



**FIDELIO**



**WOMEN'S  
IRON DEFICIENCY  
MONITORING  
MADE EASY**

# FIDELIO IN A NUTSHELL

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## THE FIRST DIGITAL DIAGNOSTIC solution to manage WOMEN'S IRON DEFICIENCY

Combining a MULTIMARKERS IRON PANEL  
Point-of-Care Testing device and Digital Monitoring



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Iron deficiency  
impacts the life of  
**1B women**  
worldwide

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**No. 3**  
leading cause of  
DISABILITY

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**> 3B\$**  
total diagnostic  
Iron Deficiency  
Anemia market

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# A GLOBAL PUBLIC HEALTH PRIORITY

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**1 OUT OF 3 WOMEN** globally impacted by Iron Deficiency

Iron Deficiency is easy to treat, but **significantly underdiagnosed**



# >70% OF WOMEN UNAWARE UNTIL COMPLICATIONS OCCUR

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**3rd**

Global leading cause of **DISABILITY**  
in female population

**+20k €/y**

INCREASED COST/PATIENT  
due to complications



**Anemia**  
**Cardiac & Renal**  
**damage**

**+20%**

Maternal  
**MORTALITY** and risk  
of low-weight birth

# THE DIAGNOSIS RELIES ON A MULTIMARKERS BLOOD TEST

EARLY DIAGNOSIS AS THE KEY, BUT....



Symptoms

Diagnosis

CURRENT **CONVOLUTED** PATH  
TO GET A DIAGNOSIS



PHYSICIAN'S OFFICE



PHARMACY

CURRENT POINT-OF-CARE DEVICES  
GET **PARTIAL** INFORMATION



WOMEN **LACK**  
AWARENESS OF SYMPTOMS  
AND SUPPORT IN MONITORING

**6-8 MONTHS**

FROM THE ONSET OF THE IRON DEFICIENCY TO CONFIRMED DIAGNOSIS  
**FREQUENT RECURRENCES**

## THE FIRST DIGITAL DIAGNOSTIC solution to manage WOMEN'S IRON DEFICIENCY

Combining a **MULTIMARKERS** IRON PANEL  
Point-of-Care Testing device and **Digital Monitoring**

**QUANTITATIVE  
MULTIMARKERS  
IRON PANEL**

**RELIABLE  
POINT-OF-CARE  
SCREENING**



**DATA  
ANALYTICS  
DIGITAL Engagement**



PHYSICIAN'S OFFICE



PHARMACY



# VALUE PROPOSITION

Empowering all doctors and women to have the best iron deficiency care **before complications occur**



