

# Half-year 2010 results

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**Solid growth of half-year revenues**

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# Speakers

- Loïc Maurel, M.D., President of the Management Board
- Hervé Duchesne de Lamotte, Chief Financial Officer and Member of the Board
- Matthew Pando, Ph.D., Executive Vice President, Therapeutics and Member of the Board
- Jacques Bonte, Vice President, Neurosciences, Diagnostics

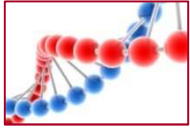
# Agenda

- **First half 2010 key highlights**
- Financial performances
- Update on therapeutic activities
- Update on diagnostic activities
- Conclusion
- Q&A session

## First half 2010 key highlights

- Out-licensing of EHT/AGN 0001 program by Allergan to Bristol-Myers Squibb
- Solid growth of half-year revenues and significant reduction of operating loss
- Announcement of the planned acquisition of RedPath Integrated Pathology, Inc.
- Significant progress in product development
- Preparation for the CE marking of AclarusDx™
- ‘Innovative Company’ accreditation granted by OSEO
- TEPA capital increase

# Planned acquisition of RedPath (1)



- Patented DNA-based molecular diagnostic platform applicable to multiple indications



- PathFinderTG® launched in the US for pancreatic cancer (~10% market share) and recently for differentiating metastasis from primary cancers



- Comprehensive pipeline of products including 2 launched molecular diagnostics



- Experienced management team

- CLIA lab + CAP accredited



College of American Pathologists



## Planned acquisition of RedPath (2)

Date	Event
April 25, 2010	Signature of a merger agreement for the acquisition of RedPath
June 18, 2010	Announcement of a potential discontinuation of coverage by Highmark* for PathFinderTG®
June 28, 2010	Extraordinary shareholders' meeting on first notice
July 8, 2010	Extraordinary shareholders' meeting on second notice
July 9, 2010	Submission by RedPath of a file supporting maintenance of coverage for PathFinderTG®
<b>Awaiting Highmark's decision</b>	

*\*Medicare is the US federal health insurance agency for elderly people*

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## Growth of half-year results and reduction of loss

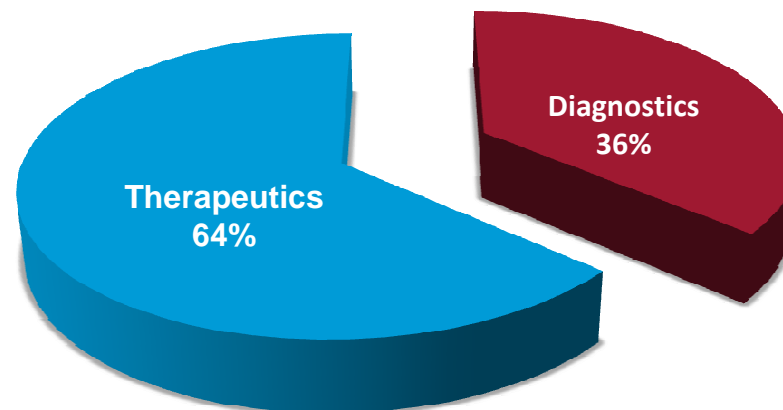
<b>Consolidated income statement</b>	<b>1H 2010*</b>	<b>1H 2009*</b>	<b>2009</b>
Thousand €			
<b>Total revenues</b>	<b>5 474°°</b>	<b>2 491</b>	<b>4 892</b>
Research and development expenses	(4 080)	(5 407)	(8 984)
Marketing and sales expenses	(703)	(635)	(1 239)
General and administrative expenses	(2 402)	(2 190)	(4 329)
<b>Total operating expenses</b>	<b>(7 185)</b>	<b>(8 232)</b>	<b>(14 552)</b>
<b>Loss from operation</b>	<b>(1 711)</b>	<b>(5 741)</b>	<b>(9 659)</b>
Interest expenses	(1 371)	(161)	(277)
Interest income	153	323	690
Net exchange gain (loss)	1 118	(26)	(70)
Tax benefit	722	1 126	1 616
<b>Net income (loss)</b>	<b>(1 090)</b>	<b>(4 478)</b>	<b>(7 701)</b>
Net profit (loss) per share (€)	(0.03)	(0.16)	(0.27)

\* unaudited

°° Non recurrent product : payment of \$4M (~ €3M) by Allergan (deal with BMS)

# R&D investments in Therapeutics and Diagnostics

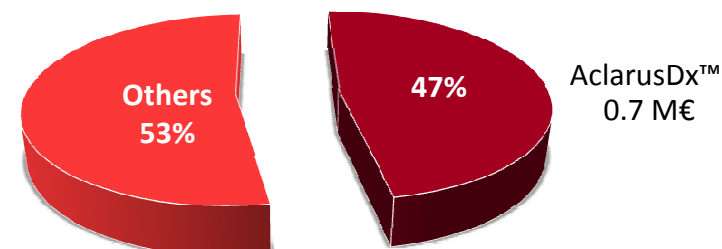
## Consolidated R&D expenses (4.1 M€)



