

Formation of new companies based on Upstate Intellectual Property

Upstate Medical University desires to promote the commercialization of intellectual property discovered at Upstate and has established a framework to promote the development of the innovation by a new company.

Upstate faculty, student or staff will be a founder or involved in the formation of the new company and must comply with Upstate's Policy on Relations with Pharmaceutical, Medical Device and Biotechnology Industries (policy is found at <http://www.upstate.edu/about/policy/>).

Management and Communications

Individuals involved in new companies must report to the Research Conflict of Interest (COI) Committee outlining their role and provide more information about the company; both prior to the initial formation of the company and as involvement in the new company changes in any form. The information that will be required by the COI Committee will be evaluated on a case-by-case basis.

During the review by the COI Committee, it will be determined if Upstate will support the individual's idea for a new company to the next phase as outlined below under New Company Formation.

Throughout this process, it is expected that Upstate's Office of Industry Relations and company management will meet in person or via conference call on a regular basis.

New Company Formation

Faculty, staff or students who desire to become founders of companies and have been through the conflict of interest review discussed above, should participate in the Pre-Seed Workshop. The Pre-Seed Workshop, an external resource that Upstate supports, provides academic researchers with patented inventions an efficient path to determine if the technology is a solid entrée into the pre-seed stage (and vet ideas that possibly shouldn't go forward).

It is desirable that all new companies being formed by Upstate faculty, staff and students be based on intellectual property owned by Upstate and as such the company can obtain a license from Upstate if the following guidelines are met:

- Upstate will work with the company's CEO or his/her designee for matters about the license. The Upstate faculty member who is founder of the company should not be the primary point of contact for the company
- The following information will be presented to COI Committee for approval prior to license
 - A Business Plan (provided by the company-see description in Exhibit A)
 - Milestone Proposal (provided by the company- suggested milestones in Exhibit B)
 - List of intellectual property to be licensed by company and related patent expenses already incurred by Upstate and estimated to accrue over the next 18 months.

SBIR Grants

As many new companies lack funding, Upstate Medical University supports Upstate faculty, students and staff through a relationship with CNY TDO, a locally based not-for-profit economic development organization, to provide support in identifying, preparing and obtaining federal funds thru SBIR (Small Business Innovation Research) grants. Upstate faculty, students and staff that are recipients of SBIR grants, based on Upstate intellectual property, may contract with Upstate to use Upstate's facilities including labs and core facilities at internal faculty rates. The recipients of SBIR funding, based on Upstate intellectual property, will be charged indirect/F&A rates of 10% for the duration of a Phase 1 grant and 25% for the duration of a Phase 2 grants.

Questions: Please contact Cindy Dowd Greene, Associate Vice President for Industry Relations: 315-464-4398 or dowdgreec@upstate.edu

December 2010

Appendix A

Business Plan Review Criteria

Organizational Plan/Management Team

- Current status of business (*e.g.*, proof of concept stage, seed stage, initial product development, pre-clinical/prototype/development, product in advanced development, phase 1, etc.):
- Type of legal entity
- Advisors and Management (CVs for those already on board and skills/knowledge for those still needed)

Opportunity

- Product(s), customers, market needs and size, and competition, both other products and companies
- Competitive advantage: barriers to entry, intellectual property, business model
- Product development status

Major risks current and future

- Technical, regulatory, competition, etc
- Variables and level of uncertainty that might lead to risks occurring
- Contingency plan if a risk occurs

Development/Financial Plan

- Requirements and timeline to first commercial sale and/or exit strategy
- Current and needed technical capabilities (include a plan on obtaining the needed capabilities)
- Current and needed facilities (include a plan on obtaining the needed capabilities)
- Budgets/Cash Flow (both operational and capital) for 3-5 years
 - Consulting and/or Salaries
 - Regulatory
 - Rent
 - Patents
- Sources of funding (both available and plan for obtaining that still needed)

Appendix B

Milestone Proposal

Milestones should be proposed by the company consistent with an approved business plan and should at minimum include the following:

1. Licensee shall have a management team in place by _____
2. Licensee shall have financing in the amount of _____ by _____
3. Licensed Product Development Milestones
 - (i) IND filing by _____
 - (ii) Phase 1 study by _____
 - (iii) Phase 2 study by _____
 - (iv) Phase 3 study by _____
 - (v) FDA filing by _____
 - (vi) Product Approval by _____
4. Exit Strategy achieved by _____

Milestones serve as measurable development benchmarks however it is understood that unexpected delays may occur. In these situations, Upstate is usually willing to re-negotiate milestones based upon the demonstration of good faith efforts to resolve such delays.