Roche Diagnostics
Leading and creating new markets

Heino von Prondzynski
*Head of Roche Diagnostics*

*Exane Pharma Conference*
*Paris, May 10th 2004*
This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as “believes”, “expects”, “anticipates”, “projects”, “intends”, “should”, “seeks”, “estimates”, “future” or similar expressions or by discussion of strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation among others: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market conditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity or news coverage.
Roche’s strategic decisions 1990–2003

Building the new, highly focused Roche

starting point 1990 …
CHF 9.7 billion

… result in 2003
CHF 29 billion

- Spun off or sold
  • Fragrances and Flavours
  • Vitamins and Fine Chem.

+ Acquisitions
  • Genentech
  • PCR
  • Syntex
  • Boehringer Mannheim
  • Chugai
  • AVL
  • Disetronic
  • Igen

Diagnostics
Fragrances and Flavours
Vitamins and Fine Chemicals
Pharma
Diagnostics
Integral to the healthcare mix

2003 sales of healthcare products:
US $ 570 billion

Source: EDMA
Roche Diagnostics

Well positioned in changing environment

2003 total market
US$ 25.6 billion (+6 %)

- Clinical Chemistry (+3%)
- Molecular Diagnostics (+22%)
- Diabetes Care (+6 %)
- Immunochemistry (+4%)
- Near Patient Testing (+1 %)
- other IVD

- Leading in fastest growing, most profitable areas
  - Molecular Diagnostics
  - Diabetes Care
  - Immunochemistry

- Healthcare reforms changing landscape
  - Cost pressure driving instrumentation consolidation
  - Shift to evidence based medicine
  - Emergence of tailored medicine

source: Roche analysis, Boston Biomedical Consultants, company reports
Strong Operational Performance

Key Areas of Focus

Diagnostics of the Future
Roche Diagnostics
Clear market leader

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Market Share</th>
<th>Sales Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche</td>
<td>20%</td>
<td>10%</td>
</tr>
<tr>
<td>Abbott</td>
<td>12%</td>
<td>-3%</td>
</tr>
<tr>
<td>J &amp; J</td>
<td>10%</td>
<td>4%</td>
</tr>
<tr>
<td>Bayer*</td>
<td>8%</td>
<td>4%</td>
</tr>
<tr>
<td>Beckman C.</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Dade Behring</td>
<td>6%</td>
<td>5%</td>
</tr>
<tr>
<td>IVD Market</td>
<td></td>
<td>12%</td>
</tr>
</tbody>
</table>

1 source: company reports, Boston Biomedical Consultants, Roche analysis
2 in local currencies, excludes Life Science research market
* based on 2003 results
Roche Diagnostics
Growing at double the market

Growth rate

source: Roche analysis, Boston Biomedical Consultants, company reports
2004: Off to a good start
Double market growth continues

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2004</th>
<th>growth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF m</td>
<td>CHF m</td>
<td>local</td>
</tr>
<tr>
<td>Diabetes Care</td>
<td>617</td>
<td>710</td>
<td>15 %</td>
</tr>
<tr>
<td>Molecular Diagnostics (ex. ind. bus)</td>
<td>203</td>
<td>231</td>
<td>14 %</td>
</tr>
<tr>
<td>Centralized Diagnostics</td>
<td>622</td>
<td>671</td>
<td>5 %</td>
</tr>
<tr>
<td>Near Patient Testing</td>
<td>137</td>
<td>137</td>
<td>-1 %</td>
</tr>
<tr>
<td>Roche in vitro Diagnostics</td>
<td>1,579</td>
<td>1,749</td>
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</tr>
<tr>
<td>Applied Science</td>
<td>127</td>
<td>139</td>
<td>10 %</td>
</tr>
<tr>
<td>Molecular Diag - industrial business</td>
<td>19</td>
<td>20</td>
<td>14 %</td>
</tr>
<tr>
<td>Life Science business</td>
<td>146</td>
<td>159</td>
<td>10 %</td>
</tr>
<tr>
<td>Roche Diagnostics</td>
<td>1,725</td>
<td>1,908</td>
<td>10 %</td>
</tr>
</tbody>
</table>
Above local market growth in all regions
January to March 2004

