

Interview with George Varkanis, Managing Director, Celgene

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As a biopharmaceutical company, how have the PBS reforms affected Celgene?

Celgene looks at the PBS reforms more positively than negatively. As a company with a smaller product portfolio of predominantly innovative medicines in haematology and oncology, it makes sense that the government looks to cut costs in the generic area to free up funds to pay for newer, typically more expensive innovative drugs. Purely from a Celgene perspective, as a company with not a large generic portfolio, the reforms, in theory, would be considered positively. Given that the government spends a certain amount of dollars on medicines each year, if they decrease spending on older drugs and proportionately spend more on newer drugs, it's a good thing – as long as the benefit goes to the government in terms of savings. On the other side of the equation, the government intends to formulate its action plan on industry spending with the newly-created PISG. What do you expect to come out of this group? The PISG is a good initiative like others before, where the government engages industry representatives to help create a vision for the industry in the country. Like groups before it, the PISG is a good collection of industry experts who are qualified to be there, and I look forward to their findings. I hope the government ultimately acts on these findings, and takes them into consideration when investigating investment into manufacturing and R&D. I'd like to think that the government won't shy away from the real reasons why companies invest in certain countries, and this has to do particularly with financial incentives. Why is there a big pharmaceutical industry in Ireland, Singapore, or Puerto Rico? It's quite a

consistent common theme, so let's not ignore it if we're going to be serious about putting an investigative group together. Financial incentives are what most companies look at when they're looking to establish a business, or part thereof. Yes, there needs to be a high level of people and technical capability, which are present in Australia, but it takes more than that. Australia is not a low cost country, and we need those incentives to be competitive. I don't know many companies who have set up large scale manufacturing or R&D divisions for reasons other than incentives.

Should such incentives be coordinated from a state or federal level?

Both. A federal approach is necessary, otherwise every state will want to be the best at everything, be it pharmaceuticals or any other industry. It's great that Victoria invests significantly in biotechnology, and Queensland and other states to a lesser extent, and it's OK from a small Australia start-up biotech perspective, but talking about major investments from larger multinational pharmaceutical companies, it's predominantly a federal government issue.

In 2006, you began Celgene's operations in Australia. Would you please tell us the company highlights and milestones since that time?

Globally, Celgene is one of the top 10 performing stocks on the NASDAQ over the last 10 years, so as a company Celgene has done very well internationally. The last few years have really been about establishing a global presence, on top of continued product development and the acquisition of Pharmion. This presence has involved major geographical expansion, predominantly into Europe, Asia Pacific, and Japan.

What role has the Australian expansion played in this strategy?

Europe is obviously the next stop after the US, with many of the next biggest countries. Australia is only 1% of the global industry, but it's a sophisticated and mature kind of market, and follows closely with the US and Europe in terms of medical practice, appearing in the top 15 for most companies. There is relevance financially, but more importantly, there is high-level R&D and clinical trials, and there are internationally renowned thought-leaders. Australia is a country that provides people in the corporate offices of major corporations, so quite often there are not only physicians but people from industry who spend time in corporate offices, proportionately a lot higher than our population.

How has Celgene taken advantage of these local strengths?

Even before Celgene Australia was formed, Australian hospitals and institutions participated in global, pivotal clinical trials. The company recognized that doing clinical trials in Australia was

important, and hence when deciding to set up the business there had been some indirect experience. There is a good level of internationally known key opinion leaders, who quite well-published. It's very rare for global studies to take place without any Australian centres, and one of Celgene's goals is to have Australia present as much as possible. Not only is it good for the corporation and delivering on larger goals, but it helps with awareness and engaging the company locally, with early access to medications, and creating early experiences to new compounds for physicians.

Although understandable given its relative youth, Celgene is not currently ranked in the country's top 50. What will it take to break into this visible list in the upcoming years?

