

Join us on  
our journey



# EXECUTIVE SUMMARY

## Proposal

Investing in Biocross, a company with technologically mature products (TRL7 & 8)



Demonstrated ability to identify and quantify a biomarker [**ApoE4**], present in highly prevalent pathologies:

- Alzheimer’s and other dementias.
- Cardiovascular diseases.
- Diabetes Mellitus Type II
- Others

Free from technological risk

## Biomarker

This **biomarker** can be determined using any system and is compatible with the automated analysers of any clinical laboratory.

Highly Compatible

[**ApoE4**] is implicated in the development of these pathologies and their poor evolution

Risk Factor

## Offers an early diagnosis

Cost-efficient

It improves therapeutic control and health management of these pathologies and is demanded by Patient Associations.

High Demand

Identification and monitoring of patients at higher risk, reduces the economic and social burden on health systems.

No Ethics Committee

Diagnosis using biomarkers is very well established in clinical practice.

# APOE4: THE BIOMARKER FOR THE RISK OF VASCULO-METABOLIC DISEASES

## Apolipoprotein E4 (APOE4)

- Influences lipid function and accelerates the development of chronic metabolic diseases in its carriers.
- 20% of the population are carriers of ApoE4. ApoE4 carriers experience an earlier onset of metabolic diseases than the general population, with faster disease progression and worse evolution.
- They do not respond well to usual treatments, especially those based on monoclonal antibodies.

## Cardiovascular Diseases

Numerous trials have shown the association of ApoE4 with the risk and poor outcome of these pathologies.

\*Valentín Fuster et al. Apolipoprotein E-ε2 and Resistance to Atherosclerosis in Midlife — The PESA Observational Study

## Diabetes Mellitus Type II

Several meta-analyses have shown the risk of developing Diabetes Mellitus Type II in patients with Apolipoprotein E4.

## Alzheimer (AD) / Dementia

- 2023 FDA approval of the first treatments based on monoclonal antibodies that modify and delay the onset of AD symptoms (Leqembi).
- ApoE4 is one of the most established biomarkers for the diagnosis of AD.
- Clinical trials have shown that treatments are more effective with an earlier diagnosis of AD.
- ApoE4 carriers present serious risks to monoclonal antibody-based treatments.
- The first early diagnostics in plasma based on biomarkers (Aβ, Tau, pTau y ApoE4) appeared in 2023.
- There is a worldwide consensus, ratified by the FDA, regarding the importance of determining the ApoE4 status, as a complementary diagnostic and companion diagnostic, essential for the administration of new treatments.



# THE COMPANY

## The Company

### Spanish biotech company, spin-off of the Spanish National Research Council (CSIC),

with Health Licence Number 7358-PS, granted by the Spanish Medicines Agency, owners of a patented method adaptable to turbidimetry for the identification of ApoE4.

## Target

To position apolipoprotein E4 in plasma as a reference biomarker of risk/prognosis in Alzheimer's Disease and other dementias, atherosclerotic cardiovascular diseases, and metabolic syndrome.

## Investment Made

More than €6 Millions

## Products



CE marked and adaptable to any automatic analyser on the market. It identifies ApoE4 carriers in plasma (TRL8).