CHF 1,908 million

<table>
<thead>
<tr>
<th>Region</th>
<th>Growth Rate</th>
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</thead>
<tbody>
<tr>
<td>Europe¹</td>
<td>48%</td>
</tr>
<tr>
<td>Asia-Pacific</td>
<td>6%</td>
</tr>
<tr>
<td>Japan</td>
<td>5%</td>
</tr>
<tr>
<td>Iberia</td>
<td>6%</td>
</tr>
<tr>
<td>Latin America</td>
<td>3%</td>
</tr>
<tr>
<td>Others</td>
<td>1%</td>
</tr>
<tr>
<td>North America*</td>
<td>31%</td>
</tr>
<tr>
<td>Others</td>
<td>1%</td>
</tr>
</tbody>
</table>

local sales growth
Jan to Mar 2004 vs. 2003

<table>
<thead>
<tr>
<th>Region</th>
<th>Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>9%</td>
</tr>
<tr>
<td>North America*</td>
<td>8%</td>
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<tr>
<td>Iberia</td>
<td>13%</td>
</tr>
<tr>
<td>Latin Am</td>
<td>24%</td>
</tr>
<tr>
<td>Asia-Pacific</td>
<td>15%</td>
</tr>
<tr>
<td>Japan</td>
<td>13%</td>
</tr>
</tbody>
</table>

¹ Europe, Middle East and Africa (excl. Iberia)

*US: underlying growth + 13.1%
Roche Diagnostics Performance

Significant market share gains and improved profitability

**Sales Development * **

<table>
<thead>
<tr>
<th>Year</th>
<th>M CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>6252</td>
</tr>
<tr>
<td>2001</td>
<td>6900</td>
</tr>
<tr>
<td>2002</td>
<td>7194</td>
</tr>
<tr>
<td>2003</td>
<td>7409</td>
</tr>
</tbody>
</table>

*Including cash discounts
Source: Roche Diagnostics

**Market Share %**

- **Dade Behring**
- **Beckman C.**
- **Bayer**
- **J&J**
- **Abbott**
- **RD**

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dade Behring</td>
<td>14%</td>
<td>11%</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Beckman C.</td>
<td>14%</td>
<td>14%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Bayer</td>
<td>14%</td>
<td>14%</td>
<td>13%</td>
<td>12%</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>15%</td>
<td>17%</td>
<td>18%</td>
<td>20%</td>
</tr>
<tr>
<td>Abbott</td>
<td>39%</td>
<td>38%</td>
<td>38%</td>
<td>37%</td>
</tr>
</tbody>
</table>

**Profitability %**

- **Profit margin**
- **EBITDA margin**

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit margin</td>
<td>14.4</td>
<td>18.5</td>
<td>26.6</td>
<td>28.4%</td>
</tr>
<tr>
<td>EBITDA margin</td>
<td>19.0%</td>
<td>20.0%</td>
<td>27.6%</td>
<td>28.4%</td>
</tr>
</tbody>
</table>

*New accounting rules*
More than 20 products launched in 2003

- TaqMan 48
- AmpliChip CYP450
- Accu-Chek Advantage (III)
- Accu-Chek Go
- Prionics-Check LIA
- Elecsys SHBG
- DataCare POC
- TaqScreen WNV
- OMNI S
- RIG (Remote Information Gateway)
- Accu-Chek Compact Strips (super fast)
- Diavant internet
- LC SARS
- Accu-Chek Active (new)
- MagNA Pure Compact
- LightTyper
- LightCycler 2.0
- LC Factor II
- LC Factor V Leiden
- Amplicor HPV
- RIG (Remote Information Gateway)
- Accu-Chek Go
- Urisys 1100
- Accu-Chek Advantage (III)
- DataCare POC
- TaqScreen WNV
- OMNI S
- RIG (Remote Information Gateway)
Strong Operational Performance

Key Areas of Focus

Diagnostics of the Future
Diagnostics Strategy

_Innovation is the key to growth_

**Key Objectives**

- Be among the top three players in each market where we choose to participate
- Expand market share leadership in key focus areas through technology/product innovation
- Drive paradigm shifts through innovation; actionable health information, molecular medicine
- Attract, nurture, and grow global talent to harvest future Diagnostics leaders

**Current Business**

- Stretching our boundaries
- Creating new markets

**Future Growth Drivers**

- Shaping our market space
- Developing our future growth drivers
- Creating new segments

**Aspirations**

- Strengthening our current business
- Setting the foundation of future growth
## Broasted product portfolio in the industry