# MARKET OPPORTUNITY

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## WE ARE ADDRESSING **HIGH VOLUME AND FAST-GROWING** MARKETS

### IRON DEFICIENCY AND ANEMIA **DIAGNOSTICS**



GLOBAL MARKET VALUE **3,2B\$**  
EUROPE **1,5B\$**  
POINT-OF-CARE SEGMENT **700M\$**  
CAGR **7%**

### **WOMEN'S HEALTH** POINT-OF-CARE TESTING

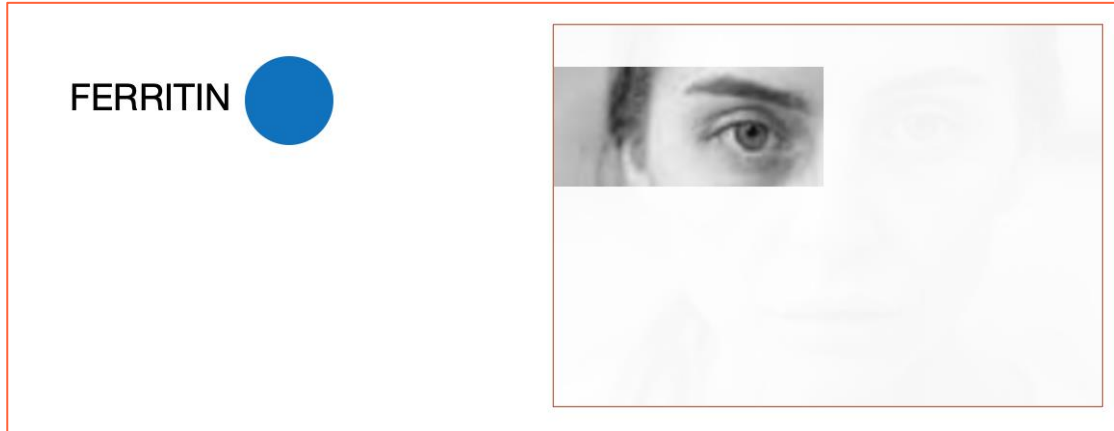


GLOBAL MARKET VALUE **4B\$**  
EUROPE **1,2B\$**  
CAGR **8%**

## **LOW BARRIERS TO MARKET ENTRY** in EU and USA



# OUR COMPETITORS



## FERRITIN TEST

Current point-of-care testing  
get a **PARTIAL** picture



# OUR UNIQUENESS



IRON MULTIMARKERS  
TEST



DIGITAL  
ENGAGEMENT

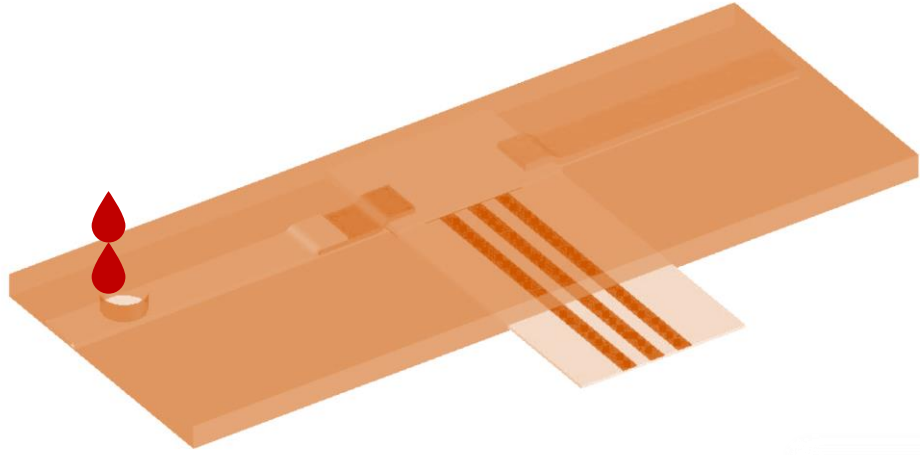
Fidelio aims to get a **FULL** picture  
and **DIGITAL** monitoring

# FIDELIO

# CORE TECHNOLOGY

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## A SINGLE USE **MULTIMARKERS** DIAGNOSTIC STRIP



The first **Iron Panel MultiMarkers** unit system coupled with **existing reader devices**

