D-Tails

Hybrid Biosensor

Non-invasive, affordable and scalable

Early Cancer Detection via Urine

Where Precision Meets Passion

Company: D-Tails Srl SB (Rome, Italy)

Presented by Viola Folli, CSO, folli@d-tails.com

D-TAILS
Disruptive Technological Advances In Life Science

D-Tails – Disruptive Technological Advances in Life Science

Breakthrough Diagnostics for Global Health

Mission

Non-invasive, accurate, fast, and accessible early detection of cancer from a few drops of urine.

Vision

Global leadership in scalable, preventive cancer diagnostics to reduce financial burden of undetected cancer.

Who we are

20+ professionals and a Scientific Advisory Board with experts from multiple Universities, backed by international collaborations

Sapienza Università di Roma

Københavns Universitet

iit Istituto Italiano di Tecnologia

Columbia

UCL

Berkeley University of California

Sistema Sanitario Regionale IRCCS Istituti Fisioterapici Ospitalieri

Istituto Superiore di Sanità

Gemelli

Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore

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Cancer Screening

A Critical Challenge

Rising Incidence

Cancer rates rapidly increasing worldwide.

Late Diagnosis

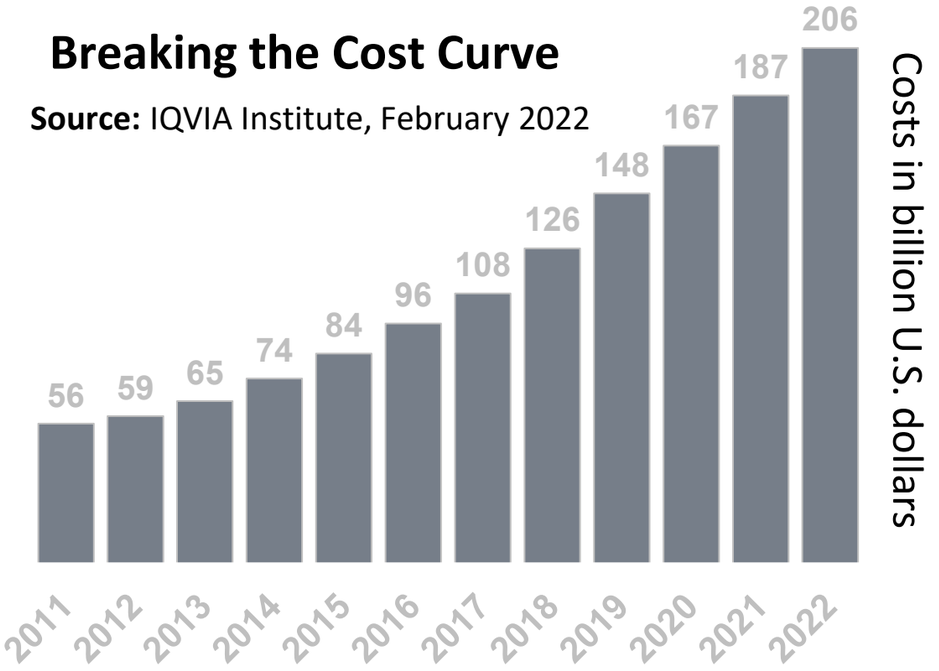
Leads to lower survival rates and higher healthcare costs.

Invasive Testing

Current methods are uncomfortable. Many avoid regular screening.

Limited Access

Costly procedures restrict widespread early detection efforts.



$190B+

Global Market

Early diagnostics market size

$ 16.1B

Cancer Screening

CAGR (2024-2032): 8.5% *

* Current market size and CAGR sources: Grand View Research, Fortune Business Insights, Precedence Research

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Our Solution

Revolutioning cancer detection

Simple & Non-invasive

Urine test that's comfortable and accessible for routine screening.

Highly Accurate

Over 90% sensitivity and specificity in detecting early-stage cancer.

Instant Results

Get results in minutes without specialized facilities.

Cost-effective

Scalable solution ideal for large-scale screenings, price <€70 per test.

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Groundbreaking Patented Tech

Highly sensitive detection of cancer-related VOCs

Strong IP moat with in-house prototype manufacturing capabilities

Urine Sample
Patient provides a non-invasive urine sample.

