Interview with Dan Zhang, CEO, Fountain Medical Development

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You have an MD and you've worked in industry, but then you decided to become and entrepreneur. What challenges did you face in transitioning to starting your own company and in growing your organization?

Entrepreneurship is nothing new in China. Half the population of this country seems to want to start its own company. However, in reality I have a mixed background. I got my training in Beijing, at Peking University. Then I continued my education at Harvard where I earned an MPH and did my business training at Wharton at the University of Pennsylvania. The culture in business school involved talking frequently about business cases and China in addition to other emerging markets. I actually started to build my own consulting firm while I was still a student. I offered services to Pharmaceutical and insurance companies. I was in a PhD program at Wharton, where I stayed for five years and also built up a list of fourteen major clients including Medtronic, Eli Lilly, Pharmacia, Signa, and later on Merck. At that time I was one of the few and one of the first MD's to study health economics. When industry representatives came to the university they heard that I was studying in this new field and that I also come from China. They would come to me and say, "hey Dan, could you help us try things from a combined economic and clinical perspective?" So at first, I helped them deal with HMO's and later I began to offer consulting on efficiently and strategically entering China. That was the first step in familiarizing myself with doing business with the big guys.

There are some challenges in the Chinese market, and one is the time it takes to get studies approved. From your experience on the Expert committee for New Drug R&D and also your experience in the market, what is being done by the government to expedite the process and on the industry side, what are companies doing to mitigate and overcome this issue?

The lengthy approval process is something of a misperception. It is true that getting approval for the study itself takes longer than in many other markets. However, in the end, this doesn't represent much of a delay in the drug development process. The best index for comparison is from the time the company considers filing for IND to the time the first patient enters the study. The timelines of intermediate steps are not as important as the length of the overall process. In the US, IND takes one month if there's no objection. However, it takes quite a while to get a pre-IND meeting with the US FDA. You have to get your package approved by internal people and consultants, wait for an FDA response, then have a meeting with the FDA, then get consensus and recreate the IND filing package. The whole process takes 6-12 months. Then you have to have a scientific committee review and it can take at least another six months for the academic assembly to approve the first patient in. So we're talking about twelve to eighteen months from the time the company decides to file to the first patient in.

In China it's a whole different ballgame. The longest portion is the IND filing, which takes 8 to 12 months. However, there is no pre-IND consultation at all, you can submit whatever IND package you want to the agency. The reason for the perception of delay is that when big pharma began to consider China they never put china at the same starting point as the US or Europe, only when they had trouble in enrollment did they begin to consider doing clinical work in China. That's too late. However, if they start China at the same time as the US, then there is no delay whatsoever. That's the key message that I want to send to the readers of Pharmaceutical Executive: include China, India and other emerging markets at the beginning of the process. Even if you never enroll a single patient, you want to apply and obtain clinical trial approval as an insurance policy. The cost is extremely low, just thirty or forty thousand dollars, which is very worthwhile to obtain a back up option for fast enrollment in emerging markets.

Another important point is that if you're going for Chinese approval, it's best to go through South East Asia first. Hong Kong is supposed to be part of China but Hong Kong has a very unique system, generally known as 'one country, two systems.' Hong Kong has a capitalist system while Mainland China has a mix of Capitalism and Socialism. A great example of the mixed system is in the drug approval process. The Chinese SFDA recognizes data from Hong Kong sites. However, Hong Kong accepts US IND. Thus, if you get US IND, you can get a Hong Kong IND very quickly. So

you can do a first round very quickly in Hong Kong while China recognizes that data. So the path of least resistance is to enter China through Hong Kong. Many people don't realize such an obvious fact and are trapped by trying to come directly to China.

The Chinese SFDA is already doing things to improve the approval timeline and also the quality of approvals. Beginning in 2009, you will see new guidelines issued by the SFDA specifically saying they will speed up approval for four classes of drugs. First are New Chemical Entities (NCE), candidates that have never been approved anywhere. Second are unmet medical needs such as oncology or pandemic diseases. Third, orphan medications. Fourth, new uses or combination uses of Traditional Chinese Medicine (TCM). For the first time the SFDA now allows pre-IND consultation. Those minutes can be legally binding. They also now allow rolling submission, meaning you don't need a complete dossier before getting an initial review, which is a huge improvement. Also, whatever the workload, the SFDA is committed to reviewing new applications immediately. Because the Chinese government has these innovative policies, the SFDA has begun to cook up innovative methods to treat submissions with special potential. Additionally, the SFDA has begun to systematically translate US drug development guidelines into Chinese. This is a big signal regarding the direction in which China wants to move.

My personal view is that China will very soon have a huge improvement in IND applications. One-month turnarounds are impossible, however the treatment of applications will be more transparent. The SFDA promised that they will allow the sponsor to know who precisely in the SFDA reviewed the specific part of the application so that if issues arise, a sponsor can immediately have the opportunity to respond to any deficiencies as they are being identified. This gives firms many more options to deal with issues, as compared to the past when they were kept completely in the dark. I think this will be a huge improvement in managing expectations of applications.

