Managing out-licensing collaborations: a big pharma perspective

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European PLG Conference, Copenhagen, Sept. 25-26
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Agenda

- Overview Novartis
- BD&L at Novartis
- Alliance Management of out-licensed assets
- Conclusions
Overview of Novartis group: a strong and diversified portfolio

Pharmaceuticals
- Cardiovascular and Metabolism
- Oncology and Hematology
- Neuroscience and Ophthalmics
- Respiratory
- Immunology and Infectious Diseases
- 2007 sales: 24.03 USD bln (+2%)

Vaccines and Diagnostics
- Novel vaccines
- Chiron
- 2007 sales: 1.45 USD bln (+47%)

Sandoz
- Generics
- 2007 sales: 7.17 USD bln (+13%)

Consumer Health
- OTC (Over-The-Counter)
- CIBA Vision
- Animal Health
- 2007 sales: 5.43 USD bln (+6%)
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Novartis is a leader in licensing activities

Number of deals 2005 – 2007

Source: PharmaDeals, Data download March 2008

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Over half of our recently launched brands have been developed with partners

<table>
<thead>
<tr>
<th>Developed alone</th>
<th>Developed with partner</th>
<th>Partner</th>
</tr>
</thead>
<tbody>
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Novartis highly rated by partners

# of criteria on with top rating (#1)
BCG industry survey, 2006

- Novartis: 7
- Pfizer: 5
- Roche: 3
- Genentech: 2
- J&J: 1
- GSK: 1

- #1 partner of choice for licensors¹
- #1 choice for top 30 VC firms²

¹ Licensing trends survey, 2006  ² MSD VC meeting 2006

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Pharma BD&L organization

Pre-selection → Initial Evaluation → Full Evaluation → Negotiation → Implementation

Search & Evaluation

Negotiation

Alliance Management
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Out-licensing - partnering Novartis’ assets

- Novartis is open to many partnering / deal structures
  - Out-licensing of development compounds
  - Divestment of mature products
  - Commercial arrangements for existing Brands

- Objective is to realize value from:
  - Compounds which have been deprioritized during development
  - Products which are not receiving sufficient commercial support
  - Products for which Life Cycle Management has received too little attention internally
  - New ideas on existing Novartis assets (new indications, new formulations, new combinations)
This presentation focuses on alliance management of out-licensed development-stage drugs.

- **Divestments of mature products**
  - Number of Novartis transactions 2006/07: 7
  - Limited alliance management need after completion of hand-over

- **Global out-license collaborations of development assets**
  - Number of Novartis transactions 2006/07: 6
  - Alliance management required – level differs by type of asset/degree of ongoing collaboration

- **Local/regional commercial collaborations**
  - Number of Novartis transactions 2006/07: >50
  - Alliance management on local/regional level required – but not focus of this presentation
Examples of Novartis out-licensing transactions

- Speedel / Rasilez® - Tekturna® (aliskiren) 1999
- Guidant / everolimus (for drug eluting stents) 2002
- TopoTarget / Zemab 2003
- Chiron / aerolized cyclosporine 2003
- Avera / NKP-608 2003
- Vanda / iloperidone 2004
- Eisai / Inovelon® (rufinamide) 2004
- Cerimon / Simulect® (basiliximab for IBD) 2006
- Kythera / LAV694 2006
- Synosia / rufinamide (for anxiety, BD) 2006
- APT / Pulminiq® 2007
- Santhera / TCH346 (for muscular dystrophies) 2007
Alliance Management of out-licensed drugs is generally less complex than of in-licensed drugs...

% of collaborations under active Novartis Pharma alliance management

<table>
<thead>
<tr>
<th>Type of Collaboration</th>
<th>Complexity of Alliance Management</th>
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<tr>
<td>in-license</td>
<td>high complexity</td>
</tr>
<tr>
<td></td>
<td>medium/low complexity</td>
</tr>
<tr>
<td>out-license</td>
<td>71</td>
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<td>29</td>
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..however: level of Alliance Management for out-licensed drugs differs by type of asset

- Deprioritized assets
- Second indication of Novartis in-market asset
- Once/twice yearly update in writing
- Quarterly JSC meetings
- No dedicated governance structure
- Dedicated alliance manager
What does Alliance Management for out-licensed assets encompass?

- Facilitate transfer of data/information/know-how/product or compound
  - Especially difficult for deprioritized assets with no existing project team
  - Usually work-load peaks prior to deal execution (due diligence stage)

- Prepare business case and align internal organization to decide on call back right

- Provide strategic input through governance structure
  - In particular for development of second indications of in-market asset

- Renegotiate if appropriate
  - E.g., extending option/exclusivity period, adding territories,…

- Act as a “go to person” for any type of deal-related questions/concerns
  - Novartis takes alliance management of out-licensed assets seriously to ensure both companies can capture full value from collaboration
Potential issues…

- Availability of data in case of terminated projects
  - Development/business owners may have moved on

- Prioritization of workload to support partner
  - Spending resources on supporting/providing input for out-licensed assets sometimes perceived as lower priority – needs education of organization

- Coordination of supply and strategy with partner if partner develops second indication of Novartis in-market drug/if Novartis supplies
  - Not too many case examples within Novartis – not everybody may be familiar dealing with such questions

- Your alliance manager will support you in overcoming such problems, trying to create value for your company and Novartis
Case example: Collaboration with Cerimon on Simulect® in Ulcerative Colitis

- **Deal execution:** Feb 2006

- **Collaboration partner:** Cerimon Pharmaceuticals, Inc.

- **Compound:** basiliximab (Simulect®)
  - monoclonal antibody, selectively blocking IL-2 receptor (inhibits T cell activation)
  - Currently marketed by Novartis for the prevention of organ rejection in renal transplant recipients

- **Deal terms:**
  - Novartis grants Cerimon the exclusive worldwide right to develop and commercialize Simulect® (basiliximab) for the treatment of Inflammatory Bowel Disease (IBD), including Ulcerative Colitis (UC) → “indication partnering” of an in-market Novartis drug
  - Novartis continues to market Simulect in transplant indications
  - Upon approval for its use in IBD, Cerimon will market Simulect and Novartis will share revenue from net sales in this field with Cerimon
  - Cerimon will receive performance-based milestone payments
Promising development and well running alliance

- **Achievements to date:**
  - IND successfully filed
  - PhIIb Study (ARREST UC-1) of basilixmab in patients with steroid-refractory ulcerative colitis initiated Apr 2007 – results expected later in 2008

- **An example for a successful alliance**
  - Quarterly Joint Steering Committee meetings, involving several functional experts in both companies, and a dedicated alliance manager
  - Open, trustworthy relationship, as ranked by both companies (alliance healthcheck)
  - New work flows between the companies established (e.g. drug supply ordering process)
  - Desire to create additional value: in Mar 2008, Cerimon obtained additional right to conduct a proof of concept study of basiliximab in noninfectious uveitis; this study has been initiated in July 2008

**Cerimon management:** “I have had a very positive experience working in this alliance. Our interactions have been thoughtful and productive”

**Novartis management:** “The Cerimon collaboration is a good one. The teams work well together, there is a lot of trust and open discussions and we see the benefit for both parties”

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Conclusion

- Out-licensing transactions are on Novartis’ radar screen!
- We take our responsibility seriously to actively manage an alliance – also of out-licensed drugs!
- The level of alliance management will differ by deal type
- Implementing out-licensing deals has its specific challenges – but we work with you to solve them
- Novartis seeks to maximize value for our partners and ourselves