Experiences of a Scientific Entrepreneur

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Pieter Cullis delivered a webinar in AllerGen's Planning for Research Success *series on March 10, 2016, sharing his 'stories from the trenches' as an accomplished scientist-businessman with 30 years' experience in conducting academic research and commercializing results. His key messages follow.*

ADVICE FROM A SCIENTIFIC ENTREPRENEUR

Don't let the fact that you don't know anything about business inhibit you from starting a business. Almost all business people learn by experience, not from books. On-the-ground experience is the best teacher of what needs done to achieve success.

If you have a good idea and you feel passionate about it, start something up. You can over-plan; if you aim for something perfect, you often find that when you get out into the business world, your customers are not who you think they might be, and what you are providing is not exactly what they want. Get out into that real-world environment as soon as you can to test and validate your ideas, products and services.

Take advantage of opportunities even if you lack a solid intellectual property position. While it is nice to have a patent base for any product you are putting out there, you can do it with no patent at all—I did with my first company, which sold an unpatented device mainly by word of mouth until it became a well-established instrument. The technology remains unprotected, but no viable competitors have emerged. If a product earns a scientific reputation—for example, a published paper mentions the use of it—other scientists take interest, and when a product works, customers come back to the original source.

Get a good team together and keep it together. Build up a reputation and you can start new initiatives more easily. Building a community around your ideas and products is essential to start things off; a strong team where people know and trust each other is like an engine with which you can push out a good idea with relative ease. It is also fun to work with people with whom you have a history and a great deal of compatibility.

Prioritize scientific knowledge when building a start-up team. It is easier for a scientist, if motivated, to learn about business practice than for a business person to penetrate the science. It is important, at least initially, to have people at the top who appreciate the nuances of the science. In the start-up phase, an accomplished business-person may have no way of knowing whether the group he/she is leading is good; it is difficult to judge if you don't understand the science.

Take advantage of commercialization support services, like those offered by The Centre for Drug Research and Development (CDRD). In academia, you can't undertake proof-of-concept experiments to make a potential drug candidate attractive to industry. Agencies like CDRD aim to fill this gap between academic work and commercialization by facilitating the extensive preclinical validation needed before taking a drug into the clinic—validation that can amount to a $20M investment (in preclinical toxicology, and in the Phase 1 and 2 trials needed to obtain evidence of efficacy in the target disease).

With drug development, consider licensing the drug at an early stage. Drug approval is a remarkably difficult, cumbersome and expensive process. The average length of time for drug development, from the original prototype to approval, is 15–20 years. My experience with drug approval entailed $150M in expenditures in a

22-year process. Given another drug development opportunity, I probably would try to license the drug off at an earlier stage: Once the drug goes into clinical trials, the scientist is superfluous anyway – you can't change the composition of the drug at that point. It is better to go back to the lab and develop the next drug, to build the same kind of portfolio behind it, and to try to commercialize that. Don't get involved in clinical trials; from a basic research point of view, there is not much you can contribute.

OBSERVATIONS OF A SCIENTIFIC ENTRPRENEUR

By initiating business enterprises based on your research, you do not compromise your scientific efforts but rather you enhance them: You get exposed to interdisciplinary activities and opportunities that you wouldn't necessarily encounter in a straightforward academic career.

Successful ventures can emerge from accidental opportunities; taking advantage of chance encounters can have major ramifications.

You cannot anticipate how an enterprise will evolve—through mergers, acquisitions, name changes, *etc*. Nothing remains static in the business world. Things sometimes end up bigger than you anticipate.

Scientists have a responsibility to educate their students about the opportunities in areas other than academia because not all of them can go on to positions in academia (only 10%-20% will do so), and there are many benefits to a career in industry. One of my motivations for starting companies was to generate employment opportunities.

Building up a big organization that is dependent on the success of a drug is a very risky undertaking. In my experience with drug approval, when the FDA unexpectedly requested additional studies at an advanced stage of the process, my company lacked the additional finances required so I had to license the drug out to another company. As a result, my company had to cut staff, recalibrate and re-focus, which was a painful set-back.

Advances in medical practice are made daily, but the process for approval to use a drug in a clinic is no longer tenable, in terms of timeline and cost. Emerging models are changing this dynamic, like the personalized medicine approach in which you have direct information about your own body; you can search on internet to identify the best source for treatment, and then catch a plane to that place. Thanks to such new approaches, we will see timeframes for approval compressed.

A variety of models exist for founding companies from academia: The more classical model of spinning the company out and going the venture capital route really doesn't happen anymore for a variety of reasons: it's a long process—the investors and the scientists get tired. The CDRD model is a better solution, where you put together a technology dossier beforehand that sets the stage for the drug moving into the clinic. Another option is to take advantage of the translational grants available from various sources to incubate a company in your laboratory, applying for funds to move the product forward. Or you can establish collaborations between basic life science researchers and clinicians, develop a diagnostic test, identify a patient cohort through the clinicians, and then apply for funding to establish a company. The CRO model is also a good way to go, but for this you have to have a long-standing record of expertise in a particular area, built up over years—it takes time to establish a reputation to attract customers; the CRO route is not an overnight win.

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