



LABOPHARM INC.

Innovative Drug Development for a Global Market

Talking with James Howard-Tripp, President and CEO, Labopharm Inc.

Please review your career path to date, leading to your appointment as President and CEO of Labopharm Inc.

My career in the pharmaceutical industry spans more than 25 years and three continents. My diverse roles in pharma have included responsibilities for research and development, manufacturing, including quality assurance and quality control, sales and sales management, marketing management at both the domestic and international level, as well as strategic planning and portfolio management. My business development activities have included acquisitions, mergers, divestitures, licensing, as well as the negotiation of co-development and co-selling agreements.

Prior to joining Labopharm Inc., I was Senior Vice-President, Operations with Allelix Biopharmaceuticals, which is now NPS Allelix and also President and CEO of its subsidiary, Allelix Neuroscience Inc. Before that, I was Vice-President, Business Development for Wyeth-Ayerst Canada Inc., with responsibility for licensing and acquisitions, new product development and health economics. I have also held positions with Miles Laboratories (now Bayer), Rouselle Uclaf (now sanofi-aventis) and G. D. Searle (now Pfizer).

**What sets
Labopharm Inc.
apart from other
pharmaceutical
companies?**

Labopharm Inc. has a novel business model. We apply our proven drug delivery technologies and development expertise to currently marketed drug compounds with proven efficacy and safety. We then reintroduce them to the market as branded products with improved deliverability and efficacy and significant commercial potential. Because we are developing improved formulations of existing drugs, our products typically require fewer clinical trials to generate the safety and efficacy data needed for approval, than compared to drug formulations that have not been previously marketed. As a result, we benefit from shorter development timelines and lower risk, compared to traditional drug developers. Our lead technology, Contramid[®], can be applied to a wide variety of drugs in a solid oral dosage form to improve oral administration and performance. Contramid[®] is the technology behind our lead product, a once-daily formulation of the analgesic tramadol, which has received regulatory approval in Europe and has been commercially launched in several countries.

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Labopharm Inc. is evolving into a fully integrated international specialty pharmaceutical company with the expertise and infrastructure to successfully advance multiple drug products through the entire development and commercialization process.

What is your key business priority at Labopharm Inc.?

Right now, our top priority is the global commercialization of our once-daily tramadol product, beginning with Europe, followed by the US and then the rest of the world. Our product has been approved under Europe's Mutual Recognition Procedure in 22 countries and launched in Germany (the second largest market for tramadol products in Europe), the Czech Republic and Slovakia. We are currently working with our partners to launch in more than 40 key markets both in Europe and around the world.

We are very excited about the European market. Last year in Europe, more than 2.3 billion individual doses of tramadol were sold, primarily in formulations that require multiple times per day dosing. This translates into sales of more than \$638 million US. And that market is growing almost 13% annually, which is impressive considering that tramadol was first launched in Europe almost 30 years ago. Importantly, some of the highest growth rates among the European countries are occurring in some of the largest markets. For example, sales in France, the largest European market for tramadol, have grown in excess of 23% on a compounded annual basis over the last five years. Sales in Germany, where we launched our product at the end of last year and in the United Kingdom (UK) (the second and third largest markets for tramadol in Europe), have grown at 11% and 16%, respectively. Clearly, as a once-a-day alternative, our product represents a significant commercial opportunity.

How is the European launch progressing?

The launch across multiple countries is always complex and the timing is somewhat uncertain due to the need to meet many regulatory requirements. Germany, where we first launched, is meeting our expectations, as well as those of our partner, HEXAL. Launches for products like our once-daily tramadol in Europe ramp up differently than what is typical in the US. In Europe, the ramp is generally a little slower, but growth tends to be steady and spreads out over a longer period of time. We are currently in the process of initiating launch in the UK and expect to initiate in Italy, France, Spain and Belgium before year end. We look forward to reporting on those in the coming months. We are very optimistic about the potential for our product in Europe. We have strong partners and we have a strong label that designates our product use in a dose range from 100 mg q.d. to 400 mg q.d. for the treatment of moderate-to-severe pain, which includes both acute and chronic conditions. Additionally, we set a benchmark for achieving effective royalty rates of 20% or better and are realizing these rates.

