Key Elements to a Successful Spin-out

A Real Life Case Study

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Background

• I joined Isis Innovation Ltd in 2005
• I inherited around 40 projects
• One of them was focused on an organ preservation technology
• The academics concerned were a transplant surgeon (Prof. Peter Friend) and a biomedical engineer (Prof. Constantin Coussios)
• A patent had been filed whilst they had been at Cambridge University in 1999 and this had been assigned to Isis in 2004 when they moved to Oxford
The Technology & Market

- A method of preserving organs outside body prior to transplant (auto-regulation)
- Autoregulation works by monitoring output pressures and flows in order to regulate input pressures and flows to an organ
- Exemplified using porcine liver model and an early prototype machine – around 200 perfusions
- Platform (but not broad platform) technology
- Market need – 12,000 liver transplants in EU and US combined annually
- However, 30,000 on the waiting list and growing
- Around 15% die on the waiting list each year
Current clinical practice consists of the use of a polystyrene box and a cold preserving solution

Only have 8 – 12 hours from donor to recipient and is therefore an unplanned emergency procedure

Organ viability is determined solely by visual inspection

Marginal organs (fatty and from DCD) are discarded

Use of some marginal organs could double the supply of livers for transplantation
The Technology & Market

• The OrganOx technology works as follows:
  o The device is pre-primed with oxygenated whole blood and nutrients at 37 degrees Celsius (normothermic)
  o Three main vessels and bile duct of the liver are cannulated
  o The liver is connected into the device
  o Perfusion of liver is fully automated for up to 24 hours
  o On-board oxygen concentrator therefore no gas cylinder required
  o Graphic user interface displays, pO2, pCO2, base excess and bile production
  o The device is fully portable with an independent power supply

• Objective assessment of organ viability
• Planned procedure for the surgeon
• Use of fatty and DCD derived livers
Barrier (Dilemma) 1

Licence or Spin-Out?
The case for Licensing

- Existing companies for preservation of kidneys (Waters Medical & LifeLine Scientific Inc.) and hearts (Transmedics Inc.)
- Why reinvent the wheel, this technology is perfect product line extension material for an existing player in this market – capitalise on existing infrastructure
- Although the patent is platform (it can be applied to other organs) it is not “broad platform”
- The potential licensee could work with the academics via a Sponsored Research Agreement to develop the technology
The Case for Spinning Out

- Existing players geographically remote to Oxford, UK
- Greater control over development and subsequent sales and marketing activities
- Good opportunity for an exit via trade sale
- Opportunity for greater equity returns upon exit compared to royalties under a licence
- The academics wanted a spin-out because they were jealous that some of their colleagues already had one!!!
Licence or Spin-Out

• So..... We agreed we would try both in parallel and see which route won...

• I would contact existing players and sell technology to them

• I would also start pulling together a rudimentary business plan and use this to embark on.......
Barrier 2

Finding the Right CEO
Finding the Right CEO

What we were looking for:

- Technical knowledge of organ transplantation / blood processing / medical device development
  - Technology in the early stages of development
- Proven ability to build and sell a business case to investors
  - Raised capital before and delivered
- Financially self-sufficient whilst fund-raising
  - No salary until the company is financed
- Had worked in a small company environment
  - Able to make own cup of tea!!!
- Can work with the founders!!!
  - Founders very choosy about who they wished to work with
Finding the Right CEO

We sourced potential CEO’s in three main ways:

• Using recruitment agencies
  o With payment upon contingency of spin-out becoming financed

• Using local networks such as OBN
  o Word of mouth within the local business community

• Oxford attracts business leaders
  o Enquiries were made to Isis frequently by potential CEO’s

We interviewed around 30 candidates over a period of around 9 months without success…..
Meanwhile...

In my parallel pursuit of a licence deal....

