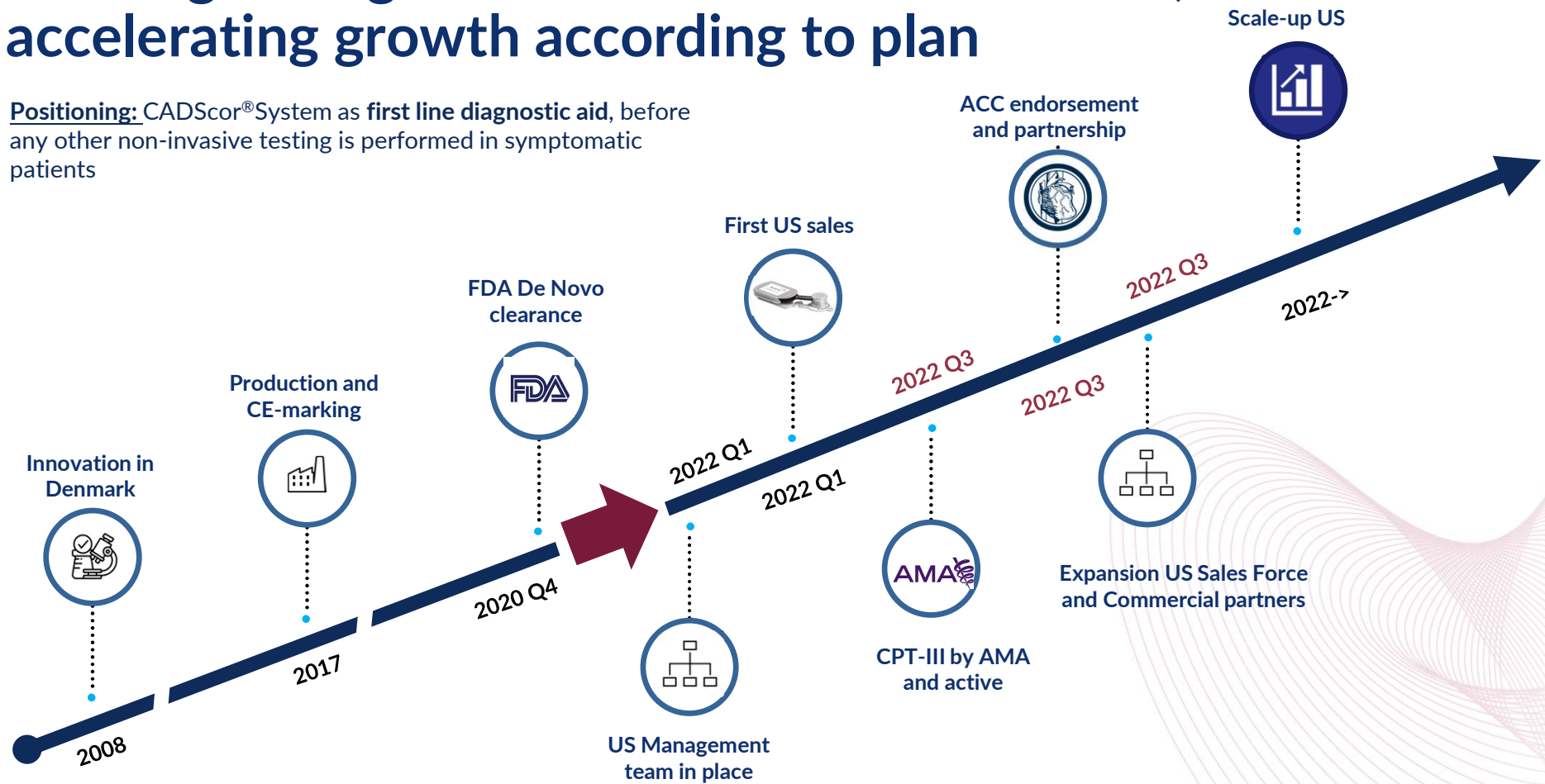
**New Chest Pain Guidelines and endorsement from clinical leaders**

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Acarix has support from the ACC and the solution fits well within clinical guidelines for chest pain management

# Building strong commercial momentum in US, accelerating growth according to plan

**Positioning:** CADScor® System as first line diagnostic aid, before any other non-invasive testing is performed in symptomatic patients



