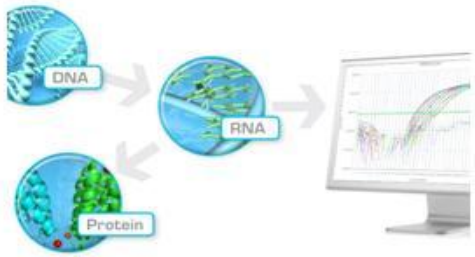
DIAGENIC for early disease detection

DiaGenic ASA

Worlds First in on blood based MCI biomarkers

Enable patient selection in clinical trials
and deliver companion diagnostics
to maximize product revenues

Erik Christensen, MD PhD, CEO



DiaGenic

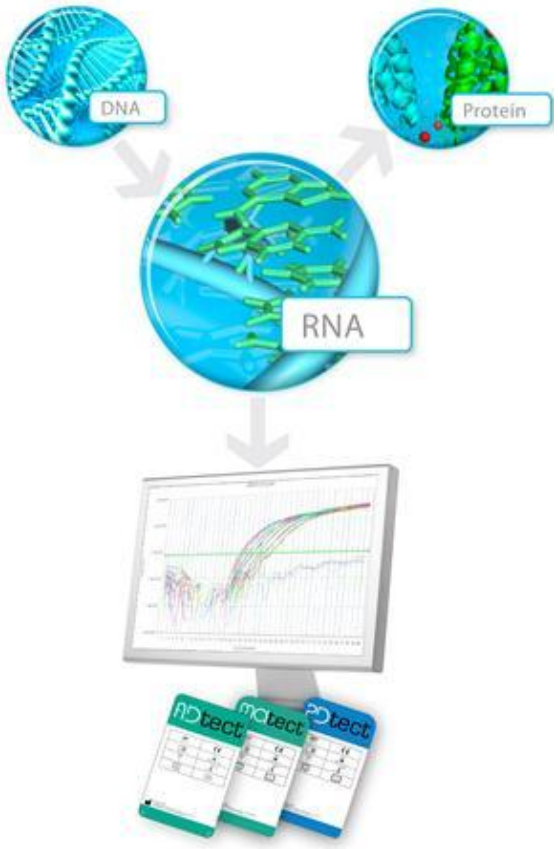
Business strategy and background

- The goal of the company is to take a leading position in the area of blood based diagnostics within selected CNS disease areas through its ability to deliver precise well-documented tools for early detection.
- This position is achieved by expanding committed pharma partnerships, sale of commercial rights and co-development agreements with large pharmaceutical and diagnostic companies.
- Successfully delivered on collaboration agreement with Pfizer in Alzheimer's disease.
- Non-exclusive pharma strategy enable potential significant revenues in the large AD market.
- Stock listed (OSE:DIAG) life science company based in Oslo.

DiaGenic

Core Assets

- Worlds first in gene expression biomarker development in Alzheimer's & Parkinson's Disease
- Solid IP in US and Europe for diagnosing AD and stages thereof in blood
- Partnered with providers of commercially available, quality assured and robust platforms that are suitable for diagnostic use in clinical medicine (Qiagen, Life Technologies)
- Up scalable robust FDA compliant technology
  - Concept applicable in other CNS disease areas e.g. Parkinson's disease
- First in market with ADtect, CE regulatory approved in EU
  - Product development documented in peer reviewed journals (e.g. JAD 2011)



DiaGenic has the experience on taking a product from discovery to market

Utility of blood based gene expression applications

A multitude of opportunities

Application	Utility	Biomarkers
Patient selection tool for clinical trials	• Reduced size of clinical trials • Reduced cost of clinical trials	Early onset
Selection tool for expensive imaging procedures	• Selection tool which potentially can open up the market for expensive PIB PET imaging	PET enabler
Monitor disease progression	• Classification of patients into different stages of the disease (e.g. drug efficacy measurement)	Staging
Prospective tool to differentiate expected speed of progression	• Classification of patients into different treatment schemes (e.g. dosage optimisation)	Progression
Select patients for therapy – Companion Diagnostics	• New therapies and expanded target populations	Companion Dx
Early disease and prodromal stages detection	• Speed up diagnosis and reduce cost of diagnosis • Enable earlier intervention	Prodromal

