



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



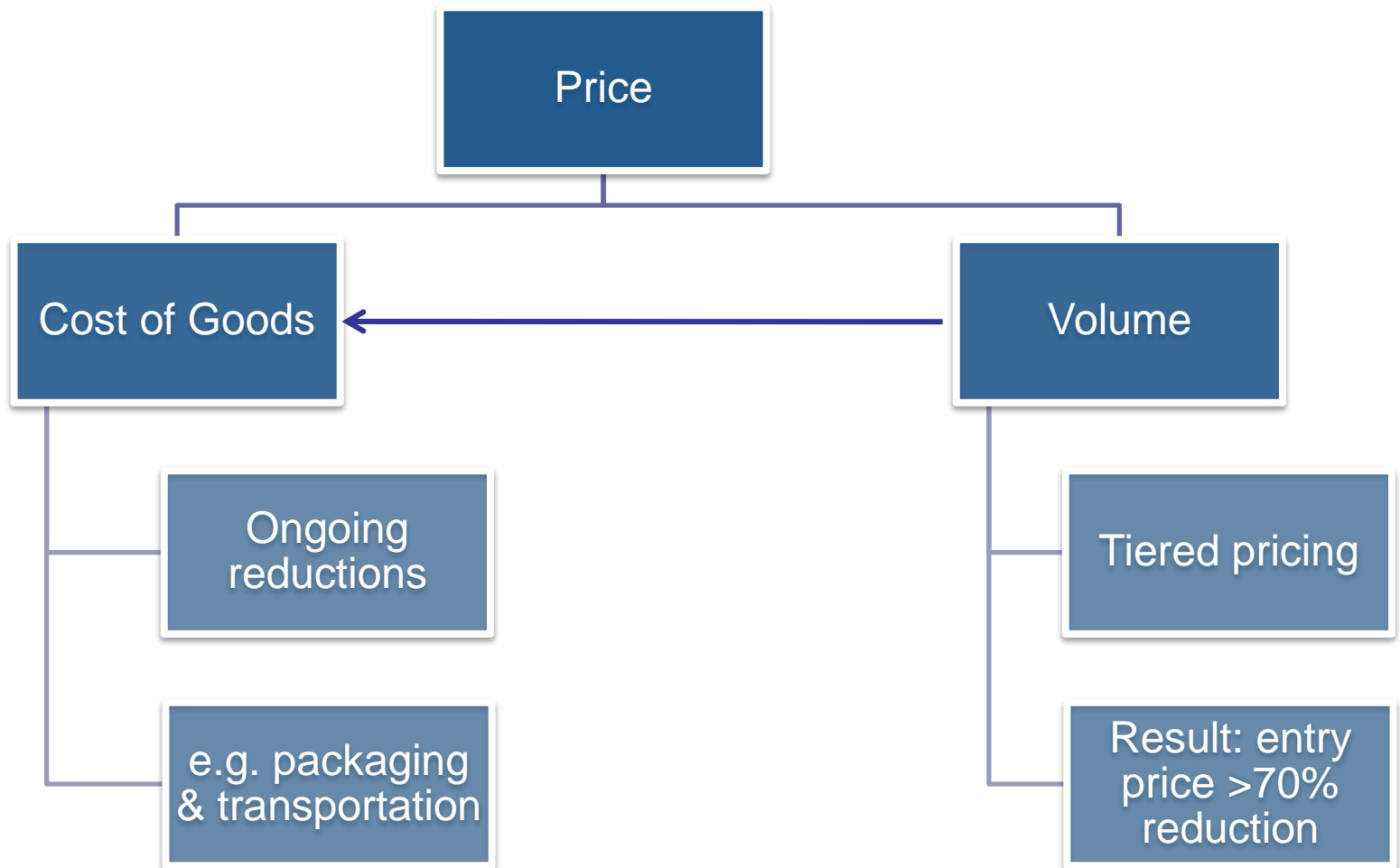
*Giorgio Roscigno  
30 November 2010*

*Partnering for better diagnosis for all*

- **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)



# Pricing (III)

| Royalty on                 | Expiry (% royalty)  |
|----------------------------|---------------------|
| RPCR                       | 2011-2012 (3%)      |
| Beads                      | 2011 (3%)           |
| rpoB                       | 2011 (1%)           |
| Instrumentation ( various) | 2012-2013 (15-20 %) |

Patents expire in different countries at different times

# FIND-negotiated volume/price relationship



| <b>Forecasted per-test cost for FIND markets</b>          |                                      |                           |                           |                           |
|---|--------------------------------------|---------------------------|---------------------------|---------------------------|
|   | FIND<br>Demonstration<br>study price | FIND-<br>negotiated price | FIND-<br>negotiated price | FIND-<br>negotiated price |
| Applicable<br>global volumes<br>(cartridges per<br>annum) | > 150,000                            | > 600,000                 | >1,700,000                | >3,200,000                |
| Estimated year  | Now                                  | 2011                      | 2012                      | 2014                      |
| <b>Price (FOB)</b>  | <b>US\$ 18.40</b>                    | <b>US\$ 16.84</b>         | <b>US\$ 14.00</b>         | <b>US\$ 10.72</b>         |
| <b>Ave %<br/>Reduction<br/>over EU*</b>                   | <b>72%</b>                           | <b>75%</b>                | <b>79%</b>                | <b>84%</b>                |

