GrowingSLU Business Plan

**Project title:** CREATION OF A BIOTECHNOLOGY COMPANY FOCUSED ON PRECLINICAL TO CLINICAL TRANSLATION OF SLU BIOMEDICAL RESEARCH.

**One sentence project description:**
A for-profit company, initially supported by SLU and approved investors, would be eligible for small business research grants (SBIR/STTR), and would partner with CWHM and other key departments to promote the translation-to-practice of SLU research discoveries and proprietary technologies.

1. **One paragraph summary of project:**

   Research funding has become increasingly competitive and difficult to sustain in the current budget environment at NIH and other traditional sponsors of university research. In contrast, NIH program officers frequently acknowledge that small companies have an advantage over universities in that they are uniquely eligible to apply for research funding via the SBIR and STTR mechanisms which receive far fewer quality applications. Furthermore, such companies are traditionally the preferred targets for private investment from individual investors, venture capital firms, and established pharmaceutical companies. We propose that SLU form an independently managed for-profit subsidiary that engages with the Center for World Health & Medicine (CWHM) and other key departments to identify and license promising SLU technologies with the potential to address the critically unmet needs of patients. The company will submit Phase 1 and Phase 2 SBIR/STTR funding applications with input from CWHM and other SLU collaborators likely to be subcontractors on awarded projects. The company and its collaborators will advance projects to a stage where they will either: a) be out-licensed to a larger established pharmaceutical company under favorable terms, b) be transferred to a more project-focused spinout company for further development, or c) be directly developed by the company if there is sufficient public or private investment. SLU is expected to benefit financially in the short term through the expected increase in research subcontracts coming from the company which is able to raise research funds through mechanisms not available to university researchers. In the medium to longer term, SLU may receive highly attractive milestone and royalty payments associated with pre-negotiated key company achievements that can be re-invested into the university’s non-profit mission. An important competitive advantage of the proposed model for SLU is that the CWHM represents an ideal existing partner for the company capable of providing a range of expert preclinical research services such as medicinal chemistry, and in vitro and in vivo pharmacology. Other potential SLU participants include, but are not limited to, the Vaccine Center and the departments of Pharmacology and Physiology, Biochemistry, Molecular Microbiology and Immunology, Pediatrics, and Internal Medicine.

2. **Expected timeline for implementation, including stages or phases if necessary:**

   **Phase 1 (months 0-6):** SLU forms the company and creates the framework of legal agreements. SLU interviews and hires the CEO. SLU identifies and equips appropriate initial office and laboratory space that has potential for expansion. Company begins seeking external investments.
Phase 2 (months 7-12): Company establishes a starting portfolio of IP and projects. Company submits a first SBIR application. Company continues to seek angel or VC investments.
Phase 3 (years 2-3): Company establishes and grows its lab capability as permitted by successful funding and investment.

3. Positive financial impact on SLU (additional revenue), including business model:

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>0</td>
<td>125k</td>
<td>250k</td>
<td>750k</td>
<td>1.5M</td>
</tr>
<tr>
<td>Expenses</td>
<td>55K (min) – 125K</td>
<td>55K (min) – 125K</td>
<td>55K (min) – 125K</td>
<td>55K (min) – 125K</td>
<td>55K (min) – 125K</td>
</tr>
<tr>
<td>Net income</td>
<td>(55k)</td>
<td>70k</td>
<td>195k</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Revenue** refers only to funds received in association with expected research contracts from the company. These conservative estimates predict one successful Phase 1 SBIR subcontract in Year 2, two in Year 3, and combined Phase 1 and Phase 2 awards starting in Year 4. No estimate is made of other research contracts that the company may issue to SLU with its expected privately acquired investment funds. Revenue also does not include estimates of the potential for SLU to receive income from licensing, milestone payments, and recurring royalties on product sales, which could be quite considerable in later years. Finally, no estimate is made of the potential value of SLU’s ownership equity (value of shares) in the company.

