

The University of Mississippi



BUILDING LOCAL AND REGIONAL PARTNERSHIPS IN PHARMACEUTICAL DEVELOPMENT

**WALTER G. CHAMBLISS, PH.D.
DIRECTOR OF TECHNOLOGY MANAGEMENT
PROFESSOR OF PHARMACEUTICS AND DRUG DELIVERY**

Pharmaceutical Licensing



- ***Background:***
 - UM has a long history of drug discovery with an emphasis on compounds derived from natural sources.
 - UM has strengths in natural products drug discovery, medicinal chemistry, and formulation development.
- **Pre:2000**
 - licensing of compounds at the preclinical stage to established pharmaceutical companies was more likely.
- **2000 thru today**
 - need to advance the compound into clinical trials in order to obtain interest from pharmaceutical companies.

Partnership Models for Drug Development



- Faculty started company located in the Oxford's industrial park.
- A regional public/private partnership located in Nashville.
- A privately held virtual pharmaceutical company located in Memphis.
- A publically traded start-up company with offices in California and laboratories on campus in the Innovation Hub at Insight Park®.

Faculty Started Company



- Elsohly Laboratories, Inc.(Oxford, Ms.)
 - Formed by Dr. Mahmoud ElSohly of the School of Pharmacy in 1985.
 - Initial focus area: to provide analytical and advisory services to the drugs of abuse testing community.
 - Added capabilities for drug development in the 2000s:
 - ✦ Analytical method development
 - ✦ Prodrug development
 - ✦ Formulation development
 - ✦ GMP synthesis
 - Conflict of interest management:
 - ✦ General MOU with UM.
 - ✦ Several specific project approvals from the Mississippi University Research Authority (a state agency).

Faculty Started Company



- Elsohly Laboratories, Inc.
 - How we collaborate:
 - ✦ Self-funded development on promising technologies.
 - ✦ Small business research grants (SBIR/STTR).
 - Basic model:
 - ✦ Patent rights are assigned to UM.
 - ✦ UM is responsible for patent prosecution, business development and licensee management.
 - ✦ Licensing income is shared after out-of-pocket patent expenses are captured.
 - ✦ Memorialized in specific Intellectual Property Sharing Agreements.
 - Outcomes: will get back to this...

Regional Public/Private Partnership



- Cumberland Emerging Technologies (Nashville, Tn.)
- Joint initiative of:
 - Cumberland Pharmaceuticals, Inc.
 - Vanderbilt University
 - The State of Tennessee
- Focus area:
 - Partner with university researchers/tech transfer offices to develop therapeutic products to address unmet needs.
- Broad expertise:
 - University culture
 - Technology evaluation
 - Product and regulatory development
 - Project and grants management
 - Commercialization
 - CET Life Sciences Center (incubator)

Regional Public/Private Partnership



- Cumberland Emerging Technologies (CET)
 - How we collaborate:
 - ✦ Co-develop new pharmaceutical products.
 - ✦ Direct funding and small business research grants (SBIR/STTR).
 - ✦ Ongoing since 2006.
 - Basic model:
 - ✦ UM approaches CET with a technology of potential interest.
 - ✦ Patent rights of individual technologies are exclusive licensed by UM to CET.
 - ✦ UM is responsible for patent prosecution.
 - ✦ Patent expenses and licensing income are shared during the development stage.
 - ✦ CET is responsible for business development and licensing.
 - ✦ Memorialized in individual license agreements.

Regional Public/Private Partnership



- Cumberland Emerging Technologies
 - Outcomes
 - ✦ 2 license agreements (both in preclinical development).
 - ✦ Several other technologies evaluated.
 - ✦ Cumberland Pharmaceuticals sponsors the School of Pharmacy's Research Award.

Privately Held Virtual Pharmaceutical Company



- VirtualCo™ started in Memphis.
- Formed by executives with experience in pharmaceutical marketing and management of healthcare companies.
- Licensed an early stage compound from UM.

Virtual Pharmaceutical Company



- VirtualCo™

- How we collaborate:

- ✦ UM exclusively licensed patent rights to VirtualCo with typical terms.

- Basic model:

- ✦ VirtualCo assembled a strong group of consultants to manage preclinical development activities.
- ✦ UM's lead researcher serves as a scientific advisor.
- ✦ One of VirtualCo's founders serves as project manager.
- ✦ UM is responsible for patent prosecution.

- Outcomes:

- ✦ Preclinical development studies completed.

Publically Traded Startup Company



- Nemus Biosciences, Inc. (Costa Mesa, Ca.; Oxford, Ms.).
- Formed by executives with extensive experience in pharmaceutical marketing, sales and clinical development in a variety of therapeutic areas.
- Licensed a prodrug of a currently marketed drug from UM for targeted delivery in three routes of administration.

Publically Traded Startup Company



- Nemus Biosciences, Inc.
 - How we collaborate:
 - ✦ UM exclusively licensed patent rights to Nemus with typical terms.
 - ✦ Nemus leases a cGMP laboratory suite in the Innovation Hub at Insight Park®.
 - Basic model:
 - ✦ Nemus assembled a strong group of full time employees and consultants to manage preclinical development activities.
 - ✦ UM's lead researcher serves as a scientific advisor.
 - ✦ UM is responsible for patent prosecution.
 - Outcomes:
 - ✦ Preclinical studies are ongoing.
 - ✦ New areas of research are being funded at UM.

Putting It All Together



- **Elsohly Laboratories – OUTCOMES...**
 - Partnered with UM on an STTR grant for one of the compounds subsequently licensed to Cumberland Emerging Technologies.
 - Partnered with UM on an STTR grant for the compound subsequently licensed to VirtualCo.
 - Partnered with UM on an STTR grant for the prodrug subsequently licensed to Nemus Bioscience.
 - Overall:
 - ✦ 7 license agreements (4 active).
 - ✦ 2 active option agreements.

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