

By OBIO<sup>®</sup> with Contributions from Domestic and Multinational Health Science Companies

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How Canada should be Engaging in a \$9 Trillion Dollar Health Economy

> Industry Engagement & Perspectives Report

## **Opening Message**

In late 2015 and early 2016, on behalf of the Ontario Health Sciences sector, OBIO directly engaged with 125 domestic and multinational health science companies, to determine how Canada and Ontario should be engaging in a \$9 trillion global health economy. We are grateful for the overwhelming response and support from industry for realizing this work at a critical stage in our nation's economy.

This report is not a traditional dataset that looks back on the progressive state of our industry, but rather a forward looking vision on where our industry should be and how we need to get there. We have asked industry to describe for us what the health sciences industry will look like in the future, and what it will take to attract investment and to compete at a global level. We have recognized Canada's strengths and weaknesses, and we have clearly outlined the issues that are preventing industry from securing Canada's leadership position in the global health economy.

The recommendations from this report provide actionable solutions for industry, in partnership with government and other stakeholders of the health sciences economy, to achieve the desired health and economic outcomes for Canadians, for which we have already so heavily invested.

We offer our experience and collective strength at implementing strategy and look forward to engaging you in applying these solutions.

Harland

Gail Garland President & CEO, Ontario Bioscience Innovation Organization

#### **OBIO**

Since its founding in 2009, the Ontario Bioscience Innovation Organization (OBIO<sup>®</sup>) has engaged in strategy and policy development, advocacy and government relations to further development and commercialization of Ontario's human health technologies through investment, strategic alliances, stakeholder engagement and industry promotion. In 2010, OBIO led the **Ontario Bioscience Economic Strategy** Team (OBEST<sup>®</sup>), in developing a province-wide strategic vision for addressing key issues such as capital access, capabilities/people, innovation adoption, market receptivity and export. The goal is to ensure a sustainable health sciences sector in Ontario that creates jobs, attracts expertise and ideas, elevates health outcomes and builds a more prosperous economy. OBIO has a successful multiyear track record for implementing OBEST having established and funded programs like CAAP<sup>®</sup> and Pre-CAAP that focus on capital access for Ontario companies and achieve results. Other OBIO programs address other priority goals identified by our stakeholders such as, OBIO®'s Innovation Adoption Initiative ("Realizing the Promise of Healthcare Innovation in Ontario", 2013) which is designed to strengthen capacity for delivering cost-effective, outcome-focused care for patients while catalyzing health technology commercialization. adoption and dissemination. OBIO continues to work with stakeholders to develop policies that will revitalize market conditions for a thriving industry.

## Table of Contents

Execut	ive Summary1		
1.1	Recommendations to encourage development and growth of Canada's Health Science		
Indu	Industry3		
1.2	Recommendations for Ontario5		
2 In	troduction6		
3 The Future			
4 Attracting Investment in a Global Industry 10			
5 Competing for Investment 12			
6 Ca	nada: Strengths and Weaknesses 14		
7 Issues for Industry 17			
7.1	Capital Access		
7.2	Talent/Human Resources26		
7.3	Intellectual Property		
7.4	Ecosystem		
7.5	Policy31		
8 Re	8 Recommendations		
8.1	National Industrial Policy for the Health Science Industry		
8.2	Building a Strong Health Science Industry in Ontario37		
8.2.1	Addressing Barriers to Scale-up for Ontario Companies		
9 Di	scussion		
10 Ap	opendix 1: Demographics of Ontario Health Science Companies		
11 Appendix 2: Case Studies of Ontario Health Science Companies			
11.1	LEO PHARMA A/S47		
11.2	SPARTAN DIAGNOSTICS48		
11.3	NOVADAQ		
11.4	VBI VACCINES		
11.5	SYNAPTIVE MEDICAL		
12 References			

## **Executive Summary**

#### Canada Needs an Industry Specific Strategy to Succeed in the \$9 Trillion Dollar Health Sciences Economy

The global health sciences market is an ever evolving, innovation-based economy, where many countries are competing to nurture a domestic ecosystem that will deliver true innovation, optimal health, economic growth and overall prosperity for its citizens. The potential to offset growing demand and rising costs through commercial enterprise and exports, represents a compelling reason for a strong healthcare industry. Further, the commercialization of health technology is an opportunity to diversify Canada's economy, create quality jobs and to ensure our highly educated workforce can stay here and build a future.

According to Deloitte's Global Health Care Outlook Report for 2015<sup>1</sup>:

"Health spending is estimated to have increased by 2.8 percent in 2013 — an uptick from two percent in 2012 — to total \$7.2 trillion+, or 10.6 percent of global gross domestic product (GDP). As the global economy recovers from prolonged recession, health spending is expected to accelerate, rising an average of 5.2 percent a year in 2014-2018, to \$9.3 trillion. This increase will be driven by the health needs of aging and growing populations, the rising prevalence of chronic diseases, emerging-market expansion, infrastructure improvements, and treatment and technology advances."

The same report goes on to say:

"Treatment advancements and government initiatives to increase access to care should drive sector expansion but pressure to reduce costs is escalating. Growing populations and consumer wealth are increasing demand for health care services but aging societies and chronic diseases are forcing health payers to make difficult decisions on benefit levels. In the midst of this tug-ofwar, many historic business models and operating processes will no longer suffice."

In the face of this substantial opportunity and the accompanying challenges, Canada has yet to identify and implement an industrial policy for a commercial, globally competitive, healthcare industry that will bring us into the future. We cannot build our economy without the industries of the future and we can't build or attract those industries without an environment that is conducive to their success.

In the fall of 2015 and early 2016, the Ontario Bioscience Innovation Organization conducted a series of consultations with senior executives from multinational healthcare companies (MNEs) and with CEOs of companies headquartered in Ontario. The consultations were designed to: gather a picture of the future of the global heal care industry; understand Canada's competitive position in today's environment; and gather ideas and recommendations for change that would see us compete for a place near the top of the global health care industry rankings.

Overall, there was broad recognition for the potential of scientific breakthroughs and disruptive technologies plus the changing roles and approaches to innovation within industry. At the same time the interplay between healthcare and the economy is changing "willingness to pay" to "ability to pay" and affecting long range business planning in new and challenging ways. Winning global jurisdictions/environments are characterised by their market opportunities and processes, agility, expertise and science and by data and analytics infrastructure accelerating discovery, development and commercialization.