\*Average cost per cartridge in EU €50

# FIND-negotiated instrument cost



## Instrument cost for FIND markets

GeneXpert 4-module  
with desktop

GeneXpert 4-module  
with laptop

**Price (FOB)**

**US\$ 17,000**

**US\$ 17,500**

**>60% reduction over EU/US**

# Maintenance and calibration costs



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

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

# 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

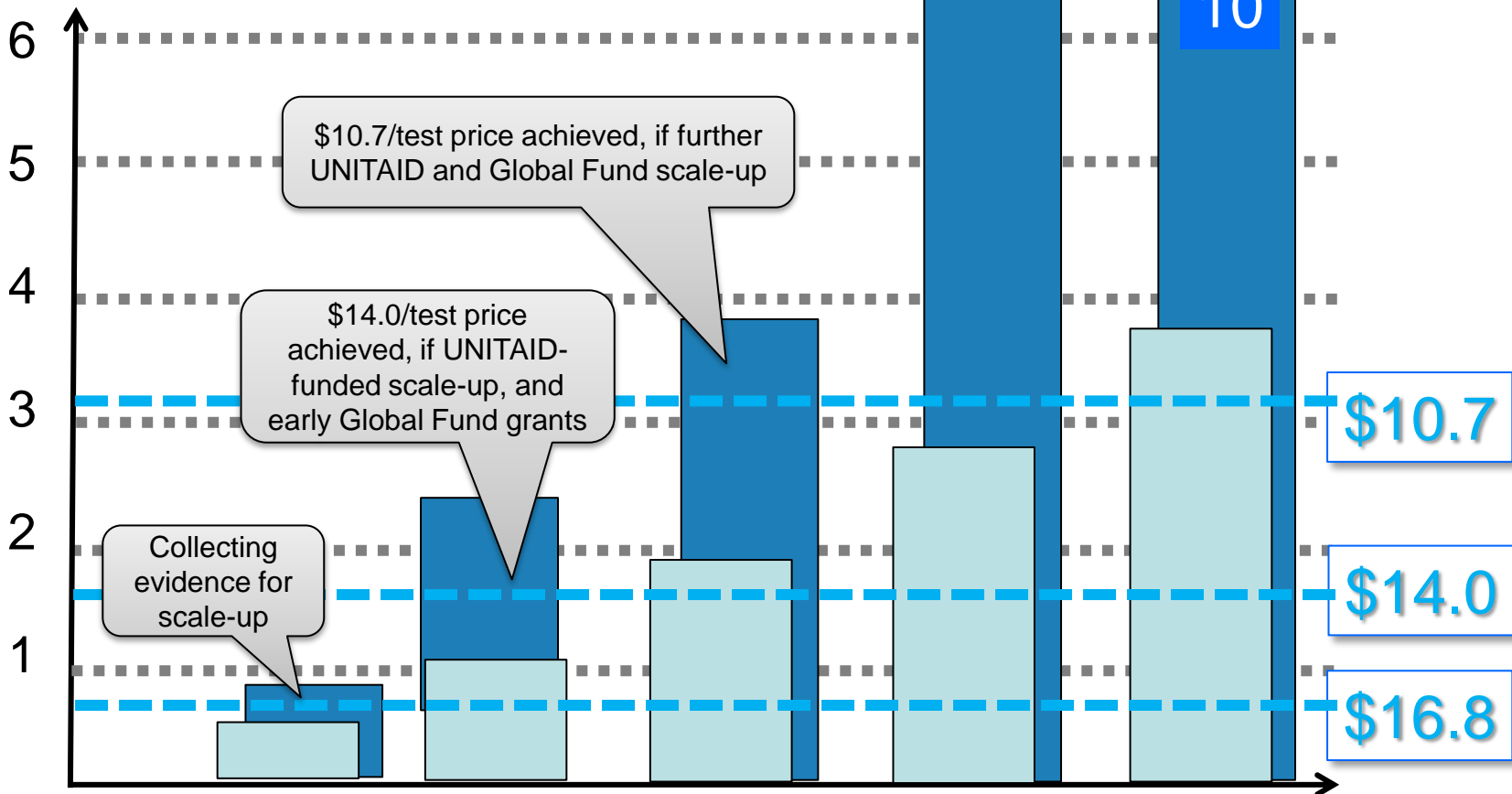
# Cepheid manufacturing capacity

- 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

Expansion to greater number of countries, and introduction of other funding mechanisms

Annual test volumes (million cartridges)



Conservative  
Aggressive

2011 2012 2013 2014 2015

10

\$10.7

\$14.0

\$16.8

Collecting evidence for scale-up

\$14.0/test price achieved, if UNITAID-funded scale-up, and early Global Fund grants


\$10.7/test price achieved, if further UNITAID and Global Fund scale-up

# 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!*

