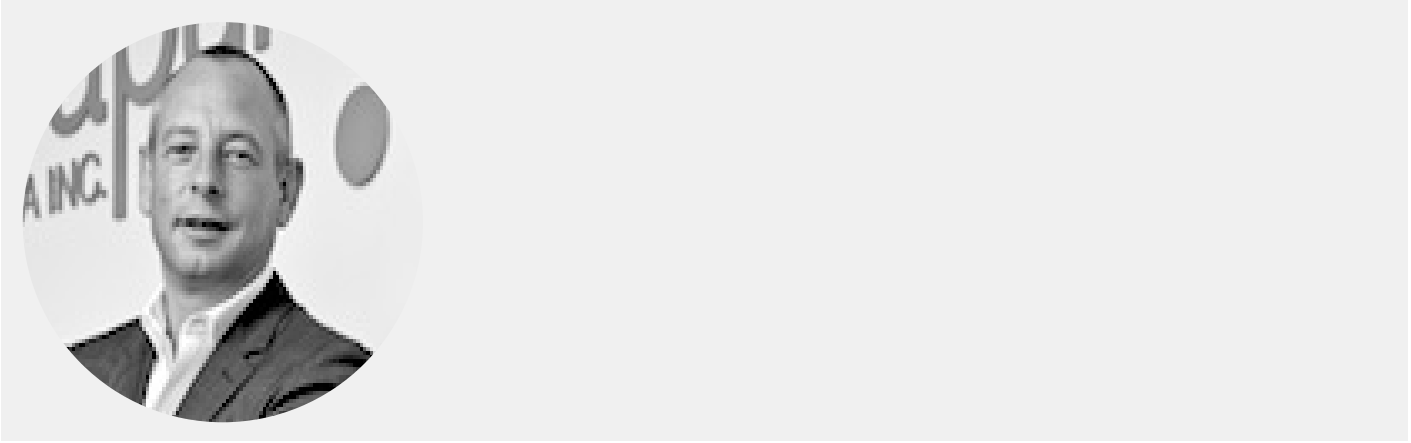
Interview: Nick Green, President and CEO, Therapure Biopharma, Canada



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Therapure President and CEO, Nick Green, speaks about the environment for contract development and manufacturing in Canada and the integrated services that Therapure can offer its global customers as a leading CDMO in the biopharmaceutical sector.

What does Canada have to offer in terms of its manufacturing strengths?

There is a wealth of talent in terms of educated local and foreign individuals with biologics experience. Therapure is truly one of the most multicultural organizations in Canada and we certainly leverage this diverse talent. Canada's proximity to the largest and most valuable markets in the world is also helpful.

There is a lot of energy in terms of intellectual horsepower in Canada, which is significant for a country of this size. Toronto is also home to a good cluster of healthcare organizations and Canada is very well represented in the pharmaceutical space with a great deal of promotion of the sector from both government and industry. Canada is also internationally recognized for its high quality standards and scientific achievements.

What initially attracted you to Therapure, and what was your initial mandate?

I was actively looking at the biologics sector in the pharmaceutical contract manufacturing space. As you can see when you visit Therapure, it is almost impossible not to be impressed with the

state-of-the-art biomanufacturing facility. As well, when you spend a little time with the people, you immediately know that there is a wealth of experience, commitment and passion residing within the organization. These two factors alone gave me great confidence that together we could grow a vibrant and global business. I was also attracted by Therapure's development pipeline consisting of a number of products in preclinical development, which addresses significant markets and unmet medical needs. I had always wanted to become more involved in drug development, therefore the combination of developing biotherapeutics and platform technology products of our own, and creating a world class contract development manufacturing organization (CDMO) in the biologics field, was frankly something I could not turn down.

One other major factor was the fact that the company was backed by Catalyst Capital Group. My initial meetings with the partners gave me a strong feeling that they were serious about creating a truly great company and that they were prepared to fund a strategy that would achieve this goal. I am pleased to say that looking back, my first impressions have been confirmed. We have built Therapure Biopharma Inc. to support two divisions where Therapure Innovations is successfully advancing their product pipeline, while Therapure Biomanufacturing is securing major global manufacturing contracts and receiving industry recognition through CMO leadership awards for our efforts.

What are the characteristics of today's market for biologics manufacturing given the pressures of manufacturing shifting to emerging markets and biosimilar drugs?

I have spent much of my career working with small molecules and am very familiar with the impact of generics and also competition from lower cost or developing markets as it pertains to CDMO's.

Small molecules are manufactured to a specification that allows for verification of finished product quality. Biologics involve more complex characterization and it is generally accepted that the process plays a major part in the determination of the biologic product. As a result, finished product analytics do not provide adequate verification of product quality. Proximity, experience and process control are therefore key considerations in CDMO selection. Furthermore, with respect to small molecules, we have seen a number of articles written on the pharma industry returning to the more traditional western CMO's in search of security of supply, and quality over price. In summary, for the foreseeable future I believe North America will remain a preferred choice when it comes to CDMO selection.