Currently, Canada is reasonably competitive with its well educated workforce, tax policies, clinical trial capabilities and the quality of the federal regulatory agency. Unfortunately, it is no longer differentiated on these measures as other countries have made significant investments in their own sectors and education systems. Canada has fallen behind on a number of metrics that are of concern if we are to compete in the global healthcare industry of the future. Key among these are: cost, speed and agility, health data infrastructure, innovative market access processes, an experienced labour force and access to capital for commercial purposes.

Closing the gap in order to ensure that Canada secures a leadership position in the global health sciences economy, requires placing a priority on building a competitive environment and private sector industry as part of the healthcare ecosystem. This priority needs to be reflected by: an industrial policy, specific funding and tax incentives for health technology, and strategies for building an environment where industry will succeed.

Neither industry nor government can implement these recommendations alone and the complexity of the Canadian health care market requires many levels of co-operation. However, the ability to compete in a \$9 trillion dollar global market while at the same time delivering better health outcomes through innovation and creating high quality jobs for Canadian talent, is well worth the effort.

# 1.1 Recommendations to encourage development and growth of Canada's Health Science Industry

#### 1. Policies to address procurement and innovation adoption

Build the environment for industry to thrive through market access policies, targeted at growing, attracting, and ultimately retaining globally competitive companies to provide innovative products and solutions for the Canadian health system.

#### Policies to build the environment and enable market access should include:

- Aligning Canadian intellectual property rights with those of other advanced countries.
- Value based pricing and procurement policies that put a value on innovation, with shared risks and benefits for all stakeholders.
- Technology infrastructure policies, that will ensure that Canada is equipped with the required electronic medical records and databases that industry requires for big data analytics.
- Adoption and reimbursement policies, that streamline a predictable and timely path to market and that favors early adoption of locally developed technologies once approved by Health Canada.
- 2. Policies to attract and retain investment in Canada's Health Science Industry

Access to the right capital and maximizing its deployment for growth and success is local industry's number one priority and biggest challenge. Tax policies can influence the decision by a foreign investor to move a company or leave it where it is headquartered and should be used strategically to address Canada's competitive performance on measures of business enterprise and industrial R&D and to create more opportunities for companies to stay here and grow.

Policies to address the chronic challenges with accessing capital for Canadian SMEs and to ensure Canada can compete for global R&D investment in the health science space should include:

- Creating health science specific investment funds to address the timelines and needs of this industry.
- Capital gains tax credits/exemptions for investors in health technology companies.
- Wage tax credits or subsidies to enable job creation and the building of an experienced workforce.

- Talent attraction and retention policies or programs that will eliminate barriers to immigration and provide direct funding or tax relief for companies to competitively develop experienced personnel.
- R&D tax credits that recognize:
  - Investment in scientific development to meet regulations and commercialize.
  - MNE investment in local companies.
  - Work and jobs in Canada rather than ownership.
  - The need for refundability for pre-revenue companies.
- Industry-focused government programs that are nimble, streamlined, reward corporate investment in technology development and are unbundled from academic partnership requirements.
- Ensure the health technology sector is included in any consideration of extending the Flow Through Share regime to other technology sectors to avoid biasing sources of risk capital away from health technology.
- Incentivize technology exports without penalizing companies that have sales in foreign markets but no significant revenues in Canada.
- Eliminate program requirements that SME companies have sales in Canada to offset challenges with gaining access to the Canadian markets.

#### 1.2 Recommendations for Ontario

## Building a Strong Health Science Industry in Ontario: Addressing Barriers to Scale-up for Ontario Companies

A sustainable, successful Ontario Health Science Industry capable of solution-driven R&D and product commercialization represents significant economic potential for Ontario's economy. Enhancing Ontario's attractiveness as a jurisdiction for investment and growing companies can be achieved by investing in specific programs and incentives for Health Science Industry growth and competitive success. These programs and incentives will attract investment, fuel revenue and support knowledge economy job growth.

#### Key recommendations for Ontario:

- Attract Health Science Industry investment to Ontario by addressing procurement and market access barriers and addressing clinical trial costs and delays.
- Improve access to capital for Ontario Health Science Companies by: creating a health science innovation capital fund and by streamlining government programs and eliminating arduous eligibility requirements.
- Deploy tax credits to incentivize investment, extend runway and create jobs by introducing wage subsidies or tax credits for SMEs and removing non-Canadian companies from the associated corporations category in the taxable capital test and/or increasing the \$800 limit for taxable income and the \$50 million taxable capital cap.
- Modernize tax credit eligibility criteria to allow companies to stay and grow in Ontario by including commercial development research activities; allowing research activities that are not available in Canada to be eligible for tax credits and revising the associated corporations rules as described above.
- Build an experienced workforce through job creation within industry and by using the Provincial Nominee Program to accelerate immigration of experienced industry personnel who can transfer knowledge through mentorship and on the job training.

## 2 Introduction

Since the Science, Technology and Innovation Council published its State of the Nation report in 2014<sup>2</sup>, speculation that the strength of the Canadian economy is vulnerable to oil prices, the dollar and exports, has become reality. Numerous articles in the business media are calling for diversification of the economy into technology or knowledge based industries. Toward the end of 2015, OBIO identified a need to probe beyond quantitative summaries and interpretations of Statistics Canada and other data to examine how industry leaders view the future of the global human health bio-economy; Canada's current performance; opportunities to address existing challenges and assume a leadership position in key areas.

This report begins by looking to the future to identify opportunities and potential barriers. It then reports on the Canadian industry at the present time and identifies important gaps that need to be addressed if Canada and Ontario are to achieve future success. Finally it relates suggestions for policies to address the gaps and ensure Canada and Ontario can make a contribution to the future of healthcare and reap the benefits of a successful industry. Where the findings in this report overlap with others, there is evidence of consensus on issues and solutions and more voices in the call to action. At the same time, this report is focused purely on the Canadian industry as one of the key pillars of healthcare and Canada's knowledge economy and offers additional insights.