## Therapeutics (2.6 M€)



## Diagnostics (1.5 M€)



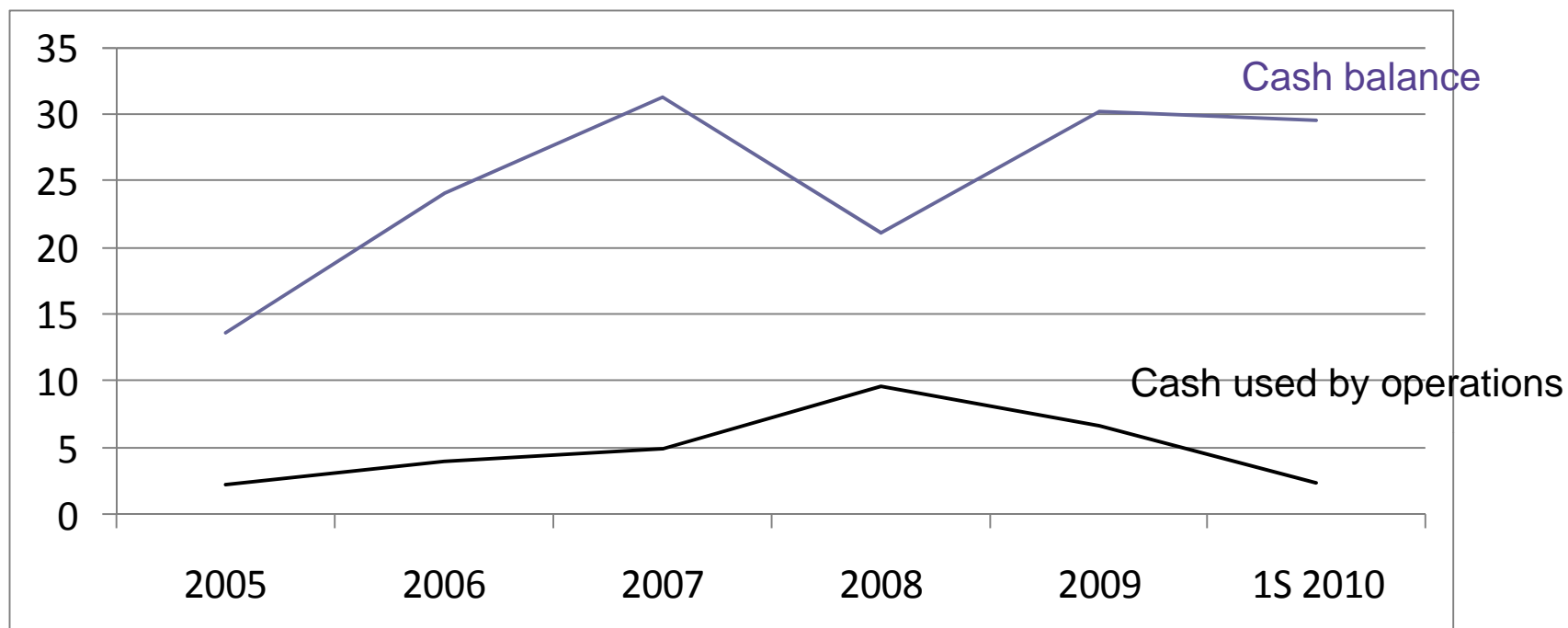
## A cash position amounting to € 29.5 millions

<b>Consolidated balance sheet</b> Thousand €	<b>30.06.2010*</b>	<b>30.06.2009*</b>	<b>31.12.2009</b>
Total long-term assets	2 121	2 721	2 307
Short-term assets	6 993	4 950	3 996
<b>Cash and cash equivalents</b>	<b>29 505</b>	<b>17 643</b>	<b>30 245</b>
<b>Total Assets</b>	<b>38 619</b>	<b>25 315</b>	<b>36 549</b>
Shareholder's equity	26 096 <sup>°°</sup>	13 567	25 458
Convertible bonds	6 522	6 522	6 522
Provisions for risks	1 546	224	344
Total long-term liabilities	88	327	200
Total short-term liabilities	4 366	4 674	4 024
<b>Total liabilities and shareholders' equity</b>	<b>38 619</b>	<b>25 315</b>	<b>36 549</b>

\*unaudited

<sup>°°</sup> TEPA capital increase

## A healthy financial situation



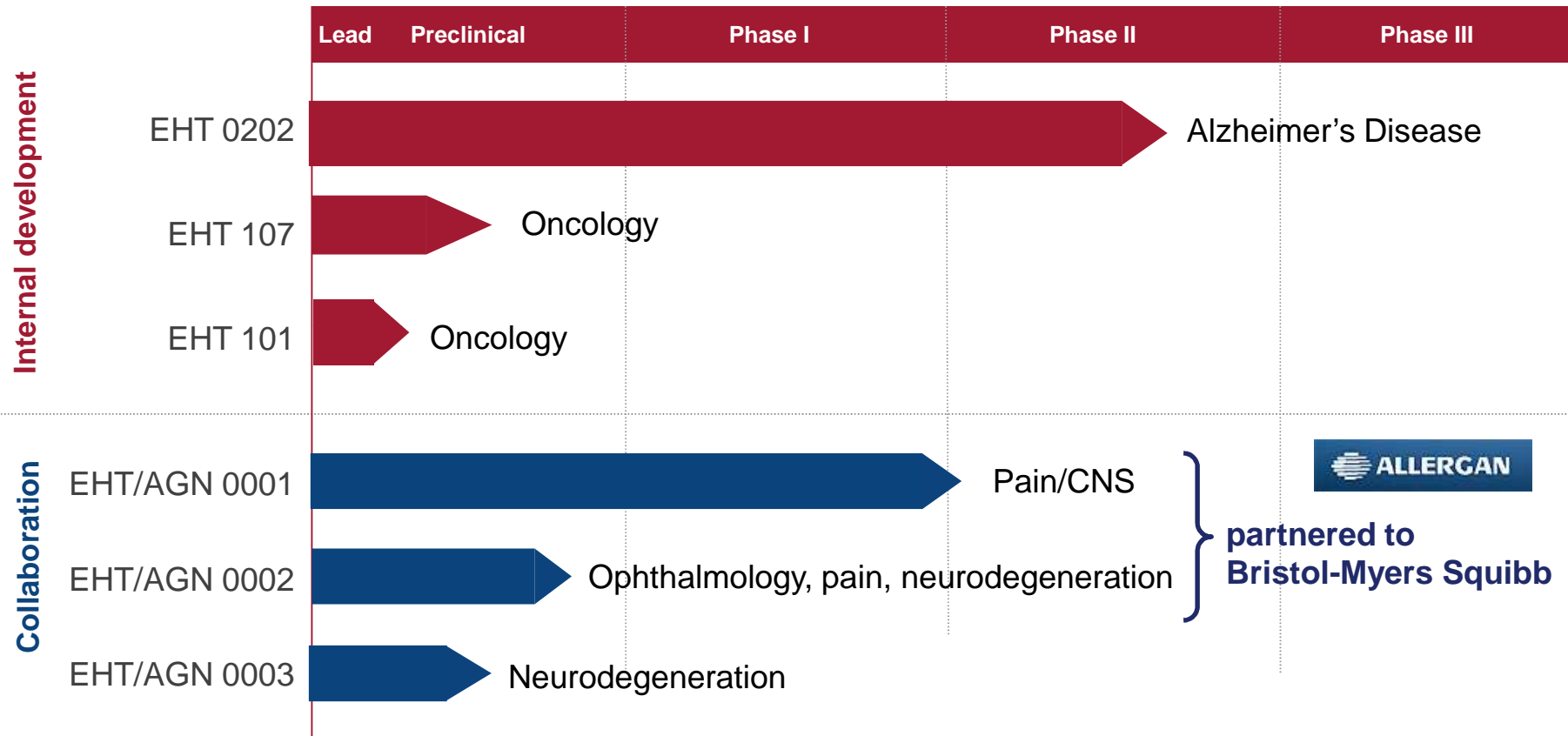
Years	2005	2006	2007	2008	2009	1S 2010
Cash balance (M€)	13.6	24.0	31.3	21.1	30.2	29.5
Cash used by operations (M€)	2.2	3.9	4.9	9.6	6.7	2.3

