

XXII Encuentro de Cooperación Farma-Biotech

15 de noviembre de 2022

Point of Care diagnostic device that identifies early bloodstream infections by detecting specific immune response biomarkers



Enrique Hernández Jiménez



XXII Encuentro de Cooperación Farma-Biotech

1. The Institution

MULTIDISCIPLINARY TEAM AND COMMITMENT

Science-Tech-Entrepreneurship

Clinical

Business



Enrique Hernández, PhD
Biomedical Innovator, CEO

> 5 years leading innovation projects



Erika Paola Plata, MD
Physician Researcher, CMO

> 10 years diagnosing in ED



Joan Vieyra, MSc
Product Development, CTO

> 2 years medical device development



Eduard Guerrero, MSc
Business Pharmacist, COO

The 3rd startup project in Healthcare



Rocío Rodríguez, MSc
Marketing and Communications, MarCom Specialist

> 4 years in marketing and sales



Hjalmar Bouma, PhD
Physician Researcher, Clinical Lead

> 10 years leading Sepsis clinical projects



Joan Sabater, MD, PhD
Physician Researcher, Clinical Lead

> 10 years diagnosing in critical care



Adriane Trash
Business, Development, CBO

>20 years helping startups



Argyris Spyridis
Financial Development, CFO

>25 years helping startups



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1. The Institution

BOARD OF IVD SPECIALIZED ADVISORS



JEAN-PIERRE HERMET

Specialized in strategy, business development, market access, distribution, mergers and acquisition experience in IVD market.



THOMAS IFF

Specialized in business management and development, marketing and commercialization experience in IVD market.



ANTONIO ARTIGAS

Clinic and Public Healthcare advisor.



TODD SNOWDEN

Regulatory and commercialization advisor.



YVES BAYON

Science and Strategy advisor.



TONI MIRÓ

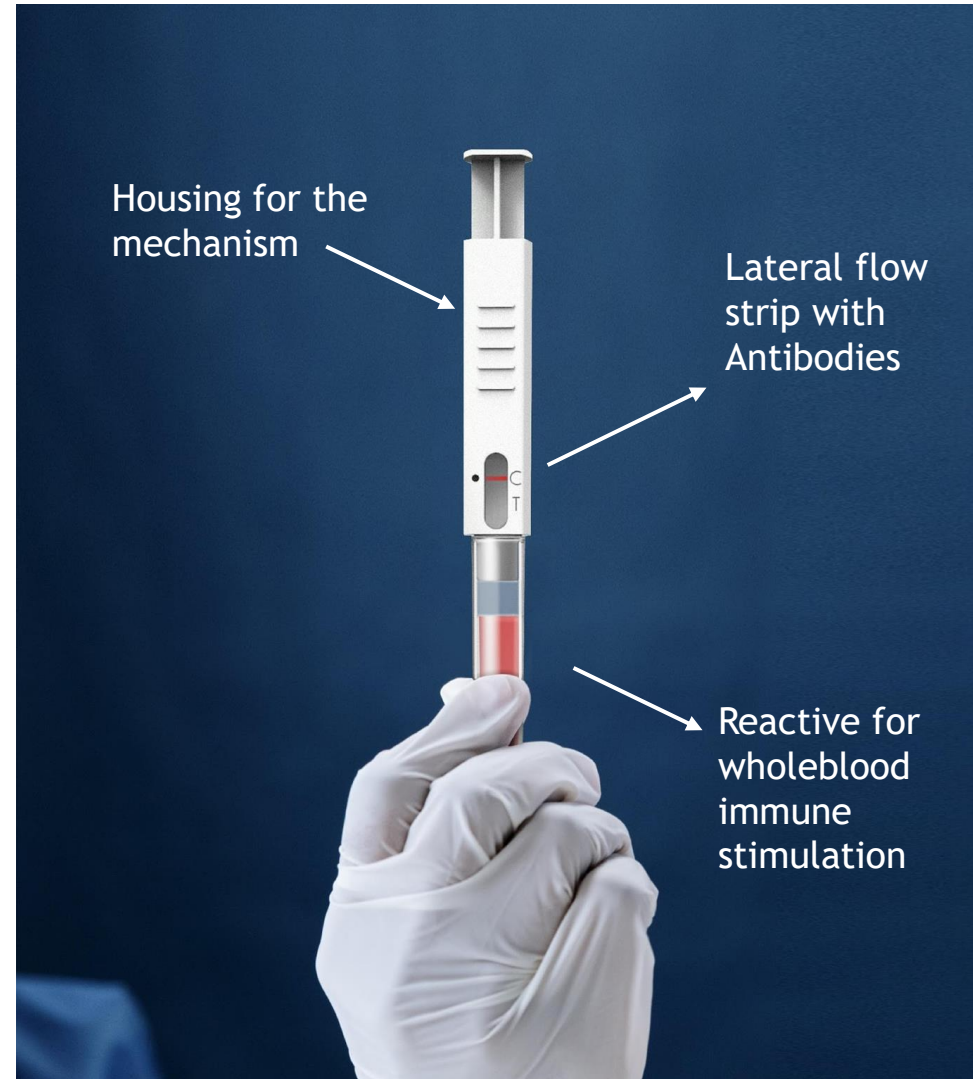
Product and Value chain advisor.