Blood based gene expression – the future in personalized and stratified medicine

DiaGenic CNS product line

MDx

Stand alone IVD assay

ADtect®

Aids in early detection of AD

Rx

Integrated biomarkers

Companion Diagnostics

ADtect® PLUS

Tailor made biomarker with [18F] PET tracer

ADtect® ULTRA

Tailor made biomarker in CoDX for drug efficacy

MCItect®

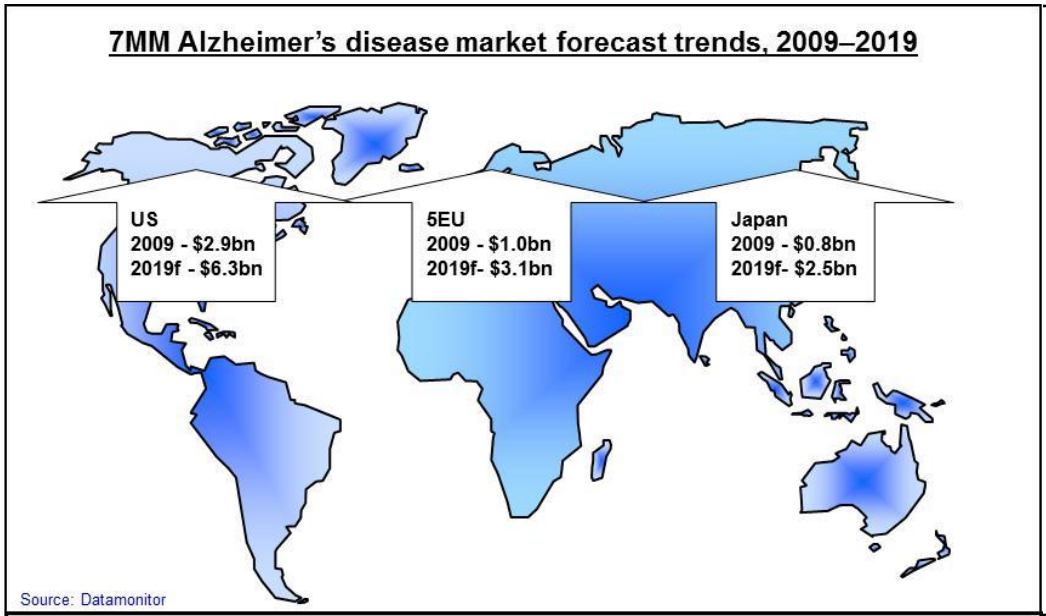
MCI to AD progression biomarker

PDtect®

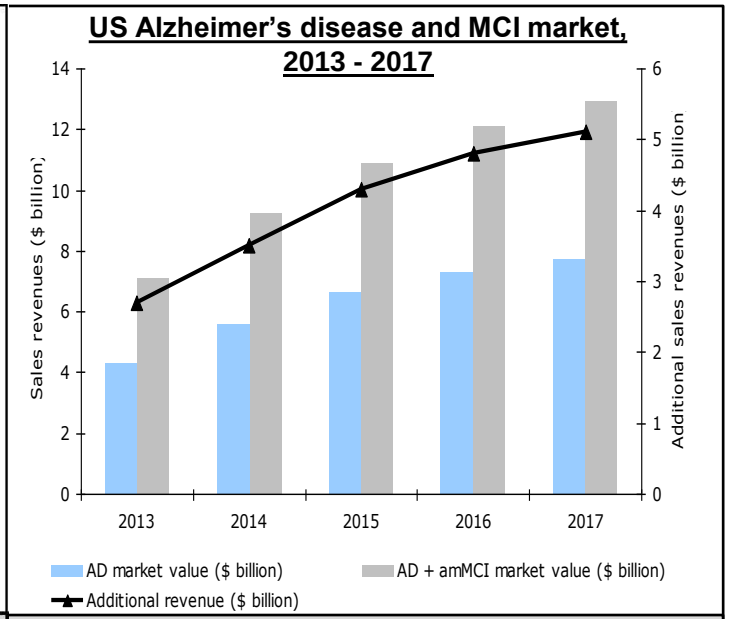
Aids in early detection of PD

Alzheimer's disease market set to expand considerably in all major markets

MCI may increase AD market by > 60%



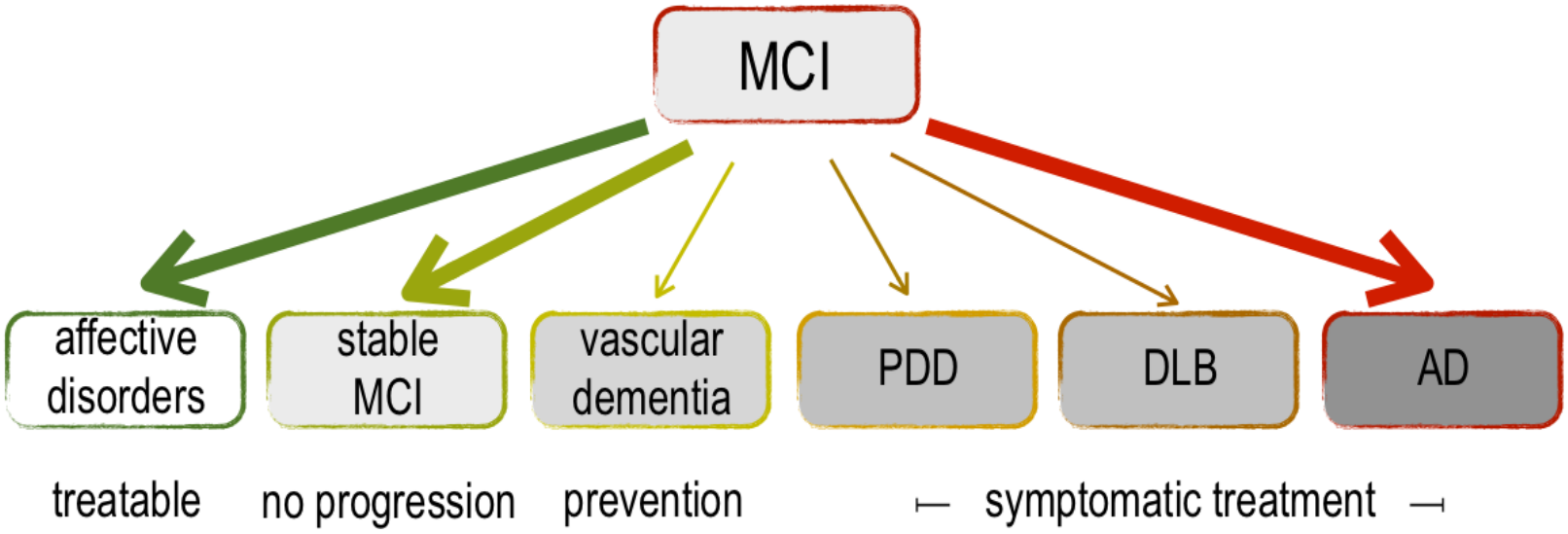
Seven major market Alzheimer's disease-specific sales will increase significantly, from $4.7bn in 2009 to $11.9bn in 2019.



60% revenue gain by including patients with amnestic mild cognitive impairment (MCI)

- The launch of potentially disease-modifying therapies, earlier diagnosis facilitated by biomarker tests and an increasingly elderly population drives growth over the next 10 years.
- Diagnostics and therapeutics in MCI may increase AD market by > 60%
- Successful drug development will increase the blood based US diagnostic market by > 500%

MCI – a heterogeneous syndrome



"The earlier in the disease process that people at risk for developing Alzheimer's are identified, the sooner we can intervene. Earlier detection will be our best opportunity to prevent continuing damage to the brain, once more effective therapies are developed."

William Thies, PhD,
Chief Medical and Scientific Officer at the Alzheimer's Association

Ongoing multicenter studies

MCI/prodromal AD development program

- Multicenter studies in collaboration with multiple university hospitals across Europe and the US:
  - UC Davis: Annual monitoring of MCI patients, controls and other dementias over 3-4 years, to include 200 MCI cases and 50 controls.
  - University of Malmö/Lund: 300 MCI patients and controls.
    - Clinical data, including CSF biomarkers and PET optionally.
  - Several sites as part of DiaGenic and EU funded studies (300 MCI cases and controls)

- >3500 unique samples (MCI/AD, PD, and technical samples from all relevant clinical groups and from age matched healthy controls)
  - Comprehensive clinical info following each sample (CRF)
  - Full DiaGenic ownership for commercial product development