This study utilizes data collected through qualitative interviews and a quantitative online survey. Participants included representatives of multinational organizations (MNEs) and Ontario based companies (SMEs). The types of companies included: diagnostic companies, combined diagnostic and pharmaceutical companies, device companies, mobile health, health IT and pharmaceutical companies. Where responses differ by subsector, this report highlights the findings, otherwise the responses are presented for the overall group. Throughout, the terms health-science industry and health-technology (health-tech) industry may be used interchangeably.

## 3 The Future

As far back as 2009 the OECD issued a report projecting the bioeconomy to 2030 and recommending a policy agenda<sup>3</sup>. The report identified health as one of the three areas of the bioeconomy that will play a key role in addressing global economic and social challenges and emphasised the need to prevent locking in inferior technological solutions by preparing for the future. Further, it recommended that foundational policies in the area of health address regulatory, research, and health record systems that can be linked and used to evaluate health outcomes. That economies prepare for "a costly but beneficial revolution in healthcare"<sup>3</sup> by addressing accessibility, effectiveness, safety and outcomes and ensuring that processes, policies and regulations are in place to evaluate and integrate disruptive technologies for the benefit of both patients and the economy. Finally, it was recommended that overcoming barriers, integration, knowledge transfer and dialogue among governments, citizens and industry be integral parts of policy development and ongoing evaluation.

Within the next five years, global health spending is expected to reach \$9 trillion<sup>1</sup> despite demands for solutions to rising costs, better patient outcomes and more efficient healthcare delivery. Numerous economies now compete for a share of the markets represented by these spending figures and are investing in their health science industries to better compete in the future.

Canadian Health Science Industry CEOs discussed the major issues facing the global healthcare economy of the future and shared their perspectives on issues that will affect: their company's ability to perform, patients' abilities to access the care they need and payers' abilities to fund the adoption of breakthrough therapies and technologies. They also commented on issues that are problematic for the whole healthcare system such as efficiency, silos and cordial disregard in the face of a need for true collaboration among stakeholders if we are to address the challenges facing us.

Business issues related to pricing, market access and future returns on investment in innovation were mentioned most frequently as factors that will shape the global industry of the future (*Figure 1*). Further, the ability of any jurisdiction to invest in healthcare will depend on the performance of their individual economy while healthcare (and other industries) function on a global rather than individual level. These issues were mentioned by leaders in the device, diagnostic and pharmaceutical spaces.

#### Industry Perspectives:

- "Globally the number one threat is the willingness and ability to understand innovation and make access decisions based on value if payers won't recognize value." MNE
- "Tradeoff between innovation ability and willingness to pay. There is an emerging feeling that "what we have is good enough" and there is less willingness to take on innovations that cost more." MNE

Pharmaceutical pricing was seen as also influencing payer's willingness to invest in diagnostic or device technologies that might lead to a prescription for an expensive drug, illustrating connectivity across sub

sectors and how purely cost-focused jurisdictions do not benefit from "right patient/right treatment/right time" savings and outcomes.



Figure 1: The ability of countries to fund and adopt new innovations is key among upcoming issues for the global health sciences industry.

Scientific breakthroughs and disruptive technologies were the next most frequently mentioned category of predictions for the future. Although there were many mentions of scientific and medical breakthroughs, the discussion of disruptive technologies was not limited to advances such as personalized medicine or gene therapies but included the entry of companies like Google and Apple into the healthcare space. The anticipation of exciting cures and treatments was tempered by concerns over the resources and expertise within regulatory and health technology assessment (HTA) agencies to keep pace with these developments and for purchasers to move from procurement models for products to those for services and solutions.

#### Industry Perspectives:

 "On a macro level medications are so precise with targeting, they are expensive to make and only address a small number of patients. There is nowhere in the world we are ready to adopt these medications (e.g. regenerative medicines, immune-oncology). These medications don't fit the healthcare system or the system cost impact models. There is no jurisdiction that comes to mind, but industry and think tanks are working on it." MNE

• *"60 countries are at the table to shift procurement from widget to solution." MNE* 

Of interest was the discussion of the future of the internal workings of the industry itself. The evolution from fully integrated companies where the R&D model is dominantly internal to one based on licensing and partnerships represents an opportunity for small health science companies who can bring their technologies to the stage of development required by the larger players to enter into a deal. Key to success are adequate financing, expertise and networks plus the ability for strategic development that addresses the concept of solution as well as technology. This transformation creates a two way street as large companies can also spin out small companies to develop technologies that no longer fit their portfolios. There has also been an exodus of talent from larger players following mergers and acquisitions and there was speculation that this may strengthen SMEs (small and medium size companies) and potentially impact the receptivity of the MNEs for partnering.

Finally, a number of CEOs raised the issue of efficiency, waste and the ability of global health systems to prepare and change in order to deliver accessible, quality healthcare at a reasonable and value driven proportion of GDP. Waste in the US healthcare system has been estimated at 30% of health spending or 5% of GDP, in the UK 10% to 15% of all medical and surgical treatments have been estimated to offer little or no benefit and although Canada doesn't have comparable data, CIHR has estimated inefficiency in Canadian Healthcare at between 18% and 35%. The 2014 Commonwealth Fund report ranked Canada and the United States 10<sup>th</sup> and 11<sup>th</sup> out of eleven countries in efficiency of healthcare delivery and 10<sup>th</sup> and 11<sup>th</sup> overall <sup>4-6</sup>.

There is concern that there is an overall lack of understanding of cost drivers in most countries and that the adoption of health innovations will be constrained by budgets where cuts are made to the most visible line items such as drugs and equipment. Countries such as Sweden with national EMRs (electronic medical records) were noted as having better understanding of the real cost drivers when looking at healthcare costs.

"In 2010 the Institute of Medicine issued a report stating that waste accounted for 30% of healthcare spending or some 750 billion dollars a year which was more than our nation's [USA] budget for K-12 education. The report found that higher prices, administrative expenses, and fraud accounted for almost half this waste. Bigger than any of those however was the amount spent on unnecessary healthcare services.<sup>4</sup>"

Atul Gawande, The New Yorker; May, 2015

## 4 Attracting Investment in a Global Industry

Building Canada's health science economy to make a contribution to upcoming global health challenges and compete in the lucrative healthcare markets will require investment. CEOs were asked for their thoughts on attracting investment from multinational head offices and from global investors.