Who have you partnered with in Europe to market your once-daily formulation of tramadol?

We have assembled a premier group of partners that are leaders in their respective markets. We have marketing partnerships in place for 22 countries in Europe, including the five largest European markets for tramadol. These countries account for more than 90% of all tramadol sales in Europe. We have taken a market-by-market approach, partnering with those companies in each country that we believe will help to maximize the opportunity there. Our roster of partners includes:

- Grunenthal GmbH, the original developer of tramadol, for Germany, France and Belgium,
- sanofi-aventis, the market leader, also for France,
- Recordati for the UK,
- Gruppo Angelini for Italy,
- Esteve SA for Spain and Portugal and
- CSC Pharmaceuticals for 15 other countries, including Austria and Russia.

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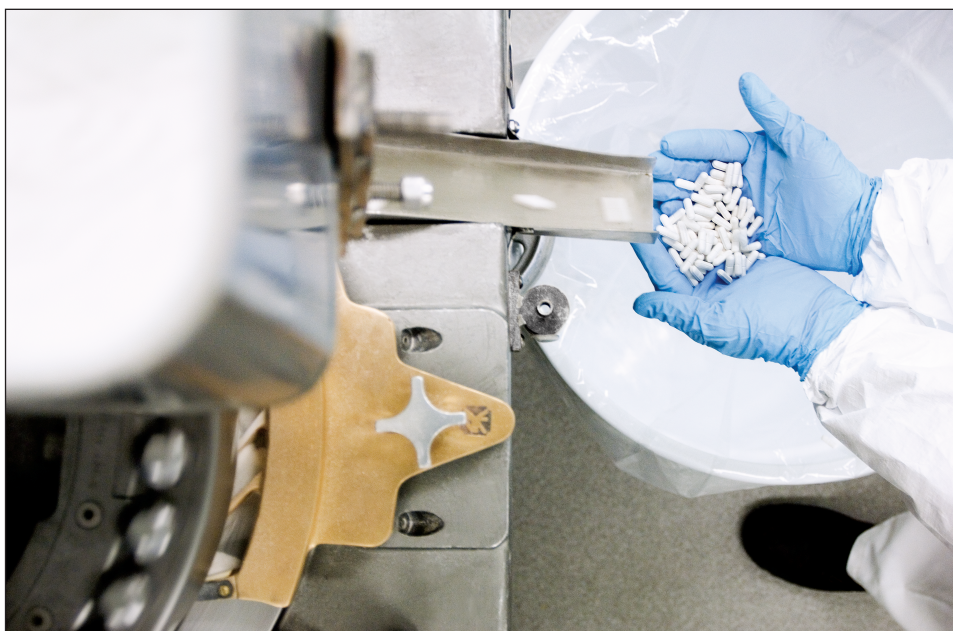


Labopharm Inc.'s once-daily tramadol product has been launched in Germany and is in the process of being launched across Europe.

When and by whom will your once-daily formulation of tramadol be marketed in North America?

In the US, we recently received an Approvable Letter for our once-daily tramadol formulation from the Food and Drug Administration (FDA). Our New Drug Application was based on data from a global clinical development program that included six Phase III clinical studies and 12 pharmacokinetic studies, in which more than 2,400 patients were treated with our product. We are currently in discussion with the FDA to identify the most appropriate course of action to obtain final regulatory approval of our product.

With a view towards the commercialization of our product in the US, last year we partnered with Purdue Pharma, the premier US marketer of long-acting pain medications. With Purdue's proven track record of success in the long-lasting pain relief market, we believe we may be able to capture a significant portion of the world's largest market for tramadol products. To give you an idea of the size of the potential US market for a once-daily tramadol product, in 2005, in excess of 20 million prescriptions were written for tramadol products in the US, all for multiple-dose products that must be taken four times to six times per day. If we apply the average pricing for Ultram® ER, the only once-daily tramadol product currently available in the US, to that prescription volume,



Labopharm applies its proven drug delivery technologies and development expertise to currently marketed drug compounds with established efficacy and safety.

we see a potential market of close to \$3 billion US. That doesn't take into account the potential to take share from both the non-steroidal anti-inflammatory drug (NSAID) and Cox-2 markets following the serious side-effect issues for some of those products and for the higher-order opioids.

