Diagnostics: Growth through innovation and Personalised Healthcare

Daniel O’Day, COO Roche Diagnostics

The future of medicine is personalised
Roche Investor Day 2012
Roche Diagnostics portfolio overview
Industry leading businesses covering the entire IVD spectrum

<table>
<thead>
<tr>
<th>Life Science</th>
<th>In Vitro Diagnostics</th>
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<tbody>
<tr>
<td>App. Science</td>
<td>Molecular Dx</td>
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<tr>
<td></td>
<td>Tissue Dx</td>
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<tr>
<td></td>
<td>Professional Dx</td>
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<td></td>
<td>Diabetes Care</td>
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<td>Academia &amp; Pharma</td>
<td>Molecular lab Blood screen.</td>
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<tr>
<td></td>
<td>Pathology lab</td>
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<td></td>
<td>Central lab</td>
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<td></td>
<td>ER / ICU</td>
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<tr>
<td></td>
<td>Doc. office</td>
</tr>
<tr>
<td>Diabetes Patient</td>
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7% of sales | 68% of sales | 25% of sales
IVD market

Our business model and strategy

Personalised Healthcare
IVD market overview

Large and growing market; Roche is market leader

Market share

Roche 20%
Abbott 12%
Siemens 9%
Biomerieux 3%
Danaher 8%
J&J 9%
Others 38%

Market size

USD bn

CAGR +5%

2011 2016E

Tissue 62 10%
Molecular 48 9%
Professional 38 5%
Diabetes Monitoring 20 4%

Source: Roche Analysis, Company reports, validated by an independent IVD consultancy
Growth in all regions
Strong double digit growth in emerging markets

Roche Diagnostics HY 2012 sales

- North America: CHF 1,281 m (25%)
- Latin America: CHF 348 m (7%)
- Asia Pacific: CHF 736 m (15%)
- Japan: CHF 284 m (6%)
- EMEA: CHF 2,365 m (47%)

CER sales growth

- Diagnostics Division: 5%
- North America: 5%
- EMEA*: 1%
- Latin America: 13%
- Asia Pacific: 17%
- Japan: 7%

1 Europe, Middle East and Africa
CER=Constant Exchange Rates
IVD market

Our business model and strategy

Personalised Healthcare
Our business model
Growing via differentiated business model and strong global presence

Reagent pull-through model

Large worldwide installed base
Our strategy
Differentiation through innovation in testing efficiency and medical value
Testing efficiency
Increasing productivity in labs

Testing efficiency value for customers

• Saving costs via automation
• Fast turnaround times due to high throughput
• Efficient workflow from sample preparation to test results
• Modular and scalable solutions with flexibility for growth
Testing efficiency
Examples of recent and upcoming innovations

**Recent launches**

**Ventana iScan HT**
- Fully digitise pathology workflow
- High throughput and superior reliability
- Improve lab efficiency and productivity

**In development**

**cobas® 6800/8800**
- The "One" molecular platform
- Broad test menu; random access capability
- Modular design to address laboratory throughput needs
- Designed to integrate pre & post analytics
Medical value strategy
Prioritise areas with unmet needs & growth potential

Selected Examples

- **Cervical cancer**
  - HPV
  - p16 / Ki67
  - p16

- **Infectious diseases**
  - MRSA
  - HIV/HCV load
  - HBsAg

- **Cardiovascular**
  - cTnT-hs
  - NT-proBNP
  - PTF

1 High Sensitivity Troponin T; 2 Platelet Function Testing
## Medical value: Expanding intended uses of NT-proBNP for biomarker guided therapy

### Heart Failure (HF)
- Over 5% of US healthcare spending\(^1\)
- Limited tools for treatment decision
- Unmet need for a biomarker to guide therapy titration

### NT-proBNP
- **Intended uses of NT-proBNP supported by clinical data**
  - Rule in/out and early detection of HF; Risk stratification of ACS\(^2\); Therapy monitoring\(^3\)
- **GUIDE-IT: NT-proBNP target to guide medical therapy in HF**
  - 1100 patient study in collaboration with Duke University and NIH
  - To repeat key results from PROTECT\(^4\)
  - Targeting new intended use in the US in a large and growing market

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\(^1\) 2008 AHA Statistical Update; \(^2\) Acute Coronary Syndrome; \(^3\) CE only; \(^4\) Januzzi et al., Journal of the American College of Cardiology, 2011
Medical value: Proving value for high sensitive troponin T in non-cardiac surgery patients

VISION study publication in JAMA¹

- Results from the first 15,133 non-cardiac surgery patients
- Peak post-operative troponin levels significantly associated with 30-day mortality
- Results will aid physicians assess individual patient risk and tailor therapy

Roche Elecsys® Troponin T hs Assay

- Latest generation high sensitive troponin T test is a new tool to diagnose AMI² earlier
- Roche is the global troponin market leader with 30% share³

¹ Devereaux et al., JAMA, June 6, 2012-Vol. 307, No. 21; ² Acute Myocardial Infarction; ³ Independent Industry Report
**Medical value: Improving the standard of care for women**

**Vision:** Roche to lead the cervical cancer screening market by cost effectively **improving the standard of care**

**Extensive Clinical Data:** ATHENA (cobas HPV test), PALMS (CINtec PLUS Cytology), Bergeron et al.* (CINtec p16 Histology)

**Endorsement of the Roche Solution:** New guidelines (ASC, ASCCP, ASCCP-LAST) recommend use of HPV 16/18 genotyping and p16 in screening and diagnosis

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**Screen**
Is my patient at high risk?

