Pre Diagnostics AS – Company Introduction

Pre Diagnostics AS *is an R&D-based biotech company developing diagnostic tests for dementia diseases, initially to be provided through an own diagnostics services laboratory. A NOK 35 million Horizon 2020 SME phase II project has funded our lab facilities with a highly skilled team, and also secured CE-mark for PreADx - an Alzheimer's disease blood test - the first phase of achieving our goal to build a leading neuroscience company. The PreADx immunoassay is the first diagnostic test in a pipeline of patented candidates within the largest neurodegenerative diseases. After PreADx, the next diagnostic product under development is a novel blood biomarker for Parkinson's disease. Currently 9 employees + active board member prof. Ole Petter Ottersen (former president of both University of Oslo and Karolinska Institutet).*

Dementia diseases: A growing health crisis

Dementia is a large and growing global burden. It is a symptom of certain neurodegenerative diseases, and Alzheimer's disease (AD) is the most common followed by Parkinson's disease (PD). Dementia care costs are soaring.

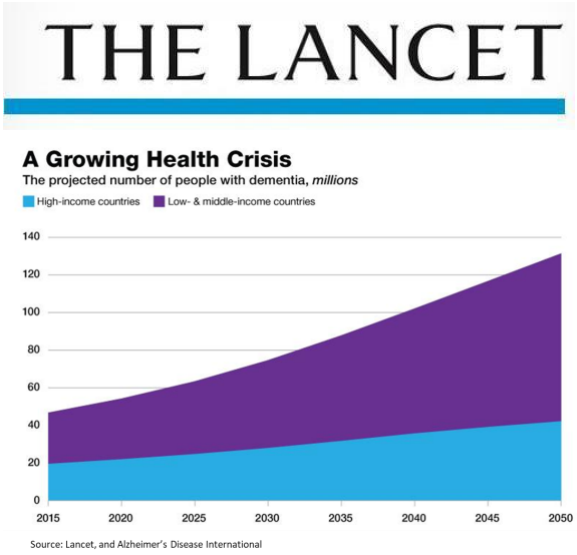
Early detection: Key in fighting diseases

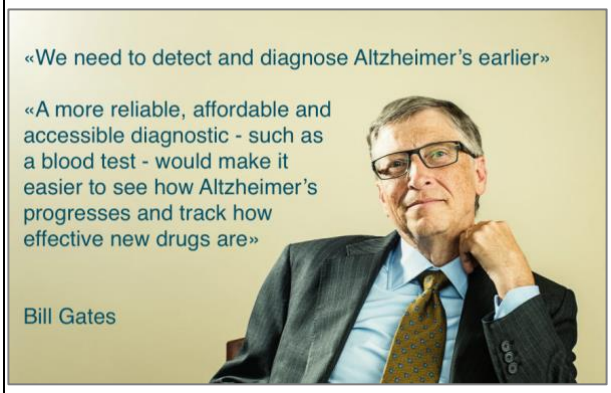
Early detection of disease will play a crucial role in AD, bringing unprecedented medical, societal and economic benefits. Early diagnosis can improve patient care and reduce public healthcare spending by billions of dollars. Pharmaceutical companies are dependant on diagnostic tools both for recruitment of the right patients for clinical studies, and for identifying a large number of patients when their new drugs become available in the market. A number of new immunotherapies against AD are expected to reach the market in the near future - increasing the demand for diagnostic tools and aid in personalized treatment. To create reliable, affordable, and non-invasive fluid biomarkers for early detection of neurodegenerative diseases is still considered "the holy grail" by scientists and industry. Currently, within PD there are no blood based diagnostic tests available in the market.

Pre Diagnostics: Large market opportunity

The dementia diagnostics market is expected to become a high-growth market, where Pre Diagnostic's technology has a strong margin potential. The company is building a unique "platform technology" that has the makings of becoming a game-changer for future diagnostics and personalized medicine in neuroscience.

A unique technology platform





The company was established in the year 2013, based on the patented technology invented by a.o. Professor Tormod Fladby, Akershus University Hospital, and Kaj Blennow, Professor and chief physician in the Neurochemistry Laboratory, Institute of Neuroscience and Physiology, Gothenburg University. They are both internationally recognized neurologists, with Prof. Fladby and his R&D team at Ahus as scientific advisors to the company.

R&D activities were conducted at a low scale until 2019, when the company obtained a MNOK 24 grant from the EU's prestigious Horizon 2020 program, allowing employing own laboratory staff and acquiring the ultra sensitive digital immunoassay Simoa instrument. 2021 saw the successful completion of this large EU project, with CE-marking of our first Alzheimer test as the main objective achieved. Since then Pre Diagnostics has strengthened its capabilities with new tailormade laboratory facilities. In addition to AD, the product pipeline now includes diagnostics for Parkinson's disease and a biomarker aiming at risk assessment of severe adverse effect and selection of patients for new AD immunotherapies.

Selected recent accomplishments

2021 - 2023 have been three productive years in terms of moving the technology towards market:

- A "Proof of Concept" study confirmed technology potential for Alzheimer's personalized medicine
- CE marking of two Alzheimer's diagnostic tests
- Significant strengthening of the patent portfolio
- Commercial traction established
- Selected as partner and service laboratory for AI-Mind
- Pilot study on saliva for early detection of AD, for widespread use without need of cold chain

In June 2022 RCN awarded a MNOK 11,5 grant for the exciting Alzheimer biomarker project, developing biomarkers to be employed in personalized medicine for the new AD immunotherapies now entering the market (*lecanemab* a.o.). In August 2023 a CDA was signed with a global pharma company (intention of entering into an R&D collaboration).