Unlike some of the larger companies that are ranked higher, Celgene focuses on haematology and oncology, rather than having six or seven therapeutic areas with many products in each. What's important is not that Celgene is considered one of the biggest companies in Australia, which is difficult to do with a limited therapeutic focus. What's important is that in the near future, as the company launches new products like Revlimid and receives reimbursement for it, and other products like Vidaza are registered, Celgene is recognized as a company with a significant portfolio and presence that physicians want to partner and work with. One of Celgene's visions is to be the best company in the haematology and oncology space in the next few years, and we have made a good start in terms of clinical activity and making products accessible to the market prior to registration and reimbursement through compassionate programs. Commercialization of Celgene's products will also allow the company to be one of the biggest players.

You speak to the upcoming Vidaza and Revlimid approval processes. How would you rate the government in terms of efficiency to market?

Celgene's portfolio currently consists of Thalidomide, a Celgene product formerly licensed ex-US to Pharmion, to which Celgene acquired the rights post-acquisition. Thalidomide has been on the Australian market for four years, and is essentially the gold standard for treatment in relapsed refractory multiple myeloma. Thalidomide will soon move into a newly diagnosed multiple myeloma setting, and the company has an approval and is embarking on a reimbursement process. Revlimid was approved in late 2007 following an expedited review from the TGA and we are working through the reimbursement process with the PBAC, anticipating to have the drug reimbursed sometime in 2009. Vidaza is currently in the regulatory process, and Celgene anticipates approval in 2009 as well. In this relatively short space of time, the company will have three products on the market. This is in addition to a fairly deep product pipeline of other immunomodulatory agents, some of which are already in clinical development in Australia as part of a broader global program, and

there are a number of other molecules the company is researching. There are many new products in those spaces that are reimbursed on the PBS, so there is a desire by the government to approve and reimburse drugs in this area. It's not always easy to achieve reimbursement, and clinical and health economic benefits need to be demonstrated.

Looking to the future, obviously new drug releases will be important, but as Celgene continues to grow, can you talk about the importance of the human side to the company?

People are your most important asset, and that's not just a throwaway line. At Celgene, we won't just hire someone because we need to fill a position, but rather search for the best possible person for that role. I'm delighted by the management team and staff recruited since Celgene's operations have begun.

How would you characterize your management style, in going from zero to 25 employees and beyond?

Starting greenfield, you can do what you want. You've got nowhere to hide and nobody to blame, and that's the fun part in building an organization. Hopefully, you don't make too many mistakes, while fostering a culture of taking calculated risks, empowering and encouraging people, and developing teams. Many people at Celgene here and internationally have worked in different positions in Big Pharma, and can apply many of the good things they've learned in terms of processes, procedures, and best practices, when building the business here. The people joining Celgene like building things, and have an entrepreneurial spirit that's related to risk-taking.

What would we see in five or 10 years in coming back to Celgene Australia?

The company's early growth has been a necessity to get started, but will level out at 40 or 50 people; it doesn't need to be much bigger when the company is in such specific therapeutic areas. Celgene would like to be in a position with several products that are considered the gold standard. The company's immunomodulatory drugs, Thalidomide, Revlimid have shown they can be so in their disease areas. Additionally, Celgene wants to have a large clinical program, and do early phase clinical trials in Australia, more early and translational research, and collaborate with institutions. For Celgene, Australia is not just a postbox for selling drugs. The country is not just a distribution centre for registering and selling drugs; we want to expand our medical presence as well. In five years, maybe we will be doing 50 or 100 studies, and although I can't point to an exact number, Celgene will have a significant presence in both commercial and in medical areas, and be recognized by physicians as a significant company with good products and who will be a partner of choice.

What is your final message to Pharmaceutical Executive readers?

Celgene is committed to establishing a major presence in Australia and the region. It is not a short-term visit into Australia to enter the market, sell a few products and disappear. Many development projects will be undertaken, and the company will invest significantly. It's not too often that multinationals establish local operations nowadays, and there's added enthusiasm to the industry by having a new player like Celgene. To the industry as a whole, Celgene represents another interesting company, and represents a fresh option for career development, as an attractive alternative offering a new environment, new products, and a new perspective.

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