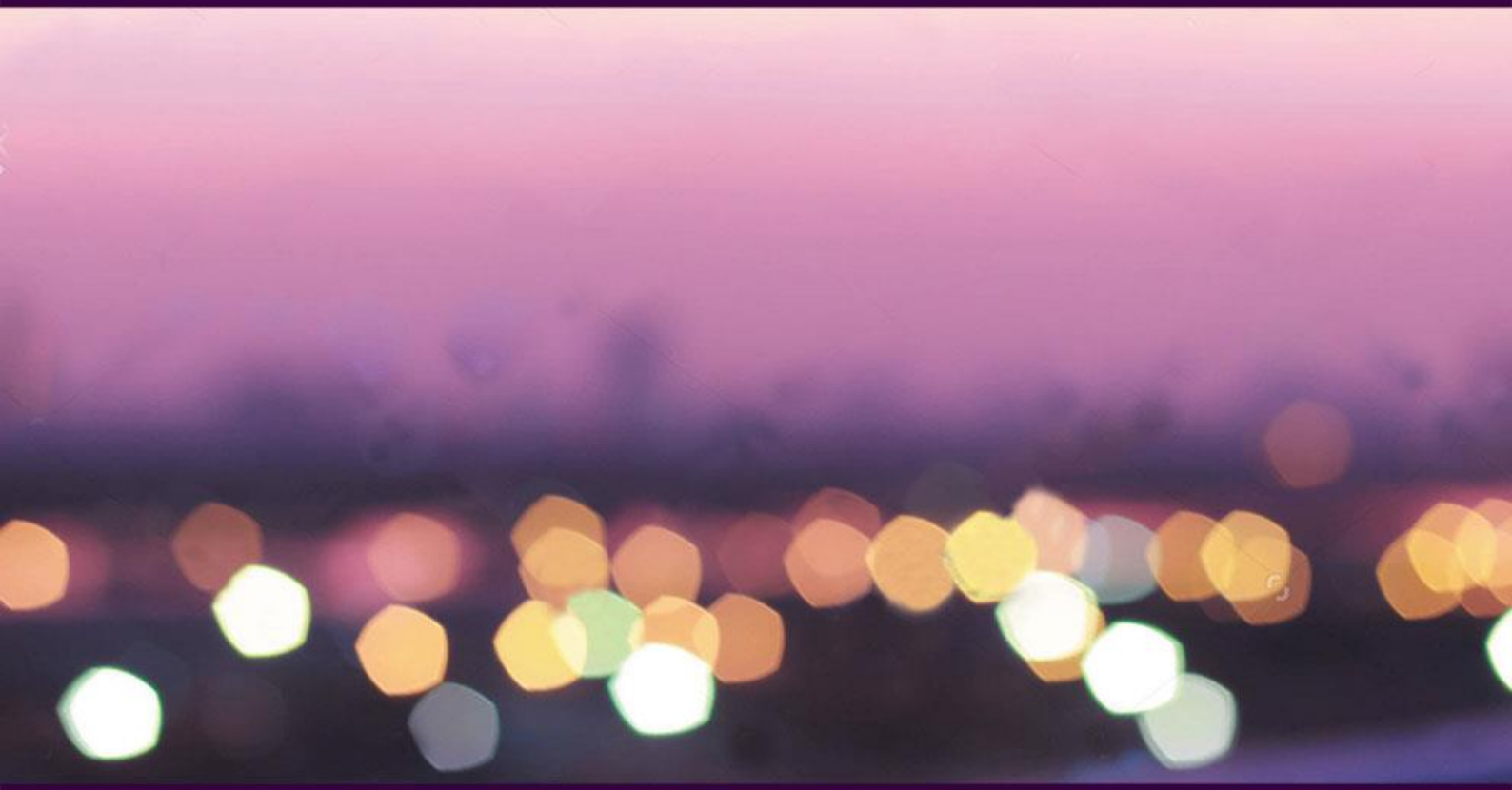
Corporate Profile



biocross

Get ahead of time

CORPORATE PROFILE

Company name:

Biocross S.L.

Established:

January 26, 2005

Head of Office:

Parque Tecnológico de Boecillo
Avda. Francisco Vallés, 8
47151 – Boecillo (Valladolid), Spain

CIF: B84250869

Phone: +34 983 54 98 96

web site: www.biocross.es

email: info@biocross.es

Management:

Matthew Mittino CEO

Pablo C. Albendea CSO

Current shareholders:

Cross Road Biotech, S.A., SCR

ADE Financiación Capital Semilla, FCR

ADE Capital Sodical, SCR

UGAZUA S.L.

