

insights

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**CREATING GLOBALLY
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Life Sciences Start-Ups Work Diligently to Overcome Challenges



UNPRECEDENTED OPPORTUNITY FOR EXCITING NEW LIFE SCIENCES DISCOVERIES is fuelling worldwide industry growth, including a small but growing Canadian contingent of start-ups. BIOTECanada's 2018 Biotechnology Industry Data Survey of more than 200 corporate respondents revealed that 47 per cent of biotechnology companies in Canada had ten or more employees, including 20 per cent with 25 or more in 2017, and that those numbers are expected to escalate to 77 per cent, and 43 per cent, respectively, by 2021.

These companies face formidable technological and business challenges, but many are using ingenuity to establish their presence.

One of those firms is Innovative Targeting Solutions Inc. of Vancouver, which has established a world-class protein engineering platform technology for drug discovery.

"We have seven large pharma collaborations, but in early 2018 we spun out our first company and are now in the process of spinning out our second company. Each will be exploiting the platform to develop novel medicines in different therapeutic settings," says Michael Gallo, the company's president.

"As a small company, or in our case when starting a new company, the limited resources and limited pipeline do not justify hiring senior full-time staff with the required expertise. It is an immense challenge and of critical importance for us to make the best decisions on how to advance our first assets, and having access to experts in the field solves a major challenge for the company," he explains.



To address that need, Gallo and his team at Innovative engaged the services of Vancouver-based Novateur Ventures Inc., a three-year-old firm that has assembled more than 100 experienced pharmaceutical and medical device development professionals from around the world – mostly through a virtual network - to service their clients in the life sciences industry in Canada and abroad.

Novateur's business model allows the company to deploy members of its professional team to various client projects on an as-needed basis. They offer a wealth of experience to assist in the clinical development of new drugs and medical devices.

This is critical, says Ali Ardakani, Novateur's founder and managing director, because Canada lacks a major pharmaceutical company.

"As soon as there is a product that gives what we call clinical proof of concept, meaning that you actually are showing that this product is working in patients, an American or a European company snatches it up," he notes.

Novateur is devoted to changing that with its team of experts qualified to assist in multiple fields.

"The ultimate goal of therapeutics, diagnostics, and medical devices is to better the lives of patients. At Novateur we can leverage our expertise in therapeutics and diagnostics to better address patient care, access, and coordination," says Ardakani, who is also the vice-chair of LifeSciences BC.



“Our newly added digital health practice will manage a suite of healthcare innovations including, but not limited to, patient re-admissions models, chronic care management, reimbursement models, population health management, interoperability and IT integration,” he adds.

Novateur also assists clients navigate the commercial and regulatory challenges that life science companies face, including providing networks to access public and private financing support, assistance with an initial public offering, corporate restructuring, and help with developing and executing their business and medical strategies.

Frédéric Leduc, chief executive officer of Immune Biosolutions Inc. in Sherbrooke, Quebec, says Novateur has worked on several projects for his firm, from evaluating their internal assets to supporting new major collaboration negotiations.

“It is very difficult for a young Canadian biotech to have access to veterans and unique talents at the right moment. Through Novateur’s team, we can build a momentary task force custom-built for the challenge. It is, by far, the best and most efficient approach we came across,” he adds.

Ardakani, a nearly 20-year veteran of the life sciences industry, both as an employee and entrepreneur in Canada and the United States, has extensive experience as a biotech executive in managing various life sciences companies, the majority being start-ups, prior to founding Novateur.

“One thing I reflected on is that the success and failure of all these biotechs that I had been part of was correlated by one thing – people. If the people had the resources and the network and the experience, the product or the company would become successful. If you didn’t, it would fail. The

right people know what to do. If they have the right connections to those people in financing, they will help you raise money, and make the right development decisions,” notes Ardakani.

Furthermore, it is necessary to understand life sciences from the investor perspective. The first priority of investors is to assess the people involved and evaluate their track record and whether they can be trusted. Then they look at the technology, he explains.

Steven Klein is the vice-president of business development at The Institute for Research in Immunology and Cancer—Commercialization of Research (IRICoR), a not-for-profit drug discovery and commercialization centre based at the Université de Montréal.

The reliance of pharmaceutical companies on external innovation offers an opportunity to Canadian groups such as IRICoR, which is focused on de-risking promising new therapies for the treatment of cancer, to partner with these companies directly, or to create spin-off companies around a given asset or platform that is then able to partner with the pharmaceutical industry, says Klein.

“By working with Novateur to better understand the competitive and commercial landscape around possible investment opportunities for IRICoR, we increase the chances of ultimately developing partnerable assets that would attract interest from the pharma and venture capital communities, and position Canada as a source of innovation in the oncology field,” he explains.

Virogin Biotech Ltd., another Novateur client, is a Vancouver-based biological drug development start-up company focused on innovative anti-cancer oncolytic viruses.

