



#### The team

Management team and board with broad experience from life science industry, now strengthening board with international scientific and business team

#### Management



**Erik Christensen CMO,** co-founder
MD, PhD









Håkon Sæterøy

CEO, co-founder

M.Sc Economics and Business







Line Amundsen
Laboratory Director
M.Sc Chem



#### **Board**



Ståle Kvitle

Chairman of the board

Former Johnson & Johnson Director

MBA



Nicolas Brun-Lie
Senior Lawyer and private investor
Law degree, Cand Jur



Partner, Great Leadership Institute
Master in Political Science

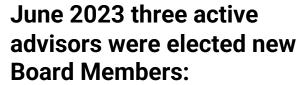
Thorbjørn Overholt

#### **Inventor & Scientific Advisor**



**Dr. Tormod Fladby** 

**Head of Neuroscience Dept. Akershus University Hospital** Professor, Dr Med



- Professor Ole Petter Ottersen, MD, PhD (Neuroscience). Former President of University of Oslo (2009-2017) and President of Karolinska Institutet (2017-2023).
- Laura Chirica, M.Sc, PhD. CEO of Cellevate AB. Former CCO of Immunovia AB, former VP Sales & Marketing of Svar Life Science AB, Global Marketing Program Director of DAKO A/S and Global Product Manager GE Healthcare.
- Marie S. Buchmann, MD, PhD. Medical Director with Fürst medical laboratory 2000-2023.







# Our Solution

# **CE marked Biomarkers enabling precision** medicine

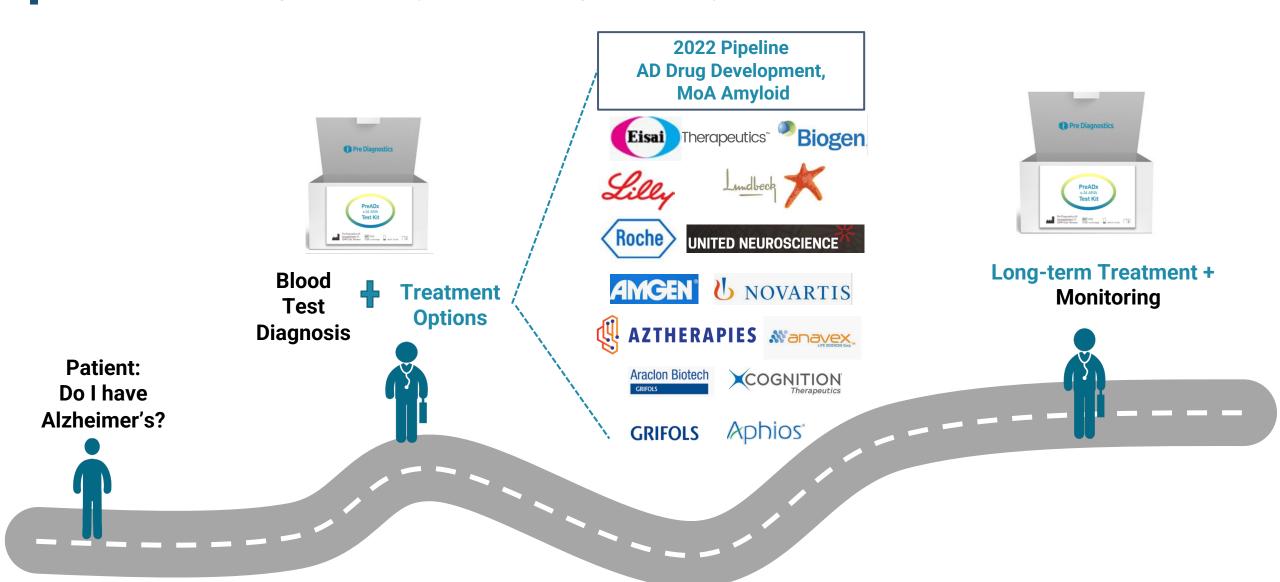
"Early days" and very large unmet need for biomarkers within neurodegenerative diseases for pharma as well as clinical diagnostics

