



Biotech Daily's CEO interview

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PEPLIN'S TOM WIGGANS: THIS ISN'T CANCER, ANYMORE, TOTO

Tom Wiggans may be new to Peplin and Australia as a chief executive officer, but he has spent his life in the pharmaceutical industry crossing paths with innovative Australians.

Born and raised in the Kansas small-town Fredonia, Tom studied Pharmacy for five years at the University of Kansas. His first Pharmacy teacher was Prof Val Stella a Melburnian who had moved from Oz to Kansas. Tom winces at the Wizard of Oz reference: in Kansas it is a standing joke, but locals wonder when the world will move on.

By the end of the course Tom said he knew "I don't want to work in a pharmacy, but I do want to work in the pharmaceutical industry". The assistant dean at the University of Kansas told him to "go get and MBA". An Eli Lilly representative came to the campus, Tom said he was going to do an MBA and wanted to work for the company and the representative said: "Do the MBA and we'll hire you". He did (at the Southern Methodist University in Dallas Texas) and they did.

His first job was selling antibiotics in Florida. The job entailed wearing out shoe leather visiting doctors and hospitals and he learnt an important lesson – the harder he worked and the more times he saw the doctors, the greater the sales. He was in Florida for two years, worked in marketing at the company's headquarters in Indianapolis for two years before being recruited to the Serono Group in Boston in 1980 as marketing manager.

When Tom Wiggans arrived at Serono sales were about \$US1 million a year and he made the decision to make a mark at Serono, rather than coast along not making an impact at Eli Lilly.

In many ways Tom Wiggans epitomizes the American Protestant work ethic. At 56 he is enthusiastic, buoyant and on the move. The fact that he has run major companies is no reason to rest on his laurels. He is available, friendly and more than happy to spruik Peplin's skin cancer treatment PEP005 (ingenol mebutate) at any time.

He reorganized Serono which at that time was based on diagnostic tests with about \$200,000 a year in sales of hormone replacement treatments. He spun out the diagnostics and over the next 10 years built the company into a \$100 million a year in vitro fertilization business.

His path crossed with a second influential Australian, Prof Alan Trouson who, with the Monash IVF team, was rapidly increasing his Australia-US frequent flyer points.

“Thanks to the Australians making it a very effective technique. It was a wonderful business because you were able to make a real difference, like a miracle,” Tom says.

He ran the Serono London office from 1990 to 1992, before setting up Cytotherapeutics with former Johnson & Johnson researcher Dr Seth Rudnick hoping to engineer cells producing dopamine to be implanted in the brain for Parkinson’s disease and implantable pancreatic cells for diabetes. He says the company was about 20 years too early.

His next move was to Connetics in California to work on Relaxin a novel therapy developed at the Howard Florey Institute in Melbourne, looking for an application for the potentially fatal scleroderma disease.

“It did not work. It was a colossal failure, a spectacular failure for an unmet medical need,” Tom says.

But it brought him into the world of dermatology. Connetics bought the Australian based Soltech acquiring the Luxiq mid-potency foam steroid for psoriasis, eczema and dermatitis.

“When we sold Connetics to Stiefel [for \$US640 million in 2006] I was looking for something to do.

“I saw [Peplin’s] phase II data and said ‘I truly believe this is a potentially a great drug for an unmet market’.

“The incidence of actinic keratosis is increasing, despite all the warnings about covering up and using sun screens, but instead of two to three months of treatment, patients apply PEP005 for two days and that’s it. So I joined the board as chairman.

“In August the board and investors decided it was time to get the ball across the line, and I was appointed chief executive officer.”

Tom Wiggans gives credit to former chief executive officer Michael Aldridge for taking the company as far as he did, but with a phase III US Food and Drug Administration approved trial and two phase II trials, there was an unmet need at Peplin.

Tom has supervised six drugs through the FDA process, two at Serono and four at Connetics. Although he didn’t personally take the drugs through the process “the people who did, reported to me”.

“I’ve seen the good the bad and the ugly of the FDA process. It’s not easy and it is suicidal to take anything for granted,” he says.

All three trials are due to report by mid 2009. The phase IIb placebo-controlled dose-ranging trial of PEP005 for actinic keratosis of the face is due before April 2009 while the phase III trial for non-face actinic keratosis and a phase IIa dose ranging trial of basal cell carcinoma are due to report before July 2009.

Tom says that 70 percent of actinic or solar keratoses are on the face due to greater exposure to the sun and Peplin is expecting to use a lower dose to treat facial lesions than non-face lesions.

He says there is “fairly conclusive evidence that some solar keratoses turn into squamous cell carcinomas”. He says the rate is debated but the general range is between one and 10 percent.

“We have three major milestones coming up. By the end of 2009 all the development work will be done in preparation for a new drug application before mid-2010 and on the market in 2011,” he says.

“We are forever indebted to Jim Aylward for wanting find out how this plant works,” Tom says.

It was Dr Aylward who took the common plant Euphorbia peplus and studied the sap that had been described for centuries for its ability to cure skin lesions. The active ingredient, ingenol mebutate, is directly cytotoxic to cancer cells disrupting the cell metabolism and causing the cell to explode and also stimulates the immune system to clean up whatever residue is left.

Tom says PEP005 is painless, easy to administer and leaves “no scarring and no discoloration”.

Asked whether the company would be seeking large pharmaceutical company partners, he smiles self-consciously and reminds Biotech Daily that he has already turned one \$US1million company into a \$100 million company.

“I know the dermatology market. There isn’t a lot of innovation. We will be launching ourselves in the US and partnering in Europe and we plan to launch the product ourselves in Australia.

“Australia has the highest incidence of skin cancer, but America has the greatest number of patients.

“I truly believe you can start a company around this product and it would just be a blast to launch it,” he says, a glint of excitement in his eyes, “to bring a unique, painless, easy to use, high patient compliant drug to market.”

Peplin had a net cash burn of \$US11,747,000 for the three months to September 30, 2008 and about \$US43.5 million in cash.

Peplin was up 1.5 cents or 5.26 percent to 30 cents.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053
email: editor@biotechdaily.com.au www.biotechdaily.com.au