2. The Product

SEPTILOOP















Blood-based in vitro diagnostic test that identifies bloodstream infection *before* it progresses to sepsis.



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2. The Product

a) Target Indications

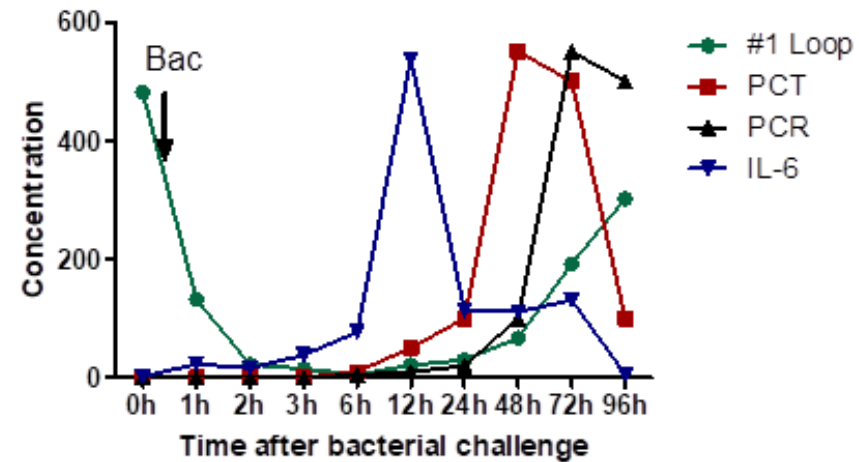
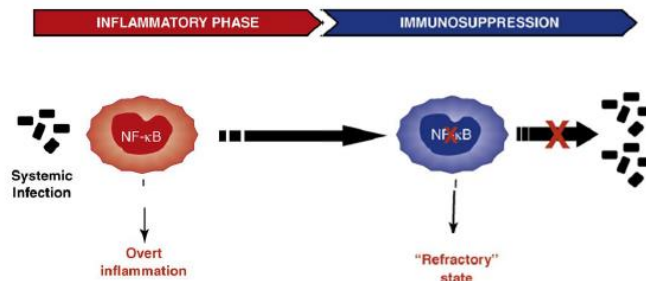
	SEPSIS STAGE		INITIATING ANTIBIOTIC	REMOVING ANTIBIOTIC	IMMUNOTERAPY	IMMUNO Checkpoints
	Emergency	UCI				
	✓	✓	✓	✗	✓	✓
 	✗	✓	✗	✓	✗	✗
  	✗	✓	✗	✓	✗	✗
   	✗	✓	✗	✗	✗	✗
   	✗	✓	✗	✗	✗	✗

2. The Product

b) Innovative mechanisms of action



Functional assay Based on immune cell activity*



* Avendanõ-Ortiz, J. et al. PD-L1 Overexpression during Endotoxin Tolerance Impairs the Adaptive Immune Response in Septic Patients via HIF1 α . *J. Infect. Dis.* 217, 393–404 (2018).