- 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

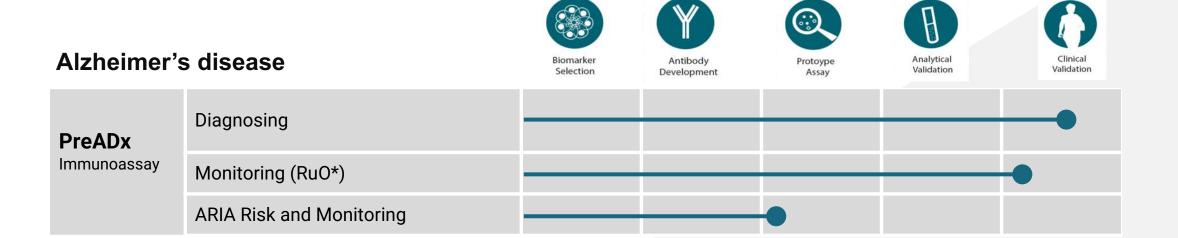
# The new Alzheimer's paradigm: The 2025 AD patient journey

New blood test diagnostics for easy and effective diagnostics in early phase and new pharma treatments available



# We are developing a suite of unique fluid biomarkers for dementia

Our proprietary platform technology with potential to move into precision medicine with ARIA-project



#### Parkinson's disease





# 4 main strategic elements makes 4 company projects 2023-25

Uniquely positioned in neuroscience for a large global market with strong need for dementia-solutions

**PreADx project** 

CE-marked immunoassays from VERDAD project need further clinical validation. Al-Mind, JPND and DDI network. Latest news: To be applied on saliva samples.

**ARIA** project

RCN grant for biomarker system applicable for pipeline of AD immunotherapies. High potential within precision medicine

#### **PrePDx project**

RCN grant for developing bloodbased diagnostics for Parkinson's disease. Very high unmet clinical need, industry interest verified.





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



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



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







Biomarker Selection Feasilbility Studies



Prototype Assay



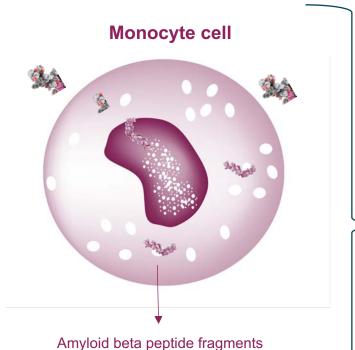
Analytical Validation



Regulatory Approval

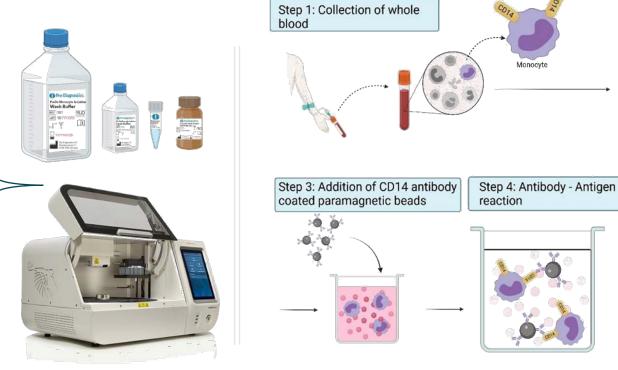
## **Recap of our technology**

Intracellular measurement of biomarkers, with a new monocyte isolation method using paramagnetic beads



#### **Intracellular Measurement**

of biomarkers inside innate immune cells (monocytes) provides disease-specific information for each patient



