The Outlook for the CMO Industry

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President, PharmSource
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Where is the CMO industry headed?

• **Drivers**
  – Propensity to outsource
  – Formulary acceptance for new drugs
  – Industry consolidation

• **Outlook**
  – Future depends on new approvals for small and mid-size companies
  – Injectables CMOs to benefit from tight capacity
  – M&A will consolidate industry but competition for most desirable assets
  – Mixed models (proprietary + contract) will be more common
CMO success depends on small & mid-size bio/pharma

Outsourced NDAs by Type

Outsourced NDAs by Company Type

Source: PharmSource Strategic Advantage database
Global bio/pharma cherry-picking winners from smaller companies

Share of NME Approvals 2004-2013
- Global: 43%
- Mid: 30%
- Small: 21%
- Generic: 5%

Share of Non-NME Approvals 2004-2013
- Global: 28%
- Mid: 26%
- Small: 20%
- Generic: 26%

Share of NME approvals in-licensed or acquired
- 2006: 0%
- 2007: 20%
- 2008: 40%
- 2009: 60%
- 2010: 70%
- 2011: 75%
- 2012: 70%
- 2013: 60%

- Global bio/pharma in-licensing most promising NMEs
- Non-NMEs are smaller volume products

Source: PharmSource Strategic Advantage database

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Global & generic bio/pharma invest strategically in captive manufacturing

Global bio/pharma capex = 11% of cash flow

Biopharmaceuticals: 52% of projects
Emerging markets: 43% of projects

Source: Bio/Pharma Capital Expenditure Trends 2010-2013 and Implications for CMOs, PharmSource, September 2014
CapEx consumes CMO cashflow

- CapEx constrained by cash availability
  - Little room for innovative technology
  - Customers must provide capital
- CapEx limits ability to reward investors, repay debt, attract new capital
- M&A less risky than CapEx
  - Known cashflow
  - Readily financed

Global bio/pharma average 2010-2014
Source: PharmSource analysis of financial reports
Coverage decisions impact CMO revenues

Coverage Decisions by UK’s NICE

- Coverage decisions in EU costing CMOs $500-1000 M p.a.
  - NICE (UK) and IQWIG (Germany) drive rest of Europe

- Insurers in US taking harder line

- CMO impact
  - Unit volumes
  - Pricing

Source: Not So NICE: How Market Access Schemes Impact the CMO Sector, PharmSource, July 2014
Injectables CMOs in best situation

- Growing demand from biologics makes injectables capacity tight
  - Except PFS, which is ample

- But high cost of capacity and commercial uncertainty make investment very risky
  - Few new investments announced

- Cyto supply even tighter but even more risky

- Pricing should be firm for injectables
# CMO exits tighten capacity

<table>
<thead>
<tr>
<th>CMO</th>
<th>Target Services</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmalucence</td>
<td>DP-injectables</td>
<td>Acquired by Sun Pharmaceuticals; announced CMO exit</td>
</tr>
<tr>
<td>SCM Pharma</td>
<td>DP-injectables</td>
<td>Acquired by Shire following loss of license for compliance issues</td>
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<tr>
<td>Exemplar Pharmaceuticals</td>
<td>DP-inhalation</td>
<td>Acquired by Allergan following product approval problems</td>
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<tr>
<td>Genhelix</td>
<td>DS-large molecule</td>
<td>Acquired by mABxience for capacity</td>
</tr>
<tr>
<td>Medreich</td>
<td>DP-injectables, solid</td>
<td>Acquired by Meiji Seika Pharma for capacity</td>
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<tr>
<td>Bayer Contract Manufacturing</td>
<td>DP-multiple dose forms</td>
<td>Need capacity for own products</td>
</tr>
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<td>B-I Contract Manufacturing*</td>
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<tr>
<td>Ben Venue Laboratories</td>
<td>DP-injectables</td>
<td>Compliance issues</td>
</tr>
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* Not BioXcellence biologics CMO

Source: Bio/Pharmaceutical Outsourcing Report
M&A consolidating CMO industry

### Strategic Acquisitions 2012-2014

<table>
<thead>
<tr>
<th>Acquirer</th>
<th>Target</th>
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<td>Patheon</td>
<td>Gallus Biopharma</td>
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<td>Patheon</td>
<td>Banner Pharmacaps</td>
<td>DP-softgel</td>
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<tr>
<td>Recipharm</td>
<td>Corvette</td>
<td>DP-Injectables</td>
</tr>
<tr>
<td>AMRI</td>
<td>Oso Bio</td>
<td>DP-Injectables</td>
</tr>
<tr>
<td>AMRI</td>
<td>Cedarburg Hauser</td>
<td>DS-small molecule</td>
</tr>
<tr>
<td>Packaging Coordinators</td>
<td>Penn Pharma</td>
<td>DP-High potency solid</td>
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<tr>
<td>Aenova</td>
<td>Haupt Pharma</td>
<td>DP-injectables/solid/liq</td>
</tr>
<tr>
<td>Catalent</td>
<td>Relthy Laboratorios</td>
<td>DP-softgel</td>
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30 largest dose CMOs ≈ 70% of the market
M&A drivers

- **Grow enterprise value**
  - Size for the sake of size
  - Offset challenges of organic growth

- **Position for emerging opportunities and technologies**
  - Biologics/injectables
  - Solubility-enhancing technologies

- **New service combinations**

- **Geographic market access**

- **Less risky than building capacity**
The outlook

• **Near-term positive outlook for CMOs**
  – Funding environment means more development, more CTM, more potential commercial

• **Commercial CMO volume depends on:**
  – Number of small/mid-size pharma approvals
  – Formulary access in US and Europe

• **Injectables and biologics API CMOs benefit from tight capacity**
  – Better pricing and terms
  – But risk increases if CMOs must finance more capacity
The outlook

• Hunger for acquisitions will benefit CMOs with specialty capabilities
  – Deal values will be driven up by competition among strategic buyers for limited number of targets

• New business models to fuel profit growth
  – API + dose manufacturing
  – Shared capacity proprietary products
  – “Pure play CMO” will be a niche
Market intelligence services

**PharmSource LEAD SHEET**

- The definitive source for targeted new business opportunities in the global Bio/Pharma industry
- Receive fresh, targeted leads plus contact information and the latest market intelligence
- Know the changing pipeline status of bio/pharmaceutical products, what companies have new funding, and which executives are on the move

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- The industry’s premier information resource, which includes:
  - Contract services database
  - Bio/Pharmaceutical Outsourcing Report
  - Emerging Markets Outsourcing Report
  - In-depth Analyses
  - Trend Reports

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