Cubillos-Zapata, C. et al. NF κ B2/p100 is a key factor for endotoxin tolerance in human monocytes: A demonstration using primary human monocytes from patients with sepsis. *J. Immunol.* 193, (2014).

Jhalova, I. N. et al. Human monocytes undergo functional re-programming during sepsis mediated by hypoxia-inducible factor-1 α . *Immunity* 42, (2015).

2. The Product

c) Differential features facing the market



Functional assay
Based on immune cell activity



1h starting of detection window

90% sensitivity* 

CURRENT DIAGNOSTICS

Serum Biomarkers



12h-24h detection window

<30% sensitivity

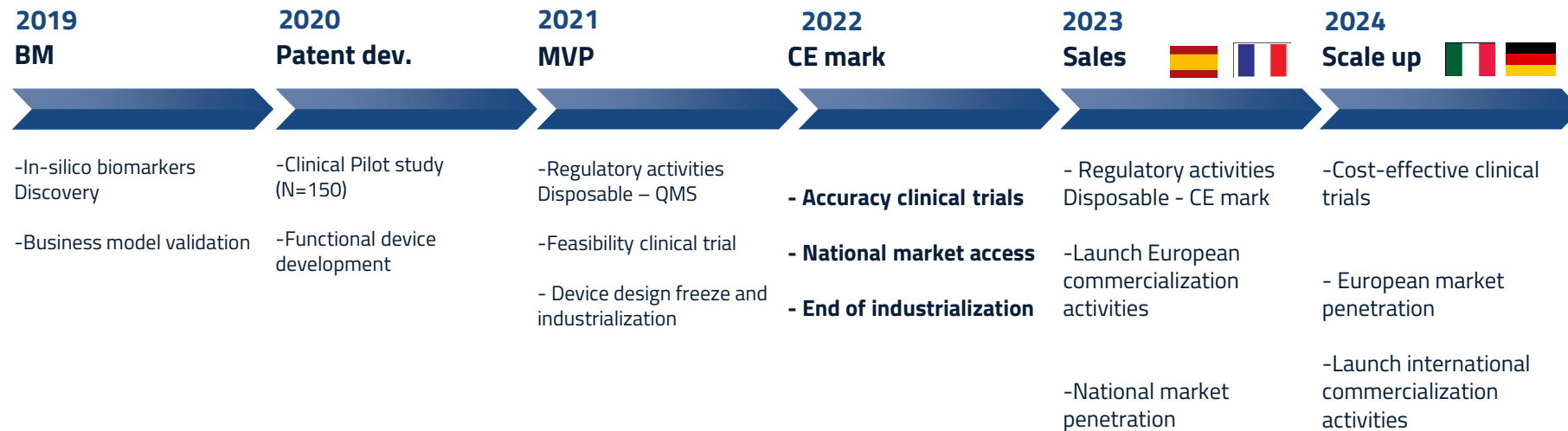
Standard of care
Pathogen detection



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2. The Product

d) Current status of development



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2. The Product

e) IPR protection

Patent applied: PCT, June 2021.

WO/2021/245025. Method And Kit For The Early Detection Of Sepsis. Ownership: Loop dx 51% - Idibell 49%

Regulatory: De novo (FDA); Class C (IVDR)

Freedom to operate: Dennemeyer Octimine:
Patent search software

Exploitation: Exclusive, perpetual ww License from Idibell
Payment: 1% royalty and non royalty basis