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# Cancer & Neurodegenerative diseases

## Therapeutic pipeline



## Focus on oncology: Program EHT 107

- Current lead demonstrated broad low to sub-nanomolar activity across a panel of more than 70 cancer cell lines including treatment-resistant lines
- No toxicity observed with high doses in acute animal testing
- Patent filed in June 2010
- In vivo animal model proof-of-concept studies to be completed in Q4 2010
- Targeted indications: treatment-resistant tumors
- Program reviewed by Wolf Hervé Fridman, M.D., Ph.D., chair of ExonHit 's Scientific Advisory Board

**Program initiated 24 months ago and moving rapidly towards proof-of-concept with broad potential in oncology**

## Focus on oncology: Target discovery collaboration

- **Successful pilot study and agreement with Genmab:**
  - Identification of novel splice variants that have the potential to be therapeutic targets for breast cancer
  - Genmab retains exclusive rights on 10 splice events identified
  - ExonHit can further exploit the database to develop new drug candidates internally or through partnerships
- **Development of target discovery platform:**
  - Leveraging existing platform in Central Nervous System
  - Facilitate additional collaborations
  - Support internal development of new oncology programs



## Progress on EHT 0202 in 1H 2010

- **Patient profiling from SpliceArray™ analysis** (Springfield Symposium, 03/2010)
  - Patients that improve while on EHT 0202 may have a specific gene expression profile, different from those that decline
  - Prior to study initiation, patients likely to benefit from EHT 0202 therapy could be discriminated from those who won't
- **Biomarkers viewed as critical to successful clinical development in challenging indications like Alzheimer's disease**
  - EHT 0202 now has potential RNA, DNA and protein based biomarkers to support its ongoing clinical development
    - Potential to discriminate patients that will benefit from EHT 0202 treatment using SpliceArray™ profile demonstrated
    - ApoE4+ genotypes appeared to benefit more from EHT 0202 treatment in Ph IIa
    - sAPP $\alpha$  observed to be elevated in the brains of treated animals; CSF\* levels to be measured in Ph IIb

*\*Cerebro-spinal fluid*

## Ongoing efforts to find a partner to initiate Phase IIb

- **Increased awareness of EHT 0202 in Alzheimer's disease community**
  - Presentation of transcriptomic analysis results at Springfield Symposium (March 2010)
  - Publication of Barnes' test results (Eur. J. Pharmacol. May 2010)
  - Oral presentation scheduled at CTAD (Nov. 2010)
  - Phase IIa results under review for publication in a peer-reviewed journal
- **Study protocol established and reviewed by EU & US key opinion leaders**
- **Quotes obtained from various clinical research organizations**
- **Seeking a partner to develop/co-develop/co-finance Phase IIb**

# The Allergan-ExonHit collaboration: A success story

- **Seven year-old strategic collaboration**

- First source of revenues



- **EHT/AGN 0001:**

- Four years from bench to Phase I
- Licensed out to Bristol-Myers Squibb for neuro-related indications in March 2010