Step 2: Loading the sample

Step 5: Collection of

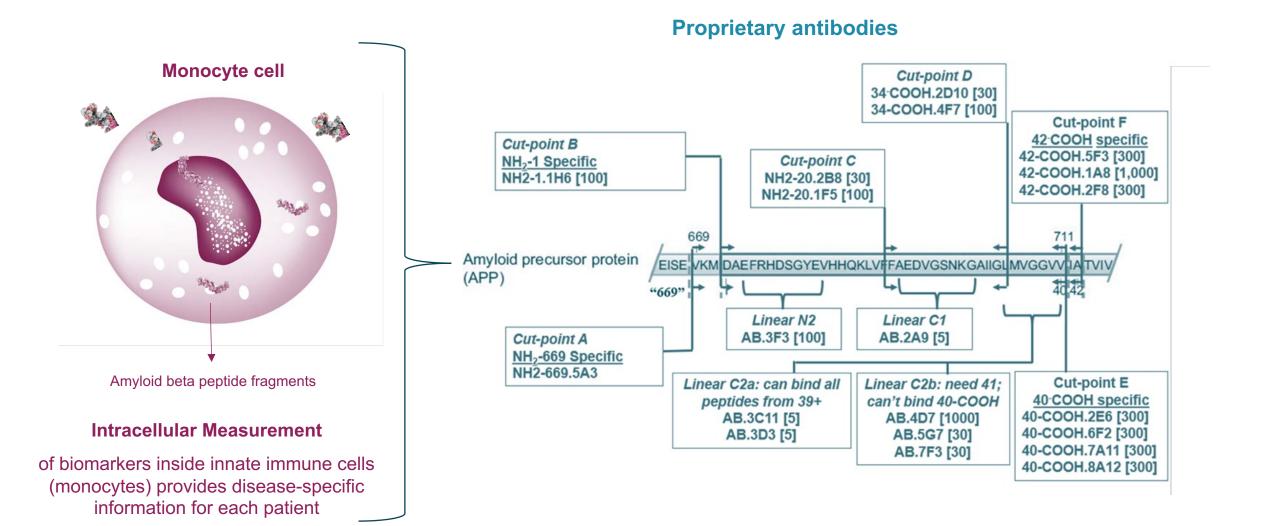
isolated monocytes

paramagnetic beads with

on a 24-well plate

## Recap of our basic technology

Intracellular measurement of biomarkers, with a new monocyte isolation method using paramagnetic beads



# Market traction: Building PreADx clinical utility documentation strategically

Leveraging European collaborations and 3d party clinical studies while building KOL-relations at specialist clinics



Expand

Launch







**Dementia Disease Initation** 

Joint Program on Neurodegenerative Disease Research European network + global industrial collaborations





























Blood and saliva samples from up to 1000 Alzheimer patients – Spain, Italy, Finland & Norway



Clinical studies with access to +5000 blood samples to build biobank

2023-2025

## US launch of new AD immonotherapies has put the spotlight on ARIA

ARIA = Amyloid related imaging abnormalities

#### **AD** Immunotherapy pipeline

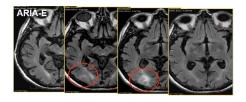
- All immunotherapy treatments that target amyloid plaque have an assosiated ARIA-risk for patients
- Big Pharma players with FDA Breakthrough Drug Designations in 2021, potential launch from 2023 onwards pending FDA approval

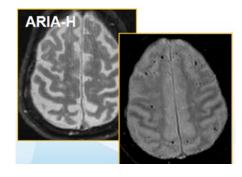












#### **ARIA: Serious Adverse Effect**

- ARIA is serious swelling/bleeding of the brain in patients as a response to amyloid-targeting immunotherapy
- Up to 40% of patients eligible for treatment at risk for ARIA
- Currently, no tools available for determining a patient's ARIA risk

CE-marked PreADx X-34 test to be used in a new category within AD diagnostics – market traction AI-Mind partner & global IVD player



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

EUROPEAN MEDICINES AGENCY

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

Application of CE marked test PreADx monocyte X-34 to measure maximal Abeta clearance capacity



#### **Blood Draw**

Maria will have her blood sample taken at the doctor's office and the sample is sent to our lab

#### **Monocyte Cultivation**

Live cells from blood sample used to cultivate monocytes for 1-2 days before further processing

