Pre Diagnostics

Company introduction

Investor presentation

20th June 2025

Håkon Sæterøy, CEO & Co-founder
Erik Christensen, CMO & Co-founder
Professor Ole Petter Ottersen, Executive Chairman

The PreDx team

Management team and board with broad experience from life science industry and family office investments

Management

Håkon Sæterøy

CEO, *co-founder*
M.Sc Economics and

Erik Christensen

CMO, *co-founder*
MD, PhD

Line Amundsen

Laboratory Director
M.Sc Chem

A dedicated R&D & lab team with key competences

- Neuroscience
- Biomarkers
- Product development
- Production of assay kits
- Chemistry
- Biotechnology
- Quality management systems
- Clinical lab operations

Board

Prof. Ole Petter Ottersen MD PhD, Chairman

- President at Karolinska Institutet 2017-23.
- Before that he served eight years (2009-2017) as rector of the University of Oslo.
- Director of Centre for Molecular Biology and Neuroscience 2002-09

Ståle Kvitle
- DEFA
- Former Johnson & Johnson executive

Nicolas Brun-Lie
- senior lawyer and private investor, owner of Orinoco AS, the largest shareholder of PreDx

Birgit Nistad
CEO Nistadgruppen AS, family office investor

Marie Skarbøvik Buchmann
MD PhD
- Former medical Director Fürst Medical Laboratory

EU grant: Project FluiDx-AD

Evaluation Summary Report

Evaluation Result

Total score: 14.50 (Threshold: 12)

Criterion 1 - Excellence

Score: 5.00 (Threshold: 4 / 5.00 , Weight: -)

Criterion 2 - Impact

Score: 5.00 (Threshold: 4 / 5.00 , Weight: -)

Criterion 3 - Quality and efficiency of the implementation

Score: 4.50 (Threshold: 3 / 5.00 , Weight: -)

- Score 14.5 out of max 15

From the Evaluation Summary Report:

- *"The objectives are **highly ambitious***
- *The proposal goes **beyond the state of the art***
- *The proposed **objectives are very clear, relevant, and highly pertinent** to the Call topic*
- *The **quality of the evidence provided is outstanding and contains convincing justification***
- *The **objectives are realistic, measurable, and adequately verifiable***

Funded by
the European Union

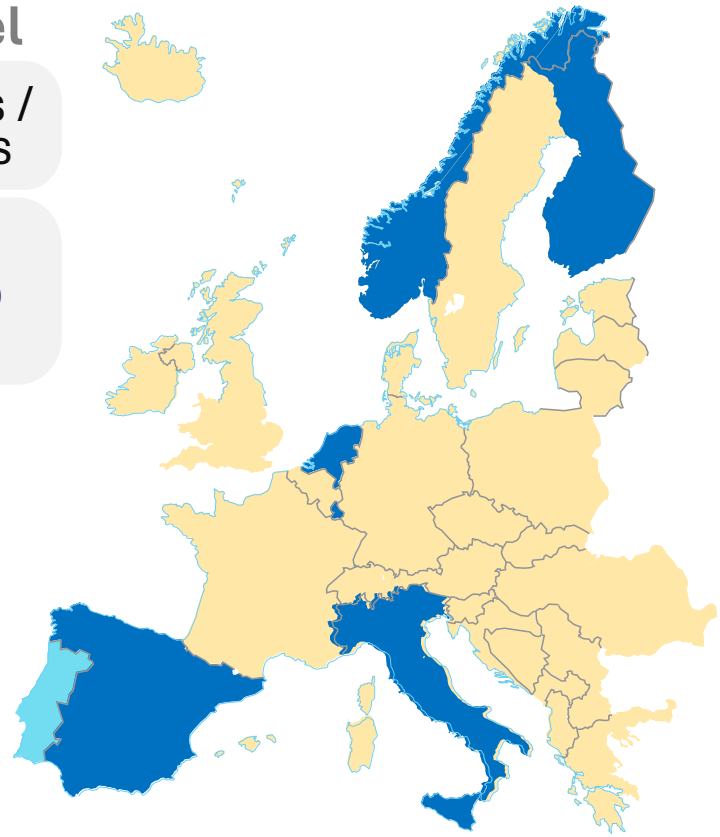
Besides contributing to FluiDx-AD's goals, our consortium is poised to accelerate the post-project translation of project outcomes

