Interview with Alex Liu, Chairman, Golden Biotechnology

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In 2002, when you established Golden Biotech, what was your vision for the company?

There has always been a focus on creating drugs to cure cancer: there are many good treatments already in the market for those suffering from, for example, prostate and breast cancer. Although there are good treatments for these cancers, but still no drug that can completely guarantee a cure. In 2002, I was invited by a group of scientists to build up a new company, the purpose of which would be to screen new candidates for cancer therapies: new leads and new drugs. I had no idea about the biotech industry at that time. I am an investor with a background in economics, and spent many years working as a fund manager. However, I was intrigued enough to start to look at different business models for entering this sector: in the end I spent over a year discussing the model, but the question in my mind was always how this process of drug screening could be successfully turned into a business. Rather, I often felt that this was the domain of basic researchers, and not an area for business to get involved in. This was because I had not realised what a key role of basic research plays in the development of a biotech company.

Taiwan is a country very focused on basic research: we have many excellent facilities, and the human resource potential is very high, with many of our scientists having gained excellent experience at some point in their careers abroad, mainly in the United States. Despite this, after one year of working on this project, I called a halt, and decided that we really needed to focus the aims of the business onto one single project. In fact, we covered too widely so that the enterprise was unable to progress. At this point, I began to feel that I was going to loose my original investment.

However, after three months the leading scientist of the project came to me, and wanted to continue. I decided to continue my investment, and the basic research continued with over 25 scientists working on the project. We were working on a fungus growing locally only in Taiwan, Antrodia camphorata, which was known to have anti-cancer properties. From the north to the south of Taiwan, we also collected other local fungi, more than 4600 strains. The collection was compiled and systemised. Our fermentation department was then grew the various fungi in a variety of mediums that allowed the unique properties of each strain to be assessed. Our chemists and molecular biologists then tested these various strains on human cancer cells in culture in an attempt to identify the cancer inhibitors. After three years of screening process, we compiled millions of pieces of data.

In 2005, it is the time to end the screening process, and to identify the top ten strains from the platform. We presented our findings to BioTokyo that year. We were surprised to find out that the reaction to our research in Japan was very different from what we had experienced in Taiwan â?? biotechnologists in other countries were simply not excited by herbal medicinal extracts. I came back

and changed the focus to identifying active components from our top 10 lists. I realized that without a compound, there was no point in continuing.

We then identified ten to twelve active compounds and were deciding which compound would be the first priority to pursue. At about the same time we received some excellent news: in human use, Antrodia camphorata was much safer than traditional cancer therapies in every aspect in treating liver cancer.

The next step was to start looking for a partner to develop our compounds. It seemed to us at the time that the Taiwan biotech industry was not ready for us, so we looked into Europe to identify a partner. At BioEurope, we identified a CRO that was capable to develop our research right through to the clinical phase. This collaboration has been ongoing for the last four years.

At this stage, we had concrete data showing our compound to have a positive effect as an anti-cancer agent. However, it is very difficult to market such a compound on the global market. Therefore, whilst developing the compound for sales in Western markets, we simultaneously launched a product in extract on the Taiwan market. We developed 16 solid treatments, which could be registered in Taiwan. The extract is today being used in emergency post-surgery treatments, and has been shown very promising results. We have saved all six patientsâ?? lives using our partially purified extract. Antrodia camphorata has been used in Taiwan for many years. Golden Biotechâ??s Antroquinonol, the new-chemical-entity anti-cancer compound from Antrodia camphorata, has just been approved by the USFDA and the TFDA as an Investigational New Drug (IND) for Phase I trials. By next year we hope to have compound in Phase II, and have the aim of completing Phase I-III in four years.

The human response of the partially purified antroquinonol is quite interesting, and the compound may have implications for late stage liver cancer and late stage breast cancer. After surgery, radiotherapy and chemotherapy, doctors are keen to try anything that might increase the chances of their patientsâ?? survival, and this is the role that our partially purified extract can currently play. However, once the antroquinonol reaches Phase III we are hoping to be able to use it as a first line of treatment, even before surgery and chemotherapy.

Besides the cancer treatment, we would like to start gathering information that the compound could be effective in cancer prevention as well. However, this process can take more than ten years, as a lot of evidence is required for submission.