While there was broad overall agreement for the factors that are driving investment decisions in the head offices of MNE's, there were different weights and nuances specific to different companies. Qualitatively these appeared linked to the size of the MNE, the location of its headquarters and the nature of the business.



Figure 2: Drivers Behind Selecting a Jurisdiction for Health Science Industry Investment

As with all industries, the decision to locate or invest in a given jurisdiction is driven by the return on investment, time to generating returns, the size of the returns, cost of doing business and the future environment (*Figure 2*). Companies in the survey were divided in their emphasis on emerging markets between those focused on growth and rate of growth and those focused on stability and predictability. All respondents agreed that the most important factors that affect return on investment are intellectual property (IP), regulations, pricing and market adoption and dissemination of new products. Many commented that pricing is experiencing huge pressure for change and the US model is unlikely to be

sustained. In the face of increasing price controls other factors and potential trade-offs, such as time to market and IP protection, become more important in the overall ROI equation for attracting investment.

Factors such as science and clinical trial infrastructure were mentioned less frequently and the point was often made that quality is now available in many jurisdictions, the education of local workforces is becoming more of a level playing field and the key R&D investment differentiators are cost, timeliness and the availability of technologies to speed up innovation and development such as EMRs and patient databases. When it comes to investing in R&D, a number of leaders mentioned the ease of working with the local universities and hospitals as a factor influencing investment decisions.

#### Industry Perspectives:

"We invest where the greatest science is per therapeutic area looking at researchers and possibilities for partnerships. Looking for high quality. We invest and look to create hubs that connect the university, the company and the hospitals. The company moves its own science from around the world to the hub. Examples include Cambridge UK for oncology, Sweden for CV and neurology. Canada is not a hub for basic research." MNE

The relationship between industry and government was often mentioned and as one CEO put it: *"The top three criteria are: Timely access to new medications, an IP environment that encourages investment and a relationship between industry and government (neither side can solve the problems alone)."* 

Opinions were diverse on the role of tax incentives in the decision to invest but there was consensus that meaningful long term investment by multinational corporations could not be driven by tax alone. SMEs were closer to the issues of tax policy as a way to attract capital and to extend runway in companies. Governments are urged to adopt globally competitive tax policies to attract investment and help companies grow.

#### Case Study 1:

Multinational **LEO Pharma A/S** is **investing in the Canadian Ecosystem** through the establishment of a Canadian-based Innovation Lab. The Lab, backed by \$100M will partner with start-ups to foster innovation in non-drug advanced technologies. A recently announced LEO venture initiative will help address access to capital - the industry's greatest ongoing challenge. Other changes that would **help companies thrive**: make it easier to adopt technology and make the rules around reimbursement clear.

Read more about Leo Canada's experience in the Appendix, section 11.1.

## 5 Competing for Investment

The US, Germany, Japan and EU were mentioned most often as being places most likely to be high on an MNE head office list to locate investment. The US stands out for its pricing, market access, market size, talent, regulatory system and IP protection. Germany and Japan were singled out for having developed certain research and manufacturing expertise as well as their market access and the EU for its review time and strengths in science. Figure 3 lists some of the rationale for investment in each country.

United States	<ul> <li>World leading science &amp; Innovation. Good R&amp;D process</li> <li>Market size, Represents 60% of the growth</li> <li>Free market and early access. Pricing. Easy to do business. License to operate</li> <li>Incredible talent, strong state support</li> <li>Fair predictable return on investment</li> <li>Strong regulatory system</li> <li>Strong IP protection</li> </ul>
Germany	<ul> <li>Access to innovation talent and expertise on chemical manufacturing</li> <li>Robust HTA, clear transparent pre-specified and agreed to criteria, negotiated value proposition</li> <li>Early market access, and set price</li> </ul>
EU	<ul> <li>World leading science</li> <li>Relatively quick review time</li> </ul>
Japan	<ul> <li>Access to large market, technical expertise and know-how</li> <li>High initial pricing</li> <li>Aging population</li> </ul>

Figure 3: Leading Jurisdictions for Health Science Industry Investment

While Industry leaders are acutely aware of the increasing need to demonstrate outcomes and value, there was broad recognition that HTA is a relatively new requirement, that different countries are farther along and better at it, and that the environment for negotiations varies from predictable and transparent to non-inclusive and exclusively cost-focused. India was mentioned to illustrate an environment where cost and negotiating strategies create a very difficult environment for industry despite the potential market size. The US and EU were often mentioned as having more advanced HTA systems despite their imperfections.

#### Industry Perspectives:

 "HTA bodies are not able, empowered or resourced properly to make complicated decisions that ultimately affect patients. The complexity comes from contributing factors: healthcare systems, patient outcomes, economics, value to an individual vs value to a population and politics." MNE The Middle East and China were mentioned as attractive for their population size and growth plus aging and growing chronic disease markets, however, the need for over-investment to do business was a concern to some. The UK was singled out for comment on leadership, innovation and translation, plus soft skills.

#### Industry Perspectives:

- "Environments with risk sharing, capacity for personalized treatment, progressive reimbursement and price increases after launch if the post marketing data support it. UK and France. Change happened with endorsement from the top and took place in phases with a road map. If there is no one in charge dialogue is impossible." MNE
- "The UK. infrastructure around universities that take ideas targeting unmet needs and bring them forward for commercialization by companies. They have a record of translational success for their commercial partners. British companies are easy to work with." MNE
- *"Competitiveness of other clusters around the world offering incentives to attract companies that would be tempted to leave Ontario." SME*

## 6 Canada: Strengths and Weaknesses

Canada's total spending on health care was estimated at US \$206 billion, (11.3% GDP) in 2013 and forecast to grow at 4.5 percent a year (in nominal local-currency terms) to US \$464.3 billion by 2018 (11.6% GDP)<sup>7.8</sup>. The Economist has commented that Canada's spending is likely to rise in line with GDP and that Canada has few federal mechanisms to bring down spending<sup>8</sup>. At the same time there are a number of reports in the literature suggesting Canada is not realizing the same health and system outcomes from government investment in health as other industrialized countries.