SalivaDx-AD | PlasmaDx-AD | BloodCellDx-AD

Commercial partners	KOLs	Customers (hospitals)	End-users (patients, carers)
PreDx PreNeuro HemoDx	OUS UCSC FPG FCIEN HUS AE	OUS FPG FCIEN HUS	AE

HTA simulation model

Commercial partner	Customers / End-users
Medip	PreDx PreNeuro HemoDx



Total budget is 90 mill NOK, 65% to Norway

- OUS legal and financial coordinator
- PreDx scientific coordinator

[innovayt] *Supported the grant application out of Portugal*

Pre Diagnostics AS
A Norwegian neuroscience company

Founded in 2013 - based on exclusive and global rights to IP (patents, antibodies and know-how)

In house neuro service laboratory – dedicated team of scientists with state-of-the-art instruments

Collaboration-based model wit academia and industry Partner in the European Consortium “AI-Mind” - with leading academic institutions and a global IVD company

Research grants from the prestigious EU Horizon 2020 program and from the Research Council of Norway (RCN) for ARIA and Parkinson’s projects:

- 2019-21: EU-project VERDAD – AD biomarkers
- 2024: Awarded funding for the European consortium FluiDx-AD for developing new tools for AD diagnosis and management.

Goal: Enable precision medicine for patients by partnering with academia and industry

The new Alzheimer's paradigm: The AD patient journey

Clinical need of diagnostics for easy and effective diagnostics in early phase and new pharma treatments available

Blood Test Diagnosis + **Treatment Options**

2025 Pipeline
AD Drug Development, MoA Amyloid

Eisai Therapeutics · Biogen · Lilly · Lundbeck · Roche · UNITED NEUROSCIENCE · AMGEN · NOVARTIS · AZTHERAPIES · anavex · Araclon Biotech (GRIFOLS) · COGNITION Therapeutics · GRIFOLS · Aphios

Long-term Treatment +
Monitoring side effect

Patient:
Do I have Alzheimer's?

Our **Solution**

CE marked Biomarkers enabling precision medicine

“Early days" and very large unmet need for biomarkers within neurodegenerative diseases for pharma as well as clinical diagnostics

- Identifying patients with active neurodegeneration earlier
- Predicting the likelihood that a therapy may be effective in certain individuals by identifying subgroups
- Predicting risk groups with regards to adverse effects to ensure safety

Enabling pharma researchers and clinicians to provide the right treatment to the right patients at the right time. **Potentially a strategic tool to improve market penetration for effective immunotherapies with ARIA concerns.**

Strong patent portfolio around PreADx assays for use in AD, CAA and ARIA

PreADx patent portfolio currently comprises 6 patent families

Initial IP developed by key inventors prof. Tormod Fladby (Akershus University Hospital) and prof. Kaj Blennow (University of Gothenburg)

- **2009 & 2013:** Patents filed covering diagnostic and monitoring use of Ab X-34 peptides in AD management
  - Additional granted patents and applications within PD, MS, FTD, ALS & Lewy body
- **2020:** Patent application filed covering “Clearance assay concept” i.e. *ex-vivo* cell model
- **2022:** Patent application filed on the specific “ARIA” concept
- **Jan 2024:** Patent relevant for ARIA allowed in the US

PreADx tests are proprietary immunoassays

Measuring intracellular clearance of biomarkers for Alzheimer' disease through a two-step process

Monocyte isolation

Automated isolation of monocytes using antibody-based paramagnetic beads for positive extraction (proprietary process)

Immunoassay

Quanterix' technology with digital detection of PreDx' proprietary monoclonal antibodies with high affinity for specific peptide cut-points

Proprietary antibodies

- Proprietary antibodies
- Exclusive supply rights

Know how

- Inhouse-developed blood handling method
- Immunoassay

Patent Families

- 2 core diagnostics patents (priority year 2009 +)
- 1 use patent (filed 2021, includes clearance assay concept + ARIA application
- Global excusive rights global rights secured

PreADx platform consists of two CE-marked immunoassay kits and monocyte isolation kits and procedures

20-X

Ab 20-X assay demonstrates robustness and improved diagnostic performance characteristics vs X-34, incl. stronger early-phase signals

