Xpert MTB/RIF:
Update on price negotiations and market dynamics

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Pricing (I)

- **FIND is leveraging its investments in development of Xpert MTB/RIF assay (2005 – 2010)**
- **FIND-Cepheid contract based on COGS*, cost plus model**
- **Current price situation (private sector, Europe, US):**
  - **Instrument:** €40,000 – €45,000 ($55,000 – $62,000)
  - **Test cartridge:** €40 – €60 ($55 – $82)
- **FIND-negotiated pricing is volume dependent**
- **Full, ongoing, cost-reduction programme underway**

* = cost of goods
Pricing (II)

- **Cost of Goods**
  - Ongoing reductions
    - e.g. packaging & transportation
- **Volume**
  - Tiered pricing
  - Result: entry price >70% reduction
Pricing (III)

<table>
<thead>
<tr>
<th>Royalty on</th>
<th>Expiry (% royalty)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPCR</td>
<td>2011-2012 (3%)</td>
</tr>
<tr>
<td>Beads</td>
<td>2011 (3%)</td>
</tr>
<tr>
<td>rpoB</td>
<td>2011 (1%)</td>
</tr>
<tr>
<td>Instrumentation (various)</td>
<td>2012-2013 (15-20 %)</td>
</tr>
</tbody>
</table>

Patents expire in different countries at different times.
## FIND-negotiated volume/price relationship

<table>
<thead>
<tr>
<th>Applicable global volumes (cartridges per annum)</th>
<th>FIND Demonstration study price</th>
<th>FIND-negotiated price</th>
<th>FIND-negotiated price</th>
<th>FIND-negotiated price</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 150,000</td>
<td>Now</td>
<td>2011</td>
<td>2012</td>
<td>2014</td>
</tr>
<tr>
<td>Estimated year</td>
<td>US$ 18.40</td>
<td>US$ 16.84</td>
<td>US$ 14.00</td>
<td>US$ 10.72</td>
</tr>
<tr>
<td>Ave % Reduction over EU*</td>
<td>72%</td>
<td>75%</td>
<td>79%</td>
<td>84%</td>
</tr>
</tbody>
</table>

*Average cost per cartridge in EU €50
<table>
<thead>
<tr>
<th>Instrument cost for FIND markets</th>
<th>GeneXpert 4-module with desktop</th>
<th>GeneXpert 4-module with laptop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price (FOB)</td>
<td>US$ 17,000</td>
<td>US$ 17,500</td>
</tr>
</tbody>
</table>

>60% reduction over EU/US
## Maintenance and calibration costs

Standard: one-year warranty; 24-hour hotline and e-mail support

<table>
<thead>
<tr>
<th>Scenarios for after-sales service, support, maintenance and calibration</th>
<th>Model 1: Cepheid Toulouse</th>
<th>Model 2: Distributor</th>
<th>Model 3: NTP staff</th>
<th>Model 4: Web-based</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated year</td>
<td>Now</td>
<td>Now</td>
<td>2012</td>
<td>2014</td>
</tr>
<tr>
<td>Calibration (4 modules)</td>
<td>US$ 1,400</td>
<td>US$ 1,400</td>
<td>US$ 1,000</td>
<td>US$ 500</td>
</tr>
<tr>
<td>Description</td>
<td>In Toulouse (requires 2 shipments: site-Toulouse)</td>
<td>Local distributor basis (requires 2 local shipments: site-distributor)</td>
<td>On-site (no swap out)</td>
<td>Remotely, using a calibration kit (no swap out)</td>
</tr>
<tr>
<td>Shipment (4 modules)</td>
<td>US$ 400</td>
<td>US$ 200</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Total</td>
<td>US$ 1,800</td>
<td>US$ 1,600</td>
<td>US$ 1,000</td>
<td>US$ 500</td>
</tr>
</tbody>
</table>
Monitoring sales volumes

- Annual FIND-Cepheid joint forecasting process (12-24 month horizon)
- Bi-annual reviews of actual total volumes at top management meetings
- Total sales volumes include:
  - Private and developed country markets
  - Sales to FIND-target markets
- Volumes are subject to audit (as part of Cepheid’s normal financial auditing and reporting process), and reported to FIND
- FIND has option to carry out independent audit
- FIND intends to regularly update WHO/GLI on sales volumes, for further public dissemination
Post-marketing surveillance

- Cepheid is FDA-registered and ISO 13485 (as is FIND), and has fully functional regulatory affairs group in-house
- Cepheid is contractually bound to inform FIND of any major field event in relation to both instruments and reagents
- Cepheid technical management team reviews such events, and informs FIND on regular basis
- FIND will update WHO/GLI on a regular basis
- All GeneXpert systems have continuous online monitoring
- Cepheid gathers and analyses all data centrally, and can respond in real-time on instrument problems
Cepheid manufacturing capacity

- Xpert MTB/RIF manufactured in Bromma, Sweden
- GeneXpert instrument manufactured in Sunnyvale, California, USA
- Based on forecast volumes, no capacity constraints foreseen for instruments or assays in foreseeable future
- Manufacturing processes are scaleable to higher volumes as required
Test volume as function of capacity

- **Conservative**  
  - $10.7/test price achieved, if further UNITAID and Global Fund scale-up
  - Expansion to greater number of countries, and introduction of other funding mechanisms

- **Agressive**  
  - $14.0/test price achieved, if UNITAID-funded scale-up, and early Global Fund grants
  - Collecting evidence for scale-up

Annual test volumes (million cartridges)

- 2011: $10.7  
- 2012: $14.0  
- 2013: $16.8  
- 2014:  
- 2015: 10
Critical path moving forward

WHO endorsement
- 4Q 2010

Collecting evidence for scale up
- 1Q – 4Q 2011
- UNITAID, TBREACH, TBCARE, PEPFAR
- Selected countries, different health service levels

Scale up
- 4Q 2011 - 2015
- EXPAND-TB
- Global Fund Round 11
- TBREACH, TBCARE, PEPFAR, country budgets, etc.
Thank you!