- **Inclusion of proprietary lead compounds into Allergan collaboration**

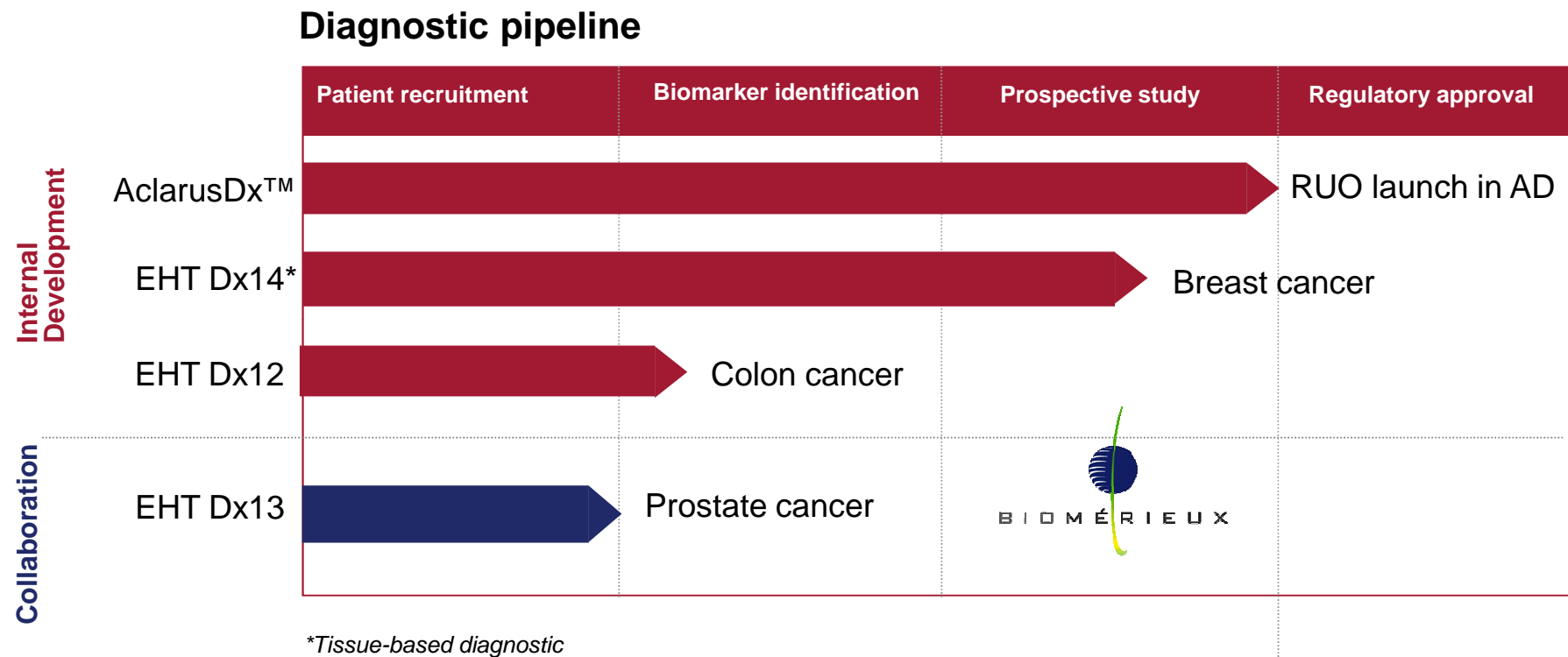
- Announced February 2010: EHT/AGN 0003
- Active against a new enzyme target
- Potentially useful for therapeutic development in ophthalmology and neurodegenerative indications
- Milestone and royalty terms of the existing collaboration apply

- **Developing proprietary genome-wide SpliceArray™ for preclinical animal model to support ongoing discovery efforts**

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## A second product launch planned in 2010



## Breast cancer: Its diagnosis today

- Mammography remains the first line screening tool
- Suspicious lesions require follow-up:
  - **Core needle biopsy** is the reference method: but invasive, and with side effects
  - **Fine needle aspiration** (FNA): minimally invasive but only practiced in experienced centers and could lead to indeterminate results
- EHT Dx14 can be used in cases where FNA is inconclusive

# EHT Dx14 in the diagnosis of breast cancer

- EHT Dx14 is a breast cancer signature developed by Institut Gustave Roussy using ExonHit's SpliceArray™ platform
- EHT Dx14 + FNA: potential increase of the performance of the FNA to differentiate benign breast tumors from malignant ones thus contributing to:
  - reduce the use of invasive procedures (biopsy, surgery) when a tumor proves to be benign
  - reduce time to results for the patients
  - generalize the use of FNA long-term
- Ongoing validation study on the targeted population
- Launch by ExonHit in Q4 2010 (RUO product)

# AclarusD<sup>TM</sup><sub>x</sub>

A blood-based test to help in the diagnosis  
of Alzheimer's disease

- Clinical research
- In vitro diagnostic

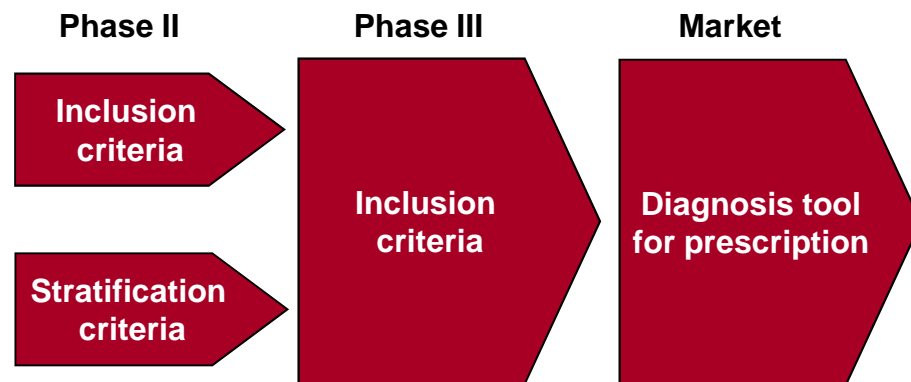
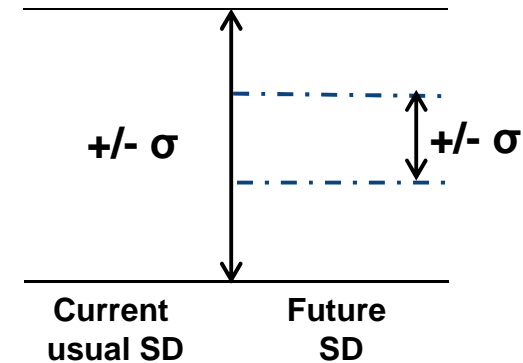


# The AclarusDx™ RUO value proposition

## AD clinical trials context:

- subjectivity in the patient evaluation,
- interpersonal variation in patient evaluation,
- no “black & white” tool.