You have a very international focus: you have looked to Europe to develop your business, and have also put some patents through in the US. Your drug has proven itself to be effective for the last twenty years here in Taiwan through traditional herbal remedies. How was the attitude when you first took this new drug to Western markets?

In Europe, introducing herbal medicines into the market is extremely difficult, and requires taking the drug through extensive clinical trials within Europe. However, Golden Biotech has already collected a lot of the supporting data necessary for entering the clinical trial stage. After Phase I is completed, Golden Biotech will apply for human use to the FDA in the US, and EMEA in Europe with the human safety pharmacology from Phase I trial to support and provide the usage.

In the United States, with good supporting data from research and clinical trials, our extract can be classified easily as a supplement. However, many companies that take this route decide to go the way of botanical drugs from this stage. This is not a great idea for Golden Biotech, as trying to get a botanical drug approved by the US FDA is extremely difficult: if the impurity level is above 5% your drug is almost guaranteed not to reach the market, despite the overall development costs being lower. It is much easier to get a purified compound approved by the US authorities. Antroquinonol

has a purity of 99.8%.

These measures are taken in both the US and Europe, because major pharmaceutical companies are able to provide large amounts of data from their many yearsâ?? research. A lot of smaller companies in Taiwan are worried that trials here for herbal medicines will become more stringent, but this is down to governmental policy and as always is unpredictable.

You started this company as an investor â?? you came to the biotech sector when it was fairly new in Taiwan. How have you seen the attitude change over the last eight years from when you first invested in this company to the attitude today?

After making money in the security market, I was not content to simply retire. Rather, I wanted to create something different and unique. I feel as though the investment mood in Taiwan regarding biotech is improving, and this is a big difference from eight years ago, but these eight years have given Golden Biotech a massive head start over the rest of the industry. I put 100% into the company: Golden Biotech has just finished constructing its cGMP facility in Taiwan for API production. Itâ??s my own design, and was created to bring Antrodia camphorata from the fermentation process, through several stages of purification, to the final purified compound, Antroquinonol. This process has taken two years to develop. We prepared for the mass production necessary for a Phase III trial.

My strategy has always been to find a way as early as possible to make a profit from this discovery, whilst still pursuing high scientific goals. This facility design enables Golden Biotech to produce a semi-purified extract to be turned into a health food and also a purified compound for the clinical trial. Every product has its own market. We have put all our energy into this product, and it is beneficial to cancer patients.

My understanding as well is that the supplement market in China is growing massively now. What opportunities does this provide for Golden Biotech?

Today, many Asian companies focus on China. My strategy is different from other companiesâ??. In Taiwan companies hope to get as far as Phase I or II, get the proof of concept in human trials and then sell their findings. In reality, this is very difficult: there are still so many uncertainties even after Phase II trial, it is rare for a big pharma to put investment into such a uncertain product.

Golden Biotech has already completed Phase III in terms of the proof of concept, and is fully prepared to enter production soon. We are ready for the market any time, and that is always my goal. We will succeed at the end.

There are other indications that can be treated by our extract, pancreatic inflammation and sprain inflammation, and step by step Golden Biotech will work on these separate indications and develop compounds for authority approvals.

What would you like our readers to know about your company? You said you have a very different business model. What message do you want to send to them about Golden Biotech?

We have a strategy for partnering in terms of the global rights of our compound. I donâ??t think we need big pharma, whose time is already passed. Small companies like Golden Biotech already have the power to change the market, especially in oncology. In Taiwan, our supplement is already changing the views of medical doctors on cancer treatment. The mechanism of our product is extremely safe. Many of the major pharmaceutical players are developing their products based on this mechanism for themselves. Golden Biotech has such a product now.

Golden Biotechâ??s medical supplement is safe and is in the market. But if the supplement wants to be sold in more countries, we could use more of the new drug information to support our refined product â?? from prevention to therapy; from early stage to late stage. I donâ??t know exactly what the future holds, but today our market is growing by 100% every month.

From now, we will proceed step by step. In the near future, Golden Biotech will go into China and also the US. Next month (September 2010) the company will establish a branch in New Jersey, close to the headquarters of the FDA. We want to send our data to support many of our supplements for the application to the FDA and begin our sales in the US. For Golden Biotech, these are exciting.

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