There is an urgent need for better diagnostic tools for these drugs to obtain widespread use:

https://www.reuters.com/business/healthcare-pharmaceuticals/european-alzheimers-experts-unconvinced-by-new-eisai-biogen-drug-2023-06-13/

International capital market advisory services

In 2022 Pre Diagnostics was selected as a client by a top-tier global financial services firm, highly specialized in Diagnostics and Device. The management team is aiming at a licensing agreement by 2025, which also could create a basis for stock-listing or trade sale of shares.

PreDx SHAREHOLDER NEWSLETTER

October 12th 2022

Pre Diagnostics AS has been selected as a partner in large pan-European dementia project AI-Mind

Pre Diagnostics will perform analysis of blood samples from approximately 1000 patients participating in the multi-site clinical study, an integral part of the AI-Mind project. This major task also creates the basis for establishing a commercial service laboratory in Oslo for dementia diagnostics. Furthermore, the AI-Mind clinical study will also include use of Pre Diagnostics' proprietary CE-marked Alzheimer's disease tests for intracellular analysis of monocytes. This is an excellent opportunity to build further clinical evidence for our Alzheimer's disease biomarkers. In addition, Pre Diagnostics becomes a part of a broad European network of researchers dedicated to AD research.

Principal Investigator and Coordinator, **AI-Mind**, Professor Ira Hebold Haraldsen, MD, PhD commented:

"It is a big step forward in the AI-Mind project to welcome Pre Diagnostics as a new partner in our consortium. Pre Diagnostics is not only the chosen partner and service laboratory for analysis of blood samples because of its cutting edge blood biomarkers portfolio in identifying pre-dementia stages, reaching from p-tau correlated ones to intracellular pathology representations by monocytes, but also the outlook to integrate Pre Diagnostics future products into our AI-Mind research and innovation portfolio is intriguing."

A BTIG healthcare analyst wrote to PreDx:

"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."

The Executive Management Team:



A team with 80 years of experience from the international biotech, diagnostics and pharma industries:

Håkon Sæterøy Co-founder & CEO

With 30 years of experience in management, corporate finance and business development, Sæterøy has an extensive international network. Sæterøy has been a co-founder and board member of several life science companies, including Nansen Neuroscience Network (Chair from 2010 – 2012) and Board Member of Oslo Cancer Cluster (2007 - 2014). Håkon is Chair of IC Targets AS and was Chair of listed diagnostic company DiaGenic ASA from 2002 – 2010, Chair of Serodus ASA from 2008 – 2012 and Chair/Board Member of Skannex AS from 2008 – 2014.

Erik Christensen Co-founder & CMO

Erik has extensive experience within blood-based diagnostics, as certified clinical pathologist at university hospitals and 10 years in Abbott Diagnostics, followed by 15 years executive management of companies with AD blood biomarkers. Experience in international pharma and diagnostic business across Europe, in the US and India. Successfully negotiated research & development contracts with large multinational companies like Pfizer and GE Healthcare, in addition to soft funded research programs for 100 mill NOK from EU and NRC. As CEO of DiaGenic ASA, he gained substantial experience with building a start-up diagnostic company. As an experienced laboratory professional manager he will be a board member of our new service laboratory.

Line Amundsen LABORATORY DIRECTOR

Introducing Line Amundsen, a chemist with a Master`s degree from The University of Bergen. Having spent many years working in an ISO-certified clinical laboratory at Haukeland University Hospital, Line has demonstrated commitment to precision and quality in her work with assay development and validation for clinical use. Beyond her contributions in a clinical laboratory, she has also honed her skills in the industry where she has further refined her knowledge and expertise in development and validation of immunoassays. Throughout her career she has gained significant experience in managing laboratory operations for both research and service purposes.

For more information and meeting requests, please contact:
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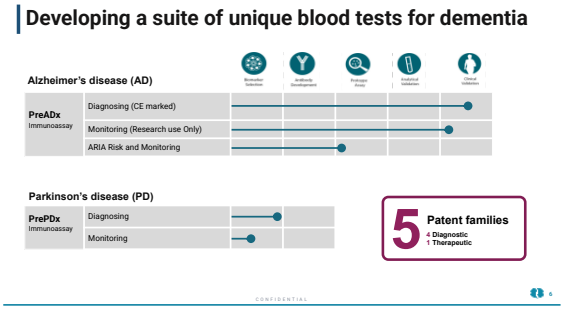

A highly skilled and motivated Lab Team:

The investment opportunity:

The company seeks to raise MNOK 20 in form of equity, a substantial part already is subscribed by current shareholders and board members.

- Validation of fluid biomarkers ongoing, industrial validation expected by end of 2023
- Substantial amount raised in form of non-dilutive grants (MNOK 70), of which MNOK 25 of the grants still remains to be received from the RCN during 2023-25
- Recently a new grant application was filed (including use of saliva specimen)

The combinaton of grants and new equity would provide a financial runway until end of 2025. “Use of proceeds” from the private placement will be as matching capital to the non-dilutive grants, building clinical evidence and commercialization of the CE-marked AD diagnostic products.