

It's a bargain at 25 million

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You might say that Robert Ashley, CEO and President of AmpliMed® Corporation knows a bargain when he sees one.

That is because Ashley hopes to get through Phase II clinical trials of a complex chemotherapy drug treatment, Amplimexon®, having expended *only* 25 million dollars.

AmpliMed® Corporation was founded by a group of University of Arizona professors in 1989 with Ashley joining in 2004.

In an industry which develops sophisticated pharmaceuticals, 25 million is indeed a modest research and development budget to demonstrate efficacy of a drug. Without demonstrating effectiveness conclusively, it is very difficult to raise the capital to complete a phase III study and get the drug to market. The company could have easily spent 40 million to get to this point and is proud to achieve the Phase II milestone at 25 million.

The total investment from inception to get the drug through Phases I, II and III and to market is estimated at 40 million.

Phase I involves the clinical development of pharmacological kinetics, information about efficacy and a wide spectrum of information including some indication of efficacy or effectiveness of the drug.

Phase II provides data on small populations, different combinations, different doses, safety, and efficacy. This data feeds into a blueprint which will be used in phase III. Researchers are particularly interested in data on sample sizes as well as determining criteria for enrolling patients in the phase III study.

Phase III is a randomized placebo controlled study for metastasis melanoma and pancreatic cancer. In both cases they will be studying the drug with currently approved treatments. The goal of the combination therapy is to contribute greater efficacy without increasing toxicity.

“In cancer drug therapy development, there are circumstances which will allow accelerated development if you have a management safety profile and high efficacy in small population,” said Ashley.

“When developing drugs, the biggest challenge is money. It is an extraordinarily expensive endeavor and the length of time to move through the process is formidable,” said Ashley. Several things gave the AmpliMed® Corporation a good start in the development of their flagship drug.

Developing drugs requires an enormous amount of data. Until the initial data has proven promising, it is very difficult to raise money. The development of the drug Amplimexon® was jump started by the collection of data by Boehring Mannheim, a company outside of the United States. This data gave AmpliMed® a starting point when they began to go through Phase I and II trials.

Another valuable aid to shorten the development process and reduce development costs is that a majority of effort was done in conjunction with the National Cancer Institute under the RAID program. This acronym stands for Rapid Access to Investigation to Drugs Toxicology.

Some of the Best Practices used by AmpliMed® to get their product capitalized and to market are:

1. Ensure that the company is staffed with people with extensive experience, surround yourself with the best people and integrate their activities
2. Be very frugal – no ivory towers or marble floors
3. Focus on small numbers of key tasks and do not become distracted with academic pursuits – work is focused on achieving the objectives you are trying to reach

A truly global company, AmpliMed® itself is an established virtual company developing several cancer drugs alongside Amplimexon®. Eighteen employees are local with data management and toxicology offshore in the United Kingdom and manufacturing in Sweden. Secondary packaging is in Holland.

Because of their careful management, AmpliMed® is poised to devise a strategy to take it into the Phase III trials building a world class cancer company in Tucson, Arizona. For more information, go to www.AmpliMed.com

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