MEDTECH ENTREPRENEURSHIP IN A NASCENT ECOSYSTEM: A PERSONAL JOURNEY



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MAIN AUTHORS



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PROFESSOR TAN SZE WEE is currently the Assistant Chief Executive of A*STAR's Enterprise Division (ENT). He previously held the appointments of Assistant Chief Executive in the Science and Engineering Council, Deputy Executive Director in the Biomedical Research Council, Director of SERC's Strategic Initiatives, and Programme Director of the Medical Technology initiative in SERC. Professor Tan is Adjunct Professor at Nanyang Technological University's School of Chemical and Biomedical Engineering and Lee Kong Chian School of Medicine, and Adjunct Professor at Duke-NUS Medical School Singapore. Professor Tan was formerly the Managina Director and Chief Executive Officer of Rockeby Biomed Limited and the Asia-Pacific Associate Regional Medical Director for Mead Johnson Nutritionals from 1997 to 2001. Professor Tan was a former Nominated Member of Parliament of Singapore. Professor Tan graduated with a Bachelor of Medicine and a Bachelor of Surgery from the National University of Singapore, and attained his Masters of Business Administration from Warwick University, UK.



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FIONA is a Senior Manager with the Medical Technology Office (MTO) of SingHealth and concurrently consults as Curriculum Head for Singapore Biodesign. As Curriculum Head, Fiona works with the team to design materials for training innovators in the Biodesign approach and related topics via workshops, as well as in the Biodesign Fellowship. At MTO, Fiona and the team provide support to aspiring clinician innovators in unmet needs finding, solution generation, engineering management, quality management, regulatory guidance and commercialization planning, adapting the Biodesign methodology for medtech innovation in the local context

Prior to this, Fiona worked in software engineering, leading a team developing healthcare applications combined with new media and providing training in healthcare interoperability standards. Fiona was part of the 2011 batch of Singapore Stanford Biodesign Fellows. She has also provided consultancy to A*STAR, Covidien (now Medtronic) and the Singapore General Hospital on medtech innovation.

MEDTECH ENTREPRENEURSHIP IN A NASCENT ECOSYSTEM: A PERSONAL JOURNEY

Looking at the illustrious career of Prof Tan Sze Wee, one is likely to think of the current Assistant Chief Executive for Enterprise at the Agency for Science, Technology and Research ("A*STAR"), as a public administrator. After all, aside from his outstanding contributions in A*STAR, he was also a former Nominated Member of Parliament. However, some of us may be unaware of the adventurous path he took prior to entering the public sector. The clinicianturned-entrepreneur spent almost a decade establishing a diagnostics company, Rockeby Biomed Limited ("Rockeby"), and listed it on the Australian Stock Exchange. Singapore Biodesign caught up with Prof Tan to find out



FIGURE 1: One of Rockeby Biotech's Prime – CanDia 5, a Rapid Candida Test Kit That Diagnoses Candida in 5 Minutes

The Beginning

Prof Tan's MedTech encounter began with a group of investors who were performing due diligence on an idea pitched by an Australian scientist. The latter was developing a rapid diagnostic kit for vaginosis. Prof Tan was then the Asia-Pacific Associate Regional Medical Director for Mead Johnson Nutritionals. Given his background and experience, the investors approached him for his views on the diagnostic kit. "I felt there was an unmet medical need," he recalled. "Women had a high incidence of vaginosis and no rapid diagnostic kit. Most of the time, treatment was self-medication resulting in recurrent vaginosis. The scientist had a cytoplasmic antiaen that could be used to develop a test for circulating antibodies, which could be sold over the counter." He decided to throw his weight behind the fledgling start-up, which he believed held great promise.

The company started off with a 15-person team responsible for sales and marketing. Research and development work continued to be conducted by a four-man Research and Development team in Perth. Production was outsourced to Pacific Biotech Co. Ltd, a Thai company.

Pearls and Pitfalls

The journey, however, was not smooth sailing. The conventional approach to diagnosing fungal infections was primarily based on cultures. Using antigen capture for a point-of-care test was an unproven approach, placing the product in the high-risk regulatory category. The market was also much more challenging. Remarked Prof Tan, "If I had known this 20 years ago, I would have been more circumspect about the time to market and resources needed."