*Competing across the entire healthcare continuum*

<table>
<thead>
<tr>
<th>Life Science Research</th>
<th>Diagnostics</th>
<th>Patient Self Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applied Science</strong></td>
<td><strong>Molecular Diagnostics</strong></td>
<td><strong>Centralized Diagnostics</strong></td>
</tr>
<tr>
<td><strong>Diabetes Care</strong></td>
<td><strong>Near Patient Testing</strong></td>
<td><strong>Diabetes Care</strong></td>
</tr>
</tbody>
</table>

**Research, Pharma/Biotech, University hospital, Commercial lab, Hospital, Clinic, GP, Patient, Consumer**

### Scientists
- Driving research productivity through work-flow solutions and innovation

### Professionals
- Driving health care productivity through strengthening medical efficacy and improving lab efficiency

### Consumers
- Driving convergence of delivery and monitoring
Roche Diagnostics

*Focusing on 3 key areas*

**Focus**
- Diabetes Care
- Molecular Diagnostics
- Immunochemistry

**Strategic direction**
- Innovative systems minimizing steps & improving patient comfort
  → Integrated strip monitoring
- Cross leveraging pumps & blood glucose monitoring
  → Blood glucose monitoring
  → Connectivity solutions
  → “Artificial pancreas”
- Information management
  → Algorithms for better health management
Roche is well positioned in growing market segments

**Blood Glucose Monitoring**
- market size 7.3 bn CHF (2003)
- CAGR 2004- 2009 7 %

**Insulin Infusion Systems**
- market size 640 mCHF (2003)
- CAGR 2004- 2009 15 %

Source: Roche analysis, Company reports
Blood glucose monitoring market
Roche Accu-Chek outperforming competitors

Source: Boston Biomedical Consultants, Company reports, Roche estimates
* based on 2003
Diabetes Care Strategy

Focused on three core product areas

- Continuous Glucose Monitoring Systems
  - Connectivity solutions/information management

Innovative Blood Glucose Monitoring Systems
  - Meter-Strip Systems
  - Integrated Systems

New Business Initiatives

- Insulin Pump Systems
Two technological approaches

*Integrated Blood Glucose Monitoring*

Reducing number of devices (combining into one cartridge)

Reducing number of steps (consolidation of lancet, capillary action and measuring)
Two technological approaches

Benefits

Roche benefits

- Reinforces innovative reputation
- Strengthens #1 market position
- Lower manufacturing costs
- Sales of over 1 bn CHF p.a. expected 4 years after launch

Customer benefits

- No strip handling
- Improved hygiene
- Less pain – no blood seen
- Small, fully integrated slim device

A. Reducing # devices

“Continuous Strip”

B. Reducing # steps

“Lancing Strip”

“Measuring Needle”
Infusion Systems: new products launched

*Business and development programs defined*

**Disetronic integration finished**
**Development programs defined**

- TÜV quality system inspection successfully passed
- Preparation for FDA re-audit progressing well
- Portfolio streamlined
- Development and technology projects defined

**new pump launched**
**Next steps in preparation**

Pilot launch April ‘04 in The Netherlands
Substantial Portfolio keeps Roche Diabetes Care ahead of the market

Diagnostics

Roche

2002 2003 2004 onwards

Continuous Glucose Monitoring

Inform LCM

Inform II

Accu-Chek Compact

Super Fast Test Strip

Accu-Chek Compact (II)

Compact LCM & Integrated System

Accu-Chek Advantage

Accu-Chek Advantage (III)

Advantage Successor

Accu-Chek Active

Accu-Chek Active (new)

Accu-Chek Go

Accu-Chek Go (new)

Inform

D-TRON D-TRONplus

D-TRONplus update

H-TRON

New pump

Insulin Delivery

2002 2003 2004 onwards

Continuous Glucose Monitoring

Inform LCM

Inform II

Accu-Chek Compact

Super Fast Test Strip

Accu-Chek Compact (II)

Compact LCM & Integrated System

Accu-Chek Advantage

Accu-Chek Advantage (III)

Advantage Successor

Accu-Chek Active

Accu-Chek Active (new)

Accu-Chek Go

Accu-Chek Go (new)

