

Interview: George Zhang - Founder and Chairman, PRO, China



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George Zhang, founder and chairman of Shenzhen-based ultrasound equipment developer and manufacturer, PRO, introduces his company's groundbreaking high intensity focused ultrasound (HIFU) Noninvasive Therapy technology, and developing an innovative mindset in Chinese medtech.

George, could you first start by introducing your company, Shenzhen PRO HIFU Medical?

Shenzhen PRO HIFU, or PRO, is the pioneer of high intensity focused ultrasound (HIFU) Noninvasive Therapy, established in 2003. Our team actually started the R&D in Shanghai. After a very long R&D period of around nine years, five of which were spent in clinical trials, we moved to Shenzhen for the commercialization stage. Clinical trials took longer than usual because it coincided with the 2007 restructuring of the Chinese FDA (CFDA), which slowed our progress.

In terms of funding, we had two rounds of private capital investment for a total of around CNY 160 million. We also participated and won various governmental grants and competitions, such as the 2015 Innovation and Entrepreneurship Competition Enterprise. As a young and innovative company, we invest everything into our R&D.

We operate in an extremely unique and niche market providing what we call non-invasive ultrasound treatment. In the past few years, we have developed a series of ultrasonic treatment equipment, with the first, PRO 2008, launched on the market in 2012, specializing in gynecological

non-invasive therapy. It is also one of the world's most advanced focused-ultrasound device. We now have three products on the market and we expect to obtain CFDA approval for two more this year. With five products on the market by the end of this year, that would make our product portfolio the largest in this area in the entire world – and what is even more impressive is that all of these products are highly innovative and developed in-house by us! With this product range, we also have high-end and low-end product options to cater to different market needs.

A great achievement I would like to highlight is that our company broke even last year! This is a great milestone for a medtech start-up. We now have 126 employees, most of which work in R&D. Rather exceptionally, we also have 11 doctors on our medical team to support our clients in installation, training and delivery, as the training process typically takes one month, which is much shorter than the three to six months it might take for other products. We are also developing our AI platform to decrease that time even further to two weeks. This will be very significant.

With such great achievements in the past few years, what do you see as PRO's competitive advantage in this space in the future?

First and foremost, there are no big companies operating in this space. International giants like Siemens, GE Healthcare and Phillips have either have not invested or have divested their HIFU operations. This means that we stand a great chance of becoming a global leader in this area!

Where there are competitors, they are very small, and often a few years behind us. We also benefit from the low cost base in China. For instance, there are a couple of companies in the US, specifically Seattle and Detroit. Their R&D costs, particularly when it comes to clinical trials for US FDA approval, are probably around six times our costs, and the timelines are around twice as long as ours – and that only considers the domestic US market! If they want to enter China as well, it is another three years for CFDA approval!

European companies lack the necessary market size needed to grow, so we are not very concerned about competition from them. In Asia, there are a few smaller companies from South Korea and Taiwan, but these are not only small countries, they are also very tough to navigate from a regulatory perspective, because they have to go through the US FDA or CFDA process, which is very cumbersome and challenging for a start-up.

Realistically speaking, our closest competitors are perhaps three to five years behind us! We are in an enviable position to become global leaders within this space, which is very exciting for a new Shenzhen company. We have already obtained CFDA approval and the European Union CE mark. Given the long US FDA regulatory process, currently we do not have plans to enter the US market

yet.

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What are the factors that make this HIFU technology so niche and special?

Firstly, there used to be some safety misconceptions surrounding high-intensity focused ultrasound, mainly because of the extreme precision required. Since then, a lot of research has been conducted proving that there are no safety implications, especially for HIFU. In addition, there have been some market failures in the past with companies in the US working in the area of MRI-guided radiation therapy, which did not see success in the field of gynecology and subsequently moved to neurology.

However, we strongly believe that there remains a huge market in ultrasound guiding. In particular, Chinese companies have made significant progress in this area over the past 15 years. New technologies are now advanced enough to bypass any potential safety issues. With the previous track record of failed investments, this market is also very under-invested, even non-invested, market! This represents great potential for a company like us.

In addition, ultrasound is a very familiar concept to consumers and patients, and it appeals in particular to women. It is very easy and safe to operate. Furthermore, the Chinese government also strongly supports the development and use of such technologies. As an indication, the government has increased the public reimbursement price of ultrasound therapy in Shanghai from CNY 2,400 to CNY 10,000. This is very important because the low reimbursement cost of ultrasound therapy discourages doctors from using it. With this change in Shanghai, we expect to see an upward trend in public reimbursement for this kind of therapy, which indicates that the market is moving in the right direction.

A challenge now is that this technology requires some training, which we do provide. But many Chinese doctors currently do not want to concentrate on tasks like this because they think it is more the role of a technician. However, under the current Chinese system, only doctors can perform these procedures. So we need to educate healthcare practitioners on the benefits of this therapy, as well as perhaps push for policy improvements on the other side.

What other innovations will PRO be bringing to this area in the future?

