Francesco Faita

*medical devices for early detection of cardiovascular risk*
THE PROBLEM

CARDIOVASCULAR DISEASE
- Kills more than accidents, AIDS and cancer together
- Is one of the main cause driving healthcare costs

**Don’t Rely on Risk Factors!**

Jim Fixx
Famous US Marathoner
- Not Overweight
- Very Fit
- Non-Smoker

Died of a Massive Heart Attack at Age 52

Winston Churchill
Prime Minister during WWII
- Overweight
- Not Fit
- Heavy Smoker

Lived to Age 89

**classical risk factors** give us information **too late:**
you are **not enough** to prevent **effectively** CV disease!
Early and customized assessment of cardiovascular risk

Software Device

Ultrasound image analysis

Hardware Device

Non-invasive sensor

PRODUCT 1/2
FMD Studio
Carotid Studio

PRODUCT 3
Pulse Wave Studio

ARTERIAL STIFFNESS
ENDOTHELIAL FUNCTION

ARDERIAL THICKNESS
Elisabetta Bianchini
M.Eng
VP R&D, Regulations

Vincenzo Gemignani
M.Eng
CEO

Francesco Faita
M.Eng
VP R&D, Product Development

Edoardo Pagnini
Marketing & Sales

Rosa Sicari,
MD, PhD

Lorenzo Ghiadoni
MD, PhD

THE TEAM

MANAGEMENT

SCIENTIFIC ADVISORY BOARD

European Society of Echocardiography
and European Society of Cardiology

American Heart Association
Current Customers

UniversitätsSpital Zürich

Charité Universitätsmedizin Berlin

Unilever

Novartis

Current Partners

Vega

SMT medical

Università di Pisa

Smart Medical
CASH GENERATED FROM CUSTOMERS

- First invoice (July 2011)
- First big customer (agreement June 2011)
- Incomes grow fast: 2011 -> 2012 +90%  
  2013 -> 2014 +200%

<table>
<thead>
<tr>
<th>Year</th>
<th>Incomes</th>
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<tbody>
<tr>
<td>2011</td>
<td>€45,000</td>
</tr>
<tr>
<td>2012</td>
<td>€85,000</td>
</tr>
<tr>
<td>2013</td>
<td>€100,000</td>
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<tr>
<td>Feb 2014 – (forecast)</td>
<td>€120,000 (300,000)</td>
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</table>

Research contract (100 k€, 1 research position)
• Commercial network with International Distributors
• Industrial partnership

• Clinical studies
• Guidelines and reference values

• Quality & Certifications
• Customer’s support & training
Quipus (which means “knots”) were recording devices used in the Inca Empire Andean region to track important events and time and to predict the future.
THANK YOU
FOR YOUR ATTENTION

Francesco Faita
faita@quipu.eu
http://www.quipu.eu
early detection of your cardiovascular risk
COMPETITIVE ADVANTAGES

- Easy to use
- Competitive pricing
- New technology
- Integration
- High reliability and accuracy
- Exercise analysis

Most of QUIPU competitors are single-product based companies addressing international market.

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<tr>
<th></th>
<th>Quipu</th>
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<tbody>
<tr>
<td>Precision</td>
<td>🌟🌟🌟</td>
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<td>🌟🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
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<tr>
<td>Real-Time</td>
<td>🌟🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟🌟</td>
<td>🌟🌟🌟</td>
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<tr>
<td>Easy-to-use</td>
<td>🌟🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
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<td>Integration</td>
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<tr>
<td>Cost</td>
<td>🌟🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟🌟</td>
<td>🌟🌟🌟</td>
<td>🌟🌟🌟</td>
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🌟🌟🌟 = excellent  🌟🌟 = sufficient  🌟 = marginal
NUMBERS:
• 17.796 pharmacies in IT
• 141.582 pharmacies in EU

CULTURAL TREND:
• Developing Pharmacy-Based POCT (Point of Care) Services
  (example: in Italy Dlgs 156/2009)

