Business Development & Licensing Journal

For the Pharmaceutical Licensing Groups

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Creating Value with Alliance Management

Driving value is of the most fundamental aspects of any successful business. In today’s increasingly collaborative business environment, alliance management can play a key role in creating value. Novartis has developed a systematic framework for alliance value creation to share best practices and develop a proactive value-creation mindset in the organisation.

Novartis Pharma currently maintains more than 50 global development and commercial alliances. About one-third of our 2008 late-stage projects involve alliances and sales from licensed products are expected to increase from under 15% in 2006 to over 30% by 2015. Through effective alliance management we help to realize the full potential of our collaborations.

Driving value creation

Our Alliance Management vision is to be recognized for our ability to drive shared value creation and innovation in strategic alliances. One strategic imperative of this vision is to focus the organisation’s attention on value-creating activities rather than only on conflict resolution and day to day management which nevertheless remain key roles for Alliance Management.

Creating incremental value from alliances – for Novartis as well as for our partners – has been established as an important part of our alliance managers’ objectives and mindset. Individual alliance managers have successfully followed multiple strategies and our research suggests that net present value of over one billion dollars was created over the last three years at Novartis, driven by proactive alliance management. We began to examine ways to proactively leverage these successful value creation strategies in our organisation in order to further enhance their application across our entire alliance portfolio.

Creating a structure, creating awareness

Our goal was to use the existing expertise within the organisation to develop a structured approach to value creation and also to generate awareness around the topic to support new opportunities. We held meetings within the Alliance Management team, focusing on driving alliance managers to think about proven value creation practices as well as ideas that have not yet been proven. The results of these efforts at value creation were collected and examined to identify the underlying structure and themes. They fell into three main buckets:

- strategies to increase revenue,
- strategies to decrease cost,
- strategies to mitigate risk.

These strategies, illustrated with more than 70 examples from Novartis alliances, have been incorporated into a database ("$AVE - Sustainable Alliance Value Enhancement") tool which is made available to all members of our global Alliance Management team, providing real-world examples of building value within corporate alliances.

by Arne Wörn,
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$AVE is used as a support tool for individual alliance managers seeking specific revenue creation, cost reduction or risk mitigation solutions. More importantly, the tool can also trigger brainstorming sessions and discussions around value creation within broader project teams outside the Alliance Management group. As such, we use the $AVE tool as a communication vehicle to foster a proactive value-creation mindset in our organisation. $AVE is also used to bring new team members on-board, for statistical analysis of value creation opportunities and to identify in-house experts for specific types of alliance value creation.

We have found that revenue generation and risk mitigation strategies are more frequently used than cost reduction in adding value to existing alliances and that deal expansion was the most frequently used revenue creation method.

Value creation strategies

- **Revenue generation**
  - Deal expansion
  - Development
  - Commercial
  - Manufacturing
- **Cost reduction**
  - Manufacturing
  - Financial/accounting
  - Development
  - Commercial
  - Increase control
  - IP/know how protection
  - Relationship
  - Termination/milestones
- **Risk mitigation**
  - Increase control
  - IP/know how protection
  - Relationship
  - Termination/milestones

$AVE examples

- **Revenue generation**
  - Development
  - Commercial
  - Manufacturing
  - Financial/accounting
  - Manufacturing
  - Development
  - Commercial
- **Cost reduction**
  - Manufacturing
  - Financial/accounting
  - Development
  - Commercial
- **Risk mitigation**
  - Increase control
  - IP/know how protection
  - Relationship
  - Termination/milestones
  - Financial

* most but not all examples have been implemented
There are multiple ways in which a deal can be expanded, creating a win-win for our alliance partners and for Novartis. This includes expanding the geographic scope of collaboration, adding a combination product, expanding the field of the collaboration (e.g., from human to animal health use), adding an indication or expanding a collaboration with an established partner into a completely new area.

Creating value through expansion of existing alliances offers many clear benefits, as it builds on an existing relationship, lowering risk and increasing efficiency for both parties.

The chart below includes several examples.