Canada's most consistently mentioned strength was research although there was a divide between those who felt Canada's basic research was a strength and those who felt that research strength was limited to clinical trials. Many, however, added caveats when commenting on both basic research and clinical trials.

#### Industry Perspectives:

- "Ontario and Canada have great centers but the bureaucracies and timelines in Canada fall short of what is needed." MNE
- "Canada is a great place to run clinical trials and quite cost effective. KOLs are exportable." MNE
- "Canada has high quality research. It is viewed as good for clinical research not for basic. We built facilities in Massachusetts, the UK and France around the basic research clusters." MNE
- "Some of the best medical institutions in the world across a number of disease categories. Canada ranks among the best institutions and individuals." MNE
- "Canada is as good (not better) as other jurisdictions in basic research but we don't approach it with an eye to commercial success. Canada scores high on basic research in medicine but after it doesn't go anywhere." SME

Canada's clinical trial strengths were related to the quality of individual investigators and the clinical trial infrastructure. The caveats included limited Phase 1 expertise, bureaucracies, timelines, costs and relationships. There was a perception that academic hospitals would benefit from being more in tune with global contracting, the loss of patent life, loss of time on the market to recoup investment and the fact that companies, particularly SMEs are burning much needed cash or incurring legal costs while negotiating the trial through lengthy delays.

#### Industry Perspectives:

 "Prior to getting key human efficacy data, the indirect costs and delays of conducting a trial at the University of xyz Institute was the near terminal blow. Without this data, private investment and OEM engagement is not feasible." SME

- "Academic hospitals. Policies and practices which are slow and basically hostile to start-ups. E.g. clinical trials." SME
- "Canada only has two Phase 1 Centers so if a drug is discovered, the work goes out of Canada to take the next steps. There is no one stop shop to develop a treatment from bench to patient." MNE
- "An efficient and cost effective clinical trial process is essential to getting regulated medical device technologies out of the lab." SME

Concerns were also raised about Canada's ability to compete for R&D investment in the future if the country doesn't invest in electronic medical records, patient databases and big data that is accessible to industry. An EU 2015 conference on market access and real world data<sup>9</sup> identified the need to be able to gather and use health data outside clinical trials in order to shift from focus on price to value. The CD Howe Institute released a paper entitled "Missed Connections: The Adoption of Information Technology in Canadian Healthcare.<sup>10</sup>" The report recommends: "The federal government and the provinces, along with professional health-related colleges and associations, should adopt EHR (electronic health record) policies that are based on principles that incorporate elements of clinician involvement, governance issues, incentives for adoption and culture change based on how clinicians would like EHRs to be used." Unfortunately, the report misses industry as a potential partner and user of this information and does not comment on how it could, and must, contribute to Canada's competitive position when looking for R&D investment.

#### Industry Perspectives:

- "[Globally] some regions have access to databases of patients for clinical trials that have the patient's permission built in. It is automatic until the patient opts out. Vastly increases speed of getting a trial done." MNE
- "The lack of EMR makes data collection and linkages to databases hard and puts Canada at a disadvantage." MNE

#### **Other Strengths**

Beyond science and clinical trials, the corporate tax rate was praised by a number of CEOs. There were also mentions of strengths in: private reimbursement, people, opportunities to develop government relations experience across the ten provinces and other transferable skills, stability, proximity to the US, a sound regulatory environment, and infrastructure (people, programs, bricks and mortar). The private reimbursement environment allows for early commercialization where there is private insurance. One or two interviewees felt the public pricing was a strength, particularly in comparison with some European jurisdictions, but, for the most part, they were outliers.

#### Industry Perspectives:

 "Advantage for staff dealing with ten governments in developing skills and GR abilities. Talent hasn't been a problem. We have been able to hire as needed." MNE

- "Canada is still a place where you can negotiate price which is positive. Feel pressure to lower prices from the provinces but not as bad as France or the EU. The discussion can be open here if you bring good arguments to the table." MNE
- "Canada is between the EU and the US culturally which is a benefit to the company. Things can be tested here before entering the US market. It is a key country where you can try new things." MNE

## 7 Issues for Industry

Leaders of both local Ontario companies and multinational corporations offered views on the major issues facing the Canadian Health Science Industry acting as barriers to growth, investment and economic success (*Figure 4*). As in the past the number one issue for local companies continues to be capital access and the number one issue for multinationals continues to be how to predict and derive a return on investment within the Canadian market. For the first time, however, commonalities are emerging between the two parts of the industry as SMEs list market access and selling into the Canadian market as a major issue. Time delays, multiple layers, inconsistencies and conflicting decisions characterised comments on regulatory, procurement, reimbursement and tax processes.

#### Industry Perspectives:

- "Our local healthcare systems need to be our first customers not our last. If we have motivated customers that are seeking out ways to improve their practices, and are willing to invest in these ideas, this will be a significant driver for growth. It will give proven traction to new ideas at a very early stage. This will help attract capital to better fund those ideas and grow sustainable companies." SME
- "Investment would be improved by greater adoption of promising technologies. Growth would be improved by an outcome-driven healthcare system. The story for medical device companies in Canada is: "go prove your technology in the US and come back to Canada." SME
- "The public reimbursement environment is among the worst in the world. The time from approval to reimbursement is among the longest and has the most hoops. Too complex and cumbersome and there is no binding decision point. The reimbursement authorities are asking the right questions but arbitrarily and systematically denying access is not the way to do it." MNE
- "The hurdles to make innovations accessible to the patients are several years longer than in the rest of the world e.g. Health Canada, HTA, PMPRB, PCPA and listing agreements with each of the provinces. Germany and France are a 1 step process and even the UK has fewer steps." MNE
- "Ability to get reimbursement for treatment from government or insurance companies in particular for innovative products. Without this, getting early stage revenue is very challenging until they reach a critical mass, and so we see many companies that have a working product, but struggling to take that critical next step." SME
- "In the diagnostic space there are successful commercial companies with no ecosystem, no reimbursement and no policies. There is no framework for these leading edge companies to exist and no way to see their products succeed here." SME