CE ✓

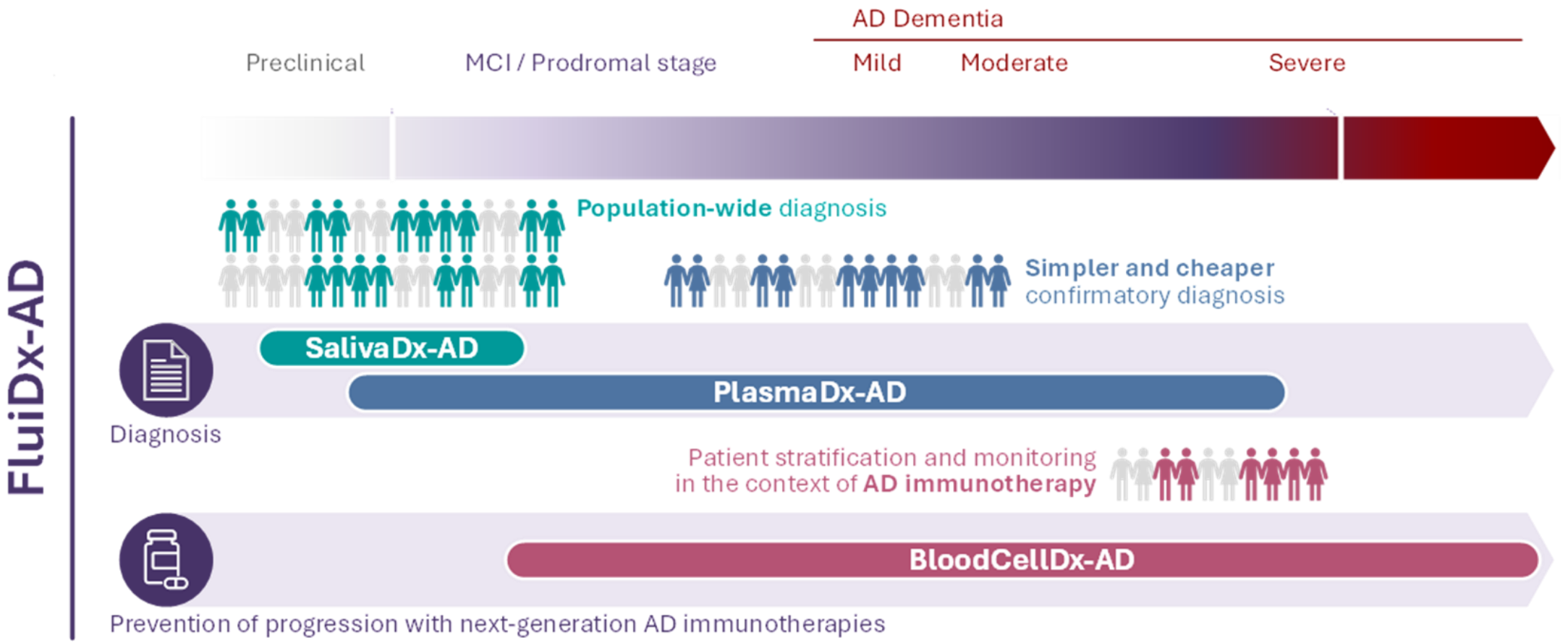
X-34

Ab X-34 demonstrates high clinical significance related to CNS amyloid pathology, and will be used in the ARIA detection project

CE ✓

Biomarker Selection → Feasilbility Studies → Prototype Assay → Analytical Validation → Research Use Only → Regulatory Approval

FluiDx-AD - A novel test trio to detect peptide biomarkers in saliva and blood for enhanced diagnosis and management of Alzheimer's Disease

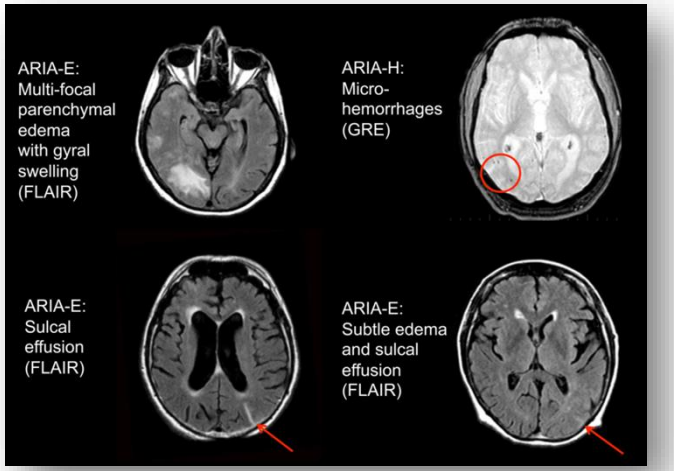


EU call: Treatments for some high-burden brain disorders are potentially on the horizon.

