THE VALUATION EXPERTS

Identifying the Best Investment Model and Valuating Biosimilar Opportunities

Dr. Patrik Frei
May 2015 | Biosimilars Asia
Agenda

• Valuation
• Valuation of biosimilar
• Strategic decision to maximize value
• Q&A
Independent assessment and valuation of Life Sciences companies / therapeutic products

Company, Deals & Investors Database
Biotechgate.com

- Switzerland (HQ); Canada; UK; Singapore; India; China
- Global experience with 25 people
- Track record of over 350 valued companies / products
- Investor clients such as Novartis, GSK, Fraunhofer Gesellschaft, European Investment Bank; Company clients: Arpida/Evolva; 4SC;
- Product valuation for licensing deals
rNPV Product Valuation

1. Development phase => investment
   Risk (r) => success rate

2. Market phase => revenues
   Patent expiry => end of revenues
   (often no terminal value)

3. Discount / WACC => non-specific risk
Five Step Process

1. Determine Cash Flows in Development Phase

2. Determine Cash Flows in Market Phase

3. Discount with Discount rate

4. Adjust for Risk

5. Sum discounted cash flows
rNPV – Example

- Phase 1 product
- 15% discount rate
- 11% Probability of success (p1 to market)

⇒ CF: USD 2'182m
⇒ DCF: USD 216m
⇒ rNPV: USD 10m
Agenda

• Valuation
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Development Phase

I. Innovative Biologics
   - Determine cost and duration of clinical trials
   - Manufacturing
   - Regulatory affairs
   - Long term animal tox. studies

II. Biosimilar
    - Shorter development timelines / costs
    - Finding patients for clinical trials
    - Comparative trials => cost for original product
Cost and Lead Times

1. Devel.
2. Market
3. Discount rate
4. Risk
5. $$$

Best case
0 1 2 4 5
Time taken for development (years)

Worst case
0 2 4 7+ 9+

Product development and comparative analysis
Process development, scale up and validation
Clinical trials
EMA and FDA review and approval

Best case
US$2
US$12
US$42
Cost (US$ million)

Worst case
US$5+
US$35+
US$135+

Source: Bernstein Research

Reference Biologic Development

Discovery | Development | Pre-clinical | Phase 1 | Phase 2 | Phase 3

Biosimilar Development

Development | Pre-clinical | Phase 1 | Phase 3

USD -+1bn
USD 60 – 200m

Source: Hospira
## Reduced time to market

<table>
<thead>
<tr>
<th>Phase</th>
<th>Original product</th>
<th>Biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>12 month / 4m</td>
<td>12 month / 2 m</td>
</tr>
<tr>
<td>Phase II</td>
<td>36 month / 20m</td>
<td>n/a</td>
</tr>
<tr>
<td>Phase III</td>
<td>36 month / 120m</td>
<td>36 month / 60m</td>
</tr>
<tr>
<td>Approval</td>
<td>12 month / 8m</td>
<td>12 month / 6m</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>8 years / 152m</strong></td>
<td><strong>5 years / 68m</strong></td>
</tr>
<tr>
<td>rNPV</td>
<td>USD 10m</td>
<td>USD 40m</td>
</tr>
</tbody>
</table>
Market Phase

Develop assumptions to predict the future market

Methods used:

- Bottom-up approach
  - Based on primary market data

- Top-down approach
  - based on comparable products
Market Phase

Biosimilars market evolution, 2010 - 2020

- Slow uptake in the US due to new legislation enabling innovators to delay the approval process of new biosimilars
- Uptake in Europe accelerates due to more mature framework
- Emerging countries (Asia specifically) ramping up

Source: IMS Health
Market Phase

Biosimilar:
- Different adaption of Biosimilar (EU / US; Germany vs. rest of Europe)
- Uncertainty in future (reimbursement, incentives)
- Average price cut of 30%
- More patients? (price elasticity)
- Different penetration (commodity vs. differentiation)
- Competition (original product / biosimilar / biobetter)
- Exclusivity / no IP protection
## Reduced market

<table>
<thead>
<tr>
<th></th>
<th>Original product</th>
<th>Biosimilar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak sales (2031)</td>
<td>USD 983m</td>
<td>USD 164m</td>
</tr>
<tr>
<td>Life Cycle</td>
<td>Drop of sales after patent expiry</td>
<td>Growth of 3% per year</td>
</tr>
<tr>
<td>rNPV</td>
<td>USD 10 m</td>
<td>USD -13m</td>
</tr>
</tbody>
</table>
**Discount rate**

Cost of Equity / discount rate in rNPV:

- **Early stage**: 12% - 28%
- **Mid stage**: 10% - 22%
- **Late stage**: 9% - 20%
- **Pharma**: below 10% (incl. debt)

Source: www.biostrat.dk

Cost of equity and non-development associated risks.
Discount rate

Used discount rate in rNPV:

- Biosimilar player => lower WACC;
- Generally higher uncertainty (+)

<table>
<thead>
<tr>
<th>Discount rate</th>
<th>Market</th>
<th>Devel.</th>
<th>Risk</th>
<th>$$$$$</th>
</tr>
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<tr>
<td>15%</td>
<td></td>
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<td></td>
<td>USD 10m</td>
</tr>
<tr>
<td>18%</td>
<td></td>
<td></td>
<td></td>
<td>USD 2m</td>
</tr>
<tr>
<td>12%</td>
<td></td>
<td></td>
<td></td>
<td>USD 22m</td>
</tr>
</tbody>
</table>
Adjust for risk (I)

Source: Nature Biotechnology; Clinical development success rates for investigational drugs; January 2014
Adjust for Risk (II)

The relation between Risk and Value

- Completion of a phase ➔ Direct value increase

<table>
<thead>
<tr>
<th>Original</th>
<th>Biosimilar</th>
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<tbody>
<tr>
<td>889</td>
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</tr>
<tr>
<td>649</td>
<td>649</td>
</tr>
<tr>
<td>167</td>
<td>167</td>
</tr>
<tr>
<td>24</td>
<td>95</td>
</tr>
<tr>
<td>10</td>
<td>49</td>
</tr>
</tbody>
</table>

Cumulative Success rate: 11%

- Phase I: 64%
- Phase II: 32%
- Phase III: 61%
- NDA/BLA: 86%
- Approval/Market: 889

Original vs. Biosimilar
Adjust for risk (III)

Used risk adjustment in rNPV:

- Biosimilar => lower risk (-)
- No phase II
- Individual adjustment

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<tr>
<td>Phase I</td>
<td>64%</td>
<td>64%</td>
</tr>
<tr>
<td>Phase IIa/IIb</td>
<td>60% / 55%</td>
<td>100%</td>
</tr>
<tr>
<td>Phase III</td>
<td>61%</td>
<td>61%</td>
</tr>
<tr>
<td>Approval</td>
<td>86%</td>
<td>86%</td>
</tr>
<tr>
<td>Cum. Success</td>
<td>11%</td>
<td>33%</td>
</tr>
<tr>
<td>rNPV</td>
<td>USD 10m</td>
<td>USD 49m</td>
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### Summary

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<td>rNPV</td>
<td>USD 10m</td>
<td>USD 13m</td>
</tr>
<tr>
<td>rNPV after phase III</td>
<td>USD 649m</td>
<td>USD 179m</td>
</tr>
</tbody>
</table>
Conclusion

• Valuation same approach as innovative drugs

• Variation on
  - Timeline (+)
  - Development costs (+)
  - Market (-)
  - Attrition rate (+)
  - Discount rate (+/-)

=> Market / Competition / Pricing as high impact
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Thank you for listening!

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