

# Pharma Braintrust

One of Canada's '50 best managed companies'  
Paladin Labs has built a business model  
of low risk and high growth  
on track to compete with the multinationals

BY MICHAEL CARIN

Just five years ago, Jonathan Goodman identified a gaping opportunity in the Canadian pharmaceutical marketplace. He has since turned that insight into a runaway success story. His public company, Paladin Labs Inc. (TSE: PLB), is tracing an impressive growth curve and reaping the reward of a soaring stock price.

"What we do," says Goodman in his Montreal head office, "is acquire the Canadian rights to innovative, niche-oriented products in late stage clinical development from small pharma and biotech companies. We then take those drugs through the Canadian regulatory process. Once the drugs are approved, we aggressively market and sell them. At the same time, as a complementary strategy, we licence products from the big multinational pharmaceutical companies. Again, these are niche products prescribed by specialist physicians, products that big pharma simply cannot bother to focus on because they are preoccupied with larger opportunities. We revitalize such brands through focused marketing and sales promotion."

**Signalling its "golden boy" allure, Paladin's performance is now analyzed for investors by CIBC World Markets, HSBC Securities, Desjardins Securities, and Yorkton Securities.**

In the U.S., there are dozens of companies that do exactly what Paladin does. In Canada, however, very few companies pursue such a strategy—and Paladin is by far the leader among them. In fact, it is one of the few pure specialists in emerging pharmaceuticals in Canada. A company like Axcan Pharma in Quebec, for example, in addition to advancing its own innovations, does what Paladin does, but Axcan is involved only in gastroenterology. Biovail is another Canadian company that takes an approach similar to Paladin's, but Biovail goes after the general practitioner and cardiologist market. Paladin is focused on the Canadian specialist sector, where it has built strong relationships with physicians in three main therapeutic areas: urology, endocrinology, and women's health. The company also has portfolios in dermatology, palliative care, and a pipeline in oncology.

The logic of the business model, combined with the high-margin environment of pharmaceutical distribution (Paladin's average gross margin is 66%, its after tax margin 20%), propelled the

## Simply Inconceivable

One of the main factors fuelling the rise in Paladin's favour among financial analysts is a drug called Plan B™. This is a "morning after" pill, taken within three days of unprotected sex or a contraceptive failure to prevent pregnancy. Obtaining the Canadian marketing rights to the product from its U.S. developer was certainly a coup for Paladin, not least because it attracted so much media attention to the company.

No one yet knows how large the market for Plan B™ will be in Canada, but a good indication might be taken from this country's abortion rate. There are approximately 115,000 abortions performed every year. The availability of Plan B™ could significantly lower that figure.

"One of our chief goals with Plan B is to increase access," says Mark Beaudet, Paladin's Vice President of Marketing and Sales. "Let's say you have a contraceptive accident on Friday night, and you can't see your doctor until Monday morning. We know that with

Plan B, if you take it within the first twenty-four hours, it's 99% effective. Taken within forty-eight hours, its average effectiveness drops to 85%. Taken on the third day it's only 56% effective. Clearly, the sooner you take it, the better. It's an emergency drug."

That fact attracted even greater media attention when doctors across the country began giving their patients open-ended, "just-in-case" prescriptions for Plan B™. Furthermore, women's associations have lobbied Health Canada to permit the product to be dispensed by pharmacists *without* a prescription, and the laws in Quebec and B.C. have already been changed to accommodate that request. In fact, upon obtaining certification, pharmacists in Quebec will be entitled to dispense Plan B™ without a prescription. In October 2001, l'Ordre des pharmaciens du Québec held mandatory training sessions for all Quebec pharmacists, of which Paladin was a proud and prominent sponsor. □



**Jonathan Goodman**  
President & CEO

Photo: Laszlo

# In Full Flight

extend patent life, my father is trying to knock them down.” Goodman’s father, of course, is industry legend Morris Goodman, founder of Pharmascience, a major player in generic pharmaceuticals in Canada.

“Rx&D is totally committed to fostering innovation in Canada,” says Jonathan Goodman. “That means Canada must continue to support sufficient duration for patents and the enforcement of patents. It means that we require an environment where innovation becomes adopted quickly and where it is not hampered by the regulatory process. It still takes drugs two to three times longer to get approved in Canada than it does in the U.S. We also have price controls in Canada. All these factors are limiting innovation.”

As if his workload were not sufficient, Goodman has also taken on high-level academic tasks at two Montreal universities. He teaches a class in entrepreneurship at Concordia, and another at McGill’s Faculty of Management entitled “Pharmaceutical Entrepreneurship.” The latter class focuses on how to take a drug from the lab to the market, and Goodman’s students range from MBAs to Ph.Ds and MD/MBAs.