## Large standard deviation in the base line population



## Opportunities for Pharma companies

1. Save compounds which are not meeting primary endpoints in global population.
2. Save time & resources by enabling patient pre-selection, including “de novo” patients.
3. Increase the number of centers and the geographic reach, while securing cross-patient homogeneity.
4. Allow a higher in market price through a better patient selection.

# AclarusDx™ and GWSA: A continuum of collaborations

## Drug associated analysis

**AclarusDx™ for  
clinical development**

**Inclusion criteria to  
reduce variability**

**Stratification criteria**

**Customized drug  
related additional data  
analyses**

Drug

**Ad hoc responder  
profiling**

Drug & placebo

**Ad hoc analyses of  
GWSA data**

**GWSA full data  
collection**

## Disease analysis

**Possible programs  
based on EHT  
technology**

**MCI**

**Early AD**

**Disease conversion**

**Disease progression**

**Disease severity**

GWSA – genome wide SpliceArray™

# Strategy in clinical research

- After the MAPT\* study, AclarusDx™ is entering into a significant clinical study
- Ongoing discussions with pharmaceutical companies
- CTAD\* congress in November in Toulouse
  - Oral presentation by Serge Gauthier, Mc Gill University, Montreal : « *How biomarkers can help investigators and the pharmaceutical industry in Alzheimer's disease clinical trials. From concept to application* »
- Recruitment of a Key Account Manager to promote the use of AclarusDx™ into the clinical protocols of pharmas and biotechs

\*MAPT: Multidomain Alzheimer Preventive Trial  
CTAD: Clinical Trials in Alzheimer's Disease

# AclarusD<sup>TM</sup><sub>x</sub>

in vitro diagnostic

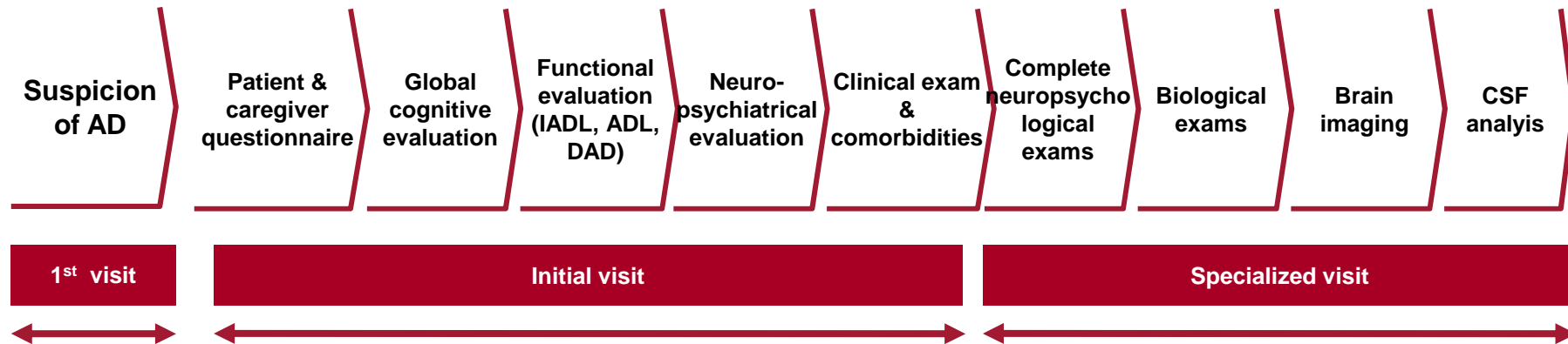
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## IVD launch: on track for CE marking in December



- Marketing authorization of AclarusDx™ requires to combine:
  - CE marking of the sampling kit and of the analysis software
  - A contract with an ISO 17025 accredited laboratory for performing the analytical work
- Finalizing of the negotiation with a European reference laboratory doing biological analysis for the performance of the analytical work
- Negotiation in process for :
  - The making and the production of the sampling kit
  - The supply of reagents and biochips