Minjie Kuai, Virogin's corporate secretary and manager of business development, says contemporary biotech startups face both higher risk and reward scenarios due to an ongoing trend in the life sciences industry whereby large pharmaceutical firms are relying increasingly more heavily on the in-licensing model to fuel their pipeline development.

As a result of this trend, there has been further specialization within the industry whereby biotech start-ups are strong in fundamental research while large pharmaceutical firms are rich in capital and development experience. This essentially shifts the risk associated with in-house research and development from large pharmaceutical firms to biotech start-ups. But it also presents potentially higher rewards for start-ups that prove successful.

To get to that stage, however, start-ups face three major challenges, notes Kuai. They include: how to stand out amongst the competition; how to obtain enough human resources and capital to prove themselves; and then the ability to retain the proper resources and network connections at a reasonable cost.

Kuai says that by establishing relationships and building trust with professionals and companies in the industry, the Novateur business model provides a central exchange for information and connection.

"By associating with Novateur, clients like us gain access to an extensive professional network that we would be very difficult to connect to if we were to reach out directly, not to mention the acquisition cost would be much higher, if not prohibitive," he elaborates.

Gina Stetsko, head of product development and manufacturing at Novateur, has worked at senior management levels and has nearly 35 years of experience with pharmaceutical companies in the United States and Europe, helping to develop and secure approval for drugs to combat cancer, diabetes, and other diseases.

Stetsko, who moved to Vancouver from the United States in 2017 after joining Novateur, describes the Novateur network of assembling a team of pharmaceutical experts from around the world to work remotely together, as very nimble in terms of providing an opportunity to define what needs to be done, and get a plan in place quickly.

Novateur's Diverse Team leads Therapeutics, Diagnostics, Devices & Healthcare IT

MEDICAL DEVICES

THERAPEUTICS

- In Vitro Diagnostics
- Cardiovascular and Thoracic Devices
- ENT Instruments
- General Surgery Devices
- Imaging Instruments
- Implants & Prosthetics
- Ophthalmic Devices
- Laboratory Devices
- Drug Delivery Devices

THERAPEUTICS

- Orphan Diseases
- Hematology
- Dermatology
- Respiratory
- Neuroscience
- Cardiovascular & Metabolic
- Musculoskeletal
- Ophthalmology
- Oncology & Immuno-Oncology
- Infection
- Diabetes & Obesity

DIGITAL HEALTH

- Chronic Care Management
- Predictive Analytics, Big Data & Machine Learning
- Patient Care Coordination
- Digital Devices, Wearables & Biosensing
- EHR & Clinical Flow
- Precisions Medicine
- Mobile Monitoring
- Health Benefit Solutions
- Telehealth

OTHER AREAS

OF EXPERTISE

- IP Development
- Regulatory
- Executive Recruitment
- Accounting & Audit
- Reimbursement
- Risk Assessment
- Health Economics
- Corporate Structuring
- Operations
- Due Diligence
- SR&ED
- Valuation
- Communications/PR
- Marketing Strategy
- Partnerships
- Global Grants

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Moreover, depending on the type of problem to be resolved, in some instances it may accelerate the timetable for developing products—including both drugs and devices—that will be approved for entry into clinical trials or for the market, she says.

Ardakani lauds the contributions of Stetsko and others on his team, who have decades of valuable clinical commercial experience in bringing drugs to market.

“We are bringing these executives up at our own expense and risk, sponsoring their immigration, so that more Canadian [biotechnology] companies can utilize their expertise as they need them. At the end of the day [the goal is to] help those companies move the bar, get partnership financing, and then get [drugs] to the [market],” he says.

“If you’ve never had a lot of people who have taken products through that last step to bring it to market, you can never have a significant pharma company. I’m bringing [professionals] here [who] have either created large pharmaceuticals or they’ve brought [those] products to market.”

The ultimate goal is to assist these companies grow into formidable Canadian and international pharmaceutical companies that remain here. This, says Ardakani, would transform the country’s business and life sciences landscape.

“Think how many [thousands of] jobs that would create,” he stresses.

Novateur’s Comprehensive & Global Operation has 100+ Advisors & Experts across Six Continents

BRINGING YOU WORLD-CLASS DEVELOPMENT, STRATEGIC THINKING AND OPERATIONS

ELIMINATING INFRASTRUCTURE OVERHEAD

TAILORING ADVISORS’ EXPERTISE AND QUANTITY TO CLIENT FUNCTIONAL NEEDS

CONNECTING CLIENTS WITH AN EXTENSIVE AND GLOBAL NETWORK OF CONTACTS

100+
NDAs & BLAs

50+
Clients

100+
Drugs & Devices

100+
Core Experts

20+
IPOs

150+
INDs

Across
6
Continents

10+
M&As

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Victoria, BC
Edmonton, AB
Toronto, ON
Montréal, QC
Los Angeles, CA
San Francisco, CA
San Diego, CA
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New York, NY
Washington DC
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Tokyo, Japan