Labopharm Inc. and the Science of Drug Delivery

Integrating Solutions in a Global Market

CPM talks to James Howard-Tripp, President and Chief Executive Officer of Labopharm Inc.

What brought you to Labopharm?

I joined Labopharm in March of 2000 and succeeded Don Buxton as President and CEO immediately post the Annual General Meeting (AGM) in July that same year. I had been asked to join the Board of Labopharm in the spring of the previous year and was appointed in the July AGM. The time that I had on the Board prior to joining Management allowed me an excellent opportunity to look at the company, the quality of its science, and to develop some assessments as to its future potential. I obviously liked what I saw. I believe the company has tremendous potential and a great future.

What is your background? Where did you work before Labopharm?

My background is one of having worked in multiple roles within big pharma, having started in research and development, progressed through sales and marketing, both nationally and internationally, to conclude my time in business development, mergers and acquisitions and global portfolio management. Having helped form the Canadian Health Care Licensing Association, I was persuaded by one of my fellow board members to make the move to biotechnology and joined Allelix Biopharmaceuticals Inc., to help with business development, as well as the establishment of a formal, neuroscience business. The time at Allelix was of tremendous benefit. The formation and management of small, public, high-science companies is different to the big pharma environment, and takes time to learn. At Allelix, we did some things very right and some things very wrong. Both were excellent learning experiences, and I left Allelix as President and CEO of Allelix Neuroscience Inc, and V.P. Operations of Allelix Biopharmaceuticals Inc, after we successfully merged Allelix with NPS Pharmaceuticals of Salt Lake City. It was this experience of managing small, public companies, overlaid with many years of rigorous training in big pharma, that has allowed me, together with an experienced management team, to aggressively move Labopharm down the path to what what we believe will be a fully integrated, specialty pharmaceutical company.

Labopharm Inc.

Labopharm is a specialty pharmaceutical company focused on drug delivery solutions. What can you tell us about the field of drug delivery?

The science of drug delivery is relatively new. It was only in the early seventies that big pharma companies, mostly from the perspective of product life cycle management in the face of generic competition, started focusing on drug delivery as a means of extending product life. It has evolved since then to be primarily the domain of small, innovative companies like ours, who have not only developed new scientific approaches, but have seen it as an excellent way in which to start a fully fledged, integrated pharmaceutical company.

How has the science of drug delivery evolved over the years?

The science has developed from one in which the primary focus was to improve on dosing frequency and side effects: *i.e.* transform a four-times-a-day drug into a once-a-day drug, smooth out the pharmacokinetic profile to reduce peaks and troughs and, as a result, hopefully reduce side effects, to a science which now focuses primarily on trying to maximize the most appropriate delivery in order to obtain greatest efficacy, with lowest dose, and consequently least possible incidence of adverse events. Additionally, the current state of the art of medicinal chemistry is pushing us ever further into compounds with less and less solubility, thereby increasing the need for more novel, alternative forms of delivery than are currently available. To this can be added the challenge of delivering macromolecules: *i.e.* proteins, which, unless they are absolutely life saving, are not generally well accepted in injectable form by patients. Today it is a truly exciting space in which to work.

How does the drug delivery sector differ from biotech or traditional pharma on the business end?

From a business model perspective, it has great appeal. A typical biotechnology or pharmaceutical product will take, on average, 14 years to develop from the time it is initiated on the bench to the point at which it is filed for regulatory approval. Estimates on costs to deliver a successful compound to market vary from $300 to $600 million US or higher. The risk of not achieving success is also high. At concept, each new project probably has a fraction of a per cent chance of achieving success. In the neuroscience area, at the point at which we were putting a new compound into Phase I clinical studies (and this could be after six years of pre-clinical development), our chance of having a successful product at the end was, on average, 11%. In drug delivery, because we typically start with products that already have been approved in the marketplace, these risks obviously drop significantly. In Labopharm's case, our average timeline for development of a new product: *i.e.* from initiation on the bench to the point at which we will file for regulatory approval, is typically two to three years, with a cost usually less than $10 million. The risks, although clearly not absent, are significantly less than those associated with development of a new chemical entity. The specialty pharma drug delivery companies, therefore, have an ability to bring multiple products forward within what, in drug research and development timelines, is a relatively short period of time.

Labopharm has attracted much attention of late, notably in the financial markets where it topped the TSE 300 last year. Tell us about some of the company's achievements.

We had a very good year last year. Being the top performer on the TSE 300 is not something you shoot for, it's something that simply happens. We would like to think it is indicative of the compa-

ny's ability to deliver on what it said it would, and to have the marketplace begin to understand the potential for a business model such as ours. During the year, a key achievement was the completion of the pilot pharmacokinetic studies, as well as a phase IIB efficacy study for our lead in-house product, a once-daily form of an analgesic called Tramadol. Having demonstrated efficacy, we were then able to initiate the pivotal pharmacokinetic and Phase III efficacy studies that will position us for registration in Europe as well as the U.S.. We should file our first new drug application for Tramadol in Europe in the fourth quarter of fiscal 03 (November 02/February 03). As a prelude to our filing, we have formed a wholly owned subsidiary, Labopharm Ireland Limited, to both facilitate the filing of this drug registration dossier, as well as manage market introduction in Europe. We also completed the Feasibility and the Formulation studies for two, once-daily formulations of Aventis' Allegra-D®; secured a definitive global licensing agreement with Aventis for the same product; were added to the TSE 300 capped and composite indexes; and completed a $40.4 million equity financing. We have now just completed putting the finishing touches to a four-year plan that should see us develop into an international, fully integrated specialty pharmaceutical company. This next year is one we look forward to with great promise.

Why is it important for Labopharm to become fully integrated? Can you elaborate on your plans to grow the company?

As we see the Specialty Pharmaceutical space, emerging companies evolve through three distinct phases; the technology validation and early funding phase, the high growth and skills development phase and, the company maturation/integration phase. As we map it, we are just entering the high growth and skills development phase. As 2004 is the year in which we believe we are likely to go profitable, we believe we have a two-year window in which to aggressively grow the organization, with respect to critical mass in both products and infrastructure. When we do go profitable, we not only have the best possible opportunity for sustained success, but also for achieving the level of revenue that is expected of small public companies in the biotechnology space. Analysis of the success factors within the specialty pharma area highlights both best practices, as well as pitfalls, with good examples of successful companies being Shire in the U.K., Alkermes in the U.S. and Biovail in Canada. We are hopeful that we may yet be able to join their ranks.

What are the biggest challenges you face in achieving these goals?

The challenge in achieving our goals? Much the same as for any small, public company involved in the specialty pharma/biopharmaceutical space. Products may fail, products and technology may succeed, yet partners may choose not to go forward with them. The markets may be depressed and restrict access to capital. New technologies may arise that make yours obsolete more quickly than you anticipated, any number of factors. None of which are that daunting that they preclude the majority of us from believing that we can create successful companies. I am often asked what keeps me awake at night. I would have to say it is the ability to attract and retain very talented staff, particularly those with true, international pharmaceutical experience. In Canada, we have not yet truly developed a home-grown, international pharmaceutical group of companies that trains, and then spins off, the kind of high calibre talent that the entire industry needs. We are therefore consistently trying to recruit either from the U.S. or Europe in order to meet our needs. That is likely to remain a problem for the foreseeable future. CPM