AD Immunotherapy pipeline

- Several of the immunotherapy treatments have demonstrated disease modifying effects, althoug moderate, and questionable efficacy due to the rather high cost of treatment and side effects
  - The first 2 with FDA approvals – non in the EU yet

Roche · Eisai · Lilly · Biogen · BIOARCTIC · neurimmune



https://doi.org/10.1016/s1474-4422(12)70015-7

ARIA*: Serious Adverse Effect

- ARIA is serious swelling/bleeding of the brain in patients as a response to amyloid-targeting immunotherapy
- Up to 30-40% of patients eligible for treatment at risk for ARIA
- **Currently, no tools available for determining a patient's ARIA risk nor any fluid biomarkers detecting ongoing ARIA**

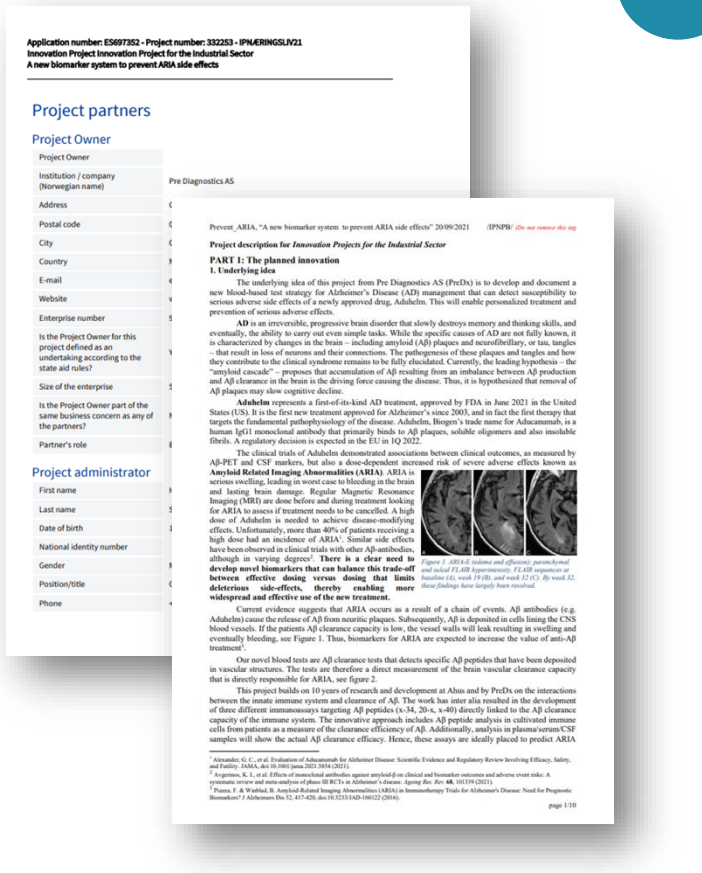
* Amyloid Related Imaging Abnormalities

"It is not clear that the abnormalities (ARIA) can be properly monitored and managed in clinical practice"

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pre Diagnostics

The Research Council of Norway - Grant #337046
“A new biomarker system to prevent ARIA side effects” - two products


Application number: ES697352 - Project number: 332253 - IPNÆRINGSLIV21
Innovation Project Innovation Project for the Industrial Sector
A new biomarker system to prevent ARIA side effects

Project partners

Project Owner

Project Owner	
Institution / company (Norwegian name)	Pre Diagnostics AS
Address	
Postal code	
City	
Country	
E-mail	
Website	
Enterprise number	
Is the Project Owner for this project defined as an undertaking according to the state aid rules?	
Size of the enterprise	
Is the Project Owner part of the same business concern as any of the partners?	
Partner's role	

Project administrator

First name	
Last name	
Date of birth	
National identity number	
Gender	
Position/title	
Phone	

Prevent_ARIA, “A new biomarker system to prevent ARIA side effects” 20/09/2021 /IPNPB/ (Do not remove this tag)

Project description for *Innovation Projects for the Industrial Sector*

PART 1: The planned innovation

1. Underlying idea

The underlying idea of this project from Pre Diagnostics AS (PreDx) is to develop and document a new blood-based test strategy for Alzheimer’s Disease (AD) management that can detect susceptibility to serious adverse side effects of a newly approved drug, Aduhelm. This will enable personalized treatment and prevention of serious adverse effects.