Promising early results reported

DiaGenic & Pfizer R&D collaboration

- The objective was to identify gene expression patterns in blood from patients who progress from MCI to Alzheimer's disease and on further disease progression
- Compared longitudinal changes in subjects with Alzheimer's disease using;
  - DiaGenic's extended gene set from whole genome studies
  - DiaGenic's blood samples from our own clinical studies on MCI patients with validated expert consensus diagnosis
  - Validated diagnostic technology platforms
  - Next generation FDA compliant instrumentation (ABI ViiA7)
- Proof of concept established
- Study results reported at the CTAD congress November 3-5th 2011

20-gene signature identified

Reflects known AD biological pathways

Amyloid-β	3
TAU/NFT processing	4
Neurodegeneration	3
Cell cycle control	7
Mitochondria	4
Calcium regulation	5
Apoptosis	6
Inflammation	4

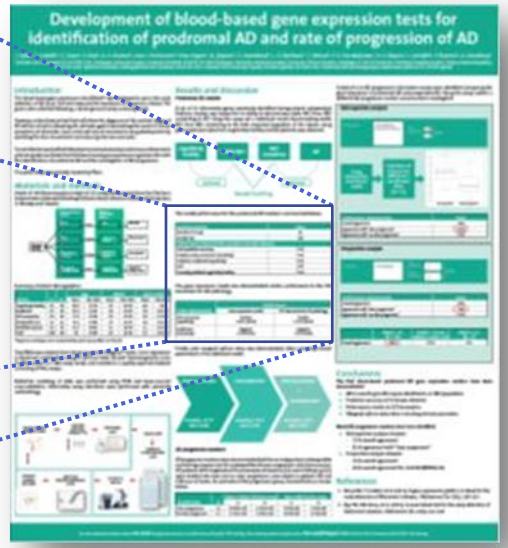
Identifies prodromal AD in an MCI population

The 20 assays also cover a wide range of known pathways associated with AD pathology, such as Amyloid-beta, pTau and mitochondrial processing. Several of the genes are involved in one or more biological pathways associated with AD pathology

Model performance using 20 genes

Model parameter	Value
Sample size	129
Performance characteristics (results on 66 MCI donors)	
Prediction accuracy	74 %
Sensitivity	74 %
Specificity	75 %

Cohort (parameter)	Performance	
	Prodromal AD gene expression model	CSF biomarkers for AD pathology
MCI conversion	*Positive* 7 of 11 (64 %)	*Positive* 7 of 11 (64 %)
Stable MCI	*Negative* 7 of 9 (78 %)	*Negative* 7 of 9 (78 %)



- A gene expression signature for prodromal AD has been identified in an MCI population
  - Stable MCI and MCI converters are discriminated with an 74% accuracy.
  - Gene expression demonstrates similar performance than CSF in identifying prodromal AD in an MCI population
  - Gene expression has demonstrated better performance than cognitive and functional testing

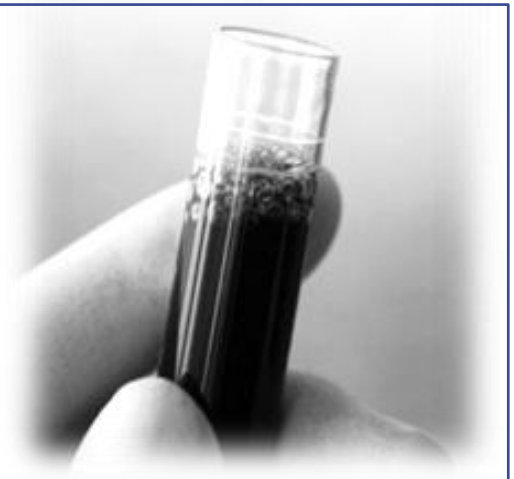
Biomarkers for prodromal AD and progression rate in AD identified

Biomarker for prediction of prodromal AD in blood

- DiaGenic has identified a 20 gene signature in blood predicting MCI conversion to AD (prodromal AD) within 2 years, n =129.
  DiaGenic's prodromal AD signature significantly reduces samples size in clinical trials
  - Cost reduction by 35%-45%.
  - Homogenous cohorts secures successful completion of clinical trials

