

Interview with Dr Donal Coveney, Managing Director, Topchem Pharmaceuticals

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Dr. Coveney, what motivated you to start this company?

I had been working for the multinationals for a number of years—Schering Plough, and a number of other organizations. In 1999, I reached a crossroads in my career when the company I was working for was sold to a competitor. I thought about remaining with the company; however, I decided that perhaps this was the motivation I needed to begin working for myself—something I had been thinking about for a number of years.

I took voluntary redundancy and used my own capital to start up a small consultancy firm, with some of my first clients being my former employers. In the year 2000, I started up a contract research laboratory in Dublin.

What room did you see in the market for a business of that kind?

I had done a lot of post-doctoral work in the UK and built up a network of contacts in firms such as AstraZeneca and other firms in Ireland and the UK. I'm an organic chemist by training, so I was looking for something that was in tune with my skill set. I was also surprised by how open some of my potential competitors were during my research meetings, and how helpful they were about offering advice.

Our company began trading in May of 2000 and our first customer was AstraZeneca. Around the end of 2002, we moved to our current site in Ballymount. We raised further capital through Enterprise Ireland, who have been very supportive of us from the beginning; we also got some seed

capital from other investors and began to double our sales in the first couple of years.

By 2005, our staff had reached 12 people and we were receiving a lot of our business from Schering Plough in the US. It was slightly risky, in the sense that we were relatively dependent on one large customer, while the industry as a whole was shifting towards a more centralized purchasing and procurement model and business was gravitating towards larger CROs. We found it was becoming increasingly difficult to grow the business.

During this time, a company called BioNiche, a niche injectable company with whom we had worked on a number of projects, were looking for very small volumes of API's. They had been finding difficulty in procurement because of the low quantities involved. This got me thinking, and I met with other potential customers and some potential agents in the US. I wanted to test the waters and discern whether it was wise to shift our business to low-volume API manufacturing.

We met a company called Vinchem, which was then run by Vincent Ursino and is now run by his son, Vincent Jr. They represent a number of API and dosage form manufacturers in India and Europe, and through our discussions, we found that we fit a desired niche for their company. They helped us find our first U.S. customer before we had even established our production operation. We then spoke to our shareholders and managed to raise venture capital totaling €2.5 million through Enterprise Ireland, Enterprise Equity and private investors

We began looking at suitable locations and buildings to base the company. At the time, the Celtic Tiger was still in full effect, so Dublin was an expensive location to operate in. We spoke to a number of agencies—including Enterprise Ireland and Údarás na Gaeltachta—and eventually decided that Sligo would be an ideal location to set up our operations.

We were able to rent the premises at a very modest rate and then eventually expanded into some of the vacant units on the site, while still leaving the capacity for further development, should the opportunity arise—or should we be acquired by a larger organization. We still regard ourselves as a small company: we only produced 400KG of our biggest product last year and just a couple of KG of our smallest product.

We have continued to raise money and to develop our business and we currently have 3 Drug Master files filed in the US and 1 in Canada, and this year we will be looking to file more in the US and hopefully file our first European DMF.

We typically secure exclusive supply arrangements with our customers, who tend to be large generic companies that have difficulty sourcing their desired API. Our customers are always helpful to us, in terms of funding development and even partly funding new equipment we may require.

We don't develop a product, and then look to source customers—we usually do it the other way around. A customer will come to us with a problem sourcing a product, and we will help them to solve that problem. We usually sign a supply agreement with them before we engage in any development work. However, in classical terms, I don't consider TopChem a contract manufacturing outfit, because we own the product, use our own processes, and own our IP and Drug Master file.

Our business model is such that we are very much looking for repeat customers, particularly when a product gains approval—as we are required to supply the customer and they must source from us. In that sense, we are tethered to our customer's success.

How large is the company, in terms of staff and revenue?

We currently employ 25 people, with a forecasted revenue of close to €3 Million for 2013.

We feel that we will need to expand our manufacturing capacity in the near future in order to accommodate some of our pipeline products. We have a strong management team in place, as well as having the physical space at our premises to allow us to expand on our current capacity. We feel that the demand exists and that the only outstanding issue is financing—a lot of the venture capital in Ireland doesn't flow towards the pharmaceutical industry at the moment, and is more inclined to go towards the medical device sector because the return on investment has a much shorter lead time.

Ireland seems to have few indigenous pharmaceutical producers. Is this changing? Or is TopChem still unique?

I think we are relatively unique. There are more Irish pharmaceutical service companies, and some successful packaging companies as well. However, there are only a handful of companies working in the chemical and API space in Ireland. Many of the traditional indigenous generic companies have been taken over by larger corporations.

There has been a trend in the media in recent years to claim that manufacturing in Ireland is 'over.' However, I still believe that there is potential for growth in this sector.

Are you concerned that you may not be able to secure the capital Topchem needs to expand?

Well, I'm always confident! I think what we have achieved in relation to the capital we have used is nothing short of miraculous. We had our first U.S. FDA inspection in 2009, and last October we had our first inspection by the Irish Medicines Board and we expect to get our EU GMP certificate in the

coming months. I think we can be very proud of what we have achieved so far.

Do you think you have any distinct advantages in being an Irish company in what is a very competitive API market?

The major advantage to us as a business is the people available to us in Ireland—potential employees and existing staff—and the uniqueness of their core competencies and experience.

Ireland also has very strong compliance record and is highly reputable from an ethical standpoint, which is why so many multinational companies have done well here and continue to operate here.

Are you looking to expand geographically?

Mainland Europe would be our next target, and we currently do not have further plans for expansion outside of Western markets. Our model is to produce low-volume, niche, high-value products. I think the Western markets are more likely to support those sorts of products.

If we came back to interview you in 5 years, how would you like the company to have developed in that time?

I suppose some of our shareholders may like the prospect of us being taken over by a larger company. Otherwise, we will look to grow organically or acquire a strategic partner. We also aim to double our capacity over these next five years.

Have you any advice to give budding entrepreneurs?

Stick to what you know and what you're good at. Figure out how much money you need—then double it. Then calculate how much time it will take you to achieve your immediate goals—then triple it. It can be somewhat of a 'Catch 22', whereby if you're trying to raise money, you have to be ambitious, and if you're too realistic about costs and time when applying for money, then no one will give it to you! So it is important to find the balance between those two extremes.

What motivates you?

Getting out of my car in the morning and seeing our logo on the side of our building, and reflecting on how it wouldn't be there had we not taken the initiative to start this company?

Do you have any final message for our readers?

Topchem are problem solvers for niche products!

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