Tuck Biogenerics Panel

Capital Markets Perspectives

April 11, 2008
Public Biotech Fundraising Remains Strong
2004 – 2008 (1) (2)

- Public market fundraising by biotechnology/emerging pharma companies remains strong
  - 2007: $13Bn
  - 2006: $17Bn
  - 2005: $11Bn

- Although broader market volatility has diminished 2008 biotech financing activity, long-term investor sentiment towards the industry remains positive

Notes
1. Includes biotech and emerging healthcare US marketed follow-on offerings above $50MM
2. Does not include greenshoe, even if exercised; excludes Warner Chilcott IPO in 2006
3. As of 3/17/08
Venture funding to biotech also continues to grow

- Resurgence in funding of early-stage discovery and platform technology companies

**Biotech Venture Funding Also Continues to Grow**

2003 – 2007

**Biopharmaceutical Venture Financing**

2003-2007

$MM

Source: VentureSource
The Biogeneric Market Opportunity is Large
2007 Worldwide Sales of Key Biologic Products

Key Biologic Product Sales

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<tr>
<td>Epogen &amp; Procrit (2013)</td>
<td>5,374</td>
<td>5,096</td>
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<tr>
<td>Enbrel (2012)</td>
<td></td>
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<td>Rituxan (2015)</td>
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<td>Remicade (2013)</td>
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<td>Herceptin (2019)</td>
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<td>Aranesp (2024)</td>
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<td>Avastin (2019)</td>
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<td>Humira (2016)</td>
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<td>Neulasta (2015)</td>
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<tr>
<td>Lantus (2015)</td>
<td></td>
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<tr>
<td>Avonex (2013)</td>
<td>1,881</td>
<td>1,680</td>
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<td>Rebif (2013)</td>
<td></td>
<td></td>
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<tr>
<td>Copaxone (2014)</td>
<td>1,614</td>
<td>1,475</td>
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<tr>
<td>Humalog (2013)</td>
<td></td>
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<tr>
<td>Neupogen (2013)</td>
<td>1,277</td>
<td>1,100</td>
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<td>Lucentis (2019)</td>
<td>1,208</td>
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<tr>
<td>Cerezyme (2013)</td>
<td>1,100</td>
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Source: EvaluatePharma; Company Reports

Notes
1. Approximate patent expiration date; in cases where multiple patents exist, the last expiration year is utilized
Pharma is Facing a Significant Near Term Patent Cliff
2007-2013 Revenue Exposed to Generics

- Patent exposure remains one of the most significant risks in the pharma industry
  - Significant number of patent expirations between 2011 and 2013
- In addition, recent court decisions and ‘at risk’ launches may weaken the position of patent holders
  - KSR decision
  - Seagate decision
  - Protonix-like launches may become more common

### Large Cap Pharma Revenue Lost to Patent Expirations by Year (1)

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue (Bn)</th>
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<tr>
<td>2007</td>
<td>16.0</td>
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<tr>
<td>2008</td>
<td>19.8</td>
</tr>
<tr>
<td>2009</td>
<td>11.9</td>
</tr>
<tr>
<td>2010</td>
<td>19.0</td>
</tr>
<tr>
<td>2011</td>
<td>51.2</td>
</tr>
<tr>
<td>2012</td>
<td>42.1</td>
</tr>
<tr>
<td>2013</td>
<td>20.1</td>
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</table>

Source: EvaluatePharma

**Note**
1. Includes Abbott, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, J&J, Merck, Novartis, Pfizer, Roche, Sanofi, Schering-Plough, and Wyeth. Revenue lost calculated as last full year of estimated sales prior to scheduled expiration.
Pharma Has Little Exposure to Biologics

Biologics Represent a Significant Future Market Opportunity for Pharma

- Most Large Pharmas have little future revenue exposure to biologics
- However, biologics represent a method for Large Pharma to replenish pipelines and address the coming revenue gaps caused by small molecule patent expirations
  - The desire for biologic exposure has fueled pharma/biotech M&A
Biotech M&A Activity Has Been Robust
2000 to 2008 YTD

- Biotech M&A volume nearly doubled in 2007, though volume increase principally driven by the $15.3Bn MedImmune and $14.4Bn Organon BioSciences deals
- Drivers include:
  - Broad interest from large pharma as significant patent expirations approach
  - Increasing number of biotech consolidators
  - Balance sheet strength / liquidity

Source: Morgan Stanley, SDC as of 3/28/08
Biogenerics are inevitable…

• Market participants view a U.S. regulatory pathway as “when,” not “if”
• European system is a likely template for U.S.
• Significant market opportunity after next wave of small molecule generic introductions

…but will likely have a slow onset

• FDA will make product-specific decisions rather than establish a uniform policy
• Complex molecules (i.e. antibodies) will require more stringent development programs
• Most biogenerics will not be granted automatic substitution
• Few generic players currently have capabilities for large scale commercialization
• Second-generation branded products may limit adoption of first-generation biogenerics
• Pricing at 20%-30% less than innovator molecules

and there is uncertainty in how to model

• What is the slope of sales curve beyond innovator patent expiration?
• What are the development timelines/FDA requirements for biogenerics?
• How will innovators respond?
Capital Markets / Investment Perspectives on Biogenerics

The Biogeneric Opportunity

Multiple players could pursue the opportunity

• Existing generic companies
• Repurposed biotech companies
• Pharma/biotech innovators
• Contract manufacturing organizations
• Players from both US/Europe and BRIC countries

However, the capabilities needed for success are significant...

• Manufacturing capacity/expertise
• Development and regulatory know-how
• Sales and marketing infrastructure
• Significant capital base

...limiting the number of entrants in near to mid-term

• Only a handful of players have or will have the necessary capabilities in mid-term
• In addition, economics will likely limit the number competitors per product
Innovators are aware of the threat and responding

- Biogeneric human growth hormone and EPO are available in Europe (and U.S. for Hgh)
- Biogeneric Rituxan available in India
- Active lobbying/PR effort to shape debate and legislation

But biogeneric success so far has been mixed

- Although early days, market adoption of first-generation biogenerics has been limited
- Second-generation biogenerics may experience greater success versus branded comps
- Largest threat, yet most uncertain, are biogeneric antibodies and derivatives

How will innovators respond longer-term?

- Reduce price to match biogenerics
- Novel product presentations (i.e. formulations and delivery devices)
- Focus marketing to emphasize product safety/history
- Combination products
- Develop own biogeneric offerings
- Innovate to grow