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2. The Product

f) Pitfalls & Risks to be considered

Manufacturing capacity, technical risk

WP: 1

Probability: Low

Impact: Medium

Cost-efficiency test, clinical risk

WP: 2

Probability: Medium

Impact: High

Obtain the CE Mark certification under IVR, Regulatory Risk

WP: 3

Probability: Low

Impact: High

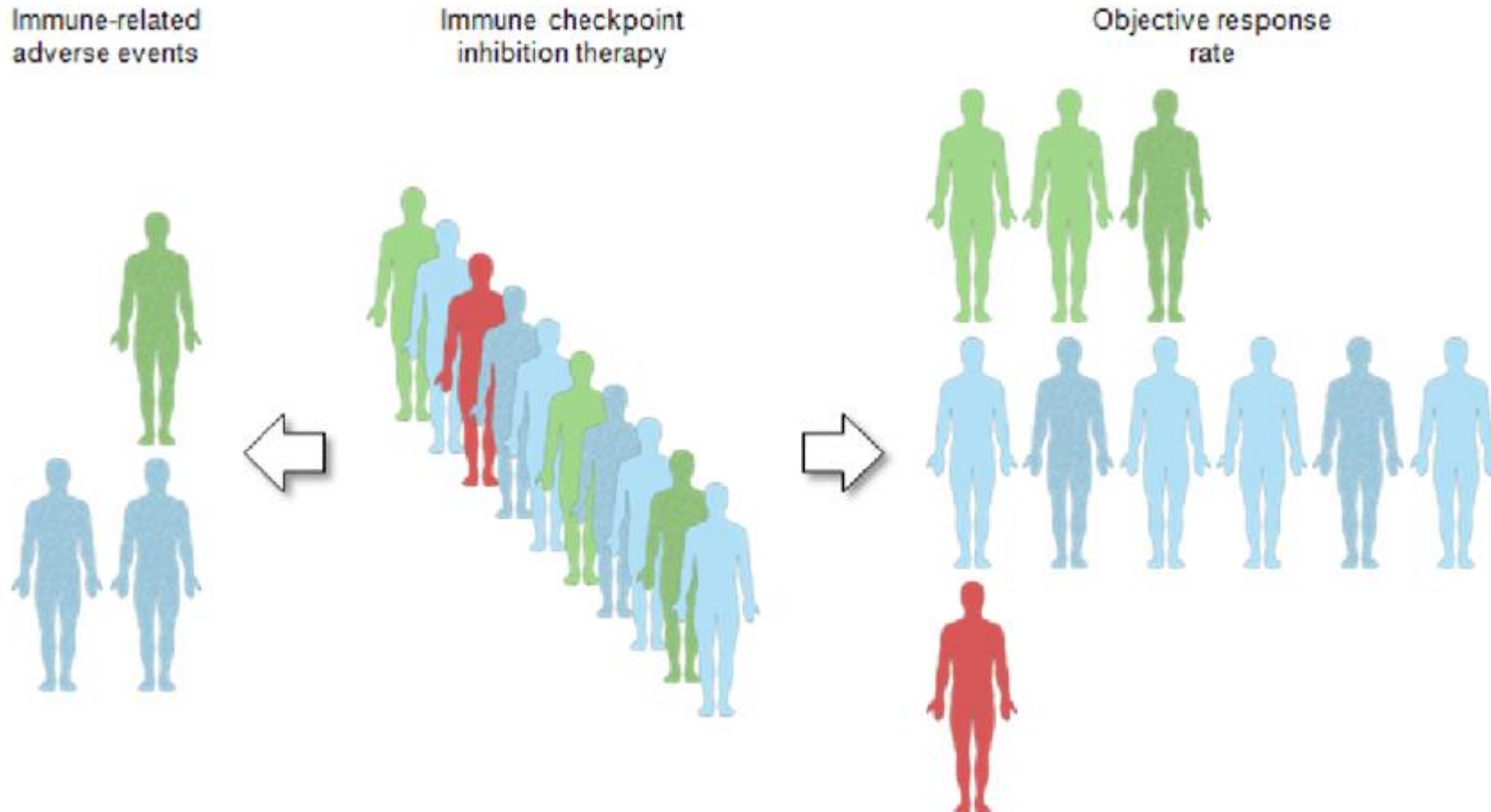
Medical application, implementation risk.

WP: 4

Probability: Medium

Impact: High

3. Partnering Opportunities



Companion diagnostics for immunotherapy by immune checkpoint inhibition.
A limitation of immunotherapy by immune checkpoint inhibition (ICI)