# Acarix addresses stable chest pain, one of the most common reasons for consulting a physician

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Every day, approx. 1 million patients globally consult emergency or primary care for chest pain related symptoms, with potential risk of Coronary Artery Disease (CAD)<sup>1</sup>

20-40% of the population experience chest pain at some point during their life time<sup>2-5</sup>

9 out of 10 patients that consult healthcare with stable chest pains do not have CAD. Many patients examined via multiple invasive, expensive and burdensome procedures only to find that they do not have CAD

Improved stratification of patients with stable chest pain is needed

Ref: 1. Ruigómez A et al. Chest pain in general practice: incidence, comorbidity and mortality. Family Practice, Volume 23, Issue 2, April 2006, Pages 167-174, <https://doi.org/10.1093/fampra/cmi124>. . 2. Wong WM, Lam KF, Cheng C et al. Population based study of noncardiac chest pain in southern Chinese: prevalence, psychosocial factors and health care utilization. World J Gastroenterol 2004; 10: 707-712. . 3. Eslick GD, Jones MP, Talley NJ. Non-cardiac chest pain: prevalence, risk factors, impact and consulting—a population-based study. Aliment Pharmacol Ther 2003; 17: 1115-1124. 4. Brattberg G, Parker MG, Thorslund M. A longitudinal study of pain: reported pain from middle age to old age. Clin J Pain 1997; 13: 144-149. 5. Locke GR, 3rd, Talley NJ, Fett SL, Zinsmeister AR, Melton LJ, 3rd. Prevalence and clinical spectrum of gastroesophageal reflux: a population-based study in Olmsted County, Minnesota. Gastroenterology 1997; 112: 1448-1456.



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



# CADScor® System for rapid cardiac assessment using AI and acoustics

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- Rule-out of CAD in just **10 minutes** with **96.2% certainty**<sup>7</sup>
- Based on over **15 years** of R&D, and covered by **45 patents**. **CE-marked** and **FDA De Novo** cleared
- Used on more than **20,000 patients**

The **CADScor® System** is a point-of-care diagnostic aid that uses highly sensitive acoustics and advanced AI to analyze patient's coronary blood flow. In just 10 minutes, it calculates a patient-specific CAD-score, indicating patient's risk of coronary stenosis as low or elevated..

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.





# Attractive business model with US reimbursement coverage

- Attractive business model with device and innovative single-use patches generating **>75% gross margin**
- **Life-Time Value (LTV)** of each device in the US market estimated at **\$75,000**
- CADScor®System approved for **US reimbursement** through own CPT III code, effective July 2022



A radiation-free and non-invasive test providing immediate results to patients and health care providers

# Illustrative business case – a US Cardiology Clinic



## Typical private cardiology clinic



General patient admissions per year to cardiology clinic	10,000
Applicable patients for CADScor®System, per year	1,000 (10%)
<u>3-year business case:</u>	
Revenues from billable procedures (average USD 170 per patient)	USD 510,000
Cost of Acarix device and patches	USD 247,500
<b>Gross Profit for clinic (3 years)</b>	<b>USD 262,500</b>

## Case for Acarix



Sale of 3 x CADScor®System	USD 22,500
Sale of disposable patches over 3 years (3,000 patients) @ \$75	USD 225,500
<u>3-year business case:</u>	
Total revenues for Acarix	USD 247,500
Average Gross Margin	80%
<b>Gross Profit Acarix (3 years)</b>	<b>USD 198,000</b>

## Win/Win split of net revenue over 3 years (Clinic and Acarix)



## And enabled:

1. Quick responses to patient and physician
2. Solution to off-load the waiting room volume and time
3. Avoided unnecessary diagnostic procedures

# Dr. Marc Bernstein MD, FACC, FCCP, FSCAI

## New Orleans, Louisiana



Board Certified Internal Medicine  
Cardiology & Interventional Cardiology

# Strategic Focus and 2024 Guidance



## Focus and strategy:

- **Full FOCUS on US** commercial execution, with direct sales team and commission-based commercial partners
- **Maximize US reimbursement** amounts to drive long-term growth
- **Reduced focus in EU during 2023**, and pending reimbursement approvals
- Continuous **product development** and involvement of **high performing team**