VOC Detection
Identifies cancer-related volatile organic compounds (VOCs) in urine

Engineered Receptors
Selected *C. elegans* olfactory receptors in yeast detect cancer-related VOCs

Bioluminescent Signal
Receptor activation triggers a measurable BRET-based signal

AI Analysis & Result
Custom algorithms interpret patterns to indicate potential cancer presence

Portable Format
Microfluidic-based design requires no special storage conditions

Core Innovation

Leveraging the extraordinary olfactory system of *C. elegans*, D-Tails converts biological sensing into a measurable, AI-interpretable signal.

This lays the foundation for a portable, user-friendly diagnostic device that brings lab-quality results to the point-of-care.

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Competitive Landscape

The early cancer detection market features **three distinct technology approaches**, each with unique advantages and limitations.

Blood-Based Liquid Biopsy

Company	Nat	Website	Technology	Funding	Strengths	Weakness/Limits
Galleri	US	https://www.galleri.com/	cfDNA methylation, 50+ cancers	$3.2B	First MCED test on market, detects 50+ cancer types from a single blood draw	Limited early-stage sensitivity, high cost (~$950), lab-based, long turnaround, accessibility barriers for large-scale screening.
Freenome	US	https://www.freenome.com/	Multiomics (cfDNA + proteins)	$1.35B	Strong CRC trial data; innovative multiomics approach	Complex and costly; pre-market; limited to CRC
GUARDANT	US	https://guardanthealth.com/	cfDNA liquid biopsy (Guardant Shield, CRC focus)	>$550M	First FDA-approved blood test for CRC; established commercial presence in US	Only CRC; poor sensitivity for precancerous lesions; still relatively expensive
DELFI	US	https://delfidiagnostics.com/	cfDNA fragmentomics	~$332M	Promising lung cancer results; scalable platform; backed by top-tier investors	Still in trials; lab-based workflow; lung-only focus; risk of false positives from non-cancer conditions
ClearNote	US	https://www.clearnotehealth.com	Targeted methylation panels	~$107M	Advanced clinical trials; focus on lethal cancers; NCI interactions	Lab-based; lung-only; potential false positives; awaiting regulatory validation

Urine-Based Tests

Company	Nat	Website	Technology	Funding	Strengths	Weakness/Limits
CRAIF	JP	https://craif.com/en	Urinary miRNA + AI, multi-cancer detection	~$57M	High adoption in Japan; non-invasive; tests for multiple cancers (7 types)	Complex workflow, expensive, limited validation outside Japan
HIROTSU BIO SCIENCE	JP	https://hbio.jp/en/	N-NOSE using live nematodes and behavioral outcomes	$22M	Non-invasive; detects multiple cancer types; widely used in Japan	Limited specificity, biological variability, poor scalability
EARLY	IL	https://earlylabs.io/	VOC biosensors + AI, promising for early lung cancer detection	ND	Non-invasive; promising for lung cancer; potential for large-scale	Confounding factors (diet/environment), limited to lung cancer
exosomedx	US	https://www.exosomedx.com/	Urinary exosomal RNA test for prostate cancer	~$119M	Clinically validated; non-invasive; useful for elevated PSA patients	Only prostate, only for elevated PSA patients, complex lab assay

Breath Tests

Company	Nat	Website	Technology	Funding	Strengths	Weakness/Limits
OWLSTONE MEDICAL	UK	https://www.owlstonemedical.com	Breath Biopsy® VOC platform, GC-MS based	>$150M	Cutting-edge breath VOC analysis; multiple pharma partnerships	Lab-based, no commercial test yet; expensive GC-MS; VOC contamination risk
spot it early	IL	https://www.spotitearly.com/	Dogs + AI hybrid for breath VOC analysis	$20M+	Innovative approach; very high reported sensitivity; strong interest	Scalability issues (dogs not reproducible); poor standardization; early-stage development