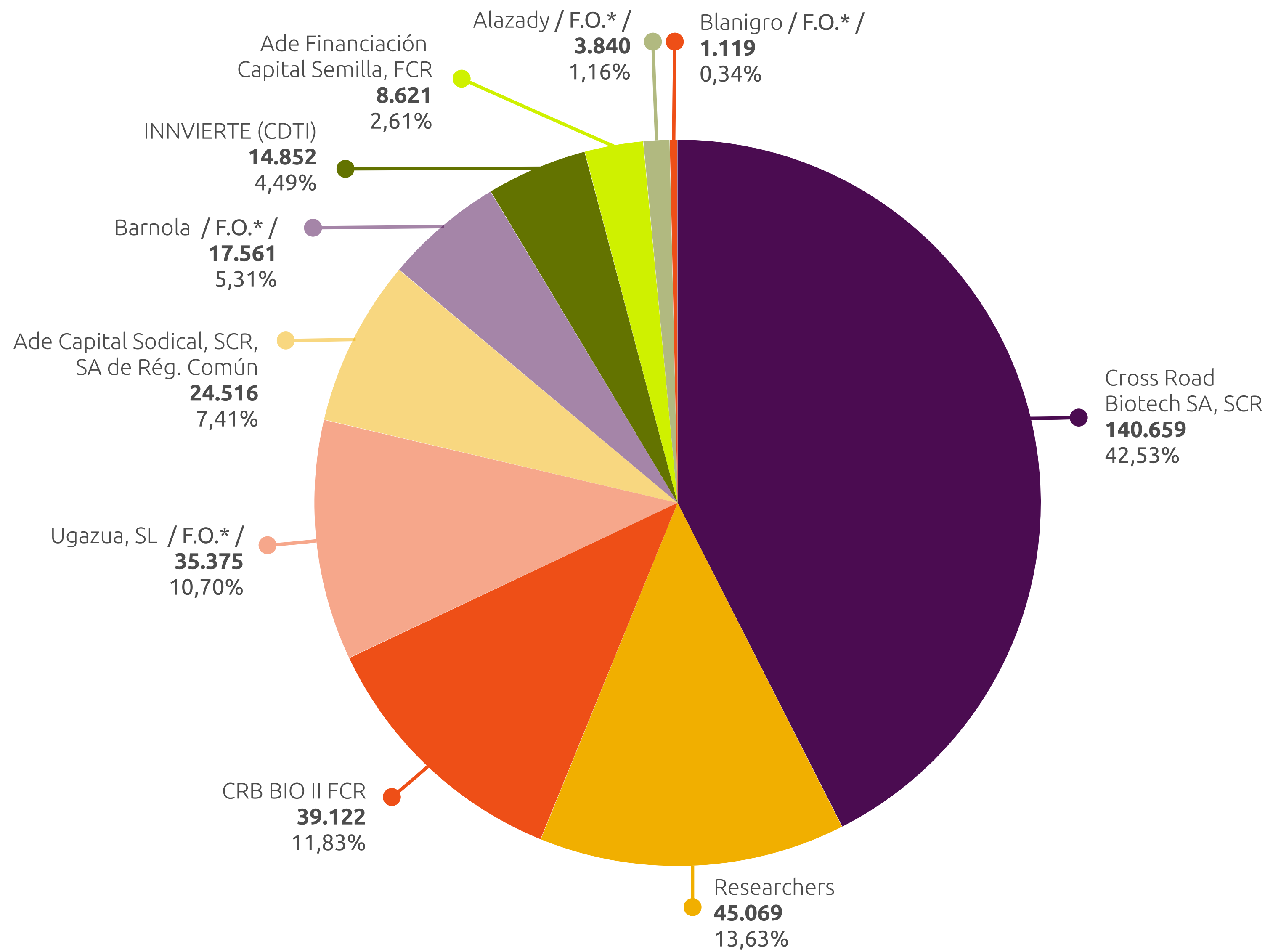
(RUO), marketable as a service. It quantifies ApoE4 in plasma (TRL7).

## Patentes

Both products (**in vitro diagnostics**) are used with a patented method adaptable to **turbidimetry**, the most cost-effective technique on the market. It can be used with any automatic analyser.

# PARTNERS AND PARTICIPATIONS

/ F.O.\* /  
= Family Office



TOTAL  
330.734

# MARKET (I): APOE4 DETERMINATION METHODS

	Genetic	Spectrometry	Elisa	Biocross
Level of Lab Expertise	HIGH (Genetic)	VERY HIGH	MEDIUM Immunoassay	LOW Any Analytical System
Complexity	HIGH	VERY HIGH	MEDIUM	LOW
Analysis Time	MEDIUM	SLOW	MEDIUM	FAST
Price	MEDIUM	VERY HIGH	MEDIUM	LOW
Informed Consent	YES	NO	NO	NO
Identification	YES	YES	YES	YES
Quantification	NO	YES	NO	YES
Allows for Massive Clinical Trial	NO	NO	NO	YES
Allows for a Large Sample	NO	NO	NO	YES

# MARKET (II): COMPETITORS



Method

Turbidimetry  
(Protein) Expected  
Certifications: IVDR

Electrochemi  
Luminescence

Inmunoassay  
ApoE4 (Protein) RUO

qPCR  
(Gene) RUO

Biochip Array  
(Protein) RUO

Microarrays  
(Gene) FDA approved\*

Samples x Time

Plasma

Plasma

Plasma

Saliva Direct PCR

Plasma

Saliva

1.600 samples / 1h

88 samples / 1h

181 samples / 35min

1 sample / 30min

262 samples / 3h

6 samples / 1h

Equipment

Any biochemistry  
analyzer

Specific equipment:  
ELECSYS

Specific equipment:  
Lumipulse

Specific equipment:  
Cube Spartan

Specific equipment:  
Evidence Investigator®  
(semi-automated)

Specific equipment  
required

Sensitivity / Specificity

100% / 97%

100% / 100%

100% / 100%

100% / 100%

100% / 100%

100% / 100%

Distinguishes 3/4 – 4/4

Yes

No (Only presence  
of ApoE4)

Yes

Yes

Yes

No (Only presence  
of ApoE4)