Only a blind and deaf journalist would fail to report that Jonathan Goodman finds exhilaration in the dynamics of business and the wine of success. And why not? He’s exactly where he wants to be, and doing what he wants to do. In his search for products that will help build his company, he’s been to practically every country in Europe and a host of American states. With hundreds of innovative products in late-stage clinical development around the world all looking for a Canadian partner, he is not likely to rest soon. □

It’s next to impossible to book a meeting with Jonathan Goodman these days. The CEO of Paladin Labs is a young man in a hurry. If he’s not in Switzerland, New York or California prospecting for products, he’s back home explaining his company’s business model to yet another appreciative audience of investment specialists.

Goodman has also just been elected to the Board of Rx&D Canada, an association of the country’s research-based pharma companies. Sitting on the Board with him are people like the Canadian presidents of Merck, Pfizer, and Novartis. “There are fourteen such individuals,” says the 34-year old Goodman, “and then there’s me.”

Perhaps the most curious aspect of Goodman’s involvement in Rx&D concerns the association’s stance on patent rights. “We represent the antithesis of the generic industry. While we are lobbying to

**Congratulations to the Paladin Labs Inc. team for its dynamic innovations and to its continued success.**



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**Paladin has done extremely well with a competitor to Viagra®. It represents MUSE®, an alternative treatment for erectile dysfunction. MUSE® is typically taken by men who are non-responders to, or who are contra-indicated for, Viagra®.**

company's 1996 revenue of \$40,000 to over \$17 million in 2001. Today, with assets of \$40 million and over \$22 million in cash, and an auspicious pipeline of new products, the company is well placed to acquire still more promising drugs which, in turn, will generate still greater growth. Little wonder, then, that the financial analysts have been uniformly positive on Paladin's prospects, and that the market has responded with bullish enthusiasm—Paladin's share price has more than doubled in the last year.

## Gentlemen, Listen Up!

**Y**ou may not know this (statistics indicate that in fact most of you are entirely ignorant of it), but an increasing number of physicians believe that there is a male equivalent of female menopause. It's called andropause, and the condition is thought to result from the fact that as men age, their bodies produce 1% less testosterone per year. That decrease actually starts as early as the mid-thirties. Men in their late forties and early fifties who have symptoms of low energy, irritability, and decreased sex drive may require testosterone replacement.

Enter the patch. Called Androderm™, it's a once-a-day treatment that does away with injections and can be worn even during showering or strenuous activity.

Paladin Labs holds exclusive rights to Androderm™ in Canada and is understandably excited at its prospects. The testosterone replacement market in Canada has grown at an annual compounded rate of over 30% over the last four years, and it is now a \$15 million market.

"We believe this is going to be a much larger market," says Dr. Katia Betito, Paladin's Executive Director for Scientific Affairs. "In the same way that post-menopausal women take hormone replacement therapy to prevent cardiovascular disease, osteoporosis and a host of other diseases, men will increasingly be taking testosterone as they are diagnosed with low physiological androgen levels. The patch happens to be the most convenient therapy, and Androderm™ is the only patch in Canada." □

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# Bringing Innovative Products to Canada

Paladin is a company driven by marketing, and marketing is driven by business development. In Paladin's case that means product licensing: the process of identifying, evaluating and acquiring the sales and marketing rights of new drugs.

"As we obtain critical mass and grow," says David MacNaughtan, Vice President of Business Development, "we are becoming more focused and deliberate, such that we are more proactive in our approaches. We are building on what we already have: solid portfolios in urology, endocrinology, and women's health. Late stage products in development in these areas, being developed by companies around the world, come under our review. And as we become known, more companies are coming to us and asking if we'd be interested in their products."

During the last couple of years Paladin has been prolific at bringing in new products, which is indicative of the company's creative dealmaking ability. After doing a technical due diligence on a prospective drug, and evaluating its efficacy and market, the negotiations begin. "No two deals are the same," says MacNaughtan. "Each company we deal with wants something different. Some look for cash up front; others want to maximize royalties on sales. Some companies want to have a lot of input in how we market the product, while others are hands-off and look to us for the solution."

MacNaughtan has two people working for him, and CEO Jonathan Goodman also takes an active hand in negotiating and closing deals. "In business development you do not necessarily have to be an expert in any one area," says MacNaughtan, who holds an MSc in chemical engineering, as well as an MBA, "but you need a broad skill set. A background in both science and business is called for. We are involved in data evaluation, and the review of intellectual property. We have to understand markets and finance to be



**David MacNaughtan**  
Vice President  
Business Development

able to value these drugs. Then come the give and take of negotiation and the fine points of legal contracts."

