

Will Colon, Oxford Biosensors

The Multisense Strip

Will Colon is the Business Development Director of Oxford Biosensors, who now operate out of the Oxford Industrial Park, in purpose-built premises which cover 15,000 square feet, including two laboratories and working space for more than forty employees.

The company's main product is a hand-held cardiac diagnostic device, which was, Will Colon says, the brainchild of Oxford professor Allen Hill.

"He holds several patents for the electrochemical detection of glucose, and about twenty years ago the company Medisense was founded on the basis of these patents. Allen was curious about why electro-chemistry had never gone beyond the detection of glucose. There seemed to be so much more that could be done. So he began to think about a system which could detect other analytes beside glucose, and he concluded you would need quite a fast system, and a method for isolating the analyte-specific reaction on a low-cost technology strip."

With colleagues from the material sciences, Professor Peter Dobson and Peter Leigh – both interested in nanotechnology – and biochemist Luet Lok Wong, Allen Hill thought about the configuration needed for a strip which could run several analyte tests simultaneously, and be simple enough to use outside a laboratory.

In 2000, beginning with seed capital of \$1 million from venture capital funding, and with Isis Innovation assisting, Oxford Biosensors was set up. "Neil Butler was the company's first employee, and its MD. With nothing there, he took the ideas from the research already done, and started to give the company physical shape. He went to the Begbroke site, and rented the first building, which was then a disused chicken coop."

In November 2002, a second financing round of \$6 million was secured. It was mainly through venture capital and private equity funding, but included contributions from Mitsui, in Japan, and a large US investor. ("That's why I tend to speak in dollar terms, rather than pounds", Will Colon explains. "Also, we think of the US as our largest potential market.") On top of this initial total of \$7 million, the company received a Smart Award of approximately £ 150,000 GBP disbursed over 2001-2003. In November 2003, they moved to their present building. A mezzanine funding round in May, 2004, open to existing investors, raised a further \$2 million.

There are five executive directors, including a recently appointed managing director, Dr David Hawksworth. Peter Dobson, Peter Leigh and Luet Lok Wong are members of the Sensors Advisory Board chaired by Allen Hill. There is also a Medical Advisory Board, chaired by Professor James Shepherd from Glasgow University.

"How to roll out our battery of different tests?"

The company research and development continues both to develop new techniques to estimate cardiac risk and to develop other tests for the platform technology. The company expects to have both CE and FDA approvals in 2005 for the cardiac risk test, with other tests to follow on.

"The cardiac test looks at total cholesterol, HDL (high-density lipids) cholesterol, LDL (low-density lipids) cholesterol and triglycerides. What we have been able to do, which is unique, is to develop a low-cost method for putting multiple tests on the same strip. And the reagents on the strips are dry, not wet. This makes storage easier, because liquids tend to require refrigeration. The strip is read by a hand-held meter, with four electrodes, one for each test being run. A single drop of blood is applied on the target area, which is a membrane where the whole blood is separated into plasma, and the plasma reaction takes place there on the electrode surface."

The results appear on a small screen in the same hand-held meter. The strips themselves are printed out as small cards, about 128 to the size of an A4 sheet.

Eventually, comparable multi-analyte testing could be used for screening in many other fields, such as estimating renal risk in pre-dialysis situations. But testing for lipids, which can lead to hardening of the arteries, remains the largest potential market, because it is linked with large scale use of the lipid lowering drugs known as statins.

"The statins market is huge; I think it's the largest class of drugs on the planet – about \$20 billion dollars. And in the UK, Johnson & Johnson has been granted the licence to take this product over the counter – you can submit a questionnaire to the pharmacist and buy a statin drug off the shelf. In the United States, it is quite possible that once they have a more available form of cholesterol testing, they will most likely take a statin drug over the counter, too. All this means we feel we're operating in the right space."

The aim of the company is to get their user-friendly biosensors into every GP's surgery, and later perhaps into chemists' shops for over-the-counter diagnoses.

"Current tests in Britain involve a blood sample being labelled and sent to a central laboratory. Our point-of-care diagnosis, which can give lab-quality results almost instantly, by-passes that whole circuit. It is a much simpler process, and if you have a simpler process, there's a lower likelihood of mistakes. The doctor can take the drop of blood from your finger, apply it to the test strip, get the results in a minute, and then have a chat with you about it. It shortens the feed back cycle, which is helpful in health care."

How does the company protect its IP?

"Herb Askew is our Director of IP and Licensing, and he now has an assistant. As the technology has transferred from Research to Development to Manufacture, we have worked to capture the intellectual property and know-how. The design and production of the strip is clearly an area that forms part of our core IP. We can contract the electronics out without losing much of value from our organisation.

And patents? We've got 20 patent applications currently, 7 of which have been granted, and others which we control. We also have 4 trademarks. We have developed our own robust IP portfolio which adds significant value to the organisation."

Bringing a product to market?

"Although we are not into sales for the cardiac risk test yet," Will Colon explains. "We are expecting clinical trials and approvals in 2005 for both Europe and the US, which is very exciting."

He explains why it can take so long from theory to marketable product. "We have a multiple analyte strip, so development on each analyte is required."

So the research team remains highly important, even while different expertise is being brought to bear on the product.

"The rest of the organisation has to complement the research. When you start getting a product out of R and into D, you start doing a lot more documentation, and that's driven by a quality system. When you begin manufacture, you bring in technical expertise. We have brought in additional engineering, quality and documentation expertise.

As the product has been transferred to manufacturing, the development teams have been involved in less and less of the manufacturing process. Until finally, it's all documented, all repeatable, and manufacturing all goes through in lock-step fashion and the research expertise is deployed on other projects."

The specific regulatory system for any kind of healthcare product, which can vary from country to country, is another challenge for a biosensor company, Will Colon explains. "There can be different agencies, each with its own process. You have to develop a body of information and submit it to

show three things: that your method is safe to use, that it is efficacious, and that it has tolerance within allowable limits in a laboratory setting. You have to test among patients with and without the specific conditions, and you have to find the required number of each kind of patient to fulfil your necessary sample size."

And there are other complications.

"In Britain, for example, the whole reimbursement structure is difficult to get a hold on. It's shifting to a Primary Trust Care structure, and each of these PCTs owns the budget for all delivery of health care in its area. Different power struggles can go on, between the doctors, the reimbursement specialists, and the administration, and all these groups can command different levels of purchasing! It's less and less clear how cholesterol testing will be managed. Some PCTs will be more forward thinking than others. Some are keen for us to trial with them, some not."

The future

Will says that as Business Development Director his role is to build an awareness of the company, and to try to identify a beneficial partnership. A marketing partnership with a large diagnostic company could be welcome, in particular for its established distribution and selling capabilities.

"In the search for our marketing partner, we have to evaluate both smaller diagnostic companies (who have tended to drive point-of-care testing), as well as larger companies (that tend to have a strong focus on laboratories). In the end however, cardiovascular disease, and testing for it, is one of the huge public health issues of today. I think it's going to be an interesting couple of years."

Biosensors' story so far shows how the line from research into development can stretch out, and how the final product may require time and persistence.

Christine Holmes and Douglas Hague, November, 2004