## 2024 Market Guidance:

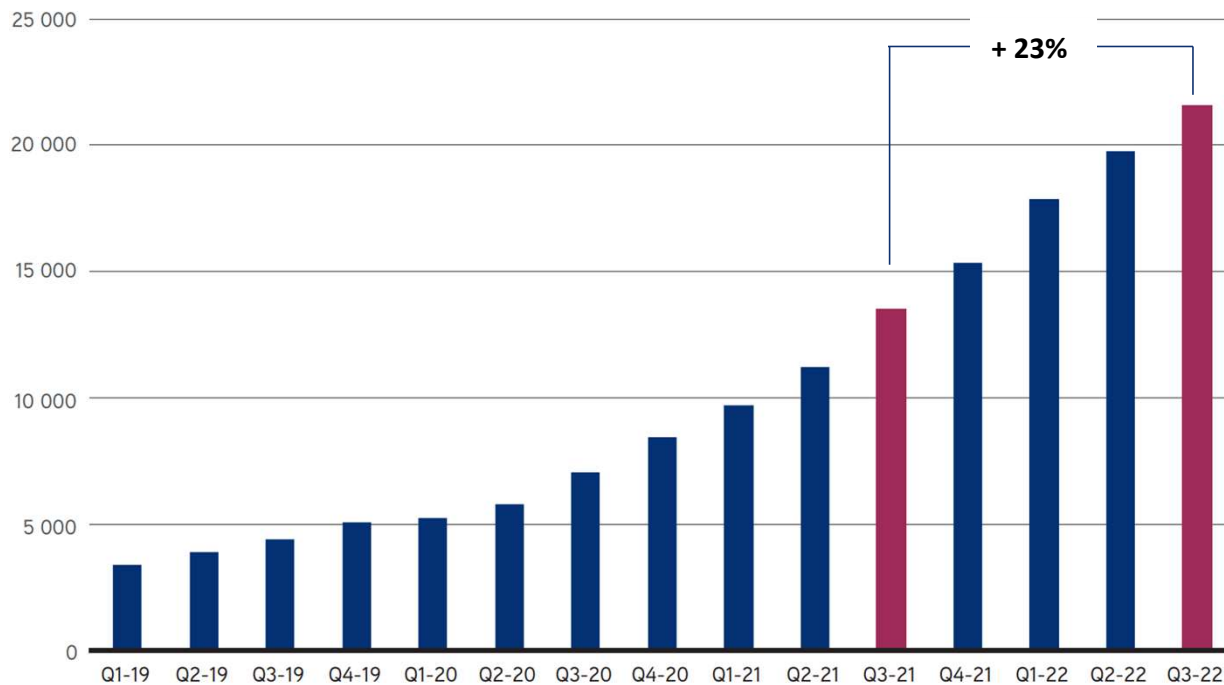
- Installed base of **3,000 CADScor® Systems**, with focus on US market
- Target revenue **>SEK 200 million** with recurring consumables sales
- Gross margin **>80%**