Competitive Landscape Analysis

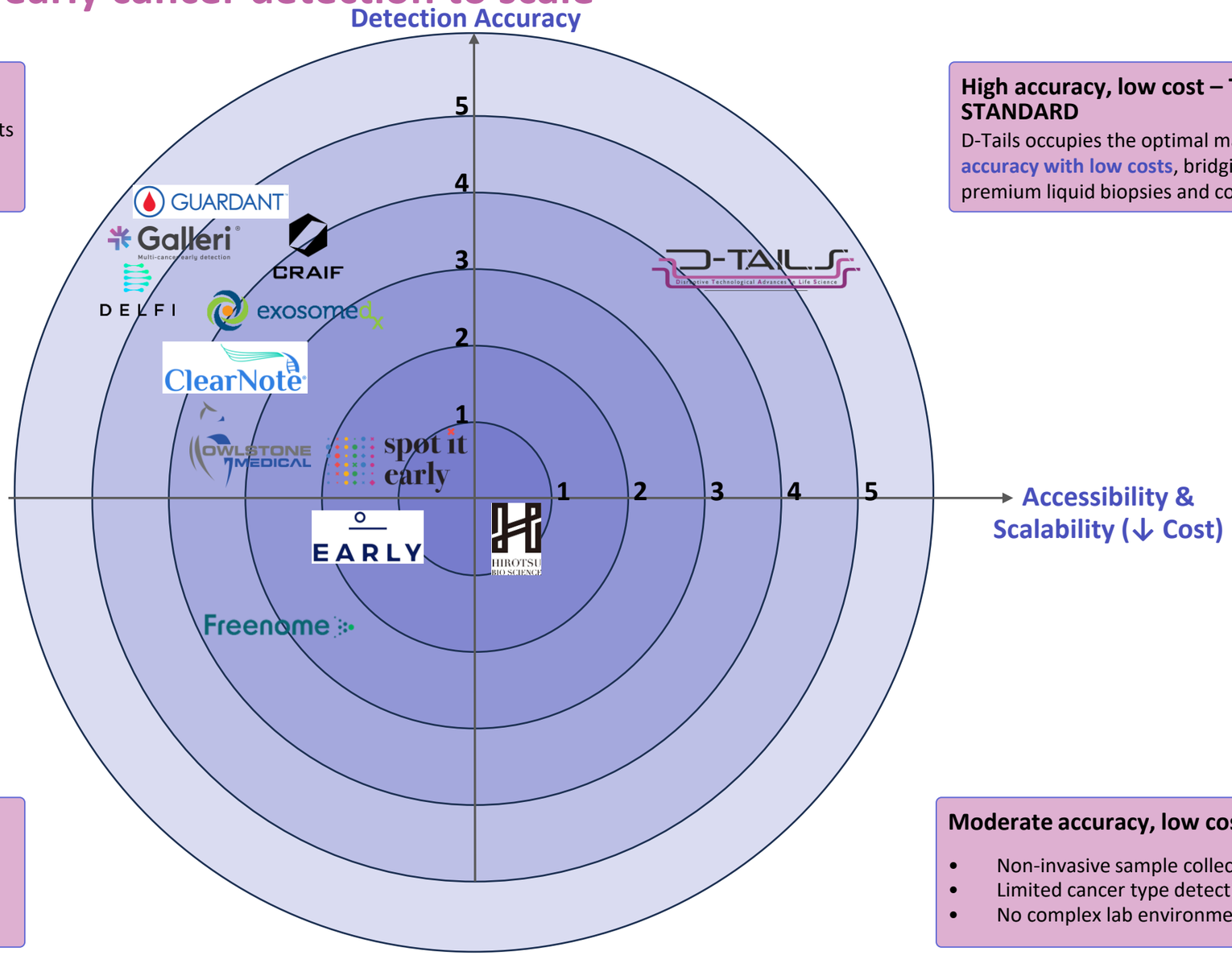
A staged strategy to bring early cancer detection to scale

High accuracy, low scalability, high cost

- Established technology with proven clinical results
- Requires specialized laboratory processing
- Premium pricing limits accessibility

High accuracy, low cost – The GOLD STANDARD

D-Tails occupies the optimal market quadrant: **high accuracy with low costs**, bridging the gap between premium liquid biopsies and cost-effective alternatives.



