

Francesco Faita

medical devices for early detection of cardiovascular risk





#### **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





<u>classical risk factors</u> give us information <u>too late</u>: they are <u>not enough</u> to prevent <u>effectively</u> CV disease!





PRODUCT 1/2
FMD Studio
Carotid Studio

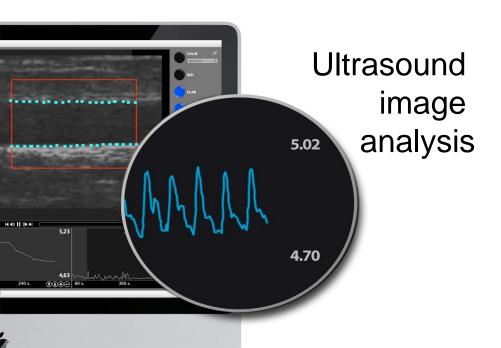
ARTERIAL THICKNESS

ENDOTHELIAL FUNCION

ARTERIAL STIFFNESS

PRODUCT 3
Pulse Wave
Studio

## Software Device



## Hardware Device

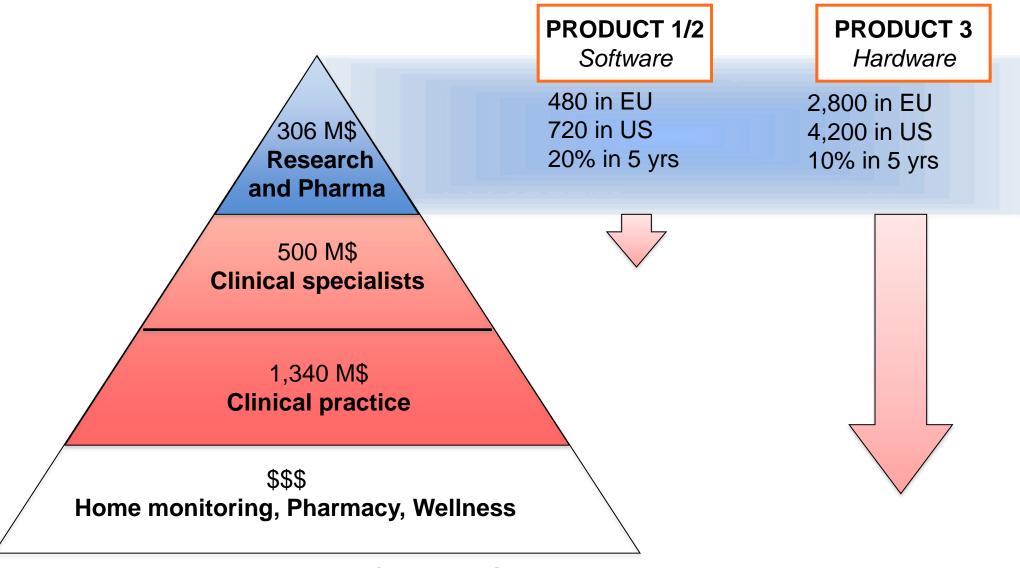
Non-invasive sensor



Early and customized assessment of cardiovascular



## **GLOBAL MARKET OPPORTUNITY**



Font: RB Milestone Group, LLC





#### **MANAGEMENT**



Elisabetta Bianchini M.Eng VP R&D, Regulations



Vincenzo Gemignani M.Eng



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



Edoardo Pagnini

Marketing & Sales

### **SCIENTIFIC ADVISORY BOARD**







Rosa Sicari, MD, PhD





American Heart Association





## PARTNERS / CUSTOMERS

#### **Current Customers**



## Zürich













### **Current Partners**













## **FINANCIAL & RESOURCES**

#### **CASH GENERATED FROM CUSTOMERS**

■First invoice (July 2011)

**■**First big customer (agreement June 2011)

■Incomes grow fasting 2011 -> 2012 +90%

2013 -> 2014 **+200**%





	€		
Incomes 2011	45.000		
Incomes 2012	85.000		
Incomes 2013	100.000		
Incomes Feb 2014 – (Forecast)	120.000 (300.000)		



**Research contract (100 k€, 1 research position)** 









Industrial partnership





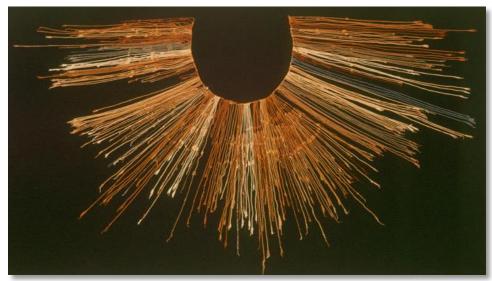
- Clinical studies
- Guidelines and reference values





- 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

	Quipu	MIA	AtCor	Alam	DiaTec
Precision	© © ©	@@	<b>999</b>	@@	@@
Real-Time	©©©	8	©©©	©©©	©©©
Easy-to-use	<b>©</b> ©©	@@	8	8	8
Integration	<b>©</b> ©©	@@	8	8	8
Cost	<b>@@</b>	8	8	@@	<b>©©©</b>