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<th>REVENUE GENERATION</th>
<th>Example</th>
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| Deal expansion      | **Geography:** Expanded Novartis’ rights for a marketed product to two new countries for an increase in overall royalty rate to the partner  
**Indication:** Expanded a license-out/license-back development collaboration from its initial osteoporosis indication to include osteoarthritis  
**Field:** Amended contract with an alliance partner to clarify terms and conditions for the development of a compound (initially acquired for human development) by Novartis Animal Health  
**Combination products:** Negotiated the option to develop a fixed dose combination in a development collaboration |
| Development         | **Sell data:** Licensed the rights to use Novartis-generated clinical data for a specific delivery formulation to an alliance partner for its own regulatory submissions |
| Manufacturing       | Discharged an alliance partner from its manufacturing obligation in exchange for a financial consideration |

**Cerimon Alliance**

A recent example of a joint ‘value creation mindset’ is the Novartis alliance with Cerimon Pharmaceuticals where a number of revenue generating strategies have been followed. Cerimon partnered with Novartis in 2006 to develop the Novartis transplantation brand, Simulect®, in a second indication for ulcerative colitis. During this collaboration, Novartis agreed to further expand the alliance and allow Cerimon to conduct a Proof of Concept (PoC) trial in uveitis. The development of a new subcutaneous formulation was also jointly investigated during this relationship which had the potential to increase value to both parties because it would enhance the commercial appeal of Simulect® among ulcerative colitis patients and their caregivers.

“This was a great collaboration. There was a lot of transparency, responsiveness and creativity from both companies. There was a genuine entrepreneurial mindset on both sides of the table as well as a strong amount of trust and confidence and a good working relationship. From the beginning, the emphasis was on moving us forward without a lot of bureaucracy. We were also given access to other Novartis products to examine new in-licensing opportunities,” said Matthew Meyer, Vice President Business Development at San Francisco-based Cerimon.

**Cost Reduction**

Value creation through cost reduction was the least frequently used approach in our database. By far the most prevalent approach to reduce costs is manufacturing strategies, where we aim to reduce COGS by taking over manufacturing or by working with our partners to change the manufacturing strategy in a mutually beneficial way.

Cost reduction approaches also encompass examples where we co-fund clinical studies with a partner who retained product rights in part of a territory. Some examples of value creating cost reduction are listed below.
**COST REDUCTION**

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<th>Example</th>
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| Manufacturing | Obtained worldwide manufacturing rights and sole commercial control for a product from its alliance partner under a renegotiated agreement  
Reducing Cost of Goods Sold (COGS): Renegotiated the supply price for API sourced from its licensor at the end of the patent period, in return for an extension of the supply period |
| Finance/Accounting | Agreed to advance an incoming milestone payment to benefit the partner’s budgeting requirements and remove the income stream risk to Novartis |
| Development | Joint studies: Conducted a joint clinical trial with a partner who holds rights in a different territory, to share risk and costs |
| Commercial | Decreased outgoing royalty flow changing the royalty structure from a fixed percent to a staggered, sales-dependent rate |

**Risk mitigation**

Value creation through risk mitigation is one area that is often overlooked. It is also often difficult to quantify. We found that these areas of risk mitigation include: increasing control over development, commercial or manufacturing in return for a revised royalty stream to our alliance partner. Another example of effective value-adding risk management is related to re-negotiation of milestone timing. In one collaboration, we postponed part of a Proof of Concept milestone in order to reduce Novartis’ budget risk for that year. (See chart for additional examples.)

**Driving a value-creation mindset**

Through all of these approaches, we are continuing to demonstrate the powerful role that alliance management plays in generating value for a company. Gathering these many examples into the $AVE tool is part of our overall efforts to establish a systematic approach to value creation within Alliance Management at Novartis. Most importantly, it is also a key communication tool to raise awareness about the importance of a strong value-creation mindset within our organisation.

**RISK MITIGATION**

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<td>Increase control</td>
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| IP/Competitive information protection | Licensed a compound from Company A which was subsequently acquired by Company B, which had a competing drug in development for the indication being developed by Novartis and Company A. The Alliance Management team trained other Novartis associates on how to appropriately limit information flow in order to prevent sensitive information from being accessed by Company B  
Reduced the risk associated with patent expiry by reducing Novartis’ royalty obligation in the event of an early generic entry in exchange for reconfirming the duration of the overall royalty obligation |
| Milestones | Re-negotiated submission milestone payments to a lower amount to limit early-stage money-at-risk, which may otherwise have jeopardized the development of this asset  
Negotiated the postponement of part of a PoC milestone payment in order to reduce budget risks for that year |
| Termination | Agreed to an accelerated data transfer and a higher share in milestones and sales royalties to Novartis in order to reduce the risks associated with the partner re-licensing its technology following Novartis contract termination |

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**Anthony A. Hörning** has headed Novartis Pharma’s General Medicines Alliance Management for five years and he has been a member of the BD&L management team since 2000. Anthony has an MBA with a background in banking and corporate finance, and is also a board member of the Association of Strategic Alliance Professionals [ASAP]. His team of professionals is measured on how much additional value they create on the approximately 40 licensing contracts they lead. Anthony can be contacted by email: anthony.hoerning@novartis.com