**Expenses** in Year 1 SLU’s cost for company formation, legal fees, rental space subsidy, and a potential initial minimum investment into the company which can be used to pay the CEO and equip the company’s office and laboratory will be a minimum of $55K and up to $125K. The minimum dollar expenses include $5K (or less) to legally establish the company and $50K to attract a part time CEO for the company at the outset. The CEO may also be the PI applying for SBIR / STTR grants. It is possible to secure a CEO on a part time basis until awarded a SBIR / STTR grant, from which additional salary compensation can then be allotted above the initial $50K. Alternatively, a second hire, acting as Chief Scientist, can fulfill the PI role, with a similar initial part time and salary structure, pending a grant award. Such salaries would need to be negotiated, but it is possible that the identified individual(s), as stated above, would be willing to defer some salary dependent upon obtaining SBIR / STTR funding that would allow for additional salary recovery. If an outstanding candidate who would fulfill both the CEO and PI roles were identified, a salary up to $120K could reasonably be expected if SLU really wanted to secure such an individual. Lastly, the University would provide lab and office space (Schwitalla Hall for example), keeping additional initial expenses to a minimum. Additional investments in the company would be sought via SBIR grants and VC investments driven by promising commercial potential from our drug development projects and related IP that have been spun out into this Umbrella Company.

4. Positive non-financial impact on SLU:
The CWHM at SLU specializes in translating primitive “hits” into lead compounds with the properties that are necessary for them to be considered as lead candidates worthy of clinical testing. The next stage of actually bringing them into the clinic is most often done by a biotechnology or pharmaceutical company which must manage the unique regulatory and scientific challenges associated with moving from animal to human studies. Funding such activities is nearly impossible using traditional academic grants from the NIH. The efficiency of this transition could be greatly increased by formation of the proposed SLU-affiliated company, thus accelerating the speed and number of lifesaving treatments that CWHM endeavors to advance to patients with rare and neglected diseases. Success of this partnership would also enable SLU to take a recognizable leadership position in the regional drug development effort for rare and neglected diseases, creating local companies and jobs in the process.

5. **Alignment with Jesuit mission and strategic plan of the University:**

The goals and mission of the Center for World Health & Medicine (CWHM) are to develop new therapies for patient populations that are underserved by the traditional efforts of the established pharmaceutical industry. Large pharma companies typically employ estimates of patient revenues in prioritizing candidate entry to human trials, often requiring a billion dollar sales threshold. Our proposal provides new opportunities to fund drug development and optimization activities at SLU while also providing the financial incentives that are more likely to be adequate for a smaller company to bring the drug to market. In this way, the proposal aligns with the SLU mission of service to humanity supported by (1) a wise allocation of resources to maintain efficiency and effectiveness and (2) serving the needs of those with life-altering or life-threatening diseases that are not currently being met by industry.

6. **What's needed, including budget (i.e. startup capital needed) and other resources (i.e. physical space, personnel, etc.):**

A possible scenario for university investment into the company during the first 5 years is shown in the Table in Section 3 above, but actual figures should be discussed in much greater detail.

The cost to legally establish the company should be less than $5,000. We already have an established relationship with an individual who specializes in setting up biotechnology companies.

Initially SLU will need to identify a CEO and a Chief Scientist and provide seed money to support their salaries for a limited term (e.g., 12-18 months). The CEO should be someone that has expertise in the biotech arena and will be an advocate for the company to SLU, the Billiken Angels and to the local and regional business community. The CEO should also be pro-active in seeking investment funding for the company. The Chief Scientist will act as the principal investigator (PI) on SBIR grant proposals and will work closely with CWHM and SLU scientists in coordinating drug development activities. It is possible the roles of CEO and Chief Scientist could be fulfilled by a single individual until the company is more established. Proposed personnel investment would be determined through negotiation with the selected individual(s) and with input from HR sources. The CEO and Chief Scientist can initially work part time until SBIR and other funding becomes available, at which time their salaries can be paid, at least in part, from the funding sources. We propose $50K as an initial salary for the selected individual working on a part time basis to get the company
off the ground and securing grant funding. Additional Company personnel can be added as funding and need arises in the future.