MARKET SIZE:
• Point of Care Diagnostic: US$ 13.7 B in 2010 worldwide, rose by 7%, driven by demand for cardiovascular testing products
  (data source: Espicom Business Intelligence, UK)
PULSE WAVE PHARMACY: self-measurement tool (DEVICE + SENSORS) for wide population measurement of local carotid elasticity
**Completed**
- Italian multicenter trial for FMD reproducibility evaluation (7 units, 150 subjects)
- International multicenter trial for IMT “reference values” definition (24 units, 24.871 subjects)
- Arterial elasticity evaluation in atherosclerotic rabbits
- Heart failure in pig model
- CArE: reproducibility and physiology of carotid distensibility in exercise (60 subjects)
- FMD/IMT/DISTENSIBILITY: agreement with gold-standard techniques

**To be completed**
- International multicenter trial for carotid distensibility “reference values” definition (24 units, 24.871 subjects)
- Electrophysiology lab: cardiac activity timing assessment for pace-maker setup
- Mechanical alteration in vascular stunting sheep

**Future**
- Cardiac alteration in different phases of exercise (sport medicine)
- Cardiac alteration in sleep disorder
- PWV Studio agreement with gold-standard techniques
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<tbody>
<tr>
<td>FMD/Carotid Studio volume</td>
<td>5</td>
<td>15</td>
<td>30</td>
<td>60</td>
<td>90</td>
<td>150</td>
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<tr>
<td>Pulse Wave Studio volume</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>50</td>
<td>100</td>
<td>200</td>
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<tr>
<td>Pulse Wave Pharmacy volume</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>200</td>
<td>1000</td>
<td>5000</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>5</td>
<td>15</td>
<td>35</td>
<td>310</td>
<td>1190</td>
<td>5350</td>
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<tr>
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<td>€8.000</td>
<td>€9.000</td>
<td>€9.000</td>
<td>€12.000</td>
<td>€12.000</td>
<td>€15.000</td>
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<tr>
<td>Pulse Wave Studio price</td>
<td>€-</td>
<td>€-</td>
<td>€10.000</td>
<td>€10.000</td>
<td>€12.000</td>
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<tr>
<td>Pulse Wave Pharmacy price</td>
<td>€-</td>
<td>€-</td>
<td>€800</td>
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<tbody>
<tr>
<td>EMD/Carotid Studio revenue</td>
<td>€40.000</td>
<td>€135.000</td>
<td>€270.000</td>
<td>€720.000</td>
<td>€1.080.000</td>
<td>€2.250.000</td>
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<td>R&amp;D Engineer</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>Commercial Engineer</td>
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<td>1</td>
<td>50.000</td>
<td>500.000</td>
<td>1.200.000</td>
<td>2.400.000</td>
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<tr>
<td>Production/service Technician</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>800.000</td>
<td>4.000.000</td>
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<td>Accountant/Secretary</td>
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<td>0,4</td>
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<td><strong>TOTAL</strong></td>
<td>€40.000</td>
<td>€135.000</td>
<td>€320.000</td>
<td>€1.380.000</td>
<td>€3.080.000</td>
<td>€8.650.000</td>
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BUSINESS FORECAST AND MILESTONES

**FORECAST**

**REVENUE LEVELS**

- 2012
- 2013
- 2014
- 2015
- 2016

**Needed equity**

1. € 750k for the first year (R&D and certification process and to get the first customers)

1. € 750k for the second year (to strongly support the promotion)

Gross margin = 55%

**MILESTONES**

- Clin trials
- P1 EU sales
- CE P1
- FDA P1
- P2 EU sales
- CE P2
- FDA P2/3
- P3 EU sales
- CE P3
- P1, P2/3 worldwide sales
- P1, P2/3 worldwide sales