Legend

Detection Accuracy

+5 = very high (>95%)
+3 = high (90–95%)
0 = moderate (~85–89%)
–3 = low (70–84%)
–5 = very low (<70%)

Implementation Cost

+5 = very low cost, highly scalable
+3 = low cost
0 = moderate cost
–3 = high cost
–5 = very high cost / complex

Moderate accuracy, high cost

- Non-invasive sample collection
- Limited cancer type detection
- No complex lab environmenty

Moderate accuracy, low cost

- Non-invasive sample collection
- Limited cancer type detection
- No complex lab environmenty

Traction and Roadmap

Key Achievements

€5.6M Funding
Raised through public and private funding sources

Strategic Partnerships
Leading institutions: IIT, IFO Regina Elena, Policlinico Gemelli

Expert Advisory Board
Columbia, Berkeley, UCPH, and Sapienza University experts

Functional Prototype
TRL 5 biosensor successfully validated in lab settings

Expanded VOC Panels
Early detection for pancreatic, prostate, and breast cancer

Industry Recognition
Featured in BioPhotonics Magazine (May–June 2025)

EU Pathfinder Open 2025 Winner
Top 50 projects out of 2,078 (<2.3% success rate, 4.9/5 score)

1 — **Q1 – Q4 2026**
Research optimization and integration with biosensor (TRL 5/6)

2 — **Q1 – Q1 2027**
Feasibility Study (100 patient urine samples) (TRL 5/6)

3 — **Q2-Q4 2027**
Manufacturing pilot process development, (TRL 6)

4 — **Q1-Q3 2028**
Expanded clinical cohort and completion (300-500 patients, multi-center) (TRL 7)

5 — **Q4 2028**
CE-IVD Submission (TRL8)

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Two-Step Path to Scalable Cancer Screening

A staged strategy to bring early cancer detection to scale

A phased commercialisation strategy designed to generate early clinical validation and revenue before scaling to a mass-market product — de-risking each transition for investors at every stage.

STEP 1

Service-Based Platform

Centralised high-accuracy testing

- Automated worm-on-chip neural readout
- Microfluidic platform
- AI-based analysis pipeline
- Urine samples sent to centralised service lab
- Demonstrated discrimination up to ~92%

~€2M	~12 Months
Investment	Timeline

Early revenue · clinical validation · dataset growth

→

De-risking & scale transition

STEP 2

Product Diagnostic Device

Decentralised point-of-care testing

- Yeast multiplex biosensor panel
- Portable reader device
- Pharmacy or clinic deployment
- Future home-test potential
- Pathfinder-enabled development

~€8M	~24 Months
Investment	Timeline

Mass-market scalable screening

Service first → product at scale — a phased approach that builds investor confidence, accumulates clinical data, and creates a clear bridge from validated laboratory service to a globally deployable diagnostic product.

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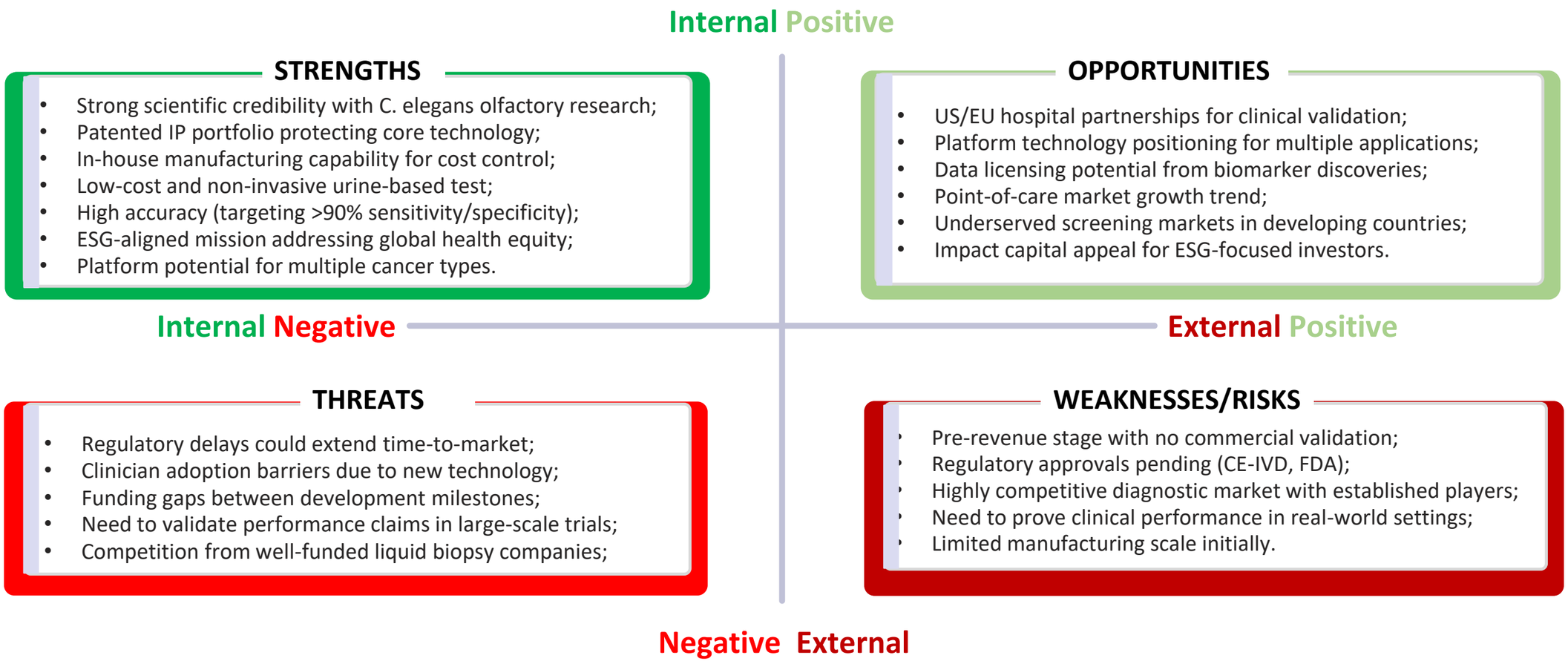
SWOT Analysis

