



Company leader in cancer research

Many biotechnology companies have failed to live up to promises made to investors, but Pacific Edge Biotechnology is boxing above its weight on the international stage, leading the world in developing prognostic and diagnostic tools for detecting and tracking certain cancers. Business reporter NEAL WALLACE profiles the small Dunedin company.

THE UNIVERSITY of California Los Angeles lecturer was aghast.

How can a bunch of scientists from a little-known university in a little-known country, she asked, be leading

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her colleagues in the battle with cancer?

The lecturer had just sat through an address by David Darling, the chief executive of the upstart Dunedin biotechnology company Pacific Edge Biotechnology (PEBL), and was astounded at the company was leading the world.

Mr Darling told her that he could not answer her question, but casually mentioned the names of US cancer research heavyweights who would verify PEBL's work in developing tests to discover and monitor certain cancers.

Last month, PEBL achieved a milestone when it signed a licensing agreement with German company Signature Diagnostics for a multi-gene assay for predicting the progression of patients with early stage colorectal cancer.

It could earn the company millions of dollars a year when operating in 18 months — and it is just one strain of cancer the company is searching for diagnostic or prognostic tools.

The deal is significant because Signature will retrospectively validate the test, commercially develop, register, market and sell it throughout Europe.

PEBL chairman Trevor Scott said the deal provided credibility and, with another licensing agreement nearing the home straight, it was perfect timing.

It had made it easier to draw the attention of international funders.

"We need two or three deals. It is not the money, but it will ensure we stay alive while we go through the validation period."

It also signals one other significant difference with other biotechnology companies.

PEBL makes technology, not pills, meaning it does not require the same time-consuming and costly accreditation.

The tests have to be validated, which takes time and money, but that can be done in conjunction with partners such as Signature.

Mr Scott said PEBL would develop and validate the technology, but taking it from the laboratory to a desk-top product would be left to licensed partners who would make milestone, then royalty, payments.

"They will throw enough dough to make it desk friendly rather than laboratory friendly," he said.

While it has taken five years to get to this point, it has been relatively quick and cheap.

In 2004, \$US14.7 billion was spent globally on cancer research. PEBL has spent \$10 million over five years developing its diagnostic tools.

Last month's licensing announcement drew the



interest of Warehouse founder Stephen Tindall, who bought 7.9% of the company.

PEBL's story started well before the company was formed in 2001, by a group of University of Otago biochemistry scientists, with a theory they were progressing through funding from the Health Research Council of New Zealand.

It had funded research to find the technology to trawl through tens of thousands of genes to find those that reacted to different cancers and the various stages of the disease.

"Genes, or assays, are like electrical switch boards. They get switched on and off in patterns so you have to understand those patterns," Mr Darling said.

The mix of expertise allowed the scientists to find the technology to capture a point in time so the gene images could be analysed.

Businessman Roderick Deane, then chairman of the New Zealand Seed Fund, heard about their work and visited the university's cancer genetics laboratory.

He was sold and the New Zealand Seed Fund was to become a cornerstone shareholder.

Prof Tony Reeve, of the University of Otago Biochemistry Department and a PEBL director, puts the company's success down in part to serendipity, in part the scientific attraction of cancer genetics and in part that meeting between Mr Deane and scientists.

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"He realised the potential if you could harness the talent in a biotechnology company," said Prof Reeve.

The concept they were pursuing was not new and scientists around the world were following similar ideas, but by tapping into the departments of surgery, oncology and pathology at Otago university, along with Auckland surgeon Dr John McCall, they made progress.

For three years, they sought and analysed cancer tumours and information from laboratories all around the world as they developed their discovery platform.

Prof Reeves said a key was protecting their discovery.

"It's great. A lot of academics have a burning ambition to publish high-profile papers, but if your work is not protected, you shoot yourself in the foot," said Prof Reeve, who has studied cancer for 25 years.

There is now a route through which research can be commercialised where, previously, companies would not touch research that did not have patent protection.

The potential of PEBL's discoveries is enormous.

Mr Darling said each year 1.1 million people were diagnosed with colorectal cancer and if PEBL could capture even 1% of the market, the potential earnings were millions of dollars.

"It's a big deal for us. It's the first commercial licensing deal for the company and, therefore, provides strong validation."

The potential in Japan for its gastric cancer test is equally startling.

Such is the gastric cancer problem in Japan, there is a free national screening test for the 65 million Japanese aged over 40.

"It is growing as the population is ageing. It's a captive market," said Mr Darling.

PEBL's blood serum assay is still 18 months to two years from the market and the company is discussing a licence with a Japanese company.

Mr Darling said PEBL's strategy had changed from early licensing of products to retaining ownership longer so it could complete early stage clinical trials and validation.

"We realised we were leaving too much value on the table."

PEBL plans to license selected commercial territories but retain some parts of the globe for itself.

Mr Darling said the search would continue for prognostic and diagnostic tests, but PEBL now had a huge database of information to make that search easier. That database was also an asset, information that could be sold on a fee-for-service basis to other research companies.

The hard work was not over, but the German deal provided a glimpse of the promised riches.

PEBL

What is Pacific Edge Biotechnology?

- A publicly-listed company formed in 2001, based on intellectual property acquired from the University of Otago.
- Leads the world in developing simple-to-use, non-invasive diagnostic and prognostic tools for the early detection and management of selected cancers.
- Early detection and regular, easy monitoring of cancer allows it to be managed

and accurately treated so the patient has a greater chance of a cure and better quality of life.

- Employs 16 people in a laboratory at the University of Otago Centre for Innovation.
- Its tools are based on gene and protein signatures which PEBL has identified using molecular biology, gene expression, micro-array and proteomics.
- PEBL is trialling or about to trial its tools

on melanoma, gastric, bladder and colorectal cancers.

- It is working on early detection tools for endometrial and prostate cancers.
- Last month, it signed an exclusive licence with German company Signature Diagnostics which will complete validation, commercial development and registration for its test to predict early-stage colorectal cancer.



Brain power . . . Pacific Edge Biotechnology scientists, from left, Dr Paul O'Sullivan, Dr Justin Harvey, Dr Cris Felipe Alves and Dr Parry Guilford
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