In former positions, MacNaughtan had worked for Hemosol, and had done venture capital investing in early stage biotech and pharma companies with Royal Bank Capital Corp. "Paladin was one of my portfolio companies," he says, "and that's how I came to know the people and the business model."

Obviously he found it appealing. Two years ago he pulled up stakes in Toronto and moved to join Paladin in Montreal. □

## The Business Model

Paladin's success derives from the fact that it has become the partner of choice for more and more companies that need a turnkey marketing solution for Canada. This country happens to be a difficult place for foreign pharma to penetrate. Many U.S. and European companies who have come here have not fared particularly well, because they don't have a marketing presence or a relationship with the key stakeholders. What Paladin offers is a one-stop shop for Canada.

This country is an enormously complex market, with very difficult market access issues. Although only one tenth the size of the U.S., Canada is really ten different markets, since each province, and each private insurance plan, decides what drugs they will reimburse. "You have to do your homework before you go see the payers," says Goodman. "You have to know what the cost/benefit ratios are. In most of the cases where you have a compelling value proposition, you'll get onto the provincial formularies."

Moreover, before a product can even reach the provinces or be



**Samira Sakhia**  
Chief Financial Officer

"Investors have obviously taken notice. The ripple effect took hold in the last few months, when it was clear that Paladin was delivering. The ramp-up will continue because our sales have been growing, we've been in-licensing more products, and we have some late stage developments in our pipeline that will be coming to market. We expect the momentum to keep going, since we will keep delivering by relentlessly executing our strategy."



**K**atia Betito heads the four-member Scientific Affairs department at Paladin, and takes responsibility for regulatory matters, drug submissions, clinical research, compliance, and QA/QC (quality assurance, quality control).

A Ph.D. in pharmacology from McGill, Betito has over the years fostered relationships with the reviewers and chiefs of divisions at Ottawa's Therapeutic Products Directorate (TPD). She began her career at Sabex, a generic manufacturer, where she became Director of Regulatory Affairs. "I came to Paladin because I wanted to move into an innovator environment. Here I am constantly exposed to different types of innovative products."

Betito and her team are involved at the due diligence stage of Paladin's product acquisitions. They examine the data, and later place that data within the optic of regulatory scrutiny: will approval be attained? "At that point, I give my input into what we need to obtain approval. My role is to make certain that Paladin delivers the most precise documentation possible, while following every regulation to the letter." □

**Paladin Labs markets over fifty drugs in Canada. Among its products for urological diseases is Valtaxin™, an important advancement in the treatment of bladder cancer. At Health Canada, the Therapeutic Products Program gave the product priority review and approved it in less than six months. Valtaxin™ has been shown to offer patients a one in three chance to save their bladder.**

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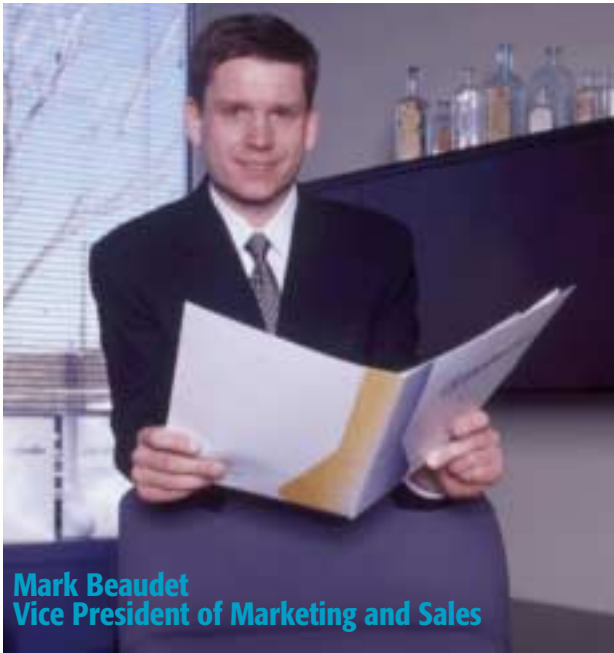
introduced to the insurance companies, it must navigate the Canadian regulatory process. Just because a drug has been approved by the FDA in the U.S. does not mean that it will ever be sold in Canada. "There may be no other sector in which Canadian sovereignty is so protected," says Goodman. "We have our own regulations and processes. The approval process here can be so costly and time-consuming that in many cases foreign companies have simply decided to forgo the Canadian market."

The team at Paladin offers such companies another option. Paladin helps take products through the regulatory process, and then becomes its partners' advocate and marketing arm in Canada. Manufacturing usually remains the responsibility of the licensor.

