Interview with Dan Brown , Managing Director, Genzyme Australia

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What impact will the recent PBS reforms have on Genzyme's operations in Australia?

Genzyme is different in terms of its focus on rare & unmet medical needs, so most of the company's products, given they are targeted therapies, are not reimbursed through the PBS, but through other government funding mechanisms. Genzyme therefore is not particularly impacted by the PBS reforms because the company brings personalized, targeted medicines to Australians, rather than more traditional prescription medicines. However, from a long-term and more indirect perspective, PBS reforms are the right move from Genzyme's standpoint, as they should free up the resources necessary to fund higher cost targeted therapies for rare disease areas. Speaking to other government initiatives which more directly impact Genzyme, the PISG, of which you are a member, is currently looking towards setting a roadmap for the industry's future.

Can you talk about the group and how you expect its outcomes to impact biotechnology in Australia?

Senator Carr's initiative to establish the PISG, and the cross-sectional membership therein, really speaks to what the industry will look like 10 to 20 years down the road. The broadly defined pharmaceutical industry is the second largest exporter in Australia, but the question of sustainability in the global context must be assessed. The PISG will help define what is important to the future, and from a biotechnology and personalized medicine standpoint, the future lies in targeted therapies which require research, biotech start-up incubation, clinical trials, and aligned tertiary education. The future of pharmaceuticals will be more about the outcomes of targeted

therapies employing a broader personalized medicine array of genetic screening, diagnostic testing, both small & large molecule therapies, and cellular and genetic therapies. Many people acknowledge that manufacturing in its current incarnation will not be the future of the Australian sector.

In terms of government support of and commitment to targeted, personalized therapies, which have the potential to be the bigger contributors in the future, and can you offer some concrete examples?

A good example is Genzyme's 2005 acquisition of Verigen, a cell therapy company with a key facility in Perth, WA, specializing in autologous human cartilage cell therapy. This innovative technology has been strongly supported by Senator Carr as well as Premier Carpenter in WA. The broader human cellular & tissue therapies (HCT) area, is an area with evolving regulation today.

It's interesting because there's a convergence where health are asking, "how do we regulate this?" while innovation and industry are asking, "how do we encourage this?

" MACI® (Matrix-induced Autologous Chondrocyte Implantation) is a relatively new, proven, third generation technology that has potential to be taken to global markets in Asia and North America. Currently, MACI is used to repair damaged joint cartilage, and is marketed in Europe and Australia. Recently, Genzyme was at a juncture deciding how to secure sustainable regulation, licensing and funding for this technology, in an environment where there is evolving rules. This is an example where involvement with Senator Carr's innovation portfolio and Premier Carpenter's state office have helped bridge the gap in terms of Human Cellular & Tissue Therapies(HCT). What Genzyme can do is partner with all levels of government by saying "this is our considerable experience with cellular therapies," and share our knowledge to help evolve policy & regulatory frameworks. Genzyme has experience in the USA with Epicel®, a cellular therapy for skin repair in burns, as well as Carticel®, a second generation cellular therapy for cartilage repair.

Cellular therapies are just one example of where, as the industry moves toward personalized medicine & targeted therapies, it must look beyond traditional manufacturing, focusing on innovation, and in a broader context ask "What does a sustainable future look like?" How does Genzyme Australia's performance compare to the company's larger portfolio?

Genzyme expects to see greater than 30% revenue growth locally this year, which compares favourably to global growth. However, these numbers merely represent a stage in time. The company's history started out with enzymes; first human, then recombinant, following CEO Henri Termeer's vision of innovating to meet rare and unmet medical needs, through an unfaltering commitment to patients. This commitment meant leading first with charitable access to therapies, then conversion to a sustainable reimbursement solution by partnering with the local governments

and payers. And that's exactly what Genzyme has done in Australia. The next question involves asking how the company can diversify to bring more therapies to different disease areas that are rare and unmet medical needs in Australia. As already mentioned, this involves personalized medicine and targeted therapies, and what Genzyme has done in Australia, similar to other countries, is diversify very quickly. This strategy of diversification will increasingly be the key to success moving forward. Genzyme cannot afford to focus solely on enzymes, however we must first secure a sustainable funding model with the Australian Government to treat all Lysosomal Storage Diseases. In the last two and a half years, Genzyme has commercialized five new products in Australia, one being the enzyme Aldurazyme®, with the remainder being targeted therapies for other areas. Genzyme has completed the Verigen acquisition to bring MACI and cellular therapies to the mainstream market. With the Australian environment changing, it makes now the right time to invest and grow. Genzyme has doubled in size in terms of headcount in Australia over the last two years, and will continue strong revenue growth by following through on its diversification plans. We hear a lot about the potential in Australia, particularly with many upstarts in the biotechnology sector, but they have been suffering due to lack of capital.