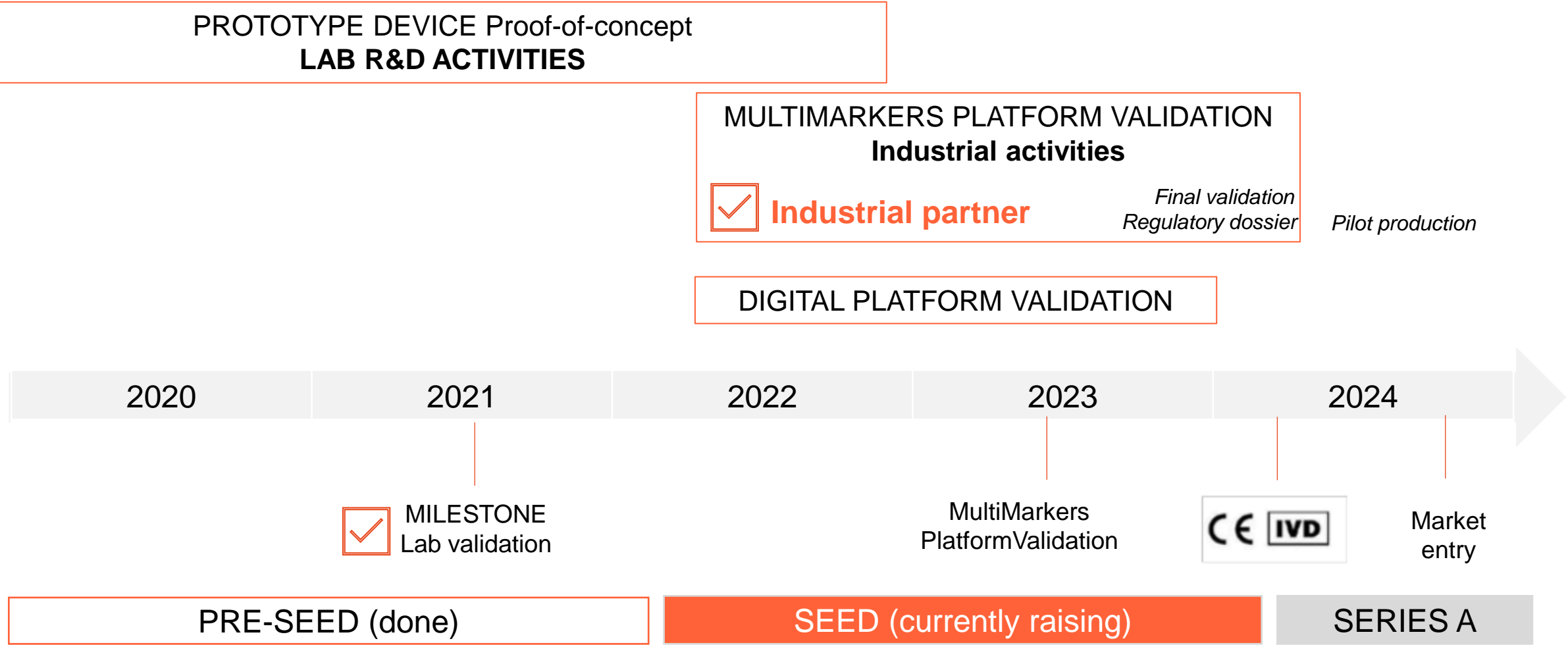


**Quantitative** data  
Digital integration capability  
Multiple Menu testing opportunity  
Timing to perform <10 min

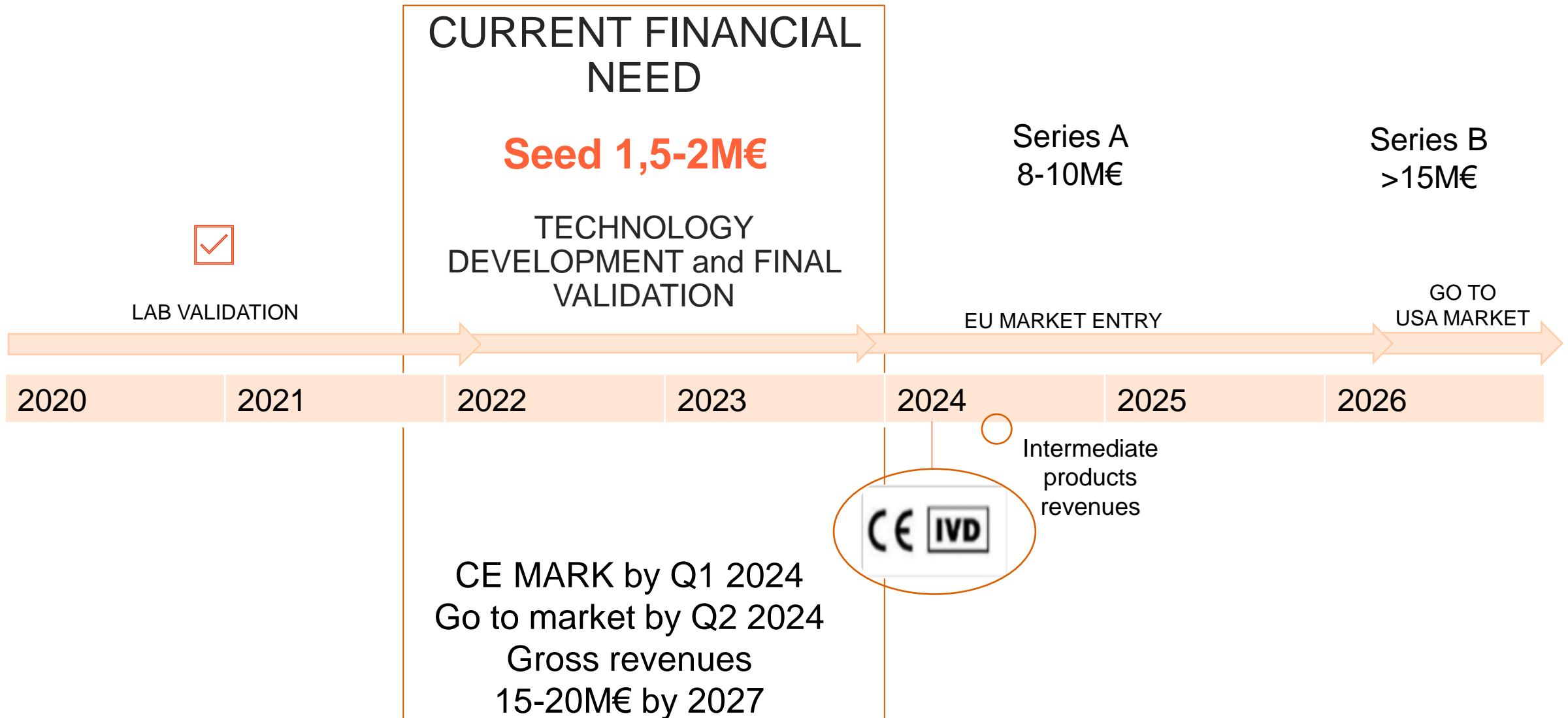


**2 Patents pending (PCT extension)**

# COMPANY DEVELOPMENT TIMELINE: FROM LAB TO MARKET



# ROADMAP AND FINANCING



# BUSINESS MODEL