Quantify ApoE4

Yes

No

Yes

No

No

No

Analysis Site

Hospital laboratory

External Laboratory

External Laboratory

Physician Office Lab

External Laboratory




Direct to Consumer





# BUSINESS MODEL: 2024 – 2028




### Local distributor network



 ES

 PT

 MX

General Screening

ApoE4 Screening **e4Risk**

ApoE4 Screening **e4Quant**





Heterozygotes risk  
Quantifies ApoE4 level


**e4Risk**


**e4Quant**

<b>Use</b>	
Screening tool for ApoE4 carriers in the general population.	Cuantificación de ApoE4 en Plasma.
Patients recently diagnosed with target pathologies.	Imprescindible para la administración y monitorización de los nuevos fármacos.
<b>Test</b>	Non-invasive / Blood test
<b>Price</b>	
€30 / test	€100 / test
<b>Result</b>	
<b>Qualitative</b>	<b>Quantification</b>
identification of carriers and non-carriers of ApoE4.	Quantification of ApoE4 in plasma. Essential for the administration and monitoring of new drugs.
<b>Equipment</b>	
Turbidimetric analyzer available in any health centre or clinic.	

### New territories



 EU

 USA

LATAM

ASIA

### New pathologies

Positioning of **e4Risk** / **e4Quant** as an IVDR biomarker for:

- Alzheimer
- Other dementias
- Cardiovascular pathologies
- Metabolic syndrome

### New applications

Companion diagnostic of the different monoclonal antibody-based AD treatments that will be introduced in the market.