# Single-use Patch utilization continues to increase



## Accumulated use of patches



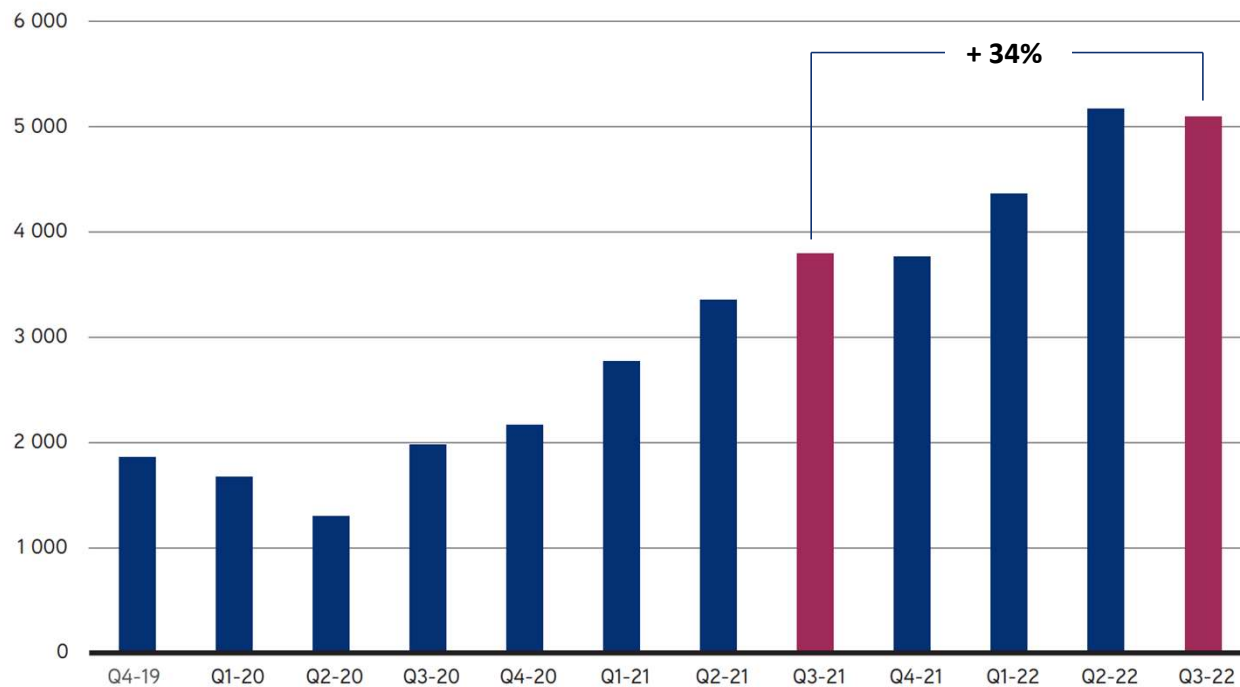
## Cumulative patch sales

- Cumulative patch sales 21,600 patches, +8,100 vs Q3 2021
- During first nine months 2022, sales of patches 6,250 (5,100 PY), +23% vs PY

# YTD Revenues Continue to Increase



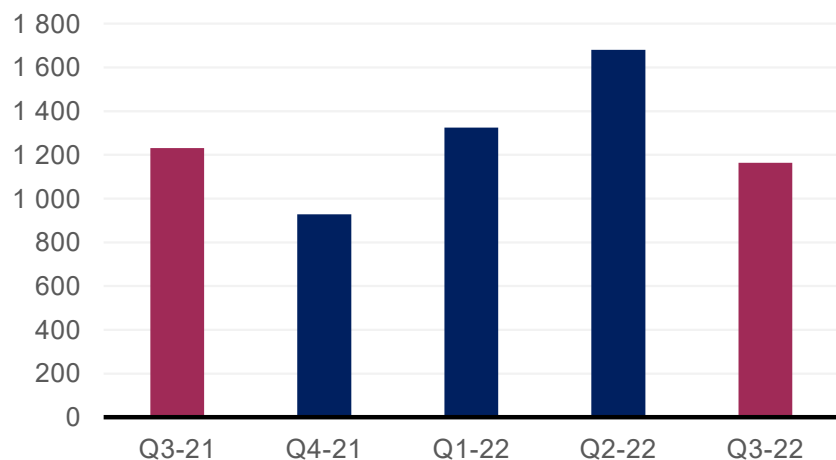
Revenues rolling 12-months (kSEK)



## Rolling 12-months revenue

- Increase from SEK 3.8M in Q3 2021 to SEK 5.1M in Q3 2022
- Increase in revenue due to increased:
  - sales of patches
  - average price of CADScor®Systems and disposable patches

# US and patch sales driving increased Gross Margin

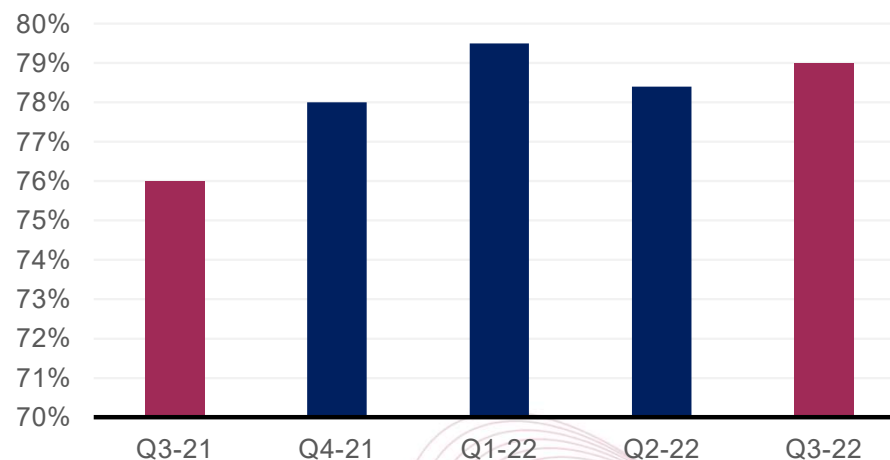


## Revenue Q3 (kSEK)

- SEK 1,164k (1,231 PY), -5% vs Q3 PY
- DACH Region SEK 889k (1,217 PY), -27% vs Q3 PY
- US revenue SEK 225k