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Women CAN take  
**FIDELIO** test



... and benefit from  
**DIGITAL** services



PHYSICIAN'S OFFICE

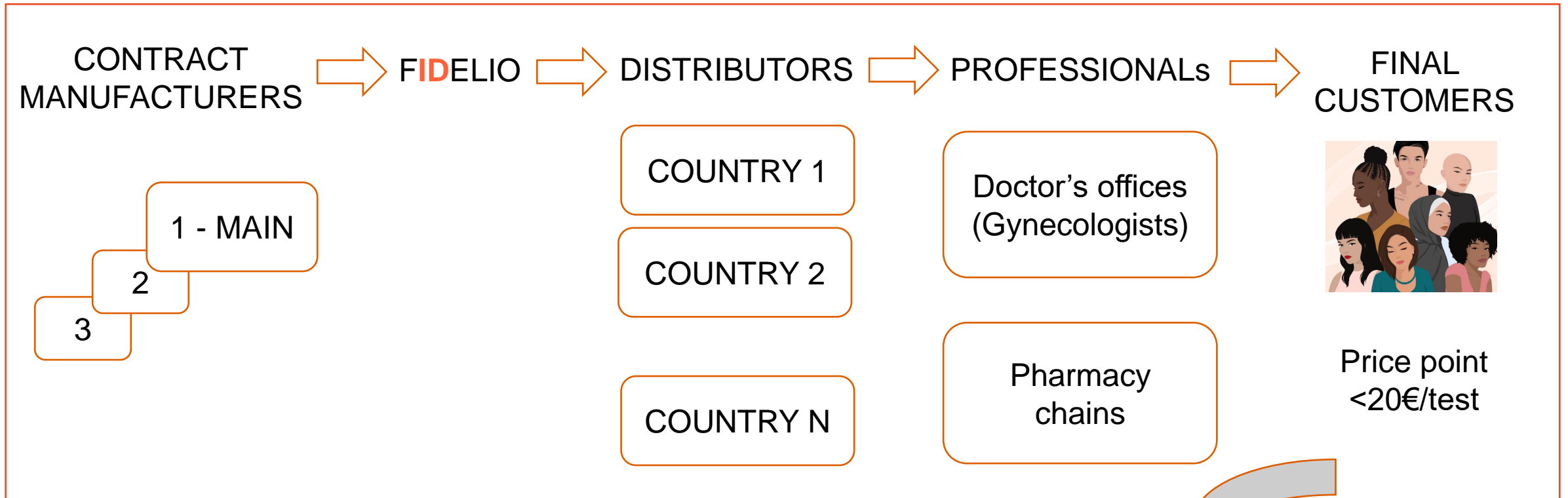


PHARMACY



**B2B2C and RAZOR BLADE BUSINESS MODEL:  
CONSUMABLES + DIGITAL SERVICES**

# WAY TO MARKET



Marketing strategy directed to:

Doctors:

- Key Opinion Leaders
- Specialized Medical Publications
- Medical conferences

Patients

- Patient associations
- influencers

Subscriptions model and homecare testing

# EXIT OPPORTUNITIES

## ATTRACTIVE ACQUISITION TARGET FOR INTERNATIONAL COMPANIES



FemTech



Medtech



Pharma



Food



# EXPERIENCED TEAM CONNECTING MULTIDISCIPLINARY AREAS

## Management TEAM



**S. ROGGERO**  
MD, PhD, Entrepreneur  
Founder, CEO



**F. ARDUINI**  
Chemist, PhD, Entrepreneur  
Chief Technical Officer



**F. CHIARA**  
Chemist, Pharmacologist  
Chief Scientific Officer



**C. BRIANZA**  
Eng., Serial Entrepreneur  
Chief Strategy Officer

## Advisory Board



**M. CAPPELLINI**  
MD, PROF, International KOL  
Senior Scientific Advisor



**M. ANTONUCCI**  
Eng, PhD, CVLab CEO  
Business Advisor



**T. RICHARDS**  
MD, Serial Entrepreneur  
Diagnostic Industry Advisor

## Partners





# CURRENT AND FUTURE APPLICATIONS



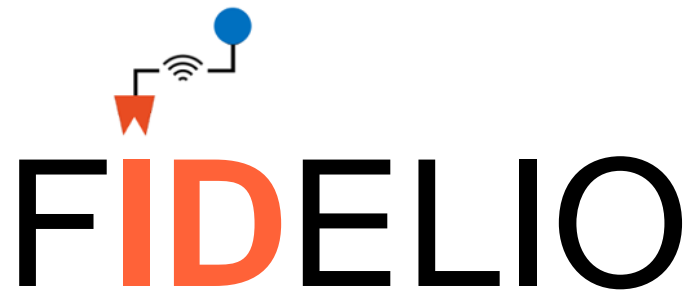
## WOMEN'S IRON DEFICIENCY



## CHRONIC DISEASES IRON DEFICIENCY



## CHILDREN'S IRON DEFICIENCY



**We look forward to change the course of the iron deficiency  
...one woman at a time**



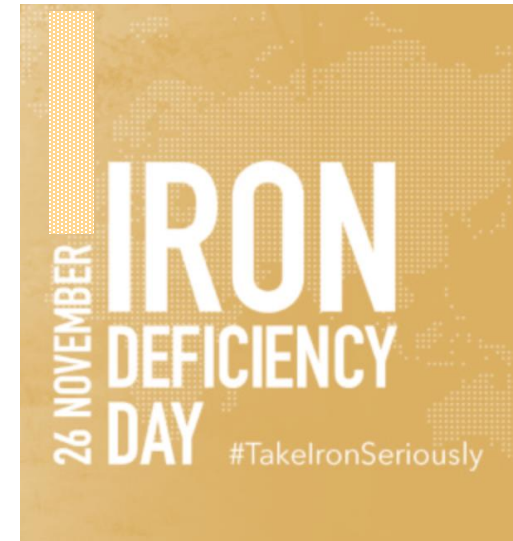
**Contact information**

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## BACK-UP SLIDES

# INVESTMENT DISTRIBUTION

## REQUIRED INVESTMENT

**SEED FINANCING  
ROUND: 1,5-2M €**



2021  
2022



## INVESTMENT DISTRIBUTION

40-45%  
R&D development – industrial activities  
10-15%  
digital platform development  
30-40%  
personnel  
5-10%  
IP  
5-10%  
G&A



## ACHIEVEMENTS

MultiMarkers platform validation

Digital platform  
development

Regulatory dossier



2023  
2024

# GOALS ACHIEVED

## BIOSENSORS THOROUGHLY TESTED IN LAB ON NORMAL AND PATHOLOGICAL HUMAN SAMPLES

- BIOSENSORS VALIDATED, compared to expensive central laboratory systems
  - ✓ IRON
  - ✓ TRANSFERRIN
  - ✓ FERRITIN