**Manage**
Does she need a colposcopy?

**Diagnose**
Should I initiate treatment?

**Monitor**
How closely do I need to monitor?

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**Screening Tools**

- cobas® HPV Test
- CINtec PLUS Cytology
- CINtec Histology

**Diagnosis Tools**
- 14HR HPV DNA with 16, 18
- Dual Biomarkers p16/Ki67
- p16 Biomarker IHC Stain

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Medical value benefits

Higher value through clinical utility and health economics

Price per test

Clinical Trials

Health Economics

KOLs guidelines

Reimbursement & medical marketing

Medical value IVD test

Standard IVD test

Standard IVD test
IVD market

Our business model and strategy

Personalised Healthcare
Roche Diagnostics enables PHC
Accelerating Companion Diagnostics (CDx) projects

Collaborations within Roche Group

1 Including R&D collaborations and CDx projects
## Importance of Personalised Healthcare

**Majority of our pipeline with Companion Diagnostics**

<table>
<thead>
<tr>
<th>Year</th>
<th>Compounds</th>
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<tbody>
<tr>
<td>2011</td>
<td>Zelboraf</td>
</tr>
<tr>
<td>2012</td>
<td>Perjeta</td>
</tr>
<tr>
<td>2013</td>
<td>Erivedge, T-DM1</td>
</tr>
<tr>
<td>2014</td>
<td>obinutuzumab (GA101), MEK 0973*</td>
</tr>
<tr>
<td>2015</td>
<td>bitopertin, ocrelizumab, onartuzumab</td>
</tr>
<tr>
<td>2016</td>
<td>EGFR ADCC Mab (GA 201), danoprevir</td>
</tr>
<tr>
<td></td>
<td>lebrikizumab, rontalizumab, etrolizumab</td>
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*MEK considered as PHC in combination with Zelboraf for metastatic melanoma

**Late Stage Pipeline:**

11 out of 18 compounds are targeted therapies for selected patients
Breast & gastric cancer
Herceptin, Perjeta & T-DM1

Key goal for Personalised Healthcare: Patients are accurately and quickly stratified

Roche Solution:
Integrated solution ensures:
• Clinical superiority
• Analytical superiority
• Testing efficiency

The only fully automated, FDA approved HER2 diagnostics workflow

2 Loftin IR, et al. Poster presented at ASCO Breast Cancer Symposium, September 2011
Non small cell lung cancer (NSCLC)  
MetMab & Tarceva

VENTANA cMET and cobas EGFR

Providing the complete system for patient identification

• Detection of two key biomarkers in NSCLC

• High accuracy, broad mutation coverage

• Standardized workflow with fast and consistent results

• Worldwide distribution

Phase 3 key inclusion criteria:

• MET positive status as determined by VENTANA cMET

• Stratification by EGFR status confirmed by cobas EGFR Mutation Test

VENTANA cMET assay¹  cobas EGFR Mutation Test²

Positive  Negative

¹ In development; ² Not available in the US
Asthma
Lebrikizumab

- Early collaboration and securing IP: UCSF-Genentech-RPD
- High quality and reliable in house IVD immunoassay based on ECL technology
- Delivered assay to meet tight Ph 2 & 3 timelines in consultation with FDA

Access to patients all over the world
- Over 40’000 SWA² instruments installed across 130 countries

Periostin¹

cobas e 601 module

¹ In development; ² Serum Work Area (clinical chemistry and immunoassay testing on a single platform)
Alzheimer’s Disease (AD)

Gantenerumab

Elecsys Aβ42\textsuperscript{1} and Tau\textsuperscript{1}

- No current approved AD therapies with identified CDx biomarkers
- CSF\textsuperscript{2} biomarker immunoassays to identify early (prodromal) AD eligible for Gantenerumab treatment
- Joint CDx development

Worldwide launch planned as fully automated IVD tests

\textsuperscript{1} In development; \textsuperscript{2} Cerebrospinal fluid
Roche Diagnostics enables PHC
Preferred Partner for companion diagnostics (CDx)

Why partner with Roche

- Proven partnership track record
- Regulatory Expertise with CDx
- Tools and Technologies
- Largest Instrument Installed Base
- World Class R&D

Selected Partners

- Clovis Oncology
- Æterna Zentaris
- MERCK
- Pfizer
- transgene
- Syndax
- Seattle Genetics
- Takeda
- Millennium
Roche Diagnostics’ commitment to PHC

Value of CDx strategy to Roche Diagnostics

If the menu meets customer assay needs, customer uses fewer instruments in their lab:

- Lower costs and complexity for customers
- More revenue for Dx company

Roche
“One-stop Shop”
Most relevant & complete offering
Summary
Roche Diagnostics well positioned to continue to outgrow the market

1. Strengthen market leadership in growing IVD market
   Leveraging global installed base and delivering new key products

2. Provide testing efficiency and demonstrate medical value
   Complete menu offering, high value assays, and building evidence

3. Roche Diagnostics enabling Personalised Healthcare
   Large companion diagnostics pipeline driving value for the Group