Inform

D-TRON D-TRONplus

D-TRONplus update

H-TRON

New pump

Insulin Delivery

2002 2003 2004 onwards

Continuous Glucose Monitoring

Inform LCM

Inform II

Accu-Chek Compact

Super Fast Test Strip

Accu-Chek Compact (II)

Compact LCM & Integrated System

Accu-Chek Advantage

Accu-Chek Advantage (III)

Advantage Successor

Accu-Chek Active

Accu-Chek Active (new)

Accu-Chek Go

Accu-Chek Go (new)

Inform
Roche Diagnostics

Focusing on 3 key areas

Focus

Diabetes Care

Molecular Diagnostics

Imunochemistry

Strategic direction

Expanding into new markets
→ Blood screening and Women’s Health

Clinical Genomics
→ Cancer Diagnostics
→ Early detection and patient stratification
→ Complex diseases
→ Risk prediction and pharmacogenomics
**Molecular Diagnostics**

Roche the undisputed market leader

### Market Share 2003*

<table>
<thead>
<tr>
<th>Company</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche</td>
<td>49 %</td>
</tr>
<tr>
<td>Chiron</td>
<td>15 %</td>
</tr>
<tr>
<td>Bayer</td>
<td>7 %</td>
</tr>
<tr>
<td>GenProbe</td>
<td>8 %</td>
</tr>
<tr>
<td>Abbott</td>
<td>7 %</td>
</tr>
<tr>
<td>BD</td>
<td>6 %</td>
</tr>
<tr>
<td>Digene</td>
<td>4 %</td>
</tr>
</tbody>
</table>

### Molecular Diagnostics:

**Q1 ‘04:** CHF 251 million (+14 % local growth)

- **Blood Screening:** (+38 %)
- **HIV quant:** (+1 %)
- **HCV qual/quant:** (+2 %)
- **CT/NG:** (+24 %)
- **HBV quant:** (+30 %)
- **Industrial business:** (+14 %)
- **Other:** (+10 %)

(source: Company Reports, Boston Biomedical Consultants, Roche analysis

* Infectious diseases incl. HPV)
Molecular Diagnostics
Brodest test menu available

Molecular Diagnostics

Clinical diagnostics

- virology/Infectious diseases
  - HIV
  - HCV
  - HBV
  - CMV
  - Tuberculosis
- women’s health
  - CT/NG
  - HPV (CE)
- oncology
  - Early Detection
    - breast
    - colorectal
    - prostate
  - Tumor Profiling
    - breast
    - colorectal
    - prostate
    - leukemia
- genetics
  - Factor II/ IV
  - CYP 450
  - Cystic Fibrosis
  - Pharmacogenomics
  - Risk prediction

Blood screening

- approved
- research/ASR/clinical trials
- in development

HIV
HCV
HBV
WNV
HAV
Parvo B19

Roche Diagnostics
Market leader in NAT blood screening

_Growth from developed & developing markets_

- Fastest growing diagnostics segment
- Current sales mainly from HIV & HCV
- Growth potential from:
  - new analytes (WNV, HBV, HAV, Parvo B19)
  - new markets (Russia, China, Brazil, South Korea)
- Fully automated single-unit system planned '06

NAT = nucleic acid testing
Introducing The cobas “s” Series
The next generation in Blood Screening Automation

cobas s200 (expected launch 2005)
- Multiplexing – Detection of multiple targets in a single test HCV, HBV, HIV-1 (Group O, M, N), HIV-2, WNV, JEV
- Regulatory trials
  - WNV - underway since mid 2003
  - Multiplexing assay late 2004

cobas s400 (expected launch 2006)
- Fully integrated automation for single unit and pooled testing
- Multiplexing reagents
- Flexibility to support mid to high volume labs
- State of the art data management and pooling software
- Regulatory trials planned for Q3 2005
Human Papillomavirus (HPV)

New growth opportunity

Market projected to grow to >1 billion CHF

**Dec ‘03**
AMPLICOR HPV (MWP)
- Detect all high-risk HPV strains
- Triage and screening
- CE mark Apr ‘04

**Q4 ‘04**
Linear Array HPV
- Genotypes 37 types of virus
- Epidemiology, vaccine trials, test of cure

**2006**
COBAS TaqMan 96/48
- Quantitates viral levels
- Fully automated real time PCR

**HPV market potential**

- **CHF m**
  - 0
  - 500
  - 1000
  - 1500

- **Years**
  - 2002
  - 2004
  - 2006
  - 2008
  - 2010
  - 2012

- **Legend**
  - Orange: test of cure
  - Blue: screening
  - Green: triage

- **Bar Graph**
  - HPV positive sample

- **Note**
  - HPV market potential chart showing projected growth from 2002 to 2012.
Roche Diagnostics
Focusing on 3 key areas