AD is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually, the ability to carry out even simple tasks. While the specific causes of AD are not fully known, it is characterized by changes in the brain – including amyloid (Aβ) plaques and neurofibrillary, or tau, tangles – that result in loss of neurons and their connections. The pathogenesis of these plaques and tangles and how they contribute to the clinical syndrome remains to be fully elucidated. Currently, the leading hypothesis – the “amyloid cascade” – proposes that accumulation of Aβ resulting from an imbalance between Aβ production and Aβ clearance in the brain is the driving force causing the disease. Thus, it is hypothesized that removal of Aβ plaques may slow cognitive decline.

Aduhelm represents a first-of-its-kind AD treatment, approved by FDA in June 2021 in the United States (US). It is the first new treatment approved for Alzheimer’s since 2003, and in fact the first therapy that targets the fundamental pathophysiology of the disease. Aduhelm, Biogen’s trade name for Aducanumab, is a human IgG1 monoclonal antibody that primarily binds to Aβ plaques, soluble oligomers and also insoluble fibrils. A regulatory decision is expected in the EU in 1Q 2022.

The clinical trials of Aduhelm demonstrated associations between clinical outcomes, as measured by Aβ-PET and CSF markers, but also a dose-dependent increased risk of severe adverse effects known as **Amyloid Related Imaging Abnormalities (ARIA)**. ARIA is serious swelling, leading in worst case to bleeding in the brain and lasting brain damage. Regular Magnetic Resonance Imaging (MRI) are done before and during treatment looking for ARIA to assess if treatment needs to be cancelled. A high dose of Aduhelm is needed to achieve disease-modifying effects. Unfortunately, more than 40% of patients receiving a high dose had an incidence of ARIA[1]. Similar side effects have been observed in clinical trials with other Aβ-antibodies, although in varying degrees[2]. **There is a clear need to develop novel biomarkers that can balance this trade-off between effective dosing versus dosing that limits deleterious side-effects, thereby enabling more widespread and effective use of the new treatment.**

Figure 1. ARIA-E (edema and effusion); parenchymal, and raised FLAIR hyperintensity. FLAIR sequences at baseline (A), week 19 (B), and week 32 (C). By week 32, these findings have largely been resolved.

Current evidence suggests that ARIA occurs as a result of a chain of events. Aβ antibodies (e.g. Aduhelm) cause the release of Aβ from neuritic plaques. Subsequently, Aβ is deposited in cells lining the CNS blood vessels. If the patients Aβ clearance capacity is low, the vessel walls will leak resulting in swelling and eventually bleeding, see Figure 1. Thus, biomarkers for ARIA are expected to increase the value of anti-Aβ treatment[3].

Our novel blood tests are Aβ clearance tests that detects specific Aβ peptides that have been deposited in vascular structures. The tests are therefore a direct measurement of the brain vascular clearance capacity that is directly responsible for ARIA, see figure 2.

This project builds on 10 years of research and development at Ahus and by PreDx on the interactions between the innate immune system and clearance of Aβ. The work has inter alia resulted in the development of three different immunoassays targeting Aβ peptides (x-34, 20-x, x-40) directly linked to the Aβ clearance capacity of the immune system. The innovative approach includes Aβ peptide analysis in cultivated immune cells from patients as a measure of the clearance efficiency of Aβ. Additionally, analysis in plasma/serum/CSF samples will show the actual Aβ clearance efficacy. Hence, these assays are ideally placed to predict ARIA

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page 1/10

1. Predict ARIA risk before treatment

Excessive immunotherapy releases a storm of peptides potentially overriding the individual Aβ clearance capacity, resulting in toxic effusion and haemorrhage i.e. ARIA E/H

We measure individual total clearance capacity ensuring optimal therapy initiating by a pulse chase study using Aβ1-40 in patient derived circulating blood cells

Goal: **Develop** a **new diagnostic method** for use in clinical labs

2. Diagnose ongoing ARIA during immunotherapy

ARIA E/H is caused by defective CNS pericytes enabling vascular leakage through a defective blood brain barrier

Plasma (or CSF) Ab X-34 measurement reflects the ongoing CNS pericyte Aβ clearance of Aβ1-40.