Strategic Assessment of Our Technology



Funding Ask – €10M

Objective: Reach CE-IVD submission with robust clinical dataset; use CE data as basis for a later FDA De-Novo filing.

€2.5M – Research & Development Optimization
Completion of receptor optimization & functional validation (remaining 5/9 strains), VOC response profiling, microfluidic platform prototyping, accelerated stability and shelf-life studies, batch reproducibility testing.

€4M – Clinical Validation (CE-focused, phased)
Feasibility cohort (N ≥ 100) → pivotal multicenter cohort (≥300–500 across 2–3 centers); endpoint definition, confounder analysis (diet, drugs, infections), regulatory-grade data management.

€2M – Manufacturing Scale-up & GMP readiness
Process development and validation, pilot lots for clinical use, QC/QA workflows, supplier qualification, transfer planning to CMOs, and preparation of GMP documentation for reproducible, regulatory-compliant production.

€0.7M – Regulatory Preparation (CE-IVD)
Clinical evaluation report, technical file assembly, conformity assessment interaction with Notified Body, submission packaging (CE focus only).

€0.8M – IP/Buffer
Expansion and maintenance of IP portfolio, freedom-to-operate analyses, and allocation of buffer capital for unforeseen technical or operational needs.

Milestones with Detailed Funding Allocation (36Mo)

Program START
Q1 2026
Project setup, SOPs, CRO/CMO & clinical site selection.

R&D Optimization
Q1 – Q4 2026
Microfluidic prototype v1, VOC profiling, functional assay validation, shelf-life>12M
Budget: part of €2.5M | **TRL:** 5/6

Feasibility Study
Q1 – Q2 2027
Cohort N≥100, primary sensitivity/specificity, initial stability data
Budget: R&D + Initial Clinical €1.5-1.8M) | **TRL:** 5/6

Manufacturing pilot process development
Q2 – Q4 2027
Pilot lots for clinical use, QC/QA workflows, supplier qualification
Budget: part of €2M | **TRL:** 6

Expanded clinical cohort
Q1 – Q2 2028
~300 patients across 2/3 centers, analytical validation, continued reproducibility.
~2/3 urine samples/day
Budget: part of €4.0M Clinical | **TRL:** 6–7

Cohort completion
Q2 – Q3 2028
≥300–500 patients, confounder analysis, final assay performance.
~3/4 urine samples/day
Budget: Clinical (~€2.0M) + Manufacturing (~€0.5M) | **TRL:** 7

CE-IVD Submission
Q4 2028
Finalize technical file & report, submission for CE mark, prepare FDA De-Novo dataset
Budget: Regulatory + IP (~€1.5M) | **TRL:** 8

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Scalability, Market Potential and US Go-to-Market

Model and strategy

Our **B2B2C strategy** integrates our biosensor into existing healthcare for broad and rapid adoption.

