

A Case Study to Demonstrate Successful Deal Making

a report by

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Claudia Karnbach joined Berlex Laboratories, Inc., the Schering AG US subsidiary in 2001, where she started working in the Department of Corporate Business Development.

Dr Karnbach is responsible for global licensing opportunities in the area of oncology. She sources and evaluates strategic opportunities, organises and conducts due diligences and provides project valuation and risk analysis. In her role, she is responsible for term sheet and contract negotiation and final project implementation. Her early responsibilities within Berlex included the global search, evaluation and assessment of licensing opportunities in the field of Dermatology. Dr Karnbach is a board-certified dermatologist. She was awarded the University of Hamburg Prize for outstanding medical school thesis and she received the Mildred-Scheel cancer grant. During her academic career, she was a Fellow in the Department of Rheumatology and Immunology at the University of California in San Francisco (UCSF).

Dr Karnbach is a member of several prestigious professional organisations and has published extensively in her field. Dr Karnbach received an MD from the College of Medicine (University of Hamburg, Germany) and an MBA from Fuqua School of Business, Duke University.

Licensing – The New Growth Driver for the Pharmaceutical Industry

The decrease in productivity in pharmaceutical research and development (R&D) during the last decade has necessitated the need to complement internal pipelines with external products to maintain long-term growth and viability, hence profitability. It is estimated that the majority of currently successful drugs are the result of in-licensing activities rather than arising from internal pipelines. Pharmaceutical companies are therefore recognising the importance of complementing their internal R&D by licensing external opportunities. Partnering activities have become top priority for all pharmaceutical companies, as reflected in an increase in budgets and capacities allocated to this strategic activity. Consequently, attractive partnering opportunities have not only become much more competitive, but also much more expensive. Nevertheless, there is every reason to believe that the future growth of the pharmaceutical industry will be a balance between internal R&D and licensing. This new paradigm is likely to become a major driver for future pharmaceutical growth.

Key Factors for Successful Deal Making

- Align search criteria with strategic business needs;
- make the right investment, for the right reason, at the right time;
- implement transparent communication processes internally;
- be aware of time sensitivity to deal making;
- make resources available to fully assess the opportunity value;
- identify and empower key people to drive the deal;

- keep the decision makers informed and involved from the beginning;
- ensure efficient and transparent communication between the parties;
- be sensitive to your potential partner's needs;
- stay on top of the process;
- be receptive and flexible to changing circumstances;
- conduct negotiations in good faith to develop trust; and
- be prepared to go the extra mile; however, be prepared to walk away for the right reasons.

Schering's Approach to Licensing is Designed to Assure Future Growth

Schering's concept on partnering is predicated upon the identification and recognition of the potential value of novel compounds that are strategically aligned with in-house R&D programmes. This concept is defined by a twelve-step integrated process that has been communicated, agreed upon and accepted by all Schering functions. This approach has positioned Schering as a potential 'partner of choice' because of its' competence, responsiveness and sensitivity to the prospective partner's needs, thereby providing the foundation for a mutually beneficial and long-term relationship based on trust and good faith.

The Structure of Corporate Business Development

Schering's Department of Corporate Business Development is comprised of five distinct but co-operating units.

Office of Technology

Responsible for the evaluation of pre-investigational new drugs (IND) projects.

Three Licensing Departments

Responsible for their respective Global Business Units.

Out-licensing Department

Responsible for out licensing of non-core technology.