# The diagnosis of Alzheimer's disease today



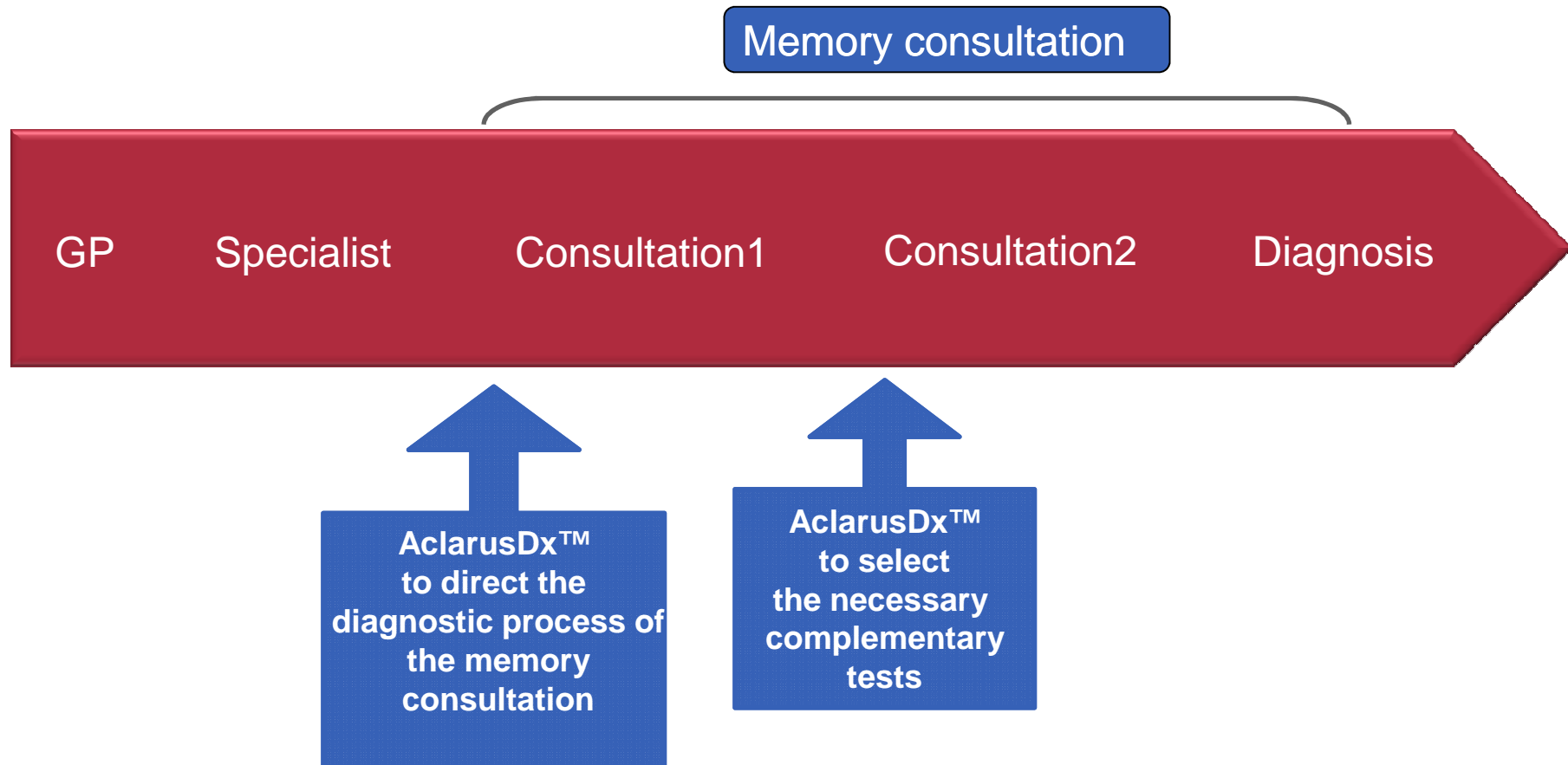
- **Current diagnostic relies on the combination of several evaluations:**
  - Medical history, clinical evaluation
  - Neuro-psychological tests
  - Brain imaging: MRI
  - Lumbar puncture (CSF analysis)
- **This diagnostic procedure is long, subject to variability, complex and depends on:**
  - the patient
  - the family of the patient
  - the clinician

## AclarusDx™: an easy to perform test

	CSF* analysis	Neuro-imaging	AclarusDx™
Length	1 – 2 days (hospitalization)	½ day	A few minutes
Easiness of performance	-- (lumbar puncture)	-- (accessibility)	+++
Human factor	+/-	Interpretation	No

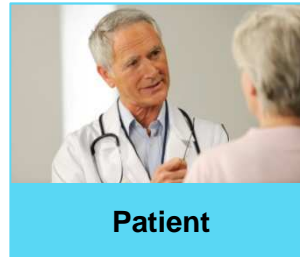
\*Cerebrospinal fluid

## Different uses of AclarusDx™ in the memory consultations





# AclarusDx™: test organization



Patient



Memory Lab



Blood sampling



Consultation with a specialist

AclarusDx™

## Résultat AclarusDx™

N° Echantillon/Fichier	
Date du résultat	
Conformité du contrôle qualité AclarusDx™	Oui <input checked="" type="checkbox"/> Non <input type="checkbox"/>

## Résultat du test AclarusDx™

### ☐ Positif

La probabilité de présenter une démence de type Alzheimer est de XX%.

Des investigations complémentaires sont recommandées pour confirmer le diagnostic.

### ☒ Négatif

La probabilité de ne pas présenter une démence de type Alzheimer est de XX%.

Des investigations complémentaires sont recommandées afin d'exclure une maladie d'Alzheimer et d'établir un diagnostic différentiel.

L'état de santé du patient pourra nécessiter une réévaluation dans un délai approprié, en fonction de son profil.

### ☐ Indéterminé

Le profil génomique du patient ne permet pas une analyse concluante.

Les investigations utiles sont recommandées pour établir un diagnostic.

L'état de santé du patient pourra nécessiter une réévaluation dans un délai approprié, en fonction de son profil.

AclarusDx™ permet d'établir une probabilité diagnostique de la maladie d'Alzheimer.

Le test doit être accompagné d'investigations complémentaires appropriées, en fonction du profil du patient.

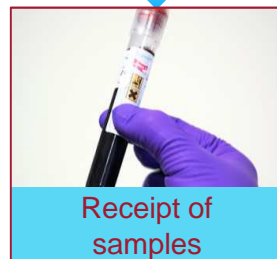
Des résultats doivent être interprétés en tenant compte des autres explorations.

