

Experiences (and frustrations) in Developing a Biotech Company in Idaho



Biomedical Problem

- ▶ Major anticancer drug has side effects on the heart that limits its use in treating cancer.

History

- ▶ Investigated the mechanism of how the anticancer drug causes heart injury since 1977.
- ▶ This work has been supported by:
 - VA Medical Center
 - MSTMRI Research Institute of St. Luke's

Motivation for Drug Development

- ▶ Interest as a Pharmacologist
- ▶ Soft money salary to do research
 - NIH established grants specifically for drug development by small companies.
 - STTR/SBIR grants allow small companies without sophisticated research facilities to combine with large, established research programs such as universities and research institutes to do some of the basic research needed to develop new drugs.

Formed a Corporation

- ▶ Following disclosure to the VA Medical Director, advice from VA legal counsel and reduction from full time to part time status,
- ▶ 1996; Gem Pharmaceuticals, Inc.
 - Began operation in Idaho

Problems

- ▶ No infrastructure in Idaho to support the fledging research company.
 - No research labs to lease
 - No animal research facilities
 - No scientific equipment
 - Investors didn't believe biotech could be successfully performed in Idaho without a medical school or sophisticated biomedical infrastructure

Solution

- ▶ Gem Pharmaceuticals moved to Alabama and leased small research lab to perform chemistry, regulatory functions, etc..
 - NIH supported research still performed at VA medical center through grants administered by MSTMRI.

Outcome

- ▶ Research performed by Gem led to FDA IND approval and the new drug has completed Phase I clinical trial.
- ▶ It is currently in Phase II clinical trial for evaluation of efficacy in metastatic breast cancer.