Case Study – Partnering of TOCOSOL® Paclitaxel

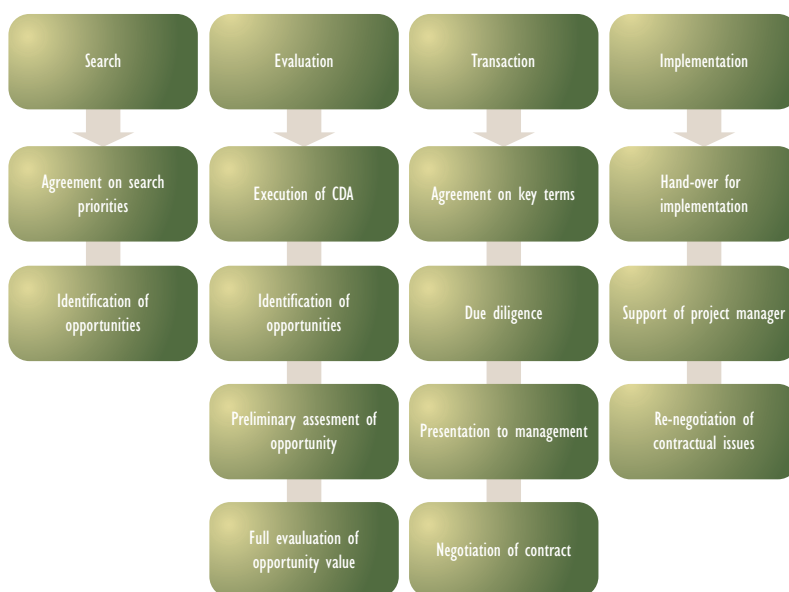
The partnering process was initiated when Sonus Pharmaceutical, a Seattle based biotechnology company, approached the Office of Technology to determine Schering's interest in a global license for a novel formulation of paclitaxel being investigated in clinical trials for solid tumors. It was believed that the product might offer improved tolerability and convenience over traditional presentation. Owing to the fact that the compound was in late-stage clinical development, the Office of Technology transferred the opportunity to the Oncology Licensing Department. Recognising the value of this opportunity, the Oncology Licensing Department immediately initiated contact with Sonus to explore the strategic value, identify the next steps and schedule a meeting to expedite the process.

After the first face-to-face meeting with Sonus, a non-disclosure agreement was executed, which was then followed by an initial assessment of the data provided. The opportunity for Schering to acquire global rights to a late stage compound that would complement the internal oncology pipeline led to the decision to establish a cross functional team and proceed with comprehensive due diligence.

The outcome of the due diligence provided reasonable assurance of the strategic value of TOCOSOL Paclitaxel and served as the basis to formulate the key terms prior to entering into formal contract negotiations. After reaching agreement of the term sheet, both parties recognised the time sensitivity of finalising the contract. The contract negotiations between Sonus and Schering proved to be efficacious and efficient since both organisations allocated all the necessary resources to assure that contract negotiations progressed quickly.

The results of these extraordinary efforts by Schering and Sonus led to consensus and agreement on the contractual issues, which were then presented to the Executive Board of Schering for approval. The Executive Board agreed on the key terms outlined in the draft contract and empowered the team to proceed. Shortly thereafter, mutual agreement was reached and the final contract signed.

Table 1: Schering Licensing Process Overview



Shortly after signing the contract, the project was transferred to an Schering Alliance Manager to coordinate the interaction between the partners during the critical phases of the collaboration. A Joint International Project Team was established and was comprised of senior representatives from both Schering and Sonus. This joint team has global responsibilities for the overall development program that will eventually lead to registration and marketing of the compound. This approach facilitates smooth project transition and exchange of information between the two parties to assure expeditious progress of the development.

Summary

In October 2005, Schering and Sonus entered into a global licensing agreement for TOCOSOL Paclitaxel reinforcing Schering's commitment to build a global oncology presence. Schering became Sonus' partner of choice since Sonus would capitalise on Schering's global drug development and marketing expertise as well as their global infrastructure. Through the licensing agreement with Sonus, Schering gained access to a late stage opportunity in the solid tumour field thereby complementing Schering's internal oncology pipeline.

The partnering process between Schering and Sonus was based on transparency and the commitment to openly communicate and exchange information in a timely manner. The availability of the decision makers from both parties permitted the teams to make prompt decisions. Owing to the result of this co-operative partnering process, the deal was executed in a relatively short period of time and is considered to be one of the fastest deals completed in Schering's history. ■