Goal: **Adapt** our current **diagnostic X-34 assay** for clinical labs

1.

The ARIA Risk Test: Predicting which patients are at risk for ARIA

Developing an ex-vivo monocyte cell model to measure Aβ clearance capacity – a surrogate for ARIA risk

Collection of blood in EDTA tubes

Ship to Lab, +4 °C, <3Days

Arrival in Laboratory

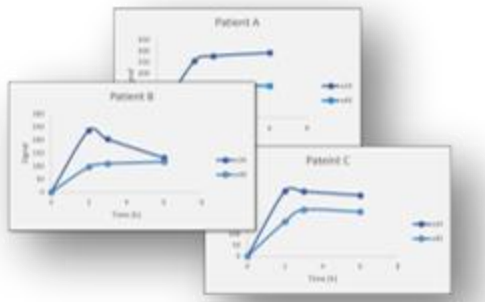
Whole blood culture system

Incubation with Aβ1-40 for different time points over 5h period

Extraction and lysis of monocytes after 37 °C incubation with Aβ

Intracellular measurement of Aβx-34 Aβ20-x and Aβx-40

Assesment of individual monocytic uptake and clearance capacity



Output

The Research Council of Norway - Grant #337046
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Size of the enterprise	
Is the Project Owner part of the same business concern as any of the partners?	
Partner's role	

Project administrator

First name	
Last name	
Date of birth	
National identity number	
Gender	
Position/title	
Phone	

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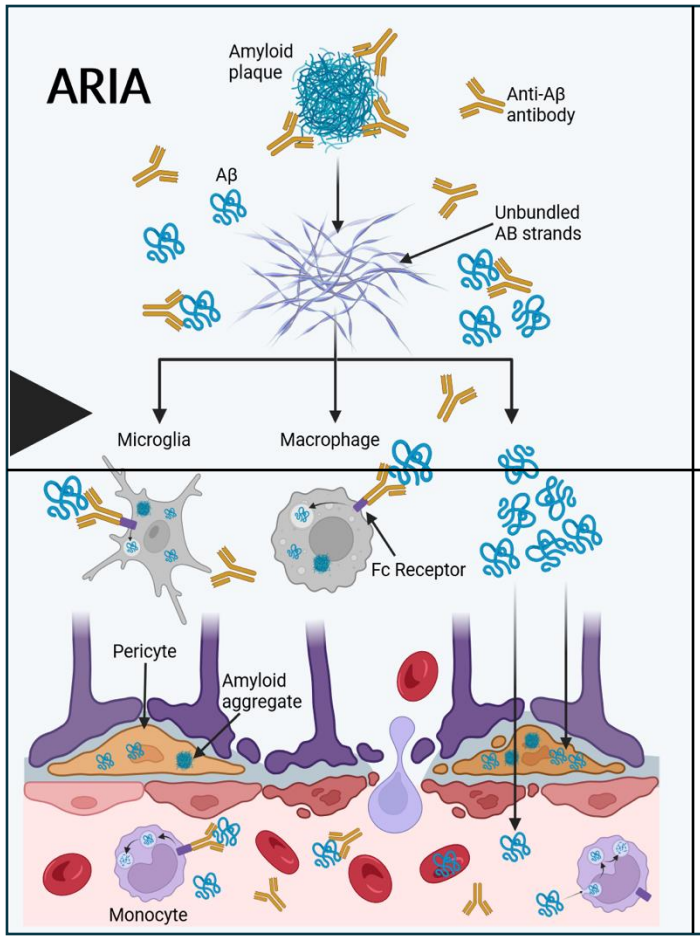
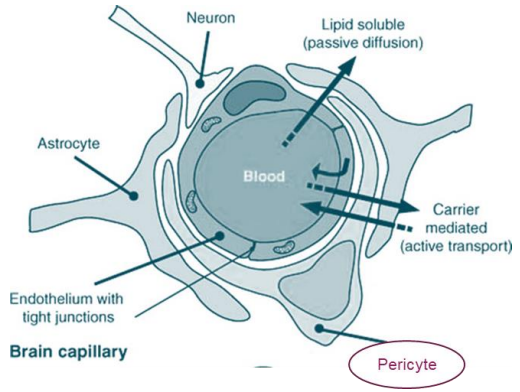
Ongoing ARIA – a result of Anti-Aβ immunotherapy