Biomarker in blood defining AD progression

- DiaGenic has identified a 113 gene signature in blood for rate of progression in AD
  - Correct staging in >80% of fast progression cases
  - Provides an independent marker of progression in AD
- Prediction of AD progression rate was demonstrated
  - >90% overall agreement for subjects with mild AD
  - Potential to reduces sample size in mild AD trials



CoDx

Business Opportunities

Biomarker for Prescription drug use

Companion Diagnostics; Creating one–to–one relationships

Companion diagnostic value proposition

DiaGenic to develop key solutions for Amyloid PET producers

Characteristics	Challenges	DiaGenic Value proposition
PET imaging diagnostics are the most accurate diagnostic tool for Alzheimer Disease	High cost per patient	Blood-based diagnostics as a tool for pre-selecting patients for PET
Expensive equipment and procedures	Capacity constraints – limited no of scanners available due to cost	Increases hit-rates
	Lack of objective selection criteria for reimbursements	Reduces capacity constraints
		Validates reimbursement

- Dialogues with producers of amyloid PET tracers on R&D collaborations since last Q3 report have advanced
  - PET producers see a potential use of blood based biomarkers together with high cost PET imaging as part of a multimodal approach of future AD management
  - Collaborative study protocols developed, clinical site reviewed and funding scenarios pursued
  - PET will ensure gene expression traceability to AD amyloid diagnostics

GE Healthcare

Lilly

Bayer HealthCare
Bayer Schering Pharma

AstraZeneca

MERCK
Be well

Companion diagnostic value proposition

DiaGenic with key solutions for AD management

	Characteristics	Challenges	DiaGenic Value proposition
 **Drug development**	• Established high-value segment, but only symptomatic treatment • Significant resources from big pharma being invested in developing new drugs	• Recruiting the right patients for clinical trials • Objective monitoring of disease progression (clinical development end-points) • Patient specific treatment	• Objective diagnostic tests to optimise inclusion • Progression based on measuring bio-markers • Predict patient specific drug efficacy based on RNA profile

Enrichment of MCI converters to AD

Reducing sample size in MCI clinical trials

- Prodromal AD population, disease modification claim, primary outcome conversion to AD supported cognitive and functional testing (CDR).
- The duration of prodromal AD trials is 2 years with annual conversion rate to AD of 12-14%
- The **theoretical example** below is based on a Phase III trial scenario with 125 MCI converters per arm required to demonstrate a statistical difference between active treatment.

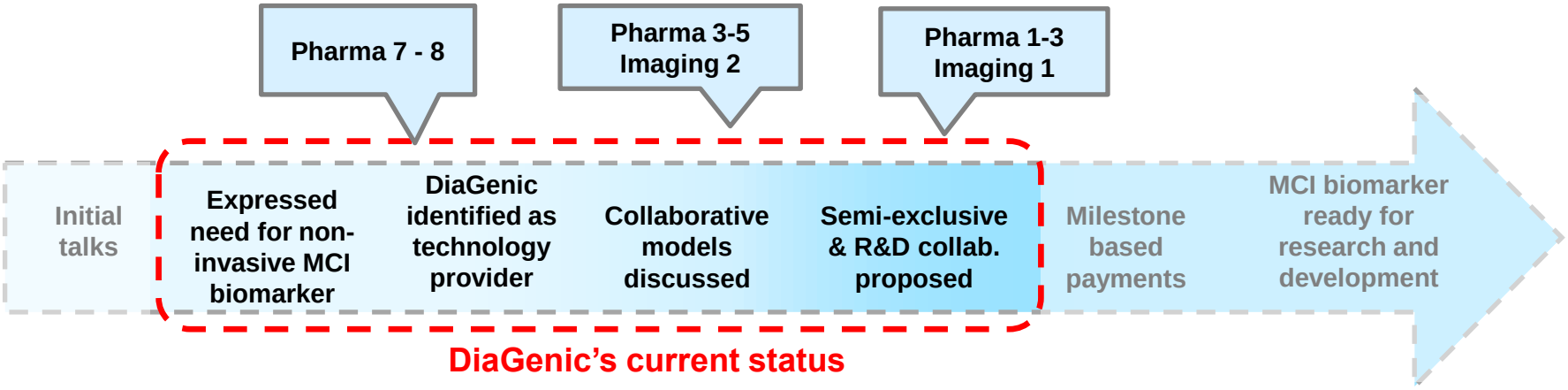
Cohort	Eligible for inclusion	MCI biomarker	Final inclusion	Estimated Conversion rate per arm
MCI	522	No	522	125 converters
MCItect enriched	685	Yes	255	125 converters

Enrichment of target population using MCItect – attracts pharma interest!