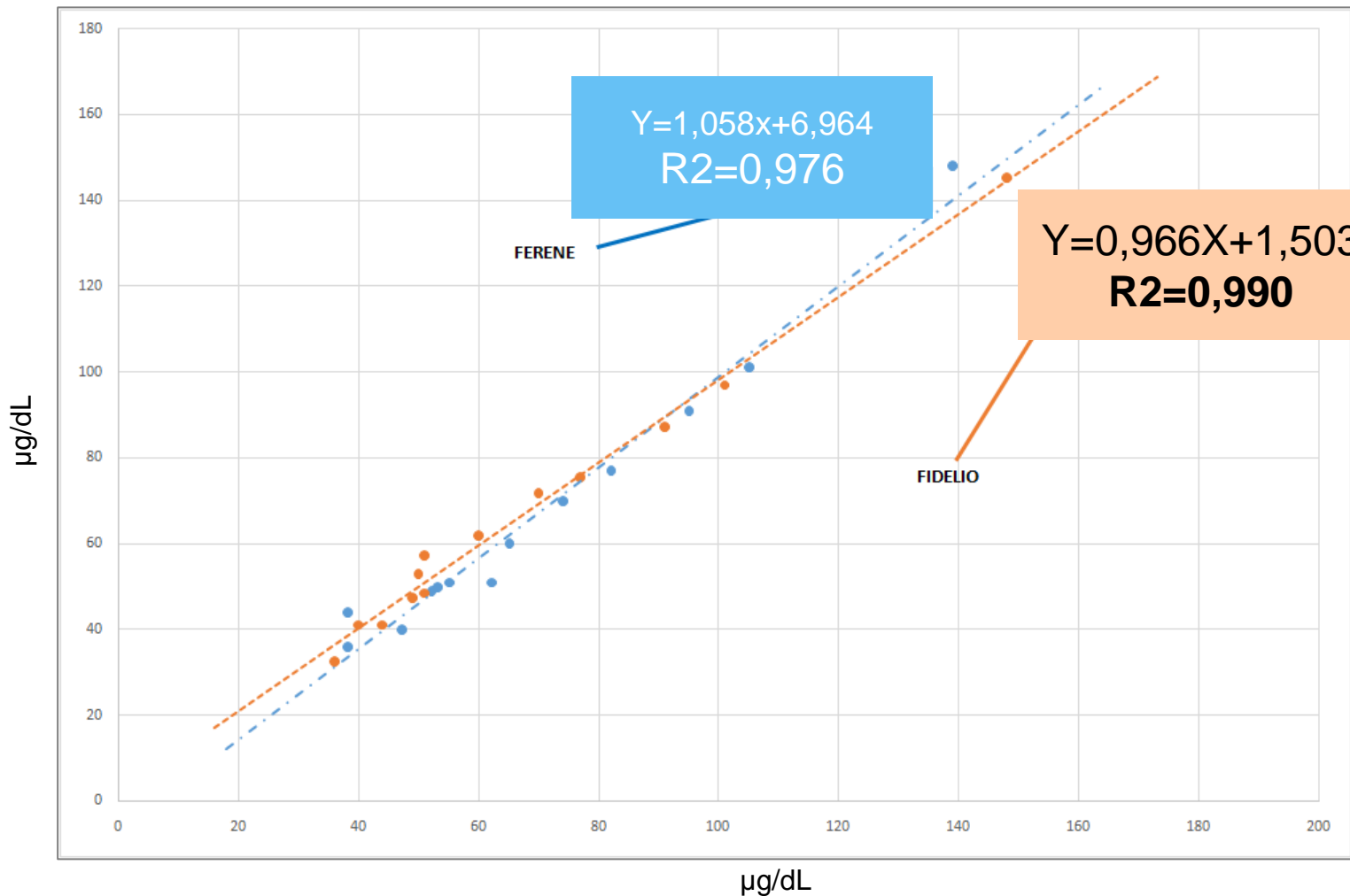
Transferrin saturation

- POINT-OF-CARE PLATFORM FEASIBILITY ASSESSED



# GOALS ACHIEVED: iron sensor validation on blood samples

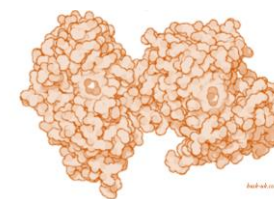
FIDELIO and FERENE



GOLD STANDARD

## IRON SENSOR VALIDATION VS STANDARD AND COLORIMETRIC METHOD (FERENE)

FIDELIO PERFORMANCE PARAMETERS  
Accuracy  $R^2 > 0,95$   
Limit of Quantification 10 µg/dL



