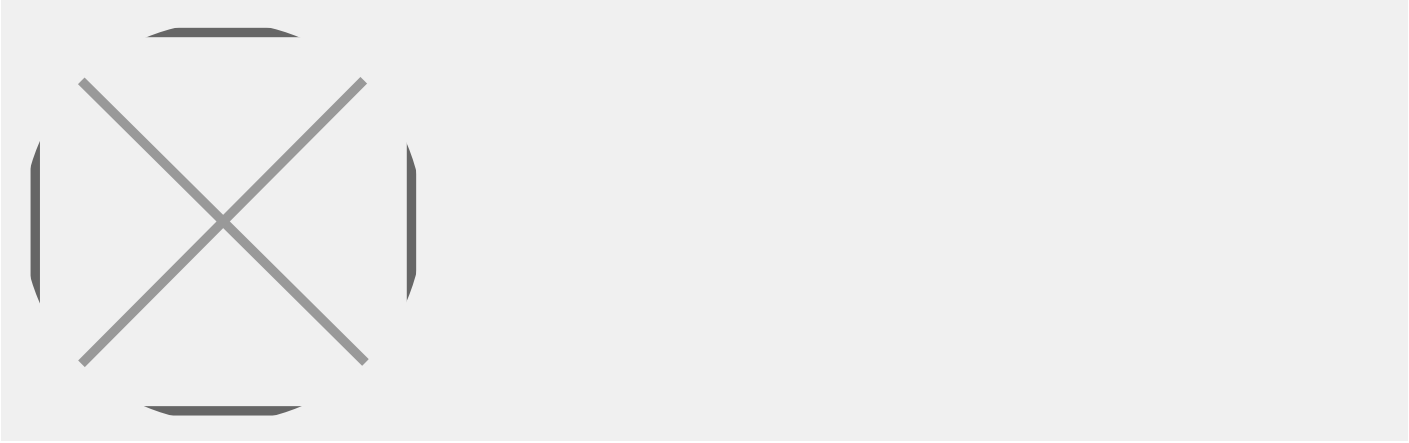
Interview: Stanley Chang Chairman and CEO, Medigen Biotechnology Corp., Taiwan



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The chairman and CEO of Medigen shares his insights on a significant past three years for the company, which included both an IPO and major developments for the company's innovative molecule PI-88. He also offers his perspective on the increasing synergies between Taiwan and China in the biotech sector.

During our first interview with you in 2010, you mentioned that Medigen subscribes to a "very conservative," "step by step" expansion strategy. But the last three years have been very eventful for this organization. Notably, you had an IPO, sold your molecular diagnostics subsidiary in Shanghai, made significant clinical advances with your flagship innovative molecule PI-88—the list goes on. These seem to be your breakout years!

The incubation of a biotech company requires a very long time. During your last visit to the Taiwanese market, Medigen still found itself in that incubatory phase. Fast forward to 2013, and we are starting to take off. We are in the midst of a turning point for our business, and we are beginning to express all of the momentum we have built over the last ten years.

Three years ago, we prepared our IPO, ensuring that all of our assets were in the right place. In 2011, we presented ourselves to the public—and we were very successful. Our IPO was well received, and we proudly took the lead to change Taiwanese investors' conception of what a biotech could be.

After we floated our stock, we worked hard to differentiate Medigen from other biotech stories. In the past, investors in Taiwan believed that this sector was hopeless, and that drug development was mission impossible. But we made ourselves very public in recent years, and we championed the idea that these goals are achievable. As long as the vision is correct, as long as the strategy is correct, and as long as the market conditions are correct, these goals are for sure achievable!

Medigen is very much focused on liver cancer therapeutics, and I believe we should have an impact in this field in a variety of ways. The market seems to agree: our share price surged very quickly after our IPO. Our listing price was less than 1 USD per share. In only two or three months, it rose to 2-3 USD. Currently, we are priced around 6 USD. All this, in only 20 months.

Indeed, judging by the recent surge of successful biotech IPOs on Taiwan's Gre Tai exchange, the local market seems quite hungry for biotech investment opportunities today. In fact, TaiGen founder Ming-Chu Hsu said that the environment was perhaps a bit over-enthusiastic. Should investors be concerned about a bubble? Is Medigen fairly priced?

I don't believe that we are looking at a bubble. Let's consider the typical case in the West: normally, when a biotech company has several projects in its portfolio, its frontier product is in Phase III, and its business fundamentals are strong, its share price hovers around 10 USD. Hence, in Taiwan, biotech stock prices are not over inflated—rather, they are approaching the international standard. It is actually the case that in the past, companies were undervalued. Today, companies like Medigen are fairly priced—in fact, I believe there is room for further growth.