Is it really a funding issue? Are there attractive acquisition options in Genzyme's view?

It's interesting, because there are over 400 start-up biotechnology companies in Australia. All of them have good ideas – some sustainable, some not – but a lot of them run out of money because they have to commercialize too early. Given the innovation environment being nurtured by Senator Carr and the PISG, which brings biotechnology players to the table alongside a broader array of stakeholders, it brings Genzyme closer to the opportunities and to see what is out there. To give an example, Genzyme had corporate development staff at AusBio last year, and conducted over 30 assessment meetings with various Australian biopharmaceutical and diagnostics companies. Genzyme processes upwards of 200 M&A reviews annually as a global corporate development effort. There are different ways to feed into the program, but anything local requires a local champion. On this local front, Genzyme is a member of AusBio as well as being a member of the BioMelbourne network in order to stay plugged in to what good ideas are coming. There's good innovation in Australia, and in working with PISG, I'm sure there will be ways to create sustainability, because the real future is in becoming involved at the clinical trial phase for these therapies. Genzyme has invested in a local clinical trials department, supported by an established regulatory and pharmacovigilance team dedicated to bridging the trials gap and providing the necessary infrastructure to bring global trials to Australia.

Queensland and Victoria are positioning themselves as biotechnology hubs; given this, why did Genzyme choose to be situated in Sydney?

Genzyme chose Sydney for its Australian headquarters to be strategically located in proximity to many other bio-pharmaceutical and medical device companies, as it was

important to be located near talent as the company grew. In addition to the North Ryde office's proximity to the Sydney CBD, the work environment offers a daycare facility, an exercise facility available free of charge, and easy motorway or train access. These type of location considerations contribute to Genzyme's reputation amongst the world's best companies to work for, and is an added incentive when attracting the necessary talent to grow the business. In managing a growing company, how would you characterize your management stile?

Overall, I hire talented people who will share the company vision personally and own their decisions. It's about enabling processes, not process for the sake of process. The environment has been called on several occasions 'organized entrepreneurialism', but it all revolves around Genzyme's Commitment to Patients. Central to working at Genzyme is a very personal involvement and connection. People come here and see that, and that is what brings them to work every day, and that is what makes us different. Genzyme proudly celebrates its 10th anniversary of official incorporation in Australia on August 20th. In fact, we treated the first Australian Gaucher Disease patient with Ceredase® in 1992 as part of the global pivotal trial. Genzyme Australia, along with Genzyme Japan, continue to be leaders for growth in the Asia Pacific region.

We are very proud of this growth, but it all translates to treating Australian patients. Is it more easy or difficult to convince government of a problem when there is such a concentrated yet expensive need?

On one side, it may be a more compelling case study, but on the other, cost-effectiveness measures may be more challenging to meet.

How would you describe the challenge of convincing a bureaucrat, who may play an important role in ultimately getting Genzyme's treatments reimbursed, and who may not be as informed as an industry insider?

Genzyme's strategy has always focused on rare diseases and unmet medical needs requiring us to develop more niche products. At a recent meeting of Medicines Australia, I considered it a great compliment when one of my peers from a large pharmaceutical company commended Genzyme's efforts on education and corporate responsibility by saying "we all need to be more Genzyme-like." With large pharmaceutical brands, the costs are more dispersed, but so are the benefits. Sometimes, senior bureaucrats may bluntly question the value of spending hundreds of thousands of dollars on a single patient. However, when the patient benefit is so strong, the value is clear, and has a deep impact in improving & sustaining human life. Consider, for the Australian government to reimburse all Genzyme Enzyme Replacement Therapies for all Australians with Lysosomal Storage Diseases, the total funding would still be less than the cost of supporting even one large blockbuster drug. Convincing payers will always pose a challenge, as it clearly is a social discussion, but Genzyme remains committed to patients with rare diseases and unmet medical

needs, and to working with government to develop sustainable funding solutions. Genzyme Australasia is still very much in the ‘heavy lifting’ phase of its growth, but remains focused to fulfil its Commitment to Patients in the Australian market.

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