## Main POC Companies acquisitions

Acquisition TARGET	POC area	Acquiring Company	Acquisition year	Price	Stage Revenues
Hemocue	Hb, glucose	Quest Diagnostics	2007	\$ 420M	\$ 90M
GeneWeave	Infectious diseases (multidrug resistance)	Roche	2015	\$ 425M	Pre-510(K)
iQuum	Infectious diseases	Roche	2014	\$ 430M	Pre-510(K)
Alere cardiac assets	Cardiac markers	Quidel	2017	\$ 440M	\$ 197M
Focus Dx	Infectious diseases	Diasorin	2016	\$ 300M	\$ 80M
BioFire Dx	Infectious diseases	BioMérieux	2013	\$ 450M	\$ 80M

# WOMEN'S HEALTH Point-Of-Care Testing TREND

## **GROWING DEMAND** FOR NEW POINT-OF-CARE TESTING SOLUTIONS FOR WOMEN'S HEALTH

- ✓ **Women's Health professionals** have already adopted point-of-care solutions (infectious tests, dipstick urine analysis, pregnancy tests)
- ✓ **Reimbursement** policies are favorable
- ✓ **Women care about their health**, particularly during pregnancy
- ✓ Clinically **actionable** tests typically have easier adoption



GLOBAL MARKET VALUE

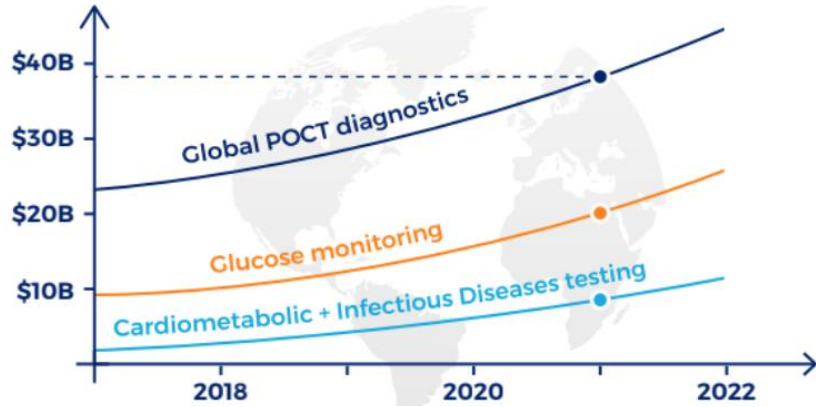
**4B\$**

CAGR 8%

**LOW BARRIERS TO MARKET ENTRY in EU and USA**



# GREAT ROOM FOR NEW DIAGNOSTIC SOLUTIONS



**Global** Point-of-care Testing diagnostics market \$38.13 B by 2021



IRON DEFICIENCY AND ANEMIA ARE AMONG THE TOP 10 DISEASES FOR WHICH **CLINICIANS WOULD LIKE A POINT-OF-CARE TEST** TO ADD TO THEIR CLINICAL TOOLKIT