With a novel biomarker and without a predicate assay, the regulatory process for the test kit, named Candia5 (Figure 1), stretched on for many years. The company expended much effort to hire staff with the needed skill sets, "The situation now is much clearer, with the Diagnostics

Development Hub and many more diagnostics companies in Singapore, as compared to 20 years ago where the regulatory pathway for diagnostics was not well-known," said Prof Tan. The Diagnostics Development Hub is a national platform hosted by A*STAR, which develops clinically validated diagnostic devices to reach commercialisation. "Nowadays, you can get a diagnostic test commercialised in three years."

The company also faced challenges on the intellectual property front, as a large multinational had an active patent on a related technology. "Those were the learning points that nobody taught us, unfortunately," said Prof Tan. "I knew how to design clinical trials, get regulatory documentation done and the right people into the team, but had no background in diagnostics. A start-up should at



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Prof Tan advised start-up companies to actively reach out to access support in areas including, product development, quality management, manufacturing, regulatory affairs and marketing. Support could come from an incubator or accelerator, for example. Setting up the company properly would also save time and avoid expensive bottlenecks that hamper productivity.

Fundraising Fears

For almost nine years from 2001 to 2009, Prof Tan's main role was to raise money for the company. To provide a basis for company valuation, the company estimated the projected sales of the test kit and used a 10vear discounted cashflow model to compute its value. "Until you can earn enough to be cashflow positive, you have to raise funds continually for the start-up," Prof Tan cautioned.

The company endured multiple blows with the 9/11 terrorist attacks



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Prof. Tan Sze Wee

Assistant Chief Executive

in 2001, the Severe Acute Respiratory Syndrome crisis in 2003 and the global financial meltdown in 2008, all of which badly impacted investors. Nevertheless, Rockeby raised sufficient investment funding to launch the product and generate sales. "We were in constant fear of running out of money," recalled Prof Tan. "Several times, I had less than \$50,000 in the bank and went without a salary to make sure our employees could be paid. A start-up must be very clear how much they need before they can turn cashflow positive and receive regular purchase orders."

Prof Tan shared that raising money through any market required management bandwidth in terms of time spent to get investors interested. For those seeking to raise funds through the stock exchange, there were compliance costs. "For a \$10-\$20 million market capitalisation for a company, listing it may not be worth the amount you would need to spend on compliance," Prof Tan pointed out.

He advised would-be medical device start-ups to get "smart money", i.e., investments from investors who were well networked and had expertise in the market. This would be more attractive for other investors to put in follow-on funding, rather than getting investments from friends or family who do not have such links. "You may end up with too many shareholders who will deter subsequent shareholders, as they prefer the initial angel investors to be in one holding unit," added Prof Tan. "The trade-off between early cash and proper cash would need to be well managed as 'unsustainable, unsophisticated' funding easily dries up," he said.

On Being an Innovator

On being an innovator and taking risks, Prof Tan mused, "It's primarily about your choice. Do you want to have control of your own destiny and in the process, benefit from the upside if you are successful? To be honest, 90% of start-ups will fail in two years. Many people have not figured out what is needed to bring universitylevel intellectual property to a point where it can be scaled up. It helps if they have worked in the industry before, selling real products."

Prof Tan observed that investors in Asia still preferred to see positive cashflow from investee companies. To improve liquidity, some companies may choose to offer services while developing their products. He shared that, "In our cultural setting, failures are not seen as a badge of honour." His motto: Failure is not an option. For innovators wanting to start new businesses in Singapore, he had this word of advice: Do so when you are young. For those with dependants, the start-up founder should ideally not be the sole breadwinner at home. Prof Tan shared that he was financially compensated for his efforts once Rockeby went public. (Figure 2) Prior to that, however, he experienced constant financial stress.

On Being a Singapore Clinician Innovator

Turning to the Singapore landscape of clinician innovators, Prof Tan felt that the opportunity cost of being a practising doctor was very high; regardless of whether the clinician worked in the public or private sector. "Most of the time, a doctor ends up being an investor in the start-up, not a founder," he commented. He noted that with Government support over the past 10 years, many doctors were keen to become scientists. These "clinician scientists" see patients part-time, work with researchers to run laboratory studies and publish papers. Nevertheless, he felt that doctors generally still did not find it attractive to do part-time clinical work in order to spend time on innovation.

While there are a number of "clinician innovators" in public healthcare and national specialist centres, most are primarily still service clinicians.

