



Creating a company

Building a company can offer a unique opportunity to realize the potential of ideas or research discoveries, but can also present major challenges. This month, two biopharma company founders discuss their experiences and highlight factors that have been important for success.



Alice Huxley, Ph.D.
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Company mergers are touted as yielding major benefits from synergies and greater efficiency, but promising projects can end up being quietly shelved, which can be highly frustrating for those involved. Following the merger of Sandoz and Ciba-Geigy to create Novartis in 1996, Alice Huxley, a global project manager who had been working on a new class of antihypertensive drugs known as renin inhibitors, was in exactly this situation, but found an unusual answer.

"I conceived a company — Speedel — to save SPP100 (the lead renin inhibitor in the programme) from a quiet death," says Huxley. "I believed strongly in the potential of this molecule, which was the culmination of years of research. So, when it didn't make it into the redesigned pipeline of Novartis, I convinced the management to let me take on the project within Speedel and prove that it would work."

Now, only 8 years after the company was created, SPP100 (aliskiren) is on the brink of becoming the first renin inhibitor to be approved, following successful Phase III trials conducted by Novartis, who exercised a 'call-back option' after Speedel had demonstrated the first proof-of-concept for a renin inhibitor with SPP100 in Phase II trials. And Speedel itself has grown from a virtual drug development company to a biopharma company employing more than 70 people, with a pipeline and research team of its own.

Three things in particular have been crucial for Huxley in reaching this point: a strong will to succeed, a highly effective team and strong support personally. "As well as saving SPP100, I was keen to gain more freedom as a drug developer," she says. "But founding Speedel wasn't an easy decision, and the past few years have been an extremely challenging time, even with a supportive personal environment. Having a team of skilled, self-confident and highly motivated people who are not afraid of risk has also been vital."

On the science side, Huxley's 15 years at Ciba-Geigy, in which she was involved in the development of several drugs in

the endocrinology, cardiovascular and transplantation fields, were valuable. On the finance side, "it was more like learning to swim in cold water," recalls Huxley. Interactions with investors made it clear that for Speedel to secure financing, it was crucial to build a pipeline. However, the years that it would take to do this through internal R&D would be far too long to wait. "So, we made the decision to build an initial pipeline through in-licensing," Huxley says. "The initial molecules we brought in are for different indications to SPP100, but resemble it in one respect — they are the result of programmes elsewhere that lacked internal support for strategic reasons."

Building on its clinical pipeline, Speedel created its own late-stage research unit, Speedel Experimenta, 4 years ago with a view to partnering with larger companies in the clinical development of compounds they discover that have large potential markets, says Huxley. "I think our success so far illustrates how the challenges facing the industry have created the opportunity for the strategic partnering approach that we have taken and, most importantly, that you should never give up on something you believe in."



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Back in the 1990s, when investor expectations of the fruits of the human genome sequence were at their highest, many companies were founded on the promise of exploiting emerging genomic knowledge through novel technologies. Today, Arena Pharmaceuticals is one of the few to have successfully navigated the path from a start-up to mid-sized biopharma company, and now has a drug candidate — lorcaserin, a serotonin-receptor modulator — in Phase III trials for obesity, and several others in clinical and preclinical development.

"Working with our team on lorcaserin from conception through to clinical trials has been an exciting experience," says Dominic Behan, who founded Arena with two colleagues in 1997 on the basis of a novel technology for discovering molecules that modulate G-protein-coupled

receptors (GPCRs), the most popular family of drug targets. "And in general, helping the company to reach its present position, where we have more than 300 employees, from this starting point, and creating a work environment that is attractive to these employees, has been very satisfying."

For Behan, several experiences have been particularly important in making it this far. "First, I received fantastic mentorship and exposure to basic research at Reading University in the UK, and later at the Salk Institute in San Diego," he recalls. "I was then involved early on at Neurocrine Biosciences, where I saw the application of research and funding efforts that transformed the company from a start-up to an established biotech."

This early exposure, and the experience of the Arena co-founder and CEO Jack Lief, have been invaluable in making it through the multiple financing steps to take the company from conception to a mid-stage biotech organization, says Behan. And on the research side, he considers that striking the right balance between pushing forward later-stage drug candidates and being able to fund future innovations has been

crucial. "I've seen a lot of companies neglect their early-stage pipeline, sometimes eliminating it altogether to fund later-stage opportunities. In biotech, this is incredibly risky because of the high failure rates," he highlights. "I think you must maintain the ability to innovate in order to build a strong and successful company. At Arena, we have a number of research programmes to sustain our broad and diverse pipeline of drug candidates, and we've done this by maintaining a longer-term view, and at times making difficult decisions in prioritizing our efforts."

Another challenge inherent in building a company is putting infrastructure and processes in place to support hundreds of employees, and doing it without creating more bureaucracy. "We don't want to hinder the ability to interact as a company and work together to achieve a common goal," says Behan. "The most valuable lesson I've learned that I would like to share is the importance of perseverance. In this business especially there are a lot of disappointments and you can't let them affect your outlook and primary goal. You have to stay focused on your goal, and keep your feet firmly rooted to the ground."