Focus
- Diabetes Care
- Molecular Diagnostics
- Immunodiagnostics

Strategic direction
- Driving system placements
  → Centralized & decentralized labs
  Elecsys – E170, 2010, 1010
- Developing novel markers
  → ProBNP, CVD, proteomic markers
  (colorectal, breast cancer & RA)
- Simplifying workflow and data management
  → Serum Work Area
Immunodiagnostics

Gaining market in the largest IVD segment ($6.1 bn)

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2003 Immunodiagnostic Market Share

- **Abbott**: 25%
- **Roche**: 14%
- **Dade Behring**: 10%
- **Bayer**: 9%
- **Beckmann Coulter**: 7%
- **DPC**: 6%
- **Bio-Merieux**: 5%

---

growth 2003 in % (local)

- **Abbott**: -7%
- **Roche**: 12%
- **Dade Behring**: 4%
- **Bayer**: 12%
- **Beckmann Coulter**: 10%
- **DPC**: 10%
- **Bio-Merieux**: 6%

---

source: Boston Biomedical Consultants report, Company reports Roche estimates

1 w/o Blood Bank Testing
### Roche Centralized Diagnostics

#### Streamlining of Current Portfolio

<table>
<thead>
<tr>
<th>Year</th>
<th>CC/HIA</th>
<th>Het. IA</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>H917</td>
<td>E170</td>
</tr>
<tr>
<td></td>
<td>P800</td>
<td></td>
</tr>
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<td></td>
<td>I700</td>
<td>D2400</td>
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<td></td>
<td>I800</td>
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<tr>
<td></td>
<td>H912</td>
<td>P800</td>
</tr>
<tr>
<td></td>
<td>I400</td>
<td>E170</td>
</tr>
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<td></td>
<td>All Cobas Mira</td>
<td>Elecsys 2010</td>
</tr>
<tr>
<td></td>
<td>H902</td>
<td>Elecsys 1010</td>
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<tr>
<td><strong>No. of systems</strong></td>
<td><strong>13</strong></td>
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</table>

Developed markets

<table>
<thead>
<tr>
<th>Year</th>
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<tbody>
<tr>
<td>2003+</td>
<td>H912</td>
<td>E170</td>
</tr>
<tr>
<td></td>
<td>I800</td>
<td>D2400</td>
</tr>
<tr>
<td></td>
<td>I400+</td>
<td>P800</td>
</tr>
<tr>
<td></td>
<td>H912</td>
<td>E170</td>
</tr>
<tr>
<td></td>
<td>C311</td>
<td></td>
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<tr>
<td></td>
<td>C501</td>
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</tr>
<tr>
<td><strong>No. of systems</strong></td>
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</table>

Emerging markets

<table>
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<tr>
<th>Year</th>
<th>CC/HIA</th>
<th>Het. IA</th>
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</thead>
<tbody>
<tr>
<td>2004+</td>
<td>C701/ E170</td>
<td>E170</td>
</tr>
<tr>
<td></td>
<td>C701</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C501</td>
<td></td>
</tr>
<tr>
<td></td>
<td>C311</td>
<td></td>
</tr>
<tr>
<td><strong>No. of systems</strong></td>
<td><strong>5</strong></td>
<td></td>
</tr>
</tbody>
</table>

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Significant reduction of systems (from 13 to 5) and reagents
Introducing The cobas “c” Series
Next generation Chemistry & Immunodiagnostic platforms
Chronic Heart Failure
The diagnostic challenge

Only HALF of the patients are symptomatic

Of these, HALF are diagnosed correctly

Only HALF of these are treated

Only HALF of these are adequately treated
Health Economics

*Elecys ProBNP reduces costs by pre-selecting patients requiring echocardiography*

- Patients with symptoms suggestive of heart failure: 122
  - Echo: 24,400 Euro
    - 87 NO Heart failure
    - 35 Heart failure
      - Correctly Identified Patient: 697 Euro