Prof Tan was thus heartened to see the NUS Yong Loo Lin School of Medicine in Singapore launch the Medical Grand Challenge. One of the objectives of the healthcare innovation competition was to promote medical innovation amona students. He was alad that the School had recognised the importance of equipping its students with expertise in writing business plans and gaining pitching skills at the medical school level. With early exposure to innovation, he hoped that the students would continue engaging in innovation activities throughout their medical training, as well as in their professional careers in future.



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FIGURE 2: Prof Tan Sze Wee (third from the right) as a Panelist at Singapore Biodesian's 2015 Thought Leader Series on MedTech Innovation

Innovation in Asia

To be an effective innovator in Asia. Prof Tan emphasised the importance of innovators being aware of these fundamentals to bring sales into a startup: (1) how long it would take; and (2) how much it would cost. He shared, "To develop a class 2 device to the point where you can get a purchase order will take maybe \$5-10 million, working with a contract manufacturer. If it is a class 3 device, it will be at least \$50 million. If a start-up does not have that cash, the founders need to figure out how to get the money." For a startup of 10 staff, manpower expenses alone would amount to \$3 million over three years. Adding on rental and consumables, the price tag would be close to \$15 million over three years. Additionally, founders would also need to consider capital expenditures. For innovators considering where to site their companies, he advised locating them near their eventual markets, to provide prompt customer service and conduct post-market activities efficiently.

Positive Outlook on Medtech

On the whole, Prof Tan is positive on the outlook for Singapore's medtech innovation efforts. "Singapore has stood up quite well in the Covid-19 pandemic, coming up with many innovations besides diagnostics products, such as masks, [Singapore spinoff] Respiree's wearable respiration and blood oxygen monitor, and so on. The quality of Singaporedeveloped products is high in the eyes of clinical users, when compared to products from the region," he said. In addition to Rockeby, he also invested in a Traditional Chinese Medicine chain and a general practice chain of clinics, both of

which did well financially. However, he commented, "Diagnostics are easier to commercialise than devices. Up to today, there are not many successful medical device companies comina out of Singapore. In Asia, you need to show investors revenue. Acquisition opportunities are not as plentiful here compared to the West." Prof. Tan cited Holmusk, MiRXES, Lucence, AIT Biotech, Veredus Laboratories, Endomaster, Biofourmis and Histoindex, as examples of companies that did relatively well locally. Some, like Holmusk, have made it big in the United States, whilst Veredus Laboratories was acquired by Sekisui Medical Co.

CONCLUSION

In conclusion, beginning with the end in mind is key to a successful start-up. Determining the length of time, amount of money and business plan to get the start-up to profitability, raising sufficient funds to see it through, and having the right skillsets on board the team to execute the plan, are vital for success. Prof Tan has used his experience as a public health physician and entrepreneur to champion causes for local SMEs and his experience as an NMP and his current role as Assistant Chief Executive, Enterprise, A*STAR to impart new technologies to revitalize local companies and to anchor larger MNCs in Singapore. In his various public sector roles, Prof Tan shared that he had always aimed to promote such skillsets and experiences within the local ecosystem, through translational vehicles such as the Diagnostics Development Hub and talent training programmes offered by Singapore Biodesign. With these enablers in place, Prof Tan is optimistic for many more successes to come.

KEY TAKEAWAYS FOR INNOVATORS

- 1 A well rounded team with domain experts towards product commercialisation is key in the success of a start-up. If the team does not have the expertise, there is no shame to reach out or to outsource.
- 2 Start with clear goals and have a clear grasp of the timelines, expenses and cash-flow projection for your company at all times. The company should be strategically placed to provide post-sales support and post-market activities when needed.
- **3** Bring in investors who can contribute to your company and whose network you can leverage on. The trade off between early cash and proper cash would need to be well managed.

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EMPOWERING ASIA'S HEALTHTECH INNOVATORS OF TOMORROW

Modelled after the established Biodesign Programme at Stanford development initiative that aims to train and nurture the innovators for Asia.

We are a dedicated talent development and knowledge resource for health technology innovation, riding on the robust biodesign methodology and our wide-ranging regional network to provide an appreciation of healthcare needs through observations from stakeholder perspectives.

MISSION

mentoring to accelerate health technology innovation and adoption for Asia's* unmet healthcare needs.

VISION

To be Asia's* leading healthtech talent development and knowledge partner for accelerating health technologies innovation towards commercialization and adoption.

*Asia refers to SG, China and ASEAN



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