- "Adoption, utility and usage. It is very difficult to sell into in Canada especially in Ontario. Need a shared approval process across hospitals or groups like LHINs (Local Health Integration Network). Need an Ontario program that mandates criteria for adoption so that companies don't have to fight each institution on a clinical and economic basis. The trend in the US and elsewhere include performance based payment, episodic care and risk sharing. Ontario is missing out on all of these opportunities as a province. It needs to adopt a holistic overview at a higher level than one doctor at one hospital." SME
- "The global growth in the diagnostic market is >5% but not in Canada due to focus on cost controls and a clamp down on diagnostics that would lead to the use of expensive drugs despite that diagnostic is 1% of the cost." MNE

Although market access, reimbursement and innovation adoption were mentioned by most if not all of the MNE CEOs and by a number of the SMEs, they were often part of an overall discussion of multiple overlapping factors and moving parts that include: the global nature of industry versus the national approach within Canada (and other countries), patent clocks, regulatory timelines, health technology assessments, pricing, procurement practices and risk management. Examples were provided of jurisdictions with publically funded healthcare that enter into negotiations where the moving parts can be used to reach an agreement that is acceptable to both payer and industry and where there are benefits to both. Canada was often seen as exclusively cost focused in the short term, siloed, and either unwilling or unable to engage in mutually beneficial negotiations, innovative practices of risk sharing and the development of expertise or leadership in value based pricing. One company did comment that Canada is an active part of global discussions on innovation in procurement practices. Finally, a few companies commented that the division between Federal and Provincial Governments in the healthcare sector can be confusing to their global counterparts.

#### Case Study 2:

**Spartan Biosciences** is a successful Ontario-based company that has achieved Health Canada approval for its molecular diagnostic technology back in 2014. There is **no clear, affordable path to adoption** by Ontario or other Canadian healthcare systems. In contrast, the company's technology has been approved for adoption and reimbursement in the United States, Europe and Korea. A system for **procurement of innovative products** would allow domestic companies to provide health care solutions to their own home markets.

Read more about Spartan Biosciences' experience in the Appendix, section 11.2.



Figure 4: Issues for Companies in the Canadian Health Science Industry

In addition to the factors mentioned above, several CEOs commented on structural and cultural issues, "soft skills" that are holding back investment and growth in the industry. The most frequently mentioned were predictability, transparency and consistency. Industry CEOs expressed concern that these qualities are not as strong as they should be in interactions with a number of government departments: CRA regarding SR&ED, Health Canada, HTA agencies, reimbursement authorities, granting agencies and policy makers. Qualitatively, CEOs felt many of the same systems are overly layered, slow and bureaucratic and do not make their decisions with the understanding that R&D and other industry functions are global.

#### Industry Perspectives:

- *"Policy related debates could be more public rather than left to Gazette publications after the fact."* MNE
- "Canada is not competitive. While the findings of health technology assessments and budgets are a reality we have to live with, the problem is the procedures not necessarily the content. There are multi layers versus efficiencies and lean procedures." MNE
- "The Canadian government plays a heavy role in healthcare delivery. It is hard to develop something in Canada then have the government refuse to adopt it because of cost constraints. The Innovation Adoption block is an upstream effect on development, i.e. we are not good at it because the system dis-incentivizes and we are working to commercialize technologies only to have them rejected. Other countries have an ongoing dialogue between governments and corporations. Canada is very low in dialogue between the corporations

doing innovation and government. Government 'consults' but doesn't listen and doesn't fuel ideas (both Provincial and Federal)." SME

- "Although the EU also has public health care, there aren't as many layers delaying time to market although price restrictions are similar, there is more time to recoup on investment." MNE
- "Layers and process interplay between Health Canada approval, PMPRB, CADTH, and the provincial formularies mean there are so many places for conflicting interpretations and places to get tripped up. [We] need to take down some walls and layers. Each body has its own remit and concerns but sees the problem differently and has a different perspective on value. It means the target is fuzzy and always moving." MNE

#### 7.1 Capital Access

Access to capital has been listed as the number one issue for industry and commented on in both national and international media for almost ten years. The 2015-16 Global Competitiveness Report<sup>11</sup> offers a comparison between 2007 and 2015 and states: "the most striking change is the surge of access to finance as one of the most serious problems for business in many countries, a consequence of the global financial crisis. Because of deleveraging and stricter regulations in the banking sector, uncertain economic prospects, and despite extremely low interest rates, obtaining finance is still very difficult, especially for small- and medium-sized enterprises." Interestingly, access to financing was the second most often chosen problematic factor for doing business in Canada behind capacity to innovate.

Access to appropriate capital for the company's needs was identified as a major barrier to scale up by 86% of the SME companies surveyed in 2015 and only one in four had one year or more of runway. This was also mentioned as an issue by a couple of the MNE CEOs in their comments on the Canadian ecosystem. SMEs report that more than one third of their total funding comes from individuals such as family and friends with 21% from government, 18% from revenues and an average of 10% from venture. Approximately half of the SME's had received funding from federal sources and 42% said they had received funding from the Government of Ontario. Health IT, Contract Research Organizations (CROs) and manufacturing companies accounted for the highest percentage of revenues while venture and public markets were most associated with clinical stage companies in the therapeutic, device and diagnostic spaces. On average, companies reported that 75% of their funding was from Canadian sources. Research and pre-clinical companies were least successful at attracting foreign capital and rely most heavily on Canadian sources of funding, pointing toward future problems with scale up and the need to relocate to obtain adequate financing.

Reports by the CVCA<sup>12</sup> suggest venture investing has improved in recent years and figures show health sciences attracted 22% or \$422 million in investment in 2014 in Canada. By comparison IT companies raised \$1,235.78 in venture funding (*Figure 5*). According to the 2014 STIC Report<sup>2</sup>, health and life sciences received the largest share of 2013-14 grant council money or \$1,099.5 million while ICT received \$183.0 million in grant money. Industry is not eligible for funding from most of the major grant councils of Canada.

The ability to move publicly funded health science research into adequately funded companies for translation and development continues to be an issue.