Nom du biologiste :

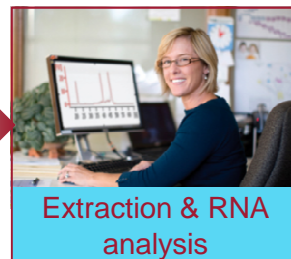
Signature du biologiste :

Date :

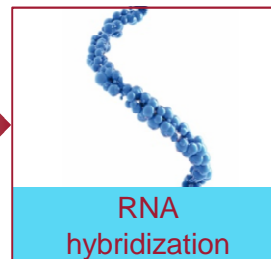
exonhit  
Bioscience Therapeutics S.A. - 42400 Boulogne-Billancourt - 75013 PARIS - FRANCE  
www.exonhit.com



Receipt of samples



Extraction & RNA analysis



RNA hybridization



Washing & staining

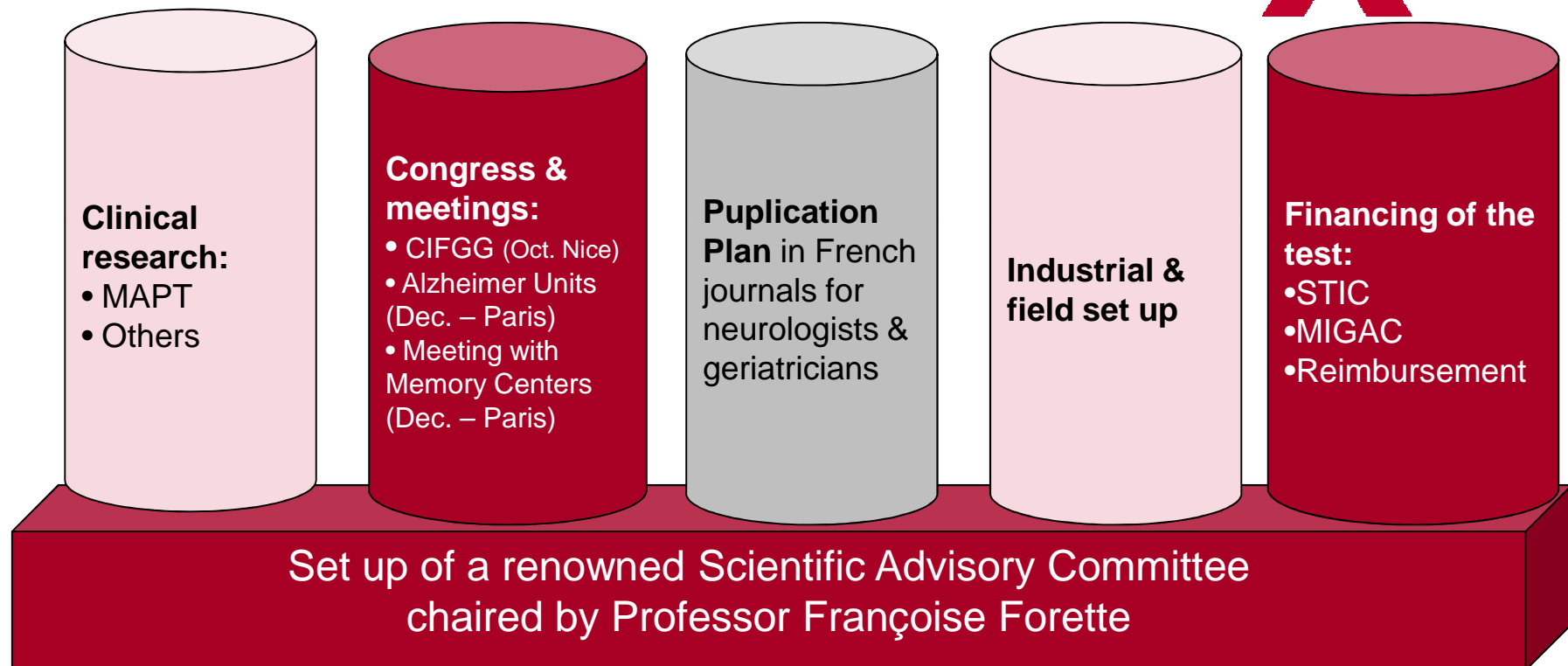


Reading and analysis

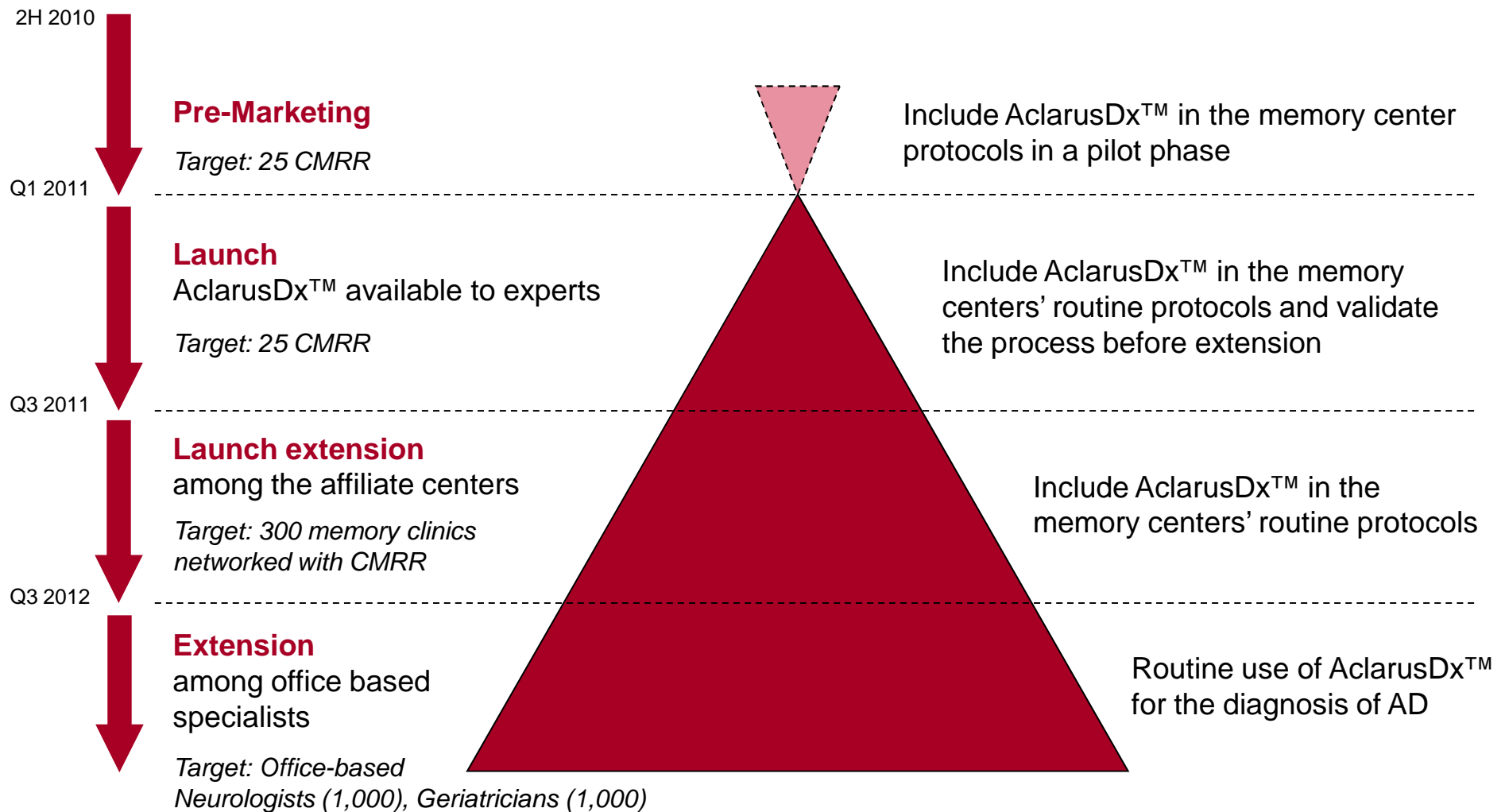
Reference medical laboratory

A launch focused on France

# Aclarus<sup>TM</sup><sub>Dx</sub>



# Sequential deployment – French market




## Conclusion

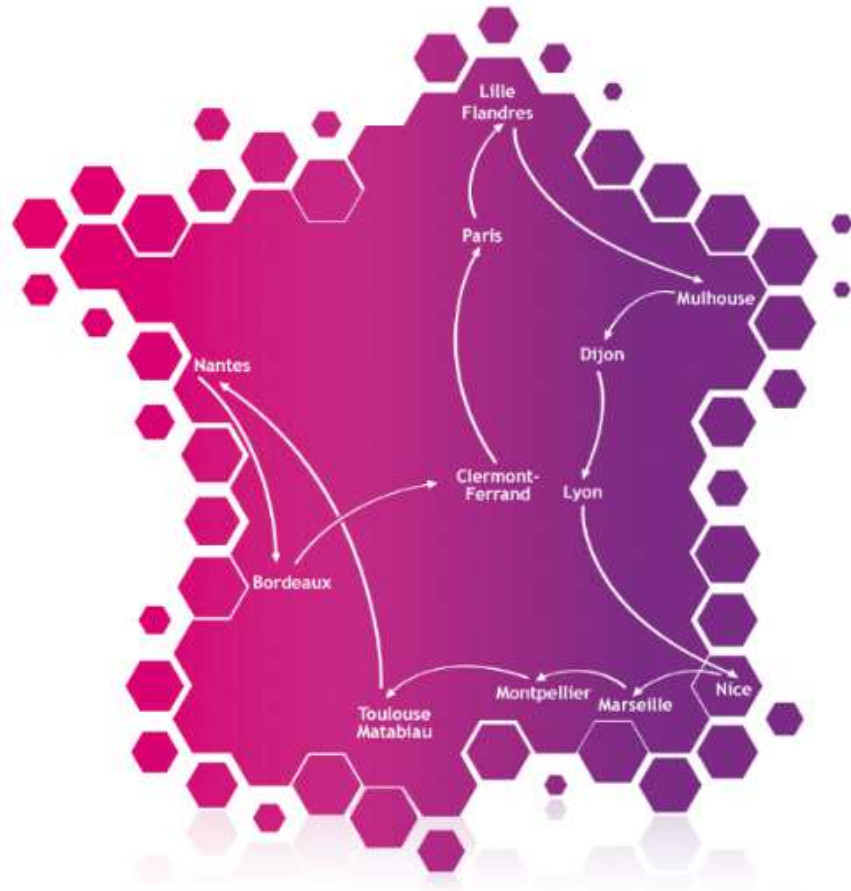
- Regulatory activities will enable CE marking of AclarusDx™ by end of year
- Contracts being put in place with major partners: Reference laboratory, reagents suppliers...
- Growing notoriety of AclarusDx™ : Scientific Advisory Board, clinical studies, publication plan...
- Organization of the financing of AclarusDx™ : STIC, MIGAC, reimbursement

# Mobilization against Alzheimer's disease in France



14 car-train from September 6 to September 21

- Inaugurated by Roselyne Bachelot, French Health Ministry
- Interview of Prof. Françoise Forette on Radio Classique on Monday, September 6 in the 8:00 am journal 



*Today, on September 16, the train is in Montpellier*

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# Conclusion

- **A cash position of approximately 24 months**
- **Moving to commercialization**
- **Significant progress in product development**
- **A clear strategic vision:**
  - Developing as a Diagnostic player
  - Partnering in Therapeutics
  - A will to proceed with an acquisition unchanged

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