As I mentioned earlier, the general public in Taiwan once wrote off our industry, believing it a poor investment. They have now reconsidered that decision. For this reason, as you rightly pointed out, there has been a surge of biotech IPOs within a very short period of time. Most of these companies are drug developers like Medigen—and their share prices are the reflections of the cumulative momentum built in-house in the past 10 years.

What do you believe gave investors such confidence?

Simply, they have seen prior phase II results. They have seen that projects in this sector are being approved—and they know that the potential markets of Taiwan, China, and Asia are lucrative.

This brings us to the Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs signed as a corollary to the Economic Cooperation Framework Agreement (ECFA) between Taiwan and China. The environment put in place by the Cooperation Agreement is a major trigger for the rising value of Taiwanese biotech companies. In the past, it was the case that if a Taiwanese company completed a clinical trial in Taiwan, it would have to conduct a duplicate trial in China. But, through this agreement, it will no longer be necessary to recreate the trial across the strait. There will be mutual recognition—saving huge amounts of time and money.

And companies can, say, conduct Phase I and II trials in Taiwan, and finish with a Phase III trial in China, correct?

Exactly: this is what Medigen is doing. The Chinese authorities recognize the clinical work we have done in Taiwan. There are several projects underway that have or will capitalize on the agreement, including late-stage developments such as Medigen's and Taigen's. Regulatory bodies from both sides are working together to ensure harmonization.

Investors saw two hurdles for Taiwanese biotech in the past: approval in Taiwan, and approval in China. In the next year or two, those two hurdles will formally become one.

Some are saying that this new paradigm of Taiwan-China cooperation in drug development will realize innovation faster and cheaper than in the West. Do you agree?

I do. Faster, because the TFDA and the CFDA will work on several projects concurrently, and put regulations in place to accelerate the process. A faster process, in turn, means that cost is lower. Furthermore, both countries are likely to ensure that after approval, the drugs will be reimbursed in the local markets by relevant state agencies.

Mr. Mao-Ting Sheen, Director of the Medical Review and Pharmaceutical Benefits Division at Taiwan's Bureau of National Health Insurance (BNHI), is indeed quite adamant that any new drug that originates in Taiwan must be fairly reimbursed in Taiwan!

That's exactly right! The BNHI will need some time to discern what level of compensation will be reasonable for the originator company and for the patient. As an industry, we will do our part to push the process forward. It is for this reason that we create unifying organizations like the Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA).

I am quite optimistic. I believe that all the fruits can be harvested two years from now.

TaiGen is poised to release Taiwan's first innovative drug, nemonoxacin, in 2014. Will Medigen's PI-88 be the second?

I hesitate to say definitively that it will be—but by all indicators, it is quite likely to be. There is a clear list of projects that will be presented by the Taiwan Food & Drug Administration (TFDA) to their Chinese counterparts. The first project is Taigen's; and others are line up in row with different stages of clinical development.

At Medigen, we are in Phase III with PI-88, and we are on the verge of finishing patient recruitment in Taiwan, South Korea, China, and Hong Kong. We are close to the final recruitment of 500 patients.

What unmet need does PI-88 aim to fill?

PI-88 is a drug for early-stage liver cancer. I am a surgeon by training, and if I was treating a patient with early-stage liver cancer today, I would suggest surgical resection of the tumor if it was not too large—about 20 percent of patients have tumors of the right size. The resection is intended as a curative procedure. However, particularly in cases where the liver is infected with a chronic disease like Hepatitis B or C, satellite invisible tumors may develop throughout the organ, which the surgery will not address. Removal of a single, larger target, therefore, may not be enough to eradicate the cancer—and up to 50% of early-stage patients experience a recurrence of the disease after surgery. Yet there is no drug available for post-surgery individuals; rather, observation is the standard of treatment.

Medigen designed a trial to discern whether we can reduce recurrence rates for these patients. Our 172-patient Phase II study demonstrated fantastic results in suppressing the recurrence of the so-called ‘residual’, or satellite, tumors—and I believe our Phase III study will fare even better.

PI-88 is geared toward the Asian market. Although it can prove impactful for Western patients who need it, the disease profile is different in the U.S. and Europe because there is a lower prevalence of chronic liver infectionaccompanying the cancer.

Our main competitor here is Bayer. Bayer has a drug that is approved for the treatment of late-stage liver cancer, which has the ability to prolong survival for up to a few months. Bayer has since tested the efficacy of their drug in the early stage of the disease, resembling Medigen’s protocol and completing patient recruitment last year. We are expecting the release of Bayer’s phase III trial data.