The ultrasound and diagnostic device markets are quite big. 20 years ago, when I first entered this market, one hospital will only buy one unit. In China today, a hospital will buy 40 to 50 units! The market is growing so fast - around 15 to 20 percent, though from a small base, as only the top

hospitals will buy new, innovative products like this at the moment. We also offer leasing programs to private hospitals. We are waiting for the middle base of hospitals to catch up.

In my view, the ultrasound therapy market shares the same characteristics as the ultrasound diagnostic market. As it is non-invasive, every clinical practice can use it. We plan to launch different product lines catering to the individual needs of different hospital departments, from gynecology to oncology to radiology and so on.

In addition, what is unique about China is that our hospitals have unique ultrasound departments. They currently do diagnostics but they can also offer ultrasound therapy because doctors, not technicians, run those departments, unlike in other countries where ultrasound diagnostics are conducted by technicians. In fact, we have developed a brand new product, a small, very precise robot, that can be connected to any ultrasound diagnostic system to help locate and position. As it connects to hospitals' existing systems, it makes it much more convenient for doctors to use.

We are also in the middle of conducting clinical trials for pancreatic cancer. This would be the first product in the area of tumor therapy in the whole world, so we are very proud. The choice of pancreatic cancer was very strategic. The average patient survival rate for pancreatic cancer is unfortunately only 3.8 months, unlike other indications, which are longer. This shortens the time needed for clinical trials as follow-up only takes one month instead of the 12 months it takes for other indications. This saves us at least a year in terms of product launch, which is very important.

The persistent image of Chinese companies is that while they may be extremely adept at developing similar versions of extremely successful products at a far lower cost, genuine Chinese innovation seems to be hard to find. As a truly innovative Chinese medtech company, how do you cultivate this 'innovative' mentality in your employees?

As a company, we follow scientific advancements and developments very closely. We keep up with the latest articles and papers being published by the leading academics in our field. We always ask ourselves, is this something we can do ourselves? In addition, we also collaborate closely with academics and researchers.

Companies need to do something innovative to survive and grow. If you are not innovative, you will not make any money in the market place! There is a great atmosphere of innovation in Shenzhen as well - everyone is thinking about doing something new.

This is why we invest heavily in R&D. Our R&D team comprises both very senior engineers and fresh university graduates to inject diversity.

Finally, what is extremely critical is that we are a market innovation company. What this means is that we do not simply focus on our products alone but we develop products specifically to meet customer needs or even drive market trends. Being able to read market trends and then design products to lead them is extremely important, because otherwise you will only be producing something that the market does not like or need.

Some of the largest Chinese medtech companies have grown by competing from a price perspective, producing cheaper products to replace imported products, therefore gaining market share. As they mature, they launch higher-end products to move up the value chain. Our strategy is the complete opposite. We want to start from the top – develop the most innovative, high-end products – and then slowly launch more mid- and low-range products to cover the whole market. This helps us to build the credibility of our brand; in fact, within the European markets, our products are actually the most expensive! This reflects our quality and innovation.

For instance, when we launched our product line for the ultrasound department in hospitals, we realized we had identified a unique market in which we were the only participants! Our competitors are at least five years behind, so we enjoy a great first-mover advantage. This gives us an extremely strong positioning in that market and strengthens our company brand.

At the end of the day, the most important aspect of a therapeutic product is its efficacy – the results it can bring to patients and users. Price is important but secondary to that.

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On a more personal note, the R&D journey for PRO has been very lengthy. Especially for start-ups, this process can be nerve-wracking because success is not guaranteed. How do you manage this stress?

Indeed, for a small company like us, the stakes are very high. If our first product fails, it may take the whole company down with it.

For PRO, during the ten years of R&D, we benefited from the scale and scalability that China offers. We had a huge base of clinical trials and doctors involved in the R&D so we were reasonably confident in the outcomes. We also chose strategic therapeutic areas like pancreatic cancer, which sped up the process and put us a few years ahead of our competition.

Finally, temperament is also very important. I am a very open and optimistic person, so I think that helps. The company did go through a few tough periods but we also received a lot of support from our investors and the government, so overall, I am grateful for that.

For me personally, family support is the most critical thing. This is what helped me survive the tough times. My 12-year-old daughter is actually my biggest fan! She loves to support me at the various competitions that PRO takes part in.

The R&D process took a long time, a lot of money. It can go round.

For a small company like us, if a project goes wrong one time, the whole company fails. I have seen a small company in Seattle making liver tumor cancer therapy, failed, and they fired the CEO and found a new CEO to raise more funds. It is very expensive. A disaster!

During those ten years - in China, it is different. We have a huge base - we have a huge base of clinical trials and doctors, we know what will happen. Pancreatic cancer made us two years faster than our competitors.

I am a very open, optimistic person! I am not like others ... we have a few tough times but they were not that long. We received a lot of support from VCs and government and our shareholders. It was not that tough.

As a final question, where do you see PRO in the next few years?

Very concretely, we hope to IPO in three years. This will give us the resources needed to drive further growth.

We aspire to be the world's most powerful therapy company. My belief is that such companies can only come from the world's two largest economies: US or China. Other markets are far too small to support the growth of global companies. In this field of HIFU therapy, I am pushing PRO to become the first one - in the world!

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