- Saving operational costs by 30%-40% by reducing study size
- Increasing trial success rate
  - Improved ratio responders vs. non responders in treatment arms
  - Homogenous study cohort
  - Reduce attrition and non-compliance

Delivering on the strategy

Driving multiple collaborative agreements forward



- Multiple interactions with pharma and imaging companies advancing according to plan, increased interest since last Q3 report
- Collaborative partner deals yielding:
  - R&D technology fees
  - Exclusive and non-exclusive licenses with milestone based payments
  - Product revenue from companion diagnostics
  - Integrated development of molecular diagnostic test for clinical use (FDA PMA/510k)
- Ferghana Partners appointed advisors on commercial transactions
  - Searches for potential licensees of DiaGenic's technology (CNS & cancer)
  - Key focus area MDx licence for the US market

Alzheimer's Disease intellectual property

- DiaGenic is ahead of competition in blood based AD diagnostics
  - US patents effectively protects our concept/technology/tools in using gene expression in AD including MCI
    - Others can not launch or perform market preparation trials in the US
  - EU patents protects concept/technology/tools
    - Exception is continued use of exploratory technologies
  - Patent filed covering the MCI study findings
    - Includes both various types of RNA and related proteins
  - DiaGenic has freedom to operate in the field
    - Confirmed by 3rd parties

Patent overview	Family 1 (WO 98/49342)			Family 2 (WO 2004/046382)			Family 3 (WO 2005/118851)			Family 4 PCT application filed on January 2011		
Expiry year	2018			2024			2025			2031		
Countries/Region	G	A	P	G	A	P	G	A	P	G	A	P
US	1	0	2	0	0	1	0	1	0	0	0	0
Europe*	2	0	1	0	0	0	0	0	1	0	0	0
Europe**	0	0	0	1	0	0	1	0	0	0	0	0
Norway	2	0	0	0	0	1	0	0	1	0	0	0
Japan	1	0	0	0	0	1	0	0	1	0	0	0
Canada	0	0	0	0	0	1	0	0	1	0	0	0
Hong Kong	2	0	0	0	0	1	0	0	1	0	0	0
China	0	0	0	0	0	1	0	0	1	0	0	0
Australia	0	0	0	1	0	0	1	0	0	0	0	0
New Zealand	0	0	0	1	0	0	1	0	0	0	0	0
India	0	0	0	1	0	0	0	0	1	0	0	0
South Africa	0	0	0	1	0	0	1	0	0	0	0	0
ARIPO*	0	0	0	1	0	0	0	0	1	0	0	0

G Number of patents granted A Number of patents accepted by examiner P Number of patents in progress

Europe*
Designated countries: Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, The Netherlands, Portugal and Sweden

Europe**
Designated countries: Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Romania, Sweden, Slovenia, Slovakia and Turkey

ARIPO* (African Regional Intellectual Property Organization)
Designated countries: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe

List of granted patents/allowed patent applications
US 6720138; EP 0979308; EP 1323728; NO 317247; NO 20040371; JP 4163758; HK 1026003; HK 03109502.9; AU 2003286262; NZ 540750; IN 2701/DELNP/2005; ZA 2005/03797; ZA 2006/10644; HK 1057217; NO 327084; EP 156557431; AP/P/2005/003317; AU 2005250219; US 11/628,300

Validating the prototype biomarker for MCI converters

Taking MCI blood based biomarkers to FDA and beyond

Calibration

- Build solid calibration model from a larger data set
- Larger cohort (n>100):
  - 50 MCI converters, including the 30 converters from pilot

Validation & Verification

- Independent validation cohort:
  - 100 MCI converters
- Additional DiaGenic samples from our ongoing clinical studies

Technical verification to prove robustness (like our earlier CE studies)