©©© = excellent

⊕⊕ = sufficient

⊗ = marginal

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





#### **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)



## THE NEW PORTFOLIO

PULSE WAVE PHARMACY: self-measurement tool (DEVICE + SENSORS) for wide population measurement of local carotid elasticity









# -QUIPU

## **CLINICAL STUDIES**

## **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



## **PRODUCTS & HUMAN RESOURCES**

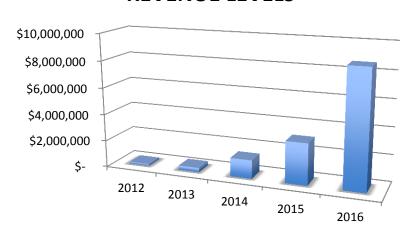
	2011	2012	2013	2014	2015	2016
FMD/Carotid Studio volume	5	15	30	60	90	150
TWD, carotta stadio volume	3	15	30	00	30	130
Pulse Wave Studio volume	0	0	5	50	100	200
Pulse Wave Pharmacy volume	0	0	0	200	1000	5000
raise wave rharmacy volume	J			200	1000	3000
TOTAL	5	15	35	310	1190	5350
FMD/Carotid Studio price	€8.000	€9.000	€9.000	€12.000	€12.000	€15.000
,						
Pulse Wave Studio price	€-	€-	€10.000	€10.000	€12.000	€12.000
Pulse Wave Pharmacy price	€-	€-		€800	€800	€800
ruise wave riiaimacy price	6-	€-		€800	€800	€800
EMD/Carotid Studio revenue	£40 000	€135.000	€270.000	€720.000	€1.080.000	€2.250.000
R&D Engineer	1	<del>€155.000</del> 2	2	3	4	5
Commercial Engineer	0,5	€1	€50.00∂	€500.00∂	€1.200.008	€2.400.00₺
Production/service Technician	0	€Ō	€1	€160.00₺	€800.00∂	€4.000.00∂
/6				3233.000		
Accountant/Secretary	0,2	0,4	0,4	1	2	2
TOTAL	€40.000	€ 135.000	€ 320.000	€ 1.380.000	€ 3.080.000	€ 8.650.000



## **BUSINESS FORECAST AND MILESTONES**

### FORECAST

#### REVENUE LEVELS



## **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

P1 = product 1 P2/3 = product 2 and 3 **CE= European Conformity approval** FDA = Food&Drug Administration approval

- **Clin trials**
- P1 EU sales
- CE<sub>P1</sub>

- 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





years

2012

2013

2014

2015

2016



Cash Flow statement	2012	2013	2014	2015	2016
Beginning CASH	€-	€397.475	€527.475	€239.175	€328.095
Cash In		00371170	33271173	02031270	6525.655
Equity	€750.000	€750.000	€-	€-	€-
Loan	€-	€-	€-	€-	€-
Boot strap	€20.000	€-	€-	€-	€-
Friends/family	€-	€-	€-	€-	€-
Other	€-	€-	€-	€-	€-
Systems 1 revenue	€135.000	€270.000	€720.000	€1.080.000	€2.250.000
Systems 2 revenue	€-	€50.000	€500.000	€1.200.000	€2.400.000
Systems 3 revenue	€-	€-	€160.000	€800.000	€4.000.000
Total Cash IN	€905.000	€1.070.000	€1.380.000	€3.080.000	€8.650.000
Cash out					
COGS - Systems 1	€40.500	€81.000	€216.000	€324.000	€675.000
COGS - Systems 2	€-	€22.500	€225.000	€540.000	€1.080.000
COGS - Systems 3	€-	€-	€72.000	€360.000	€1.800.000
Other (ex Outsourcing)	€6.750	€16.000	€69.000	€154.000	€432.500
Total COGS Expense items	€47.250	€119.500	€582.000	€1.378.000	€3.987.500
Sales	€58.750	€120.000	€173.000	€310.000	€692.500



#### **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**



- Commercial network with International Distributors
- Industrial partnership

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

- 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<sup>a,b</sup>, Jørgen Jeppesen<sup>a,c</sup>, Tine W. Hansen<sup>b,d</sup>, Susanne Rasmussen<sup>e</sup>, Kristian Wachtell<sup>f</sup>, Hans Ibsen<sup>g</sup>, Christian Torp-Pedersen<sup>c,h</sup> and Michael H. Olsen<sup>a,c</sup>
Journal of Hypertension 2009, 27:1165–1171



#### **Methods:**

<u>early parameters</u> were measured in <u>1968 individuals</u>, aged 40 to 70 years, with <u>normal</u> <u>blood pressure</u> and <u>without</u> manifest cardiovascular disease or medications

•follow-up of 12.8 years

#### **Results:**

■in <u>healthy individuals</u> with high normal blood pressure, measuring at least two of <u>early</u> <u>parameters</u> was sufficient to <u>significantly improve risk prediction</u>.