We continue to monitor this area closely, but it would be fair to say that this is not the focus of our business.

In what way can investors be attracted to the Canadian biotech market more?

It is difficult for me to comment on other companies and investors. In general, I believe investment in this market requires well-informed investors, who can understand and evaluate the risks that are clearly present in drug development and biotech. From a Therapure perspective, we spend a great deal of time and effort to ensure our investors understand our strategy, the risks and what we are doing to mitigate these risks. Another aspect, which I believe is essential, is that the scientific community is able to communicate their approach and inventions in a manner that is easily understandable to the investment community. This means simplifying the message and translating the science into a business plan that can show demonstrable returns and how the investment can be monetized.

At Therapure we have followed this approach and have been delighted with the support we have received from our investors, which has enabled our development group to move our drug candidates forward.

Therapure offers a wide variety of services; what areas are of most importance as it relates to the company's strategy today, and what synergies have you been able to create from that variety?

Therapure's first fundamental business unit is its CDMO business, Therapure Biomanufacturing, which has a full service offering. Therapure is the only mammalian cell culture CDMO in Canada, which starts by helping clients develop their processes, and maintains a continuous eye on the future development of their drug. Therapure also manufactures at commercial scale, which allows us to guide smaller companies through the clinical process with an understanding of how the manufacturing processes we develop will translate into larger scale process and commercial manufacturing. Furthermore, Therapure is extremely fortunate to have a facility that many companies cannot afford, which can be used for biologics manufacturing from mammalian cell (with capabilities up to 2,500 L bioreactors, single-use and stainless steel), plasma, transgenic or microbial sources. We have outstanding capabilities in downstream purification of proteins with chromatography columns ranging from 1 cm to 1.6 m to meet the needs of clients at all stages of

product or process development. As part of our integrated services, we can also offer aseptic fill/finish. In summary, Therapure has a broad range of integrated capabilities, supported by a strong and experienced team in all areas of biomanufacturing. This blends nicely with our own drug development portfolio under the Therapure Innovations division, which is also a client of Therapure Biomanufacturing, enabling us to manufacture clinical material supply within our organization, leveraging the skill and knowledge within both divisions.

What are your drugs in development?

Therapure has a monoclonal antibody directed at a marker on blood forming cells to help overcome anemia. We have some encouraging preclinical results and will be filing an investigational new drug application (IND) at the end of 2013 to move into Phase I clinical trials. This biological drug may be an exciting and innovative solution that addresses a significant unmet medical need in terms of anemia in the marketplace.

Our research and development also includes a hemoglobin conjugate platform technology, which allows for targeted delivery of therapeutics to the patient. Our lead candidate is a liver cancer drug for which we have filed for an IND and are in discussions with the FDA to move into Phase I. We are also exploring some new uses for our hemoglobin oxygen carriers in the field of organ preservation—a use that may allow for expedited clinical development. Another platform technology Therapure owns is based on the use of hydroxyethyl starch (HES) as a half-life extension technology for proteins and drugs. Therapure has products of its own in earlier stage preclinical development using this technology and we are in the final stages of licensing that to a company. We also have a number of other opportunities for licensing our platform technologies.

What makes Therapure the CDMO partner of choice for pharmaceutical and biopharmaceutical companies and, in particular, Canadian companies?

It would be wrong to suggest that any one thing makes Therapure a partner of choice. Our customer needs are as diverse as our service offering. Therapure has highly motivated people, with a wealth of experience. They are passionate about what they do, in development as well as commercial manufacturing. We have a keen eye on helping the client develop a robust and economic process, but realize that the reason we are here is to deliver products and services that ultimately benefit patients. We are fortunate to work in one of the best facilities in the world, but we never take any of this for granted as we endeavor to make our customers delighted with the service and the product they get from Therapure.

What would you like to have achieved in the next five years and why is Therapure successful now?

Therapure will be significantly larger than it is today. We have a healthy book of business and a very interesting pipeline of opportunities, both internal and external. I would like to see Therapure establish itself as a well-respected, global player in the CDMO space. In addition, I believe strongly that our drug development pipeline will be reaching the more advanced stages of clinical development and will start to offer true solutions to some of the therapeutic areas we are attempting to address.

Therapure is a great success story because of the people that work here. It is great to see a business that is Canadian-backed, employing a significant number of Canadians in high value jobs, growing at a tremendous rate, and developing and manufacturing products in Canada. We have every intention to continue to do that. At Therapure, I believe we do more than just R&D, the product of which ultimately ends up somewhere else in the world to be manufactured. Here, we develop and manufacture products in Canada, on behalf of third parties, as well as our own and are backed by a very supportive Canadian private equity group.

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