P1 = product 1

P2/3 = product 2 and 3

CE = European Conformity approval

FDA = Food & Drug Administration approval
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<td>Beginning CASH</td>
<td>€-</td>
<td>€397.475</td>
<td>€527.475</td>
<td>€239.175</td>
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<td>Cash In</td>
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<td>Boot strap</td>
<td>€20.000</td>
<td>€-</td>
<td>€-</td>
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<td>Friends/family</td>
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<td>€-</td>
<td>€-</td>
<td>€-</td>
<td>€-</td>
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<td>Other</td>
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<td>€-</td>
<td>€-</td>
<td>€-</td>
<td>€-</td>
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<td>Systems 1 revenue</td>
<td>€135.000</td>
<td>€270.000</td>
<td>€720.000</td>
<td>€1.080.000</td>
<td>€2.250.000</td>
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<tr>
<td>Systems 2 revenue</td>
<td>€-</td>
<td>€50.000</td>
<td>€500.000</td>
<td>€1.200.000</td>
<td>€2.400.000</td>
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<td>Systems 3 revenue</td>
<td>€-</td>
<td>€-</td>
<td>€160.000</td>
<td>€800.000</td>
<td>€4.000.000</td>
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<tr>
<td>Total Cash IN</td>
<td>€905.000</td>
<td>€1.070.000</td>
<td>€1.380.000</td>
<td>€3.080.000</td>
<td>€8.650.000</td>
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<tr>
<td>Cash out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>COGS - Systems 1</td>
<td>€40.500</td>
<td>€81.000</td>
<td>€216.000</td>
<td>€324.000</td>
<td>€675.000</td>
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<tr>
<td>COGS - Systems 2</td>
<td>€-</td>
<td>€22.500</td>
<td>€225.000</td>
<td>€540.000</td>
<td>€1.080.000</td>
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<tr>
<td>COGS - Systems 3</td>
<td>€-</td>
<td>€-</td>
<td>€72.000</td>
<td>€360.000</td>
<td>€1.800.000</td>
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<tr>
<td>Other (ex Outsourcing)</td>
<td>€6.750</td>
<td>€16.000</td>
<td>€69.000</td>
<td>€154.000</td>
<td>€432.500</td>
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<tr>
<td>Total COGS</td>
<td>€47.250</td>
<td>€119.500</td>
<td>€582.000</td>
<td>€1.378.000</td>
<td>€3.987.500</td>
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<td>Expense items</td>
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<td>Sales</td>
<td>€58.750</td>
<td>€120.000</td>
<td>€173.000</td>
<td>€310.000</td>
<td>€692.500</td>
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</table>
Customers
MDs
• First phase: researchers and innovators
• Second phase: clinical market (i.e. clinical specialists and clinical practice)

Countries
• EU
• USA
• World

Pricing
Products sold separately
• Product 1 (SW): $10K
• Product 2 (SW+HD): $12K
• Product 3(SW+HD): $8K

Integrated solution
10% discount
ACTIVITIES

- Management
- R&D
- Services & Sales
- Technical development

- Commercial network with International Distributors
  - Industrial partnership
- Clinical studies
  - Guidelines and reference values
  - Pre-clinical experimentations
- Training
  - Core lab reading
  - Customer’s support
- CE
- Prototypes
- CV Suite (new features, bug fixes, beta tester, user feedback)
Several scientific studies show the value of these early parameters in improving cardiovascular diagnosis.

Example:

*Which markers of subclinical organ damage to measure in individuals with high normal blood pressure?*

Thomas Sehestedt, Jørgen Jeppesen, Tine W. Hansen, Susanne Rasmussen, Kristian Wachtell, Hans Ibsen, Christian Torp-Pedersen, and Michael H. Olsen

*Journal of Hypertension* 2009, 27:1165–1171

**Methods:**

- **early parameters** were measured in 1968 individuals, aged 40 to 70 years, with normal blood pressure and without manifest cardiovascular disease or medications
- Follow-up of **12.8 years**

**Results:**

- In healthy individuals with high normal blood pressure, measuring at least two of early parameters was sufficient to **significantly improve risk prediction**.