Clinics & Hospitals

Seamless integration for rapid, non-invasive diagnostics.

Pharmacies

Accessible screening hubs for convenient public testing.

Public Health System

Ideal for large-scale, cost-effective screening programs.

At less than **€70 per test**, our biosensor democratizes access by significantly lowering financial barriers to regular cancer screening globally.

$190B+

Total Addressable Market

Poised to capture a significant share of the global early diagnostics market with a scalable, affordable, and accurate solution.

Three-phase strategy designed for rapid scale and sustainable growth in the US healthcare market

1

Early Access Partnerships

Pilot programs with leading hospitals and diagnostic labs

- Clinical validation partnerships
- Real-world evidence generation
- Key opinion leader engagement

2

Regulatory Pathway

Strategic CE mark to FDA transition

- Leverage EU clinical data
- 510(k) or De Novo pathway
- FDA breakthrough designation potential

3

Commercial Scale

Nationwide distribution through established channels

- Pharmacy network integration
- Population screening programs
- Insurance coverage expansion

Strategic Priority

US = Primary market for VC interest and rapid scale - largest healthcare market with fastest path to unicorn valuation

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United States Strategy

Partner-first, sequenced, capital-efficient

We do not enter the US market through a generic market-access consultant or a premature commercial buildout. We enter through a clinical-academic partner capable of supporting US-population data generation, IRB-governed studies, KOL credibility and a future CLIA/LDT bridge.

May 2026	Q2-Q3 2026	Q3-Q4 2026	Q4 2026 onward	2027–2029
SBB & Bay Area scouting *UCSF, Stanford, CZ Biohub, QB3 — open partner conversations*	**Partner shortlist & MoU** *2-3 qualified partner candidates; non-binding MoU by end-Q3*	**Legal & regulatory setup** *Delaware C-Corp; Q-Sub strategy & Breakthrough Device Designation prep*	**CLIA/LDT bridge** *US data, real-world evidence, early service revenue via partner lab*	**FDA De Novo pathway** *US clinical study; symptomatic aid-in-diagnosis claim*

US Capital Discipline

Phase 1 US setup: approximately **€110–165k over 12 months** for legal, regulatory, travel, partner development and contingency.
Clinical trial component: co-financed by academic partners, US grants or non-dilutive funding once the US structure is operational.

Logic: *identify the right partner first, then build regulatory and commercial infrastructure **behind** that partner.*

✓ Strategic Priority

United States = primary market for VC interest and rapid scale.

Largest healthcare market with the fastest path to clinical credibility and exit value for differentiated diagnostic assets.

Why a US Clinical Workstream

External validation requirement and AI classifier training

The US clinical workstream is ***not*** designed to validate a test that the company considers technically promising. **It is designed to satisfy two distinct external imperatives intrinsic to entry into the US healthcare market.**

1 External Evidence Requirement

Standard cost of entry to the US market

US payers, regulators and clinical key opinion leaders require multicenter, blinded, prospective, US-population evidence packages before clinical adoption.

This requirement applies **to any novel diagnostic**, regardless of underlying technical confidence or prior European feasibility evidence.

It is the structural cost of entry into the US healthcare market — not a question of scientific premise.

2 AI Classifier Training

The data factory in operation

Each additional clinical sample feeds the proprietary classifier. Larger and more diverse cohorts strengthen calibration, expand the biological feature space and progressively raise the accuracy floor.

A US-population dataset is structurally needed: classifier performance must be tested and refined on the population genuinely representative of the target market.

Expanded clinical work is therefore not only validation — it is the data factory in operation.

Dual-purpose logic *governs both the choice of partner-first entry and the sequencing of the clinical workstream.*

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Non-Executive Director

Scientific Founder

Renato Giacobbo Scavo

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Founder

Federico Bellan

Chief Legal Officer

Intellectual Property

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Head Cancer Detection Project

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Molecular Biologist
Bio Lab Manager
genome editing

Ilaria Cavallo
Biologist
Lab Management
Technical Lab Support
Creative communication

Valeria Lucente
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