- CDA’s in place two companies
- With one of these companies had held two technical meetings
- At term sheet stage with a proposal of key financial terms for an exclusive licence
- But discussions were proceeding very slowly and difficult to judge level of commitment
Finding the Right CEO

• One day a colleague at Isis received a speculative email with a CV attached
• On paper he looked ideal, so I contacted him and we met and subsequently he met the founders
• In March 2007 Dr. Les Russell became our CEO designate and he started to create a full and detailed business plan
• To support Les I raised £10K of Seed Funding to pay for the business plan so that we could embark on......
Barrier 3

Finding & Raising Capital
Finding & Raising Capital

The essentials:

• A justifiable and defendable business case BEFORE speaking with potential investors
• Gather the data, build the case then pitch
• Establish how much is required to reach value inflexion point AND have time to raise subsequent round(s) of investment
• For OrganOx this was to build a Prototype device – to have something tangible to show for the investment and upon which to raise more capital
• £1.5M required
Meanwhile...

In my parallel pursuit of a licence deal....

- Despite repeated attempts to continue discussions with our most promising potential licensee we continued to get no response
- In hindsight we realised that this company was probably trying to obtain as much information as possible and never really was genuinely interested in taking a licence
- All discussions were under CDA AND we never imparted our know-how to the company
- We knew we were now focused on the spin-out route — it was spin-out or bust!!!
Finding & Raising Capital

• Soon became clear that capital would be required from more than one investor
• Initial discussions led to two investors offering £500K each
• An investment term sheet was tabled and a pre-money valuation of £1.5M was agreed
• A further £500K being raised was a condition
• It was important to identify a “lead investor” that would represent the consortium to avoid negotiations going round and round in circles
• Discussions began to focus on transferring the IPR...
Barrier 4

Transferring the IPR
Transferring the IPR

The Oxford model for spin-outs is as follows:

• **Equity:**
  - 50% to Founders collectively
  - 50% to University
  - CEO could be awarded between 5-10% founding equity diluting both the University and Founders equally pre-money
  - Investment event occurs and dilution is dependent upon agreed valuation

• **IPR / Royalties**
  - IPR is usually licensed exclusively to the spin-out
  - IPR is not licensed in exchange for equity therefore licence is on commercial terms
  - There are usually several parties whom only benefit through the licensing route (funders of research, inventors that are not founders)
Transferring the IPR

The key following issues arose during negotiation:

• The Investors accused the University of “double dipping”
  o The result was that the royalty terms were reduced from those that would be levied under a stand-alone licence deal and there were no pre-sales milestone payments

• The Investors wanted the spin-out to own the IPR (i.e. have it assigned) rather than have a licence
  o We were able to agree a trigger for assignment of IPR based on future financial stability of the spin-out

• Which leads me to my final general barrier....
Constant Barrier

Keeping Everybody Happy
Keeping Everybody Happy

Throughout the entire process one of the biggest challenges is keeping all parties aligned

• The Founders
  - valuation is fundamental because typically they are not investing, they have ongoing research projects also requiring their attention

• The CEO
  - doesn’t get paid until company is financed and founding equity affected by valuation, how long can he/she hold on

• The Investors
  - The lower the valuation the better, continually distracted by other investment opportunities and continually assessing commitment of Founders and CEO

• The University / Technology Transfer Office
  - Information rights, dilution, ongoing patent costs, any reputational issues
Keeping Everybody Happy

• The most vulnerable person is the CEO
• My role was to support him as best as possible, he was the only one not receiving any salary and was most at risk of coming away with nothing
• During the fundraising process one investor that had done detailed due diligence decided to pull out without giving any clear reason
• It was a tough job to reassure the other investors to stay on board and help attract the remaining cash required to close the investment round
Keeping Everybody Happy

- In the end it took 18 months from bringing the CEO designate on board to closing the £1.5M investment round.
- We did not achieve the pre-money valuation of £1.5M... At the 11th hour the investors dropped their offer and lowered it to £1M... This was shortly after the 2008 stock market crash!..
- The tough part was keeping the founders happy and we solved this by issuing further options to them which would vest against specific technical milestones.
- This is a story with a happy ending....
Everybody Happy!...
Where we are today

- CEO raised a subsequent round of £2.75M in February 2011
- I joined the company as Operations Director in June 2011
- We are building two clinical trial devices currently
- Apply for MHRA approval in Feb 2012
- Commence clinical trial at KCL in April 2012
- Further trials planned at key centres to commence Q4 2012
- First sales in 2013
Thank You