Figure 5: Comparison between the Health Science Sector and the IT Sector in the Dollars Raised from Private and Public Sources of Funding

By comparison, the National Venture Capital Association<sup>13</sup> and PWC<sup>14</sup> in the US reported "Investments in the Life Sciences sector (Biotechnology and Medical Devices combined) during the fourth quarter of 2015 accounted for US\$2 billion going into 172 deals". The total for 2015 can be estimated from the PWC MoneyTree reports at US\$10.2 billion. Venture investing in life sciences in the UK was £527 in 2014<sup>15</sup>.

Other jurisdictions, charitable organizations (with tax receipts), the resource sector (with flow through shares), the tech sector (66% of all venture raised) and government funded organizations were seen by companies as competing for the risk capital that could help grow the industry and it was recommended that health science investment funds be created specifically to meet the needs for research intensity, longer than average timelines and risk (*Figures 6 & 7*). Current restrictions on how government funds can be spent (e.g. only on research partnered with academia), where it can be spent, and an over-emphasis on investing small amounts of money through numerous independent programs were of particular concern to the SMEs in the study as timelines, multiple diligence processes and the costs of administration and reporting negatively impact the companies' burn rates. As one company put it: "we measure productivity not in numbers of grant applications but in ROI and business activity." The role of matching

funds in non-dilutive grants and the recent Supreme Court decision on the impact of government funding programs on research tax credits were seen as further limiting the effectiveness of government stimulus for local companies.



Figure 6: Barriers to Scale-up for Ontario Companies

#### Industry Perspectives:

- "Access to the right capital for growth and sustainability and for Canada to be able to retain the companies. Need more support in the middle stages – programs for mid stage companies to get to investability by large institutions. Post-angel, pre-VC. At this stage companies don't know what to do or where to go for money." SME
- "Access to capital to get from prototype to commercialization AND revenue generation. Getting funding to build the product is possible, but due to the challenge above we are seeing many companies struggle in the next phase of getting to sustainable revenue, without enough runway." SME
- "Outside of Quebec, Canadian funds have small dollar amounts. Typically these permit incremental pre-clinical steps but little or no ability to transition from pre-clinical to clinical stage." SME
- "Government support that requires revenues from sales in Canada is unrealistic given the difficulties selling into the Canadian market." SME

Urgent requests from industry (N=70) focus on accessing capital. Market ready and revenue generating companies (N=39) were looking for simplified procurement processes.	
Establish a health innovation capital fund that invests directly in healthcare companies	67%
Consolidate Government funding programs and simplify application and review processes	56%
Eliminate requirements for academic partnerships and matching funds from granting programs	47%
Adopt globally competitive tax policies to attract investment and help companies to grow	29%
Simplify procurement processes and facilitate adoption and dissemination of new drugs and technologies throughout the healthcare system	29%

#### Figure 7: Top 5 Things the Ontario Government Should Address Immediately

In addition to challenges raising funding within companies and the need to address incentives for investors, there were a number of suggestions for helping companies keep and extend the funding they bring in. These included wage credits or subsidies for job creation, improvements to SR&ED and the provincial tax R&D tax credits and flow-through shares for the Health Science Industry. Many of these recommendations are being echoed by other sectors in the innovation economy; for example, clean tech has requested flow through shares. SMEs expressed a need for refundable tax credits beyond those for research, an idea supported in a report from CD Howe<sup>16</sup> that noted "tax policy should be focused on creating a balanced and competitive tax environment across the entire innovation value chain, from initial R&D through commercialization to the development and production of new products and services." One caveat however is that to raise the net benefit of R&D tax incentives, compliance and administrative costs need to be examined and if possible, reduced. The CD Howe report also describes Canada's approach to tax incentives as overly focused on "pushing" R&D and not focused enough on "pull" incentives for companies to commercialize and develop new products and services in Canada. One suggestion is the introduction of a "patent box" that reduces the tax rate on income derived from patents that are developed and practiced in Canada<sup>17</sup>. The success of "pull" incentives for commercializing health technologies would also depend on fixing the challenges associated with selling into the Canadian market.

#### Case Study 3:

Canada is falling behind other nations when it comes to **innovation adoption** and that makes selling into the Canadian market harder than it needs to be for **Novadaq.** U.S sales outshine Canadian sales and its products are selling faster in India, China and Japan. One thing that holds up Canadian sales? Lack of funding for new technology purchased on the premise of future savings that result from improved healthcare. A capital allocation could help hospitals buy new technology and **help hospitals adopt innovation.** 

Read more about Novadaq's experience in the Appendix, section 11.3.

CEOs were further asked about the relationship between tax incentives and investment. While tax policies will not overcome significant barriers to investment, all things being equal, they can play a role in attracting investment and promoting ongoing operations in Canada. Half of the SMEs surveyed said that the erosion of SR&ED and other tax incentives are a barrier to growth and staying in Canada and one in four said recent changes make SR&ED significantly less helpful to health science companies (*Figure 8*). Close to half of the CEOs who responded had not made a SR&ED claim in the previous year. Of those that had, 26% received 100% of their claim.



Figure 8: Impact of SR&ED Changes is Viewed Negatively by Most Ontario SME's

#### Case Study 4:

**Staying and growing in Canada** has been a challenge for **VBI Vaccines.** As the company grew and attracted U.S. investment dollars, it lost its status as a Canadian-Controlled Private Corporation or CCPC and in turn, also the resulting SR&ED tax credits. And that has made maintaining its Ottawa-based research facilities hard to justify to foreign investors and made moving jobs south tempting. Following Australia's lead by implementing tax credits to reward where research is done and jobs are created could **help** Canadian **companies stay and grow**.

Read more about VBI's experience in the Appendix, section 11.4.

MNEs said that the eroded SR&ED criteria can make investment in Canadian trial centers or in SMEs less attractive and said that these investments do not appear to be recognized by Government and regulators.

#### Industry Perspectives:

- "SR&ED eligible R&D needs to be broader to help with internal competition and bring trials to Canada" MNE
- "Recognition of investments by companies in PMPRB negotiations. Too many investments are not eligible for consideration and SR&ED criteria may be being used as guidelines. Reports of investment are always understated versus the real amounts." MNE
- "When PMPRB is reviewing investment by a company during a price review, it is hard to understand what they are counting as investment. Definitions need to be re-examined to see if they make sense. SR&ED and what is allowable is shrinking. It is 20 years old and needs to be updated. External work is not captured and needs to be brought up to date to match the fact that innovation is more often through partnerships now." MNE
- "As a cross border company we find ourselves articulating the value of maintaining our research site in Canada. It would be nice if there were incentives that made that argument easier" MNE

The most popular options for improved tax policies were related to tax credits or exemptions for capital gains or dividends from investing in the sector, wage tax credits for R&D or payroll subsidies and flow-through shares (*Figure 9*). Some also questioned the CCPC limitations.