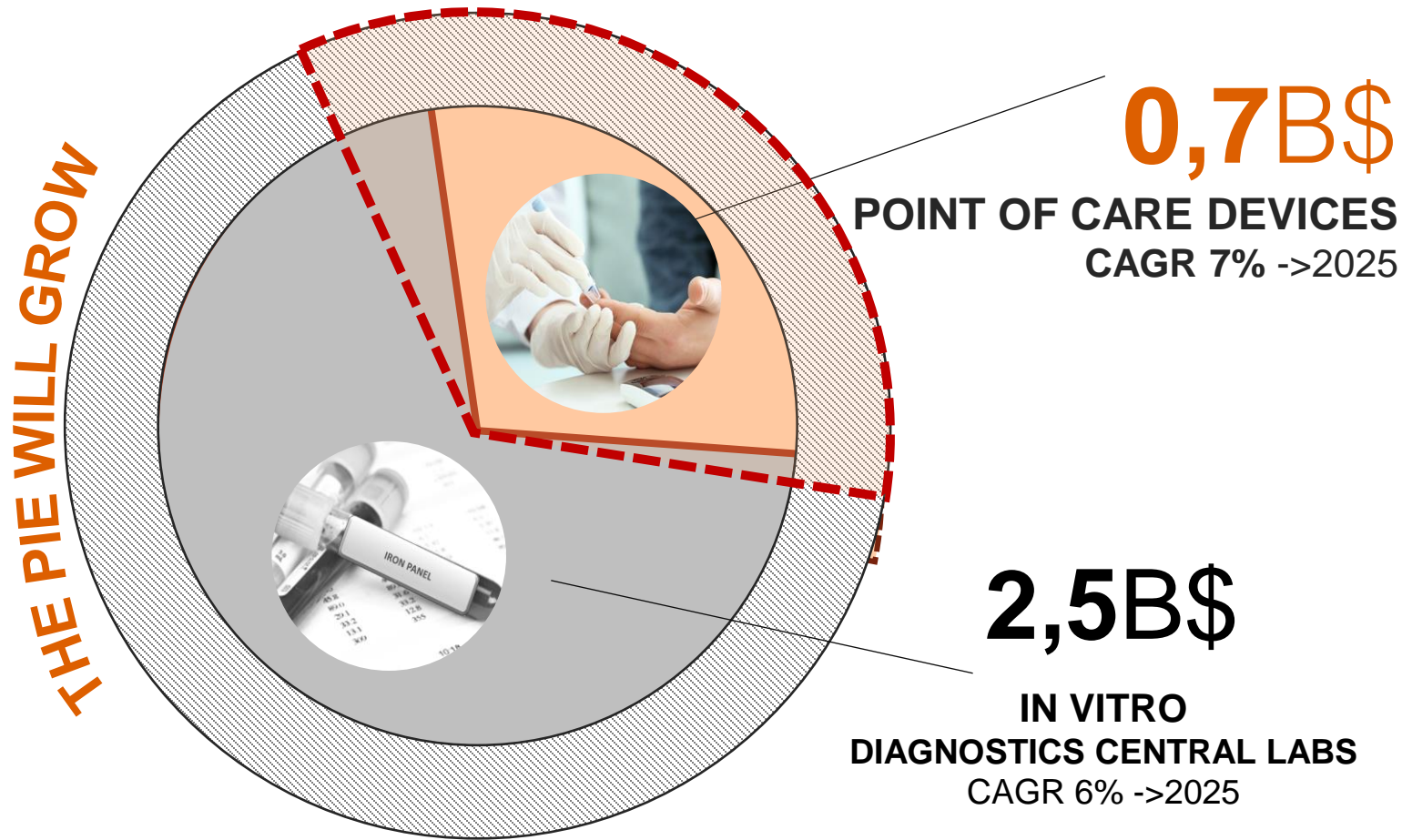
Point of Care • Volume 16, Number 4, December 2017



## **ON SITE DIAGNOSTIC SOLUTIONS** for Iron Deficiency **MAKE SENSE** for women and doctors

**real-time treatment** and solve the issue in a **single patient encounter**  
**convenient monitoring** to extend access and improve women experience and outcomes

# IRON DEFICIENCY ANEMIA DIAGNOSTICS MARKET SIZE



**1,8 B\$**  
WOMEN'S IRON  
DEFICIENCY  
TESTING MARKET

CURRENT ID  
TESTS COVER  
**<30%**  
OF WOMEN  
WHO NEED TESTS

**GREAT ROOM**  
FOR NEW  
ACTIONABLE  
POCT SOLUTIONS  
PENETRATION

Statista - 2019

**LARGE AND FAST-GROWING MARKET**

# WHY INVEST IN FIDELIO?

**Seeking for 1,5+ M€ in Seed financing**

**Value-driving milestones achievable within 18 months**

**VALUE DRIVER  
DIAGNOSTIC  
SOLUTION  
IN HIGH NEED  
WOMEN'S HEALTH  
AREA**

#great value-creation  
opportunities for women  
and doctors

**HUGE  
ADDRESSABLE  
MARKET**

>3B\$

#women's health  
#iron deficiency and  
anemia diagnostics

**COMPETITIVE  
ADVANTAGE**

#Differentiated  
technology, strong IP,  
versatile platform

**MULTIDISCIPLINARY  
AND  
EXPERIENCED TEAM**

#combining research and  
entreprise experience  
in digital diagnostic area

Time to revenue **WITHIN 3-4 YEARS**