- NT ProBNP test performed: 1,590 Euro
  - 40 BNP Positive
    - Echo: 8,000 Euro
      - 12 NO Heart failure
      - 28 Heart failure
      - Correctly Identified Patient: 342.5 Euro
  - 66 BNP Negative
R&D milestone guidelines

Idea
This is promising. Find out more and get back to us

Milestone 1
This is what we need
This is what the market needs, even though they don’t know it yet

Milestone 2
This is what we want. Best concept identified and it’s feasible
This is what the market wants

Milestone 3
Development is finished. Specifications have been met
The market is interested and wants to know more

Milestone 4
We can make it. We are ready to sell
The market wants it and is ready to pay for it

Launch
We sell the product
Post Launch
Review Lessons learnt
### Roche Diagnostics R&D Pipeline

#### Research

<table>
<thead>
<tr>
<th>Pre-milestone</th>
<th>Milestone 1</th>
<th>Milestone 2</th>
<th>Milestone 3</th>
<th>Milestone 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myoc. Infarction predisposition</td>
<td>Stroke Risk Prediction</td>
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#### Product Development

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Only includes major projects
Strong Operational Performance

Key Areas of Focus

Diagnostics of the Future
Diagnostics Strategy

Stretching our boundaries and creating new markets

Key Initiatives

Expand testing
Phenotype and Genotype

Expand market place
From IVD to actionable health information
Diagnostics in clinical practice

Increasing role in management decisions

**Today**
- Diagnosis
- Monitoring

**Tomorrow**
1. Risk prediction - what could happen?
2. Early detection - what is happening now?
3. Therapy prediction - what will happen?
4. Pharmacogenomics - which therapy to use?

**Traditional Diagnostics**
- **Diagnostic**
  - test
- **Monitor**
  - drug
  - test

**Expand Testing Market**
- Predisposition Testing
- Targeted Monitoring
- Prevention
- Diagnosis
- Therapy
- Monitoring

**Providing Health Information:**
- Disease Risk
- Drug Choice
- Health Status
- Therapy Efficacy
1. Risk Prediction for Osteoporotic Fracture

• Women tested at menopause for polymorphisms that predict risk for osteoporotic fractures

• Current diagnostics detects disease after bone loss begun or fracture occurred

• Testing aids decisions on:
  – lifestyle modifications
  – early bone mass density monitoring
  – hormone replacement therapy (HRT)
  – osteoporosis therapies

• Three genes identified and in various stages of development
  – COL1A1*, BMP2, FRRZB1

* Gene that produces the majority of bone matrix (90 %) and is highly correlated with fracture

First generation TaqMan assay for COL1A1- 2005
Second generation AmpliChip assay - 2008
2a. Breast cancer screening

*High medical need for an early detection test*

**Early detection**
Before infiltration of lymph nodes
- 5 year survival: 93%

**Detection**
After infiltration of local nodes
- 5 year survival: 69%

**Late detection**
Metastasis to other organs
- 5 year survival: 18%

**Limitations of mammography**
- No differentiation between benign & malignant
- 75-80% are not confirmed by biopsy
- Mammography can only detect lesions > 5 mm

**Current recommended screening**
Mammography followed by biopsy
2a. Breast cancer

Biomarkers can potentially detect cancer earlier than imaging

- BCM18 - First successful lead molecule from proteomics initiative
- BCM18 shows a higher specificity and a comparable sensitivity to CA 15-3, the current tumor marker for breast cancer
- The combination of BCM18 with CA 15-3 significantly increases sensitivity*
- Twelve additional breast cancer candidates under validation to further increase sensitivity

Sensitivity of CA 15.3 = 24 %, combined BCM 18 and CA15.3 = 40 %
2b. Gene chip for sub-classification of leukemia

*Leukemia is a highly heterogeneous disease*

**Diagnosis today:** complex methods, highly skilled personnel, up to 5 days for sub-classification, up to 50 % lab-to-lab-variation

**Roche’s initiative: Gene chip development**
1200 samples analyzed on Affymetrix chips with marker profiles identified

**Accuracy of classifiers for most important sub-classes so far: 95-100 %**
(expression profile of ~1000 genes)

**Diagnosis in near future:** 2006/07 planned launch of chip test

*Landmark product in oncology*
3. Therapy Selection

Traditional classification of Breast Cancer

Women with breast cancer

Biopsy / Surgery

Clinician / Oncologist

Classification of tumor based on prognostic factors

Treatment decision based on classification, general clinical condition, patient’s preference