#### PreADx test

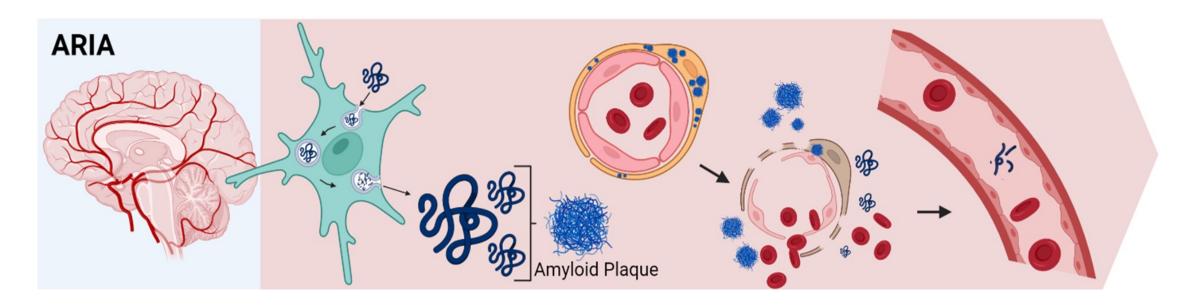
Monocytes overloaded with Amyloid, PreADx assays used to measure the maximal clearance capacity

#### Read-out

Maria's unique potential biological response to immunotheraphy will be analysed

# Amyloid-targeting immunotherapy adversely impact pericyte activity

Defective pericytes clear fewer Aβ 34-fragments, and less of this biomarker will transfer to the blood

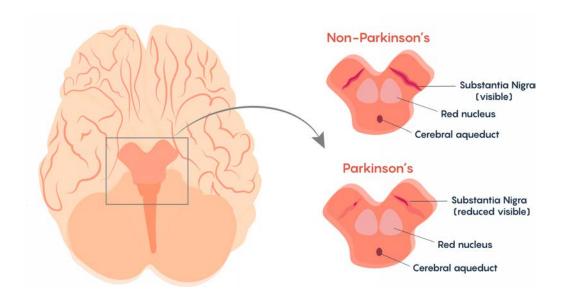


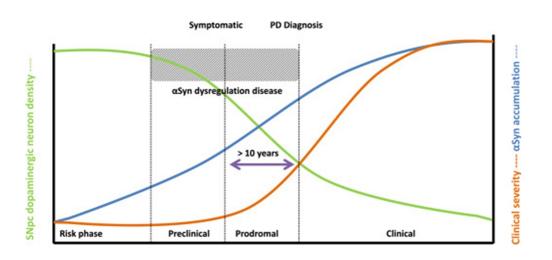
- A defective pericyte apparatus will hamper normal clearance and lead to increased Aβ flow due to the amyloid-targeting immunotherapy effect
  - $A\beta$  1-40 will be cleared by pericytes until  $A\beta$  1-42 accumulates and destroys pericytes
- This increased flow causes leakage of cells and fluid into the CNS as seen in ARIA
- Less Aβ 34 fragments are detected by PreADx X-34 in blood
- PreADx X-34 as a surrogate marker for pericyte viability



# The challenge: Parkinson's Disease

- A neurodegenerative disease; motor symptoms and eventually cognitive defects.
  - A massive neurodegeneration upon initial clinical diagnosis
- The protein alpha Synuclein (α-Syn), central in neurotransmitter release, is widely considered to be a biomarker for PD.
  - Due to extensive Post Translational Modifications (PTMs), Total α-Syn in plasma and CNS has failed as a clinically relevant biomarker.
- Early PD detection is needed to pave the way for major advances in disease modifying therapies