On the industry side, companies are working closely with the SFDA through associations such as RDPAC and even through the organization that I belong to called Bayhelix. Bayhelix is an interesting organization. It has 370 members who join by invitation only. I was a board director of the organization and there are three criteria for membership. First, you must have Chinese heritage or speak Chinese. Second, you must be in life science. Third, you must be a senior executive, defined as senior director or above in big pharma, a founder of a startup, a partner in services such as legal or VC, and a senior professor in academia. You also need two reference members to introduce you to the committee. Then the member committee which includes the research head of Pfizer Asia, and Dr. Yu who is the CEO of Epitomics, a Biotech company located in San Francisco with operations in China. New members must be approved unanimously. This membership system

guarantees an elite group of experts. This organization has a SFDA working committee and we of course understand China but also the US and Europe and can communicate in a way that is very different from RDPAC and big pharma. We simply represent the views of what is best for innovation in China, synthesizing the best aspects of big pharma and local firms, all in the context of the interests of the Chinese industry as a whole. I think this communication is very effective and the message really gets across to the regulators. We recently had a four and a half hour long discussion with the commissioner, and deputy commissioner of the SFDA, laying out a number of key issues. The conclusion was that they generally agree with our analysis of current conditions in the country. That's why we ultimately believe that the Chinese government is moving in the right direction to promote innovation in China.

There has been a huge boom in the CRO industry in China with an explosion of local companies as well as all the global CROs setting up shop. These foreign firms have a lot of know-how, infrastructure, technology and experience. How do young local firms compete with the big players that have these advantages?

Five years ago I was repeatedly approached by investors saying, "hey Dan, you should set up a CRO firm because there is a huge upswing coming." I didn't really buy the story because I came from Quintiles and I asked myself, "how can I effectively compete against my former employer?" I was intimately aware with their strengths and I knew it would be quite challenging. However, over time, I believe I came up with a solution and that's why I set up an independent clinical CRO.

There are a couple of reasons why local firms can succeed in competition with a firm like Quintiles. First is cultural understanding. Take the example of Quintiles. After I left the firm, Quintiles changed general managers a number of times. Now they brought in someone from Singapore and she really understands China, that's for sure. However, there are still cultural differences. One of the toughest challenges in the Chinese CRO industry is managing turnover. High turnover has actually been killing the quality of many CRO firms. Normally one expects 20-40% turnover for CRAs on an annual basis. This is in part due to general managers parachuting into the Chinese market without understanding the culture. Secondly, cost issues are relevant. Global CROs such as Quintiles are forced to pay top dollar to hold onto their employees. We pay reasonable dollar. We are able to compensate our employees in other ways in addition to money. One example is academic recognition for their work. Managing senior people can be a challenge. One effective and unconventional way I do this is using government recognition. My director in our Tianjin central lab also has a position at a local university. Quintiles can't do this and it's a huge golden cuff. This is a non-cash reward that allows me to be competitive with Quintiles but at a lower cost. I also have an

advantage with the SFDA because I’m Chinese and the likes of RDPAC and Quintiles are seen as only representing the interests of foreign firms.

When it comes to perception and branding, how are you working to ensure potential clients that you are fully flexible and able to accommodate any of their needs?

My management team all has US or European experience and have worked for major pharma firms for many years. Every person on my team has been involved in major approvals in the US. My second in command ran Baxter’s East Asia regulatory and clinical division and was also a medical director at Pharmacia-Upjohn. My third in command was a director at Aventis and then Daichii Sankyo in the US. My central lab director ran a clinical lab at John Hopkins and was even director of the central lab in Singapore.

What is the growth driver for the company? What is the strategy?

First is regional development. There is a lot of growth in the larger Asia Pacific region, not just in China. Second, I do see the possibility for a small firm like us to acquire a small firm in the US. This could help improve timelines, improve quality, and even lower offering cost due to higher efficiencies in certain areas. At this point we aren’t trying to become a global giant, but rather focus on niche areas.
We are targeting CV, infectious diseases, and oncology as these areas are doing very well in China and South East Asia. Data management is a booming area where we can immediately cut costs for clients.

How have results been this past year?

We grew 300% as compared to last year. We are still new, so this growth is coming from a fairly small base. However, the economic downturn has produced an increased interest in outsourcing. Our growth will double if not triple in 2009 as well.

How are you dealing with the talent war in the CRO space? How do you manage to attract and retain such highly qualified staff?

We cannot afford to participate in the talent war in Beijing and Shanghai. We set up our operations in second tier cities. Costs are lower, and people are more proactive because it’s fairly difficult to find a good job in these cities. We have a very clearly defined pay grid and have expanded the option program to key employees.

You are an MD and are committed to the improving the health of patients. But on the other hand you also have an MBA and are focused on growing your business. Big pharma is moving away from the most lethal and widespread diseases such as AIDS or Malaria, toward more niche areas. Since you are participating in this research, how do you balance these potentially conflicting directives?

Public policy and financing are major issues that need to be addressed to improve this situation. The government should do a better job in creating incentives for those with the know-how to get involved with those diseases. The government should also provide long-term recognition for companies engaged in these efforts. My firm has promised the government an innovative program to sponsor their initiatives for unmet medical needs in China. We are trying to subsidize these programs through our work completed outside of China in order to bring these crucial products to the country as quickly as possible.

What is the most exciting thing about your work, what wakes you up in the morning?

We are very excited by the upswing in demand and we are getting unparalleled support from the government to get this operation moving. In return we have promised to build a world-class development platform in China and train a team of experts to support domestic innovative firms. This is the challenge but also the reward.

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