## CADScor®System and patches Q3

- 14 (18 PY) CADScor®Systems, -22% vs Q3 PY
- 1,812 (2,319 PY) patches, -22% vs Q3 PY

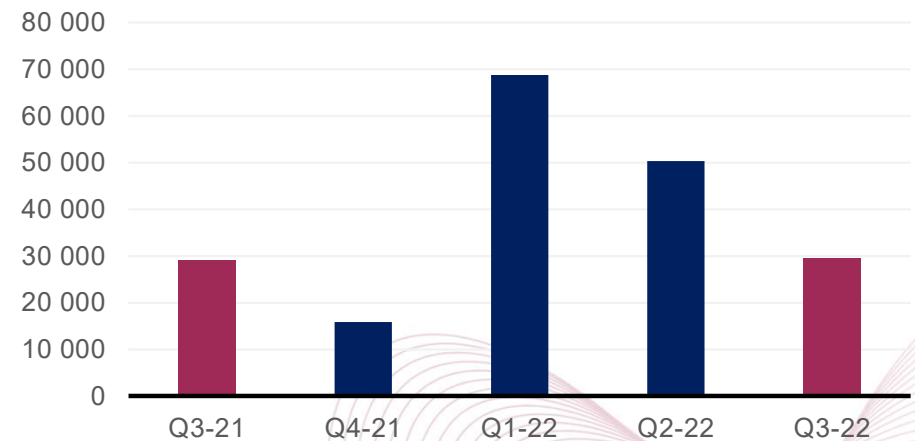
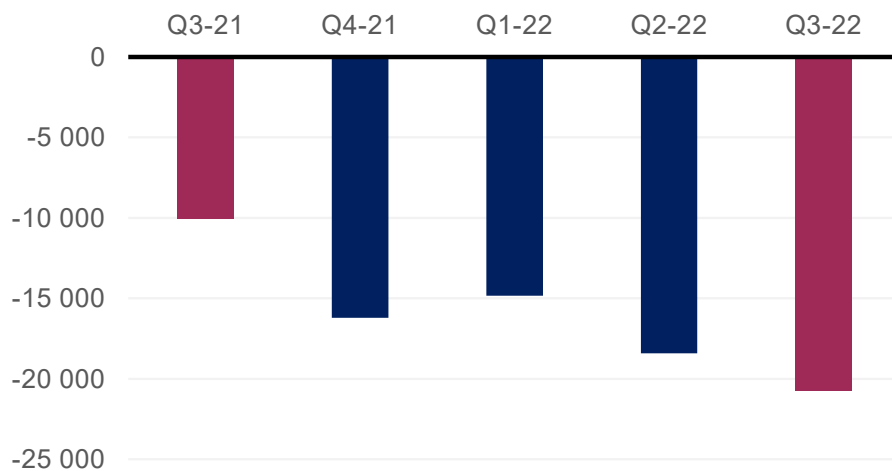


## Gross margin Q3 (%)

- Gross margin 79%, +3% units vs Q3 PY
- US Gross Margin 83.9%
- DE Gross margin 77.9% vs 71.6% PY

Increased gross margin explained by sales in US and increased sales of patches

# Investments and cash position according to plan



## EBIT Q3 (kSEK)

- EBIT SEK -20,732k (-10,702 PY), an increase in spend by 94% vs PY
- Increase in operational costs related to building US market and scaling operation to meet increased sales volumes

## Cash Position Q3 (kSEK)

- Cash and cash equivalents SEK 29,408k vs SEK 28,972k Q3 PY
- During Q1 2022 a Rights Issue was completed and generated SEK 69.3mio



# Key Summary Points

1. **Major milestones** achieved in 3Q
2. **Momentum in US increasing**, based on high interest among health care professionals and ongoing patient evaluations
3. However, **slower uptake in US sales during 3Q** due to reimbursement process
4. **Cost savings** during 2023 due to reduced investment in Europe
5. **Focus on the US** market to drive future growth of Acarix, profitability and achieving 2024 guidance



# Q & A



acarix

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