Submission

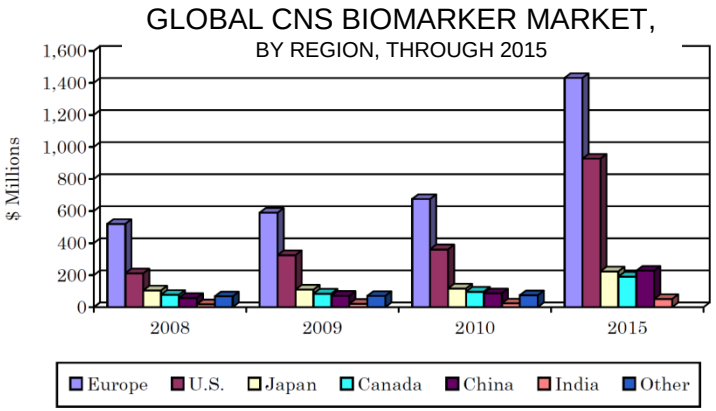
- Application in pharma phase III studies: Investigational use only qualification by FDA to support use of the biomarker during drug development

Validated biomarker qualified by FDA for investigational use

	2012 H1	2012 H2	2013 H1	2013 H2	2014 H1	2014 H2	2015	2016
Pharma (1- 6) MCI/AD	Calibration	Verification		Validation	FDA OK	Pharma / CoDx Product revenue		
US MCI/AD MDx FDA				MDx Validation		FDA OK	MDx Product revenue	
	R&D coverage & licence revenue (milestones)							

Commercial opportunities in the US diagnostic market for DiaGenic

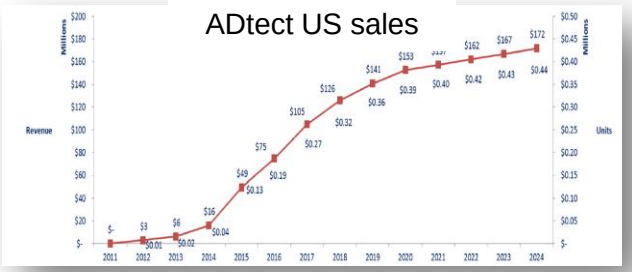
MCItect/ADtect - Limited competition in the attractive US market

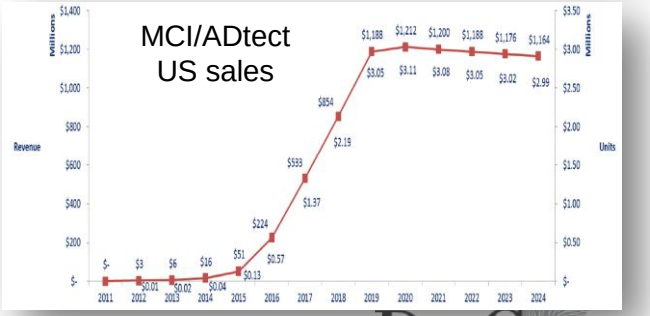


Regions	2008	2009	2010	2015	CAGR% 2010–2015
Europe	519.9	589.2	675.2	1,430.7	16.2
U.S.	211.5	325.1	361.7	927.2	20.7
Japan	104.7	109.8	117.1	224.2	13.9
Canada	77.1	84.8	97.3	191.5	14.5
China	58.4	71.2	86.5	228.6	21.5
India	18.5	21.0	23.9	51.7	16.7
Other	68.1	70.7	74.4	1,16.5	9.0
Total	1,058.2	1,271.8	1,435.6	3,170.4	17.1

BCC Research October 2010: BIO074A – Central Nervous System (CNS) Biomarkers: Technologies and Global Markets

- DiaGenic have recently performed two independent surveys of the US blood based diagnostic market for our Alzheimer's tests:
  - The current marketplace with existing treatment options and test specifications:
    - Peak ADtect US sales $170M – 195M
  - With arrival of new effective therapeutic options (includes CoDX):
    - Peak MCI/ADtect US sales $1.200M
- **DiaGenic – a dominant player potential!**





Destum Partners 2011
Medpanel 2011

DiaGenic

Your preferred partner for gene expression profiling in blood

Core competence and assets:

- Delivers unique biomarkers in a well defined market characterized by a large unmet medical need
- World's first company with
  - Approved blood based test in AD diagnosis
  - Prodromal AD proof of concept demonstrated
  - Progression markers identified
- Strong IP protection within blood based AD diagnosing and monitoring.
  - Broad claims protects against infringement.
- Competence and experience in all aspects of product development from discovery to regulatory
  - Strong knowhow on technologies, platforms & bioinformatics
  - R&D collaboration with reputable university hospitals in US and Europe
  - World Class Biobank
  - Good track record on receiving public grants
- Overall aim is to provide Companion Diagnostics tools for pharma and imaging companies and FDA approved diagnostic tests

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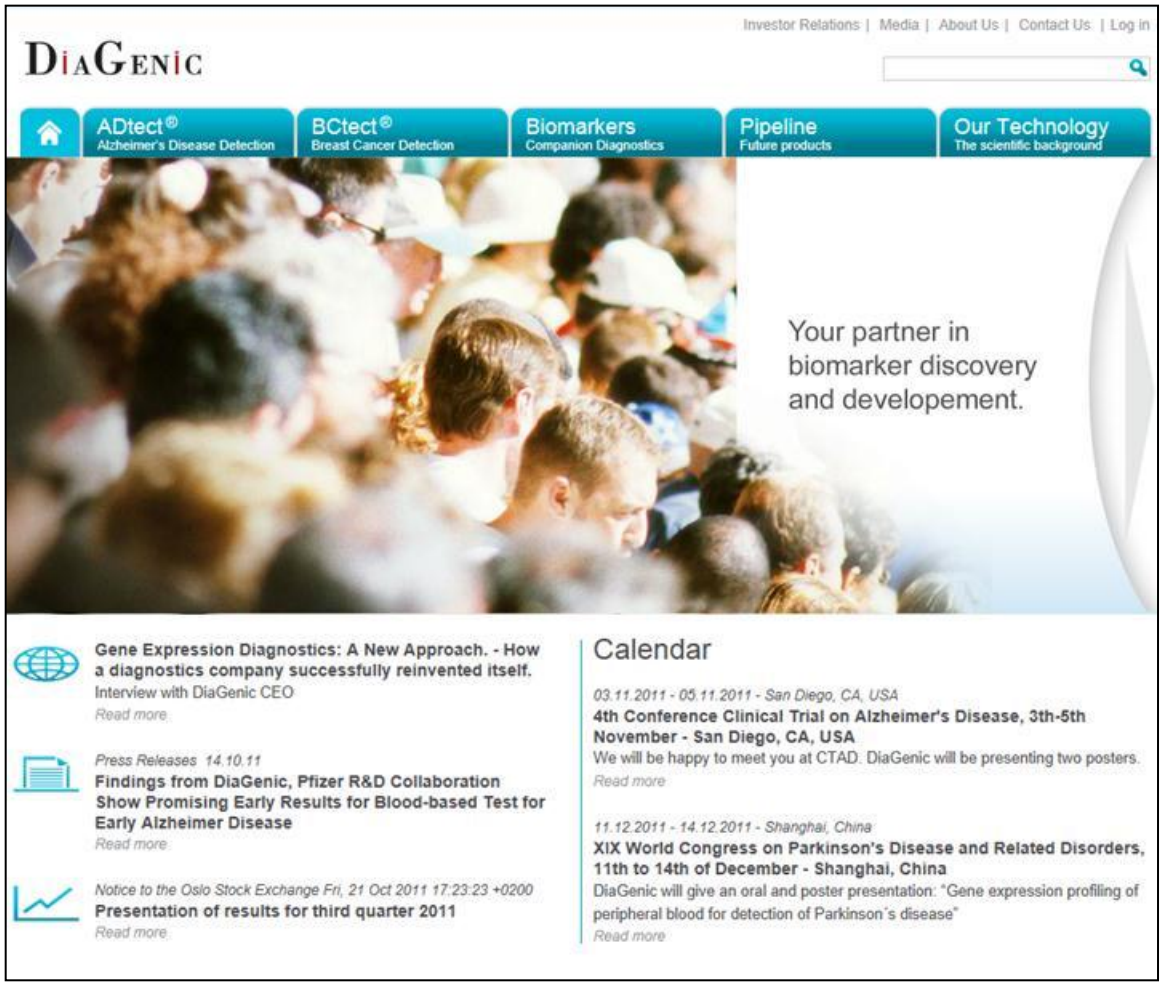

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