The attractive terms of our agreement not only underscore the potential for the tramadol opportunity, but also our partner's commitment to the product. In addition to the up-front licensing fee of \$20 million US that we received last year, we are eligible to receive a payment of up to \$40 million US upon being granted regulatory approval for our product and further payments of up to \$110 million US upon meeting specified sales targets. Royalties will range from 20% to 25% of product sales.

Beyond Europe and the US, we have a worldwide commercialization strategy for once-daily tramadol that focuses on markets with significant opportunity. In late August 2006, our New Drug Submission was accepted for review by the Therapeutic Products Directorate of Health Canada with a targeted review period of 300 days. Tramadol is currently available in Canada and only in an immediate-release, four times to six times daily formulation that combines tramadol with acetaminophen. The Canadian market represents a significant commercial opportunity and, with an eye towards approval, we are actively engaged in establishing commercial channels for Canada. In addition, we have received regulatory approval in Mexico and secured GlaxoSmithKline (GSK) as a marketing partner for that country. GSK is also our partner for 20 countries in Latin America and the Caribbean. Other key markets that we are pursuing include:

- Japan,
- Australia,
- South Africa and
- Southeast Asia.



Labopharm's senior management team. From left to right: Sylvie Bouchard, Vice-President, Clinical Development and Regulatory Affairs; Uwe Erbrich, Vice-President, Quality Assurance; Annie Gingras, Senior Director, Project Management; James Howard-Tripp, President and Chief Executive Officer; Céline Ducharme, Director, Human Resources; Anthony C. Playle, Managing Director, Labopharm Europe Limited; Mark A. D'Souza, Chief Financial Officer, Lynda P. S. Covello, General Counsel and Corporate Secretary; Damon Smith, Vice-President, Research and Development.

What other products, both proprietary and partnered, are in your product pipeline and how far along are they in the development and commercialization process?

We have a number of other products in our pipeline based on our core Contramid® technology, several of which are in clinical development. A once-daily formulation of the antidepressant trazodone has the greatest priority. Trazodone is an atypical antidepressant that is prescribed frequently in the \$13.3 billion US antidepressant market. We have successfully completed the initial pharmacokinetic studies and are preparing to initiate a pivotal Phase III study in early 2007. Beyond trazodone, we have a number of additional products in the pain and central nervous system areas that we are actively moving forward in their development. For example, we are pursuing line extensions for our once-daily tramadol product, including combination products, using our Contramid® technology.

We are also working on a second technology to complement Contramid® called Polymeric Nano-Delivery Systems™ (PNDS™). PNDS™ is an excellent complement to Contramid®, providing us with the capabilities to deliver water-insoluble, poorly bioavailable drugs, including proteins, peptides and nucleic acids, as tablets or injections.

Our oral platform increases bioavailability and may allow for targeted delivery, which could result in the substantial improvement of a wide variety of therapeutics, particularly in oncology. It may also have the potential to improve the delivery of intravenous products by converting them to oral dosage forms. We are currently completing proof of concept on three intravenous cancer drugs that have the potential to be delivered orally.

Additionally, PNDS™ has the potential to improve the performance of existing intravenous drugs through the development of superior intravenous formulations. For example, we have completed proof of concept on an improved formulation of propofol, a widely-used anesthetic administered intravenously, using PNDS™.

Do you foresee Labopharm Inc. one day becoming a fully integrated pharmaceutical company with its own sales force, etc.?

Yes, definitely. In fact, our corporate vision is to become a fully integrated, international specialty pharmaceutical company, with the expertise and infrastructure to successfully advance multiple drug products through the entire development and commercialization process on our own. Our plan is to continuously improve our current competencies in formulation, clinical development and regulatory approval while adding sales and marketing capabilities. Our agreement with Purdue Pharma provides for the development of our own specialty sales force with the costs of hiring, training and compensating that sales force to be borne by Purdue. We look forward to taking this important next step in the evolution of our company. **CPM**