The university should facilitate company office and laboratory space ideally located on the medical campus for proximity to CWHM (e.g., Schwitalla Hall), a vivarium, and university researchers. Other companies (e.g. Gateway Pharmacology Laboratories) are already operating here under this type of arrangement.

The New Company will be closely aligned with CWHM / SLU in advancing promising new therapies into the clinic and in securing funding to be successful. It will leverage the specific scientific and drug development expertise within the CWHM and disease expert collaborators. The company is envisioned to be an external partner for SLU, enabling drug development for rare and neglected diseases. Funding in subsequent years should be derived from grants and investors in the company other than SLU. Ongoing expenses to SLU may simply be provision of office and laboratory space for nominal rates.

7. Potential obstacles:

Only for-profit companies are eligible to apply for SBIR/STTR funding, and they can more easily raise venture capital. SLU must research the legal boundaries that govern the relationship between a non-profit university and a for-profit subsidiary (see below – questions still needing to be answered). If too daunting, an alternative approach is to establish a non-profit entity that provides consulting and support services to for-profit spinoff companies that each licensing a SLU technology. Examples of both models currently exist at other American universities (see section 8).

8. How this project relates to what other universities or programs are doing [OPTIONAL]:

An instructive comparator company, though now larger in scale than the small company proposed here, is the Fox Chase Cancer Chemical Diversity Center (FCCDC) founded in 2008. This for-profit company provides drug development services to collaborators at many neighboring universities including Temple, the Wistar Institute, Thomas Jefferson U., U. Pittsburgh, and U. Penn. It interacts with its partners using a variety of funding mechanisms such as: 1) SBIR/STTR grants, from which it reports a 16-20% Phase I funding rate and a 40% conversion rate to Phase II, 2) R01/U01 grants in which they act as a sub-contractor, and 3) Fee-for-service. For more details, see www.fc-cdci.com.

An alternative model is that provided by Drug Innovation Ventures at Emory (DRIVE, LLC). This non-profit company was founded in 2012 and is wholly owned by Emory University. It operates at the university’s Yerkes National Primate Center and has the capability of advancing drugs through Phase II clinical trials. Though DRIVE is non-profit, it spins out for-profit companies eligible for SBIR/STTR awards (see diagram). Its laboratory arm is the Emory Institute for Drug Development which is an Emory translational drug center with characteristics similar to our CWHM. For more information, see http://driveinnovations.org/about/overview/.
A third comparator model is UPstart, a non-profit virtual incubator at the University of Pennsylvania. The UPenn team works with university inventors to develop a commercial strategy leading to company creation. UPstart then identifies and interviews potential entrepreneurs to run the company, engages partners to provide operational services to the new company, and helps the company obtain funding through corporate partnerships, SBIR grants, and VC investment. UPstart appears to currently have 7 university startups in its company portfolio. For more information, see [http://pci.upenn.edu/upstart/](http://pci.upenn.edu/upstart/).


9. **Questions that still need to be answered [OPTIONAL]:**

- What are the legal rules that govern the relationship of a university with a for-profit subsidiary?
- How will conflicts of interest be managed?
- What monetary level of support is the university able to contribute to support the new company, and for how long?
- Should the company’s stated mission include product development for patentable biomedical devices or assays, or rather be limited to pharmaceutical development? Should drug development be limited to rare and neglected diseases?
- Should the company be permitted under the terms of the SLU investment to license technologies from other regional universities (for example, Washington U.)?

If you have any questions, please contact David at hakansond@slu.edu or Victoria at whitakervl@slu.edu.