Number of employees: 5

Previous rounds:

Invested to date: €1,789,700

Seed round: €119,000

First round: €370,000

Second round: €700,000

Third round: €600,000

Investment required:

€3,200,000

Use of funds:

European multicenter validation study

CE marking

US FDA registration

Business description

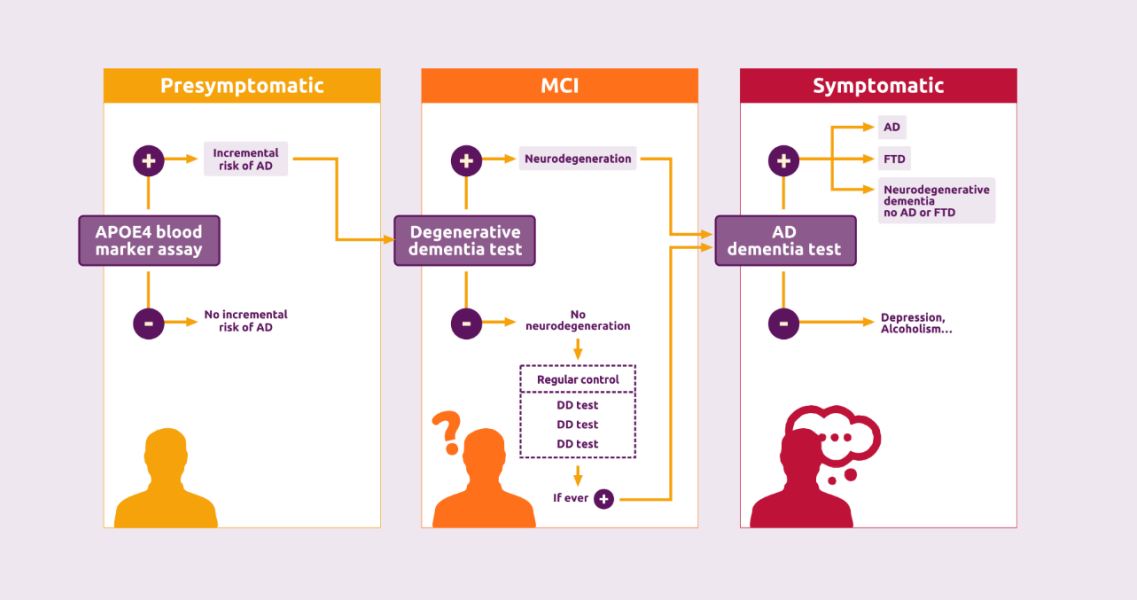
Biocross is a biotechnology company focused on the *in vitro* diagnosis of neurodegenerative diseases. Our most advanced projects involves the development of blood tests for the diagnosis of Alzheimer's disease and for the detection of ApoE4, the latter designed for use in early risk assessment for AD. All of our products are compatible with standard hospital equipment.

Unmet Need

- No blood tests have been validated for the diagnosis of Alzheimer's disease.
- Current diagnostic approaches are not very accurate; they are based on clinical criteria that allow diagnosis of Alzheimer's disease with a maximum of probability of 70%. This lack of accuracy is even more pronounced in the early phases of the disease.
- Efficacious use of treatments currently in development will be dependent on early and accurate diagnosis of the disease, as they will most likely be administered during early disease stages.
- New diagnostic techniques for Alzheimer's disease will face huge demand.
- Commercialization of a new Alzheimer's disease treatment will entail a massive demand for new diagnoses. Only simple and automated techniques will be capable of efficiently addressing this demand.

Project Status

Biocross' objective is to develop a series of blood tests for the diagnosis of Alzheimer's disease, thus providing neurologists with an integrated diagnostic solution that can be applied to any stage of the disease, including the earliest, asymptomatic phase.



ApoE4 blood marker assay

Currently, *APOE4* is detected by PCR or by ELISA (the reference technique), but no test is available that can be easily incorporated into routine hospital testing procedures.

Biocross proposes a non-genetic test designed to be used for early risk assessment for AD by identifying *APOE* ε4 carriers, and as a potential pharmacological treatment guide for targeted therapies. This blood-based test can be run on standard automated chemistry systems to identify individuals with elevated risk of developing late-onset Alzheimer's disease.