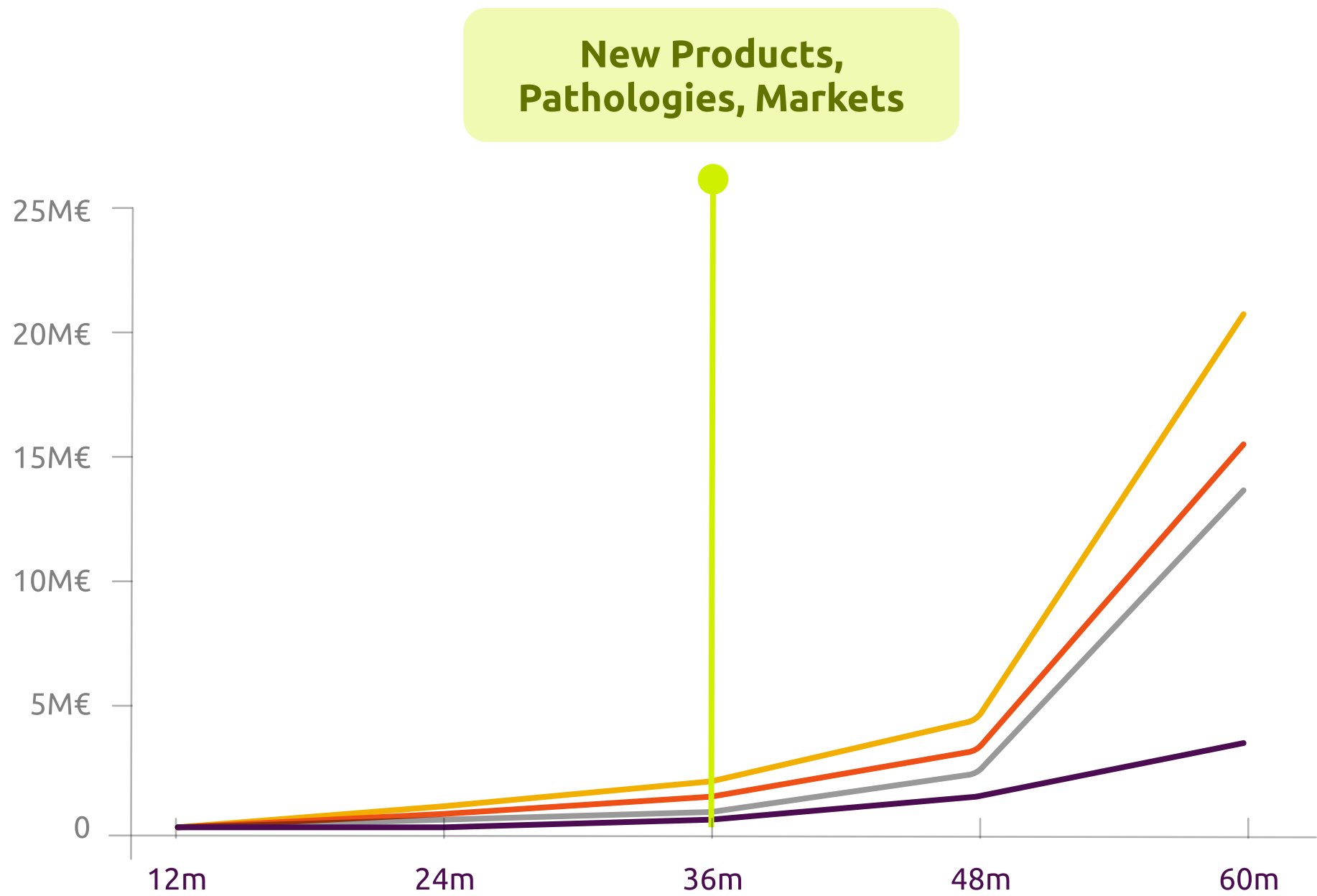


# TARGET MARKET



EA	40.000	6.000	300.000	1.788.000	1.554.000	1.172.250	9.327.600
ECV	109.772	31.000	617.400	4.800.000	3.000.000	450.000	3.000.000
DMT2	386.000	87.234	215.600	6.200.000	3.300.000	2.600.000	33.000.000
TOTAL	535.772	124.234	1.133.000	12.788.000	7.854.000	4.222.250	45.327.600

# BUSINESS CASE



	0.1% e4Risk / 0,01% e4Quant	1% e4Risk / 0,1% e4Quant	2% e4Risk / e4Quant (20%)	3% e4Risk / e4Quant (20%)	4% e4Risk / e4Quant (20%)
Months	12	24	36	48	60
	ES, PT & MX 0,1%	ES, PT & MX 1%	ES, PT & MX 2%	ES, PT & MX 3%	ES, PT & MX 4%
			EU / LATAM 0,1%	EU / LATAM 0,5%	EU / LATAM 2%
				Asia / USA 0,1%	Asia / USA 0,5%
Sales	€13.840	€138.400	€1.555.685	€3.314.762	€20.755.225
Margin	€10.640	€106.399	€1.212.812	€2.584.189	€16.180.776
Income (loss) Operating Income (EBITDA)	€286.603	€411.259	€248.567	€1.239.944	€14.436.531
OPEX	€297.243	€517.658	€964.245	€1.344.245	€1.744.245
CAPEX	€1.267.400	€1.344.800	€600.000		

# MARKET ACCESS IN PROGRESS



**ES Spain**

**Distributor**

Under negotiation

**Authorised to sell to:**

- Gregorio Marañón Hospital (Madrid)
- Ramón y Cajal Hospital (Madrid)
- Universitario Dr. Peset Hospital (Valencia)
- Virgen de las Nieves Hospital (Granada)

**ApoE4 Project Participants:**

- Biobizkaia Health Research Institute (Basque Country)
- Bioaraba Health Research Institute (Basque Country)
- Osakidetza Research Institute (Basque Country)
- La Paz University Hospital (Madrid)
- IDIAP Foundation – Jordi GOL (Catalonia)
- Juan Canalejo University Hospital (A Coruña)

- Santiago Clinical University Hospital (A Coruña)
- CREA – State Reference Centre for the care of people with Alzheimer's Disease and other dementias in Salamanca (Castille and León)
- Diabetes Group of the Catalanian Health Institute



**PT Portugal**

**Distributor**

Under negotiation

**Collaborating Institutes**

Public and private hospitals.



**MX Mexico**

**Distributor**

Under negotiation

**Collaborating Institutes**

- Nutrition Institute (Cardiology Department).
- National Institute of Neurology and Neurosurgery.



# PROPOSED OPERATION

## Operation

### Requirements

Up to **1 million euros** in one or several instalments, to complete the CDTI funding (**2 million euros**).

### Modality and Closing Date:

Direct investment – **20<sup>th</sup> June 2024**

## Investment Objective (without technological risk)

### Position

**e4Risk\*** & **e4Quant** for new pathologies (cardiovascular and diabetes)

### Validate

**e4Risk\*** & **e4Quant** as IVDR

### Authorisation

by the FDA

### Development

of an E4 and E2 antibody of its own.

### Awareness

Awareness-raising actions to position the ApoE4 biomarker.

### Approach

New markets and New pathologies

## Current Assessment

8.2 Million €

## Assessment Criteria

Last capital increase paid in by third parties (CDTI and others).

## Disinvestment / Exit 2028

- Sale to an industrial investor (licensee/transferee)
- Sale to a Growth Fund
- Secondary Market
- Estimated Value at 5 years: > 50 million €  
IRR: > 40%  
Multiple: 5X

# Thank you!

**Biocross SL**

Av. Francisco Vallés, 8

47151 – Boecillo (Valladolid, ES)

[www.biocross.es](http://www.biocross.es)