In our study design, we exclusively focused on high-risk patients: those with pre-surgery tumors larger than two centimeters in diameter, and usually afflicted by a chronic viral hepatitis. Bayer did not differentiate between high-risk and low-risk groups, and as you might imagine, the recurrence rate for the latter group is already low. Medigen’s trial design is more likely to see the difference of disease free survival (DFS) between the placebo group and PI-88 treated group. Through this, Medigen is seeking to take the leading position globally in this niche.

Assuming you successfully complete your Phase III trial, what happens next?

Well, first of all, I am sure that Taiwan and China will be very happy to reimburse the drug. South Korea, where we recruited nearly 200 patients, will also act swiftly in bringing the drug to patients. Liver cancer is a huge killer in Asia—in Taiwan, it was the leading cause of cancer death for the last 20 years. Lung cancer has only recently made a surge to overtake it, with colorectal cancer coming in third. Liver cancer is usually second or third on the list for most countries on the continent—including the major markets of China and Japan. The disease is more rare, as I have indicated, in the West.

We have a very sizeable patient population to reach, and this population is situated in our own backyard. For me, the most important factor here is that we will be able to help patients in need—people who currently have no available treatment. Business is important, but it is secondary. In any case, the beauty of running a biotech company is that I am able to combine the two goals!

What can you tell us about the health of Medigen's other businesses—the daily bread-and-butter services that sustain the company as you wait for your first proprietary drugs?

Medigen's vision, at its inception, was to be a drug development company. But as you correctly pointed out, we quickly realized that we needed something to sustain ourselves while we went about the long-term task of bringing innovative drugs to market. Investors in Taiwan typically want to see some revenue generation if they are to commit to an early-stage company. They have no appetite to wait a decade for the first return. Hence, we decided to go after other businesses that could generate cash flow.

We spent a good deal of time debating what the best potential businesses could be for us—businesses with high technical hurdles, a need for new technologies, and markets in Asia. We decided to go after nucleic acid testing (NAT) in China. We recently sold part of that business—so called 'blood safety' molecular diagnostics—to a company called PerkinElmer. The remainder of the business has partnered with PerkinElmer to sell current and future NAT products around the world, with the restriction that we are not able to develop new blood safety molecular diagnostic kits for four years' time, so as not to interfere with the interests of PerkinElmer's acquisition. We are hard at work, however, innovating other types of products in this niche. This sale and partnership structure is perhaps the best indicator that we have built something truly successful in NAT.

We also developed a vaccine business over the years, that has now been spun off as an independent entity. I continue to be the Chairman of that business, and I am acting CEO—but within five months' time, a senior scientist will take over as the chief officer. The ability of this company to stand on its own feet is, again, self-evidence of its success.

What is Medigen's vision today? TaiGen plans to fully integrate: buy manufacturing capability, develop marketing capability, and take drugs from discovery to market utilizing its own faculties—in Asia, but also beyond. What about you?

Sooner or later, we too must become involved in those businesses. We too will look to manufacture and market our drugs ourselves, and to build a presence beyond Asia.

My key comment here is that as we do so, we must move very carefully, and very deliberately. Our investments must be strategic: for instance, we have to invest in Progen—the Australian company from whom we licensed PI-88—in order to ensure that they have the capacity to produce adequate

quantities of API in the first two years after PI-88's marketing approval.

We do not want to do everything ourselves. We know that if we can properly leverage partnerships, we can move faster. On the marketing side, we are already in talks with a number of multinational Pharma companies to help us to get PI-88 to patients. For our first product, we do not believe in building our own Asian or global marketing teams—we think it is a misuse of money. However, as we move along, we will look to develop a small marketing team in Taiwan, gain experience, and move outwards from there. As the need arises, we will be happy to invest more in this aspect of the organization.

Our plan is for each of our businesses—drug development, molecular diagnostics, vaccines, and our coming foray into medical devices—to IPO on the market as independent entities. Once the strength, momentum, and timing is right, we will re-consolidate and consider re-listing as a single company in London or New York.

What is your final message to our readers?

To our peers in the Taiwanese biotech industry, I want to say that history shows us that life is a series of ups and downs. We have worked our way up from the bottom, and we see now the fruits of our labor—but we must still be cautious. We must not be overly ambitious. I warn myself of the dangers of ambition every day! I have a dream, but I know I must move very carefully, and make sure that my plans are deliverable and fit the needs of society and the market.

Public biotechs in Taiwan: do not sink yourselves in glory! You will drown very quickly. The Chinese proverbs teach us to keep calm, both in times of glory and in times of challenge. You can enjoy success, but you should know the potential risk. Conversely, when you are down, do not be frustrated—because tomorrow is a new day.

We try to embody this sense of calm ourselves. Three years ago, when Focus Reports first visited Taiwan, we sat and spoke in the very same office, with the very same furniture. The difference is that today, our company has grown almost 40 times in value.

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