The following are some of the advantages of the ApoE4 blood marker assay:

- Detection of at-risk patients (*APOE* ε4 carriers) would enable physicians and patients to make lifestyle-based interventions that could prevent or delay the development of the disease.
- ApoE4 detection is currently being used to guide enrichment strategies and stratify patients in the latest clinical trials evaluating experimental AD treatments.
- Early identification of ApoE4 carriers will allow regular monitoring of this at-risk population so that treatment can be administered as soon as symptoms develop, thereby maximizing neural tissue preservation

This test is currently in large-scale production awaiting CE marking.

AD dementia test

From the outset, we have insisted on a meticulous sample selection process in order to identify highly sensitive and specific biomarkers. We have analyzed samples from patients with other Alzheimer's-like forms of dementia, including frontotemporal dementia, the symptoms of which can be confused with those of Alzheimer's disease.

A second clinical trial has demonstrated high levels of accuracy for our blood test and has laid the foundations for a multicenter study for validation of the procedure.

Our multiparametric assay combines different types of biomarkers, including metabolites, disease-related peptides, and protein markers. Because the test involves analysis of a simple blood sample, it is easily standardized and can be adapted to standard hospital laboratory equipment.

Our priority is to reach a level of accuracy non-inferior to that offered by cerebrospinal fluid analysis. Moreover, the test must be simpler and less costly than currently available approaches (cerebrospinal fluid analysis and imaging techniques).

The test is currently in the developmental phase. More than 350 samples from patients with Alzheimer's disease and healthy volunteers with no cognitive impairment are being analyzed in a European multicenter study involving 16 hospitals and the Alzheimer's Project of the Queen Sofía Foundation (Fundación CIEN).

Degenerative dementia test

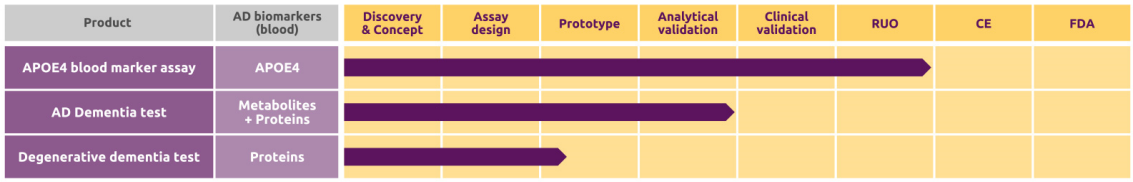
The objective of this test is to screen asymptomatic patients and identify those with and without neurodegeneration caused by Alzheimer's disease or frontotemporal dementia.

It is designed to address a future unmet need: the detection of neurodegeneration in asymptomatic individuals. While its immediate usefulness may not be apparent, its development in the context of new treatments for Alzheimer's disease is of major strategic value to Biocross.

In the medium-term, after development of an effective treatment for Alzheimer's disease, this product will constitute the first step of an overall treatment strategy, allowing the physician to detect patients with neurodegeneration due to AD or FTD. In the case of a positive result, the physician can proceed to the confirmatory ApoE4 test. Practitioners will thus have a sufficient range of diagnostic tools to monitor and/or treat patients.

The Degenerative Dementia test is a multi-parametric blood-based biochemical and metabolite test that can be performed using a standard automated chemistry system.

Pipeline



Patents

Patent	Title	Patent nº
1	Method for the diagnosis of Alzheimer´s disease and mild cognitive imparment	EP14382203.9
2	Method for the diagnosis of Alzheimer´s disease and mild cognitive imparment	EP1438261.3
3	Methods for apolipoprotein detection	EP15382537.7

Papers

Journal of Alzheimer's Disease 2015; 45(4):1157-73 DOI 10.3233/JAD-142925

Partners

Alzheimer’s disease is the most common form of dementia and the fourth cause of death in developed countries. Around 24 million people worldwide have Alzheimer’s, and a further 70 million cases are expected to be diagnosed within the next 20 years.

Biocross works in close collaboration with Fundación CIEN, a center specialized in Alzheimer's disease research. The center has a 3T MRI scanner and a biobank of patient samples. A prospective study of an elderly population of more than 1,000 participants will allow complete validation of the technology developed by Biocross.