"We are often mistaken for a biotech company," says Goodman, "but we are most emphatically not a biotech company. What we offer is the upside of a biotech without the same risk. Right now, for example, in addition to our already extensive product line, we have Canadian rights to five products in Phase III trials. If these products succeed, Paladin will succeed. If one or two or even all of those products fail, Paladin will still go on, will still make money, will still grow. We are not burning cash like a biotech company. And we have the strength of a pharmaceutical company. We don't talk about burn rate here. We talk about cash flow." In fact, in 2001 Paladin generated over \$5.1 million from operating activities, up 242% over 2000.

Big pharma companies, some with as many as five hundred sales reps in Canada, are focused on the mass market. Paladin, with a sales team of fourteen, nurtures smaller brands, or, as Goodman puts it, "This is where we are in the food chain right now." Paladin seeks out innovative products that have a unique selling proposition—because they are superior to existing drugs in terms of safety, efficacy or cost—and which are characterized by having a small number of physicians driving a large volume of sales.

For example, Paladin represents a drug (Remodulin™) for pulmonary hypertension. There are less than a dozen physicians in Canada who write prescriptions for pulmonary hypertension. But it's a \$10 million market. That's the kind of opportunity Paladin consistently exploits. "When we enter a market we focus on the key physicians who are writing the majority of the prescriptions. With



**Mark Beaudet**  
Vice President of Marketing and Sales

Physicians in Canada are under enormous pressure. Time is one of their most precious resources. When pharmaceutical representatives sit down with a doctor, they had better bring value to the table.

"We don't run across many doctors who refuse to speak to us," says Mark Beaudet, Paladin's Vice President in charge of marketing and sales. "They know that Paladin is a worthwhile meet. It comes down to a very simple question: have you established a relationship of credibility? We have a team of sales representatives that has focused on doing so, and the results speak for themselves."

Paladin's sales team consists of fourteen people across the country primarily focused on selling the company's urology,

## Creating Value

endocrinology and women's health portfolios. These reps are often individuals who hold degrees in chemistry and pharmacology; often they're former nurses or medical students. This is essential. These reps must be able to speak to doctors with rigorous authority on the efficacy and side effects of a given drug, on when the drug should *not* be used, and on what is happening competitively.

"There are only 700 urologists in Canada, and 300 endocrinologists," says Beaudet. "Each of our reps has between two and three hundred core customers. They come to know them well, and see them on average once every six weeks."

Paladin does not market directly to the consumer, but it does promote public awareness. "For example, in connection with our emergency contraceptive product, Plan B™, we are working with groups like the Canadian Pharmacists Associations, and the Society of Obstetricians and Gynecologists. It's a collaboration to help bring awareness of the availability of emergency contraception. We also recently worked with the Quebec Pharmacists Association to support the training of all their pharmacists in emergency contraception."

There are many therapeutic areas where long lists of drugs exist to treat a given condition. The typical patient would probably be surprised to learn that drugs exist for his condition that are not available in Canada, or that his physician may never even have heard about. When Paladin brings such drugs to Canada, and acquaints Canadian doctors with them, it's performing a major public service.

"We take pride in supplying these specialist products," says Beaudet. "Specialists in turn appreciate that we are keeping such products available." □

### Paladin Labs Inc. Financial data for five years (In thousands of Canadian dollars except for share and per share amounts)

	1997	1998	1999	2000	2001
Revenues	830	6,023	11,201	12,607	17,795
Income (Loss) before write-downs of intellectual property and taxes	(4)	2,437	2,856	2,991	4,330
Net Income (Loss)	(1,006)	836	2,016	2,797	1,485
Earnings (Loss) Per Share (Basic)	(0.25)	0.13	0.22	0.24	0.12
Cash & Temporary Investments	563	8,545	9,886	24,339	22,448
Shareholders' Equity	2,390	9,886	13,830	35,769	37,836
Shares Issued (Dec 31)	3,990,659	9,057,731	9,466,338	12,394,038	12,539,247

those key physicians we can compete with any multinational. We can cover them with the same frequency."

Paladin cut its teeth on drugs that do under \$100,000 in sales. Four years ago, when the company's revenues were under \$50,000, Paladin would have jumped at a product with a \$100,000 market. There's been a lot of maturing in the interim. Analysts' expectations for Paladin is that it will do \$23 million in sales for 2002. The \$100,000 product is no longer interesting, but other companies will spring up to take it to market. "Now it's our turn to be selective," says Goodman. "We've moved up the chain."

Paladin's long term goal is to be the largest Canadian-owned innovative pharma company. As CEO Goodman puts it, "Canada today, so far as branded pharmaceuticals are concerned, is owned by foreigners: the Americans, the British, the Swiss, the Germans, and the Swedes. We do not have a company in the top twenty. Well, we want Canada to have its own innovative pharmaceutical industry and we intend to be one of those companies."

Paladin isn't there yet, of course, says Goodman, "But we are doing the things that will allow us to climb to the top of the food chain." □