

In conversation with Doug Unwin



As CEO of closely held Pacific Therapeutics, Doug Unwin owes much to a two-year course at the Westlink Innovation Network, a non-profit centre of excellence that aims to accelerate the rate of successful commercialization of scientific inventions in Western Canada. He spent eight months with a venture capital firm, eight months with the tech transfer office and eight months in a small business, including stints with the Canadian Genetic Disease Network and Neuro Discovery Inc. and eventually a stint as CEO of upstart Med BioGene, where he did a couple rounds of angel financing and structured a letter of intent for a reverse takeover of a Calgary company. Not bad for an undergraduate in biology, who sold his telecom business in 2001. In this exclusive interview with BioTuesday.ca, Mr. Unwin discusses the steps Pacific is taking to tackle idiopathic pulmonary fibrosis (IPF), a progressive scarring of the lungs that kills more people in North America than either breast cancer or prostate cancer.

Let's begin with a brief historical sketch of Pacific.

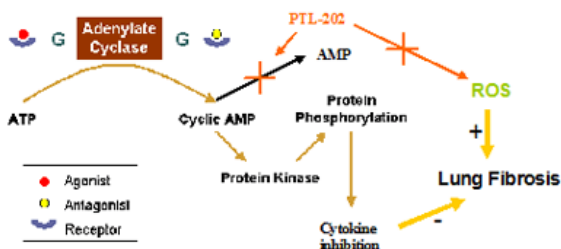
We were created in September 2005 as a virtual company, with no intention of owning our own labs, and began looking for technology in an unmet market niche. By 2007, we had settled on IPF. The original technology came from the University of British Columbia. We did some work on their product, but it was very difficult to make the peptides, so we abandoned the project within the first year or so. However, I was hooked on IPF and went looking for backup technology and licensed a combination product out of Dalhousie University. The technology, which is protected by three U.S. patents, covered the use of pentoxifylline (PTX) and vitamin E for the treatment of fibrosis. We took the product, modified it, changed some of the compounds and it's now our lead product, PTL-202.

What's in PTL-202?

It's a combination of drugs ? PTX and N-acetylcysteine (NAC) ? that have each been approved by the FDA in other indications. PTX is an oral drug used for treating symptoms of intermittent claudication, or cramping in the legs, caused by peripheral arterial disease. NAC is approved as an antidote to Tylenol in an injectable form. As a combination, we hope to inhibit the progress of lung fibrosis to prolong life. If you do that in this disease, it would be awesome. However, we don't think there's anything that's going to reduce scar tissue in the lungs once it is formed.

What's your therapeutic approach?

The combination of drugs in PTL-202 is intended stop the progression of IPF by reducing the amount of pro-fibrotic cytokines that are known to be associated with scarring. In addition, the combination has anti-oxidant properties that protect lung cells from further damage caused by the fibrosis.



There is growing evidence that PTX is an anti-inflammatory and may inhibit scarring in the lungs.

What causes IPF?

No one knows but it's probably a combination of genetic and environmental factors. In some pockets in the U.S., there is a higher incidence of the disease where they farm corn or it's dusty. Another environmental factor we've seen is with people working in microwave popcorn factories. Either, there's something in the flavouring or in the popcorn or whatever, but there's a higher incidence in this population. The mean lifespan after being diagnosed is only about 2.8 years.

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What happens is that the small air sacs in the lungs slowly fill up with scar tissue and you don't have enough oxygen going across the lungs to the blood. So you slowly suffocate over three years.sss

What's the market opportunity for IPF?

We believe it is \$2 billion (U.S.) a year based on a prevalence in the U.S. and Europe of 200,000 patients, of which only 60% are diagnosed. And of those 120,000 patients, 40,000 will die each year.

What's the clinical status of PTL-202?

When we licensed the technology from Dalhousie, the drug combination had been shown to be effective in two proof-of-principle Phase 2 trials in a disease known as radiation-induced fibrosis. We took one of the compounds covered by the license, PTX, and combined it with a powerful anti-oxidant, and conducted experiments in a mouse model of pulmonary fibrosis. These experiments showed that the combination was more effective than either of its components at reducing indicators of fibrosis in the mouse lung. We've had discussions with the FDA and they're not interested in seeing us do any further preclinical work and the next step would be a drug-drug interaction study, which is more of a Phase 1 trial in humans. Our goal is to conduct the study in 2010 and follow it with a two-year Phase 2 trial. We need around \$15 million to do our Phase 1 and Phase 2 trials over the next three years.



GLOBAL HEALTH VENTURES

[Editor's note: After speaking with Mr. Unwin, Pacific signed a letter of intent with Global Health Ventures (OTCBB: GHLV) of Vancouver to jointly develop PTL-202. Under the accord, Pacific would receive an upfront fee, milestone payments for key clinical and regulatory achievements, and royalties on potential future sales. Details weren't disclosed. The LOI is an exciting validation of our technology and strategy, Mr. Unwin said in a statement. Global Health Ventures focus on reformulation and drug delivery, and combined with their expertise in allergy, inflammation and clinical development, makes them an ideal partner for the co-development of PTL-202. Global Health CEO Dr. Hassan Salari added that PTL-202 represents a novel approach to the treatment of fibrosis and other lung diseases, and one that may provide significant advantages over the use of steroids that are known for their limited effectiveness and adverse events.]

Any plans to go public?

If someone came along and said we'd give you the \$15 million but you have to merge into a shell, we'd be flexible enough to go where the money is.

Who are the controlling shareholders in Pacific?

I am a controlling shareholder by virtue of our founder shares. And there is one other large outside shareholder, a high net worth individual.

What else does Pacific have in development?

Our other product candidate is PTL-303. It's also a combination of drugs that have been approved for use in Japan and Korea. The combination includes a cytokine modifier and anti-oxidant and is being targeted for liver fibrosis. But it's very early-stage, and we're not moving forward until money is available.

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Douglas H. Unwin

Title:
President & CEO Pacific Therapeutics Ltd.

Born:
September 14, 1956 in Vancouver, B.C.

Education:
University of British Columbia, B.Sc. Biology; University Of Saskatchewan, MBA

Career Highlights:
CEO, Med BioGene Inc.; Associate, Neuro Discovery Inc.; Associate, Canadian Genetic Diseases Network; Associate, TRIUMF Technology Transfer Office; CEO, Computer Telephone Integrators Inc.; CEO, Coastal Telephone Inc.; President, DMA Aquaculture Ltd.; VP Finance, Seagroup Financial VCC Ltd.