

Biotech Daily's CEO interview

19 April 2007

METABOLIC'S DR ROLAND SCOLLAY WON'T LOOK BACK

HAVING SURVIVED the fall-out from the failed phase IIb trial of AOD9604 for obesity, Metabolic's chief executive officer Dr Roland Scollay is wasting no time in developing the rest of his company's pipeline and looking for new candidates.

The Surrey-born, Canberra-raised Dr Scollay holds a Ph D in immunology and cell biology from the Australian National University. At 59 he has no plans to retire and believes he has the confidence of his board.

While some observers have said they were always dubious of the obesity drug, Dr Scollay told Biotech Daily that he would not have taken the job as CEO in February 2005 if he didn't believe the drug had potential.

AOD9604 was developed at Monash University and Metabolic was created around it by Circadian in 1998. Dr Scollay was appointed to the board in 2002 as a nominee of Monash University, where he was head of commercialization for the Medicine Faculty.

A previous phase IIb in late 2004 gave controversial results but he believed the drug had potential and the company undertook "a larger different trial using different doses and a different exercise and diet regime".

It was designed as "a mini-phase III" thereby effectively saving \$100 million and several years work if a complete phase III had gone ahead and failed.

Dr Scollay noted the irony that the diet non-compliant group seemed to have some benefit from the drug, but the US Food and Drug Administration won't support trials for people who do not comply with the mandatory exercise and diet regime.

Dr Scollay wants to move on from AOD9604 for obesity and is phlegmatic about the residual intellectual property.

"It might not currently be worth much, but if it were passed on there may be some downstream royalties," Dr Scollay said. "But that's a relatively unlikely event and we're not spending much effort on it."

What he is spending much effort on is ACV1 for neuropathic pain and the failed obesity compound AOD9604 for two other key uses.

Dr Scollay says existing drugs for neuropathic pain caused by physical injury, herpes, diabetes, chemotherapy and sciatica are only effective with about 30 percent of patients.

ACV1 developed by the University of Melbourne's Prof Bruce Livett, from the toxin of the cone snail, *Conus victoriae*, found near Broome, Western Australia, is in two phase IIa trials: a cross-over trial for 40 patients with sciatica with results due by July 2007; and a standard parallel trial of 30 patients with shingles and 30 patients or diabetes with results due by March 2008.

The safety and tolerability trials may show some efficacy and the most promising of the three indications will go to a phase IIb trial once the data is finalized, probably in mid-2008.

And this is where AOD9604 lives to fight another day. Dr Scollay says it is a peptide which "is intrinsically orally available" and an understanding of why this is so has led to a platform for making other peptide drugs orally available.

“ACV1 is in the clinic as an injectable, but animal models using rats and mice have clearly shown it can be made orally available with similar onset and duration times,” Dr Scollay says.

Metabolic has extended the ACV1 peptide sequence using part of the AOD9604 compound.

“If this technology applies to more peptide drugs than ACV1, then it is potentially very valuable,” Dr Scollay says.

He says there is a “massive \$US60 billion worth of peptide drugs sold every year” most of which are injected.

“There are about 1000 peptide drugs in development, mostly in injectable forms and dozens of biotechs developing peptides drugs, many of which are limited commercially by the need to be injected. Even a small percentage would make this platform an important value driver for the company.

“The core of the technology is extending the peptide sequence. We’ve taken part of AOD9604 and added it to ACV1.

“The market potential is very large.”

Also in the pipeline is AOD9604 for osteoporosis and a phase II study is being considered for later in 2007.

A preclinical collaboration is underway with Neuren on neuron-regenerative peptides for protection against nerve damage during chemotherapy.

Metabolic is also developing a group of compounds known as ADD for diabetes and is “actively seeking later stage pre-clinical or early clinical drugs to replenish the pipeline after the loss of AOD9604 for obesity” Dr Scollay said.

He says that with \$23 million in cash and a burn rate of \$4 million a year, “there’s no need to raise capital” even including the costs associated with the ongoing trials.

“We spent two years building the company back up after the last one (the 2004 controversial trial) and we’re clearly disappointed this trial was unsuccessful.

“So we have work ahead of us to rebuild market confidence in the pipeline.

“But inside the company we’re very excited by the existing pipeline.”

Metabolic was up 0.5 cents or 3.57 percent to 14.5 cents with 3.4 million shares traded.