Pericytes play several important roles

- Development and maintenance of blood–brain barrier (BBB)
- Regulation of the neurovascular system (e.g., Vascular stability, vessel formation, cerebral blood flow, etc.)
- Trafficking of inflammatory cells
- Clearance of toxic waste products from the brain

The amyloid-β degradation intermediate Aβ34 is pericyte-associated and reduced in brain capillaries of patients with Alzheimer's disease. Kirabali et al. Acta Neuropathologica Communications (2019) 7:194

CSF Aβ34 is generated by a novel BACE1-mediated Aβ clearance pathway in pericytes of brain capillaries.

As amyloid clearance is significantly reduced in AD, impairment of this pathway might be a major driver of the pathogenesis in sporadic AD

Defective pericytes can't handle the increased amyloid-load from *aducanumab* and other immunotherapies, causing BBB-breakdown and effusion into the brain parenchyma (ARIA).

Current investor base* and funding secured

Shareholders:

Number of shares: 439726				
Rank	Holding	Stake	Name	First name
1	56800	12.91713	ORINOCO AS	
2	51133	11.62838	INVEN2 AS	
3	38480	8.75090	HATHON HOLDING AS	
4	30000	6.82243	NISTAD PD AS	
5	29541	6.71805	CHRISTENSEN	ERIK
6	27500	6.25389	CANIO AS	
7	27250	6.19704	INVESTOR CORPORATE AS	
8	22500	5.11682	BIOVENTIX PLC	
9	20000	4.54829	SÆTERØY	HÅKON
10	18000	4.09346	LANDERUD HOLDING AS	
11	12050	2.74034	SWENSON	FRANCIS JOSEPH
12	11600	2.63801	JEKL Holdings Pty Ltd ATF	
13	11028	2.50793	THOV HOLDING AS	
14	9680	2.20137	NORSEMETER AS	
15	8500	1.93302	S. UGELSTAD INVEST AS	
16	7020	1.59645	ROLFS HOLDING AS	
17	6985	1.58849	KVITLE	STÅLE CHARLES
18	5000	1.13707	GIERCKSKY+NILSSEN AS	
18	5000	1.13707	BOOIJ	BIRGITTE BOONSTRA
20	4500	1.02336	CEBENOTTO AS	

FUNDING:

- Total raised equity of MNOK 60
- Before 2024: MNOK 70 raised in form of non-dilutive grants, of which MNOK 10 remaining to be paid out from RCN during 2025
- 2024: Innovation Loan MNOK 5 from Innovation Norway
- 2024: MEUR 7,7 (MNOK 90) EU grant obtained for consortium led by PreDx – a 100% non-dilutive financing for optimization and clinical validation of our AD biomarkers

**As per June 2025 (incentive warrants for board & employees not included)*

Technology potential recognized by US life science analysts

Recently PreDx has entered into an agreement with the US based financial services firm BTIG to provide strategic and capital markets advisory services

The BTIG analyst wrote:

"I am very excited about all the diagnostic/monitoring/personalized medicine opportunities in neurodegenerative diseases, and I think it's a great time to be a key player in the space right now."

“State of the art” laboratory and a highly skilled team of scientists

- Building key capabilities within assay development and production internally
- Relying on the advice of our scientific advisors and leveraging the expertise of technology partners

Oslo University Hospital

UiO : University of Oslo

UNIVERSITY OF GOTHENBURG

UNIVERSITÀ CATTOLICA del Sacro Cuore

HUS Helsinki University Hospital

cien Fundación Centro Investigación Enfermedades Neurológicas

Alzheimer Europe

MEDIP ANALYTICS Health Economic Software

Bioventix

ThermoFisher SCIENTIFIC

Quanterix

MSD Meso Scale Discovery