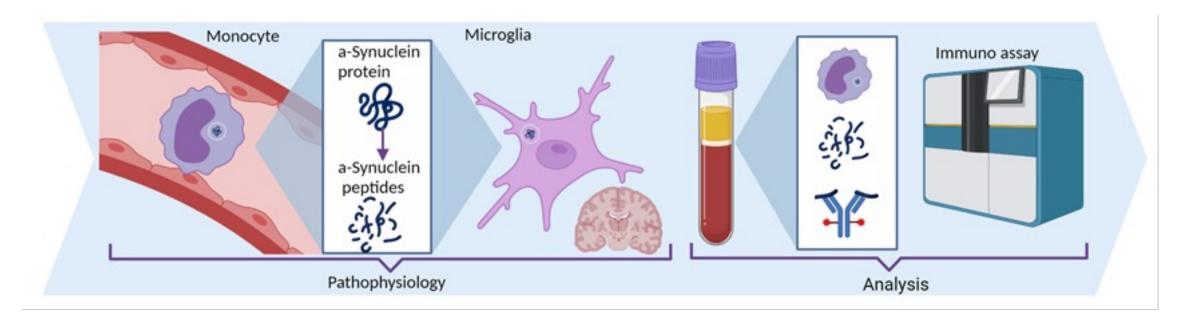




# Currently no early, specific blood-based test exists



# Our solution: Intracellular measurement of α-Syn fragments



- The innate immune system plays a pivotal role in clearance of the toxic proteins in neurodegenerative diseases
- Our hypothesis is that the  $\alpha$ -Syn clearance efficiency and cleavage pattern in monocytes of PD patients deviates from healthy persons.
- Monocytes are isolated from a blood sample followed by lysis. Specific antibodies will bind to α-Syn peptides, and their concentration are measured by an immunoassay.

# **Collaborators Parkinson's project**

#### **Academic**











Nasjonal kompetansetjeneste for bevegelsesforstyrrelser

#### Corporate









Mathias Toft, MD, PhD
Head of Neuroscience Dept
Oslo University Hospital
Professor



Lasse Pihlstrøm, MD, PhD Head of research, Neuroscience Dept Oslo University Hospital



Tormod Fladby, MD, PhD
Head of Neuroscience Dept
Akershus University Hospital
Professor



**Krisztina K. Johansen, MD, PhD**Akershus University Hospital





### Lab and **Development** Capabilities

- Assay development and method transfer
- Validation
- Biomarker and lab services
- IVD kit production
- QMS according to ISO13485
- Partnership with antibody provider
- Development platforms
- SIMOA, ELISA, MSD, MS

# Fluid biomarkers that enable precision medicine

 Large unmet need for biomarkers within neurodegenerative diseases for pharma as well as clinical diagnostics



- Identify patients for new treatment opportunities
- Monitor the safety of a therapy
- Determine if a treatment is having the desired effect on the body
- Predict patients who might respond better to a drug from a safety or efficacy perspective
- Potentially enable time and cost savings in clinical trials

Enabling pharma industry and clinicians to target the right treatments to the right patients at the right time



# Pre Neurolab Service Laboratory for market traction

Research service lab ongoing

ongoing (Al-Mind + JPND) **Pharma services** 

Pharma services

Biomarker development and sample analysis Next phase: Clinical diagnostic services lab

ISO15189 certified

# **Market Strategy for PreADx Biomarkers**

PreADx Biomarkers aimed at the pharma as well as diagnostics segments



### PreADx

# <u>Providers</u>

Antibodies
Assay
Out licensing deal
Earlier detection of AD patients

#### **Pharma Partners**

Co-development through inclusion in clinical trials
Stratification, Safety and efficacy applications

#### **Laboratory services**

Diagnostic testing within neurodegenerative diseases
PreDX CE-IVD kits as base

Early proof of concept and generation of clinical data

# Latest project: Funnelling dementia test based on saliva

#### **Extract from new grant application Research Council of Norway June 2023:**

"For the first time in 20 years new Alzheimer's disease (AD) drugs are entering the market.

- The underlying innovation of the present project is to develop a *funnelling diagnostic test* that is suitable for screening of individuals who could be eligible for these new immunotherapies.
- In addition, the novel test would be ideal as a *home-to-lab based test* grounded on a new analytic system for detecting disease specific biomarkers in saliva.

A bio resource such as saliva will allow individuals to self-collect and send samples to centralized medical laboratories for clinical investigation under ambient conditions, a much more simplistic pre-analytical alternative than currently available alternatives.

• The patent protected innovation has the potential to assist in identifying individuals in the long pre-symptomatic phase of AD, and who might benefit the most from clinical/therapeutic interventions."

## 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."