Pathologist
3a. Test to predict recurrence of breast cancer

More accurate patient stratification with DNA methylation profiles

Low to Intermediate Risk Group (currently no chemotherapy)

270 stage I/II breast cancer pts
n=72 low/intermediate risk
n=197 high risk by traditional scores

Planned test launches
• Breast cancer 2007
• Colorectal and prostate cancer 2008

Methylation score: good prognosis

Traditional stratification: patient subset is undertreated

Methylation score: poor prognosis

Patient subset should get adjuvant chemotherapy
4. Pharmacogenetics: study of genetic variation underlying differential individual responses to drugs

Roche AmpliChip CYP450
Genetic analysis of CYP2D6 and CYP2C19 may give insights on dosing in the future

4 Distinct phenotypes exist:
- Ultrarapid Metabolizers (UM)
- Efficient Metabolizers (EM)
- Intermediate Metabolizers (IM)
- Poor Metabolizers (PM)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Percent of normal dose</th>
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<tr>
<td></td>
<td>UM</td>
</tr>
<tr>
<td>Velafaxin</td>
<td>-</td>
</tr>
<tr>
<td>Desipramine</td>
<td>260 %</td>
</tr>
<tr>
<td>Fluoxamine</td>
<td>-</td>
</tr>
<tr>
<td>Mianserin</td>
<td>300 %</td>
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Studies designed to address a number of clinical indications

<table>
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<tr>
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<th>Indication</th>
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<tr>
<td>US</td>
<td>University of Kentucky: Depression &amp; Schizophrenia</td>
</tr>
<tr>
<td></td>
<td>Medical College of Wisconsin: ADHD</td>
</tr>
<tr>
<td>UK</td>
<td>Institute of Psychiatry-London: Depression</td>
</tr>
<tr>
<td>Germany</td>
<td>University of Goettingen: Dosing study of beta blockers Depression</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Erasmus Medical College: Depression</td>
</tr>
<tr>
<td>Spain</td>
<td>Clinical University Hospital: Psychiatry</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Dr. Hochstrasser: Pain Management</td>
</tr>
<tr>
<td></td>
<td>Dr. Mueller-Spahm: Depression</td>
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“The death of nine-year-old Michael Adams-Conroy didn’t seem at first like a signal event in medicine. It seemed like homicide.

...While recuperating from what seemed to be flu, Michael went into a prolonged grand mal seizure and died. His grieving parents, Jayne and Neil, soon got another shock: an autopsy showed a massive overdose of Prozac in Michael's blood and tissues, raising the specter of a murder charge against them ...

Thus began the Adams-Conroys’ painful pilgrimage to a medical frontier known as pharmacogenetics, the study of how genetic idiosyncrasies influence responses to drugs…”
Diagnostics Strategy

Stretching our boundaries and creating new markets

Key Initiatives

Expand testing
Phenotype and Genotype

Expand market place
From IVD to actionable health information

Current Business  Future Growth Drivers  Aspirations
Healthcare Information
Building block of medical decision making

Laboratory Information Systems/Hospital IT

Risk Assessment  Early Detection  Diagnosis  Patient Stratification  Therapy Monitoring

Patient Data
Clinical information
Diagnostic Results in-vitro & in-vivo

Healthcare Information – Integrating information and clinical care to enable better medical decision making
Roche Diagnostic strategic pathway

Leverage Lab IT position to enter the Healthcare IT market

- Strengthening Lab Dx position through better automation & novel markers
- Drive workflow improvements through lab IT
- Decision Support Systems—Integrating diagnostics results & medical information
- Medical Information Mgt. to improve the overall effectiveness of patient care
- Explore strategic options to enter the Healthcare IT market
- Software systems to support healthcare professionals make the optimal selection for diagnosis and treatment
- Leverage lab IT position

Value vs. Time
Summary

• Roche is the leader in diagnostics, growing significantly above the market

• Expansion through strengthening core businesses and creating and shaping new markets

• Focusing on 3 high growth, high profit areas
  – diabetes care, molecular diagnostics, immunochemistry

• Innovative technologies and programs in place to extend leadership in each area

• More than 20 major product launches planned for 2004, with > 70 new products in the pipeline

• Roche well positioned to drive expansion into new untapped markets such as risk prediction, early detection and therapy prediction