#### Industry Perspectives:

"Our SR&ED tax credit policy is a missed opportunity. It gets so many things right... it's accessible it leaves judgment to the market/competitiveness, it is efficient. It's problems are: I) it caps itself so that the pie can never get bigger... how incongruent is it to have a

policy that only imagines that successful R&D would mean an investment of 2M/annum. Where is the optimism in hoping our biggest SR&ED successes might create and support 20 R&D jobs?!? (20 x 100K), ii) it is closed off to successful companies that DO attract foreign investment and compete globally. Why would we do that?" SME

- "If the objective of SR&ED is to create jobs, why do we care whether the VC investors are Canadian or US?" SME
- "Funding programs for R&D and commercialization of new products; of course we are all worried about the SR&ED program continuing and would be very wounded should that program see drastic changes, or worse still, be gone." SME
- "Tax incentives are a variable (in making investments) but organizations are looking more long term." MNE
- "Need the right tax credits to encourage innovation and patient capital." MNE

In 2011 the expert panel tasked with reviewing Federal support to R&D released its report (Jenkins<sup>18</sup>) recommending: streamlining government programs, simplification of the tax credit system with a focus on labor costs and using the Business Development Bank of Canada to help innovative firms access risk capital at the start up and late stages. Five years later industry continues to support many of these recommendations. There continues to be a need to expand direct investment for companies, simplify Government programs and to update tax credits.

# SMEs are looking for tax policies that will incentivise investors and assist companies with job creation.

Tax exemptions or tax credits on capital gains or dividends	82%
from innovation companies	
Wage tax credits or payroll rebates for R&D	74%
Flow through shares for health science companies	33%

Figure 9: Tax Policy Recommendations from Industry Focus on Incentivising Investment and Creating Jobs

#### 7.2 Talent/Human Resources

Canada's talent pool has both positive and negative effects on the industry. On the plus side, there are a number of examples of commercial stage companies that are headquartered here and manufacture here because their founders and founding technical experts are here. Although this type of talent creates a certain degree of "stickiness", most of these companies open sites in other jurisdictions once they reach a certain level of production and sales and once knowledge transfer is mature within the organization. In

many cases this type of "stickiness" is not very robust as several of these companies have been unsuccessful getting their products adopted and reimbursed here.

On the down side, the talent pool is seen as neither wide nor deep. While talent was less of an issue with the MNEs, experienced and networked talent was seen as lacking in Canada and a number of CEOs talked about the value to an MNE of people who have worked in a number of countries and have exposure to new and different ways of thinking and doing things. SMEs reported more challenges with finding and retaining the human resources they need. Barriers that were mentioned include Canadian immigration policies, competition from jurisdictions with better financing, less risky companies, lack of incentives and security for employees to join and stay in the industry and lack of support for companies to create jobs and build an experienced workforce. Many felt there are too many co-op and "new grad" programs and an absence of support for long term training within companies in the Health Science Industry. Some felt there is too much focus on management and not enough on the other layers needed for scale up and commercialization.

The need for international talent and skills is not unique to the Health Science Industry and recent lobbying efforts by the Canadian IT sector have also included stock options to attract and retain talent and changes to immigration procedures to address the need for experienced workers to come here and share knowledge and expertise.

#### Case Study 5:

A lack of deeply experienced talent has led to **hiring challenges** for **Synaptive Medica**l, resulting in unfilled positions, untapped potential and unrealized growth. Retention is an issue too. Canada needs programs to attract people with optimal industry experience to build the talent pool on the job and provide knowledge transfer. Streamlined immigration processes and timelines, a re-imagining of the Job Board and visibility on stock option and share grants could help. Current job-related grant requirements that disqualify pre-revenue companies are a missed policy opportunity. Just some of the changes that could help **make hiring easier**.

Read more about Synaptive's experience in the Appendix, section 11.5.

#### Industry Perspectives:

- "People's experience is limited mostly to Canadian experience even if in multiple companies. Across the board, we need more diversification and exposure to innovation in other places for talent to draw on." MNE
- "We have talent but if you talk about experience, there are certain types of experience that we do not have in Canada e.g. a Director of Marketing in cardiovascular and wound healing

but if you are looking for an MBA, ours are as good as the US. Our approach is to find experience in the US and bridge with talent from Canada by sending bright people to the US and bringing them back." MNE

- "Trained scientists and professionals leaving the field, leaving the country due to lack of career opportunity." SME
- "Talent. We need anything that can help develop people. We need investment in training programs and support networks, mentorship and sounding boards for less experienced people. Best practices from big companies are unknown if people only have start-up experience. People are young, smart and logical but not experienced." SME
- "Because Canadian companies sell out early we don't have the commercial talent that have taken products to a sales success." SME
- "We don't like to admit it, but the Canadian ecosystem has difficulty attracting the best senior talent (with global experience). The industry is risky and accepting a job in Toronto/Montreal/Vancouver could put one's career at personal risk. So how can we get cross pollination to cultivate our own talent?" SME
- "Clinicians and scientists are good but there are layers of talent that are missing e.g. physician entrepreneurs on their third company after successful exits. On the industry side there are not a lot of companies in Canada that started from scratch like [my company] with a team of 4 and grew to a successful organization so industry can't provide the missing layers right now either. No translational experience from science to commercial product or in building science companies from nothing." MNE

#### 7.3 Intellectual Property

Canada's IP protection and interpretation of patent rights were raised by many of the MNEs particularly those in the pharmaceutical space. Concerns centered on compliance with international standards and setting aside rights to achieve cost savings. IP was seen as a key ingredient of a successful health science economy and the BCI 2015<sup>19</sup> report states "Canada's relatively low score is primarily due to a mediocre life sciences IP environment that deviates from international norms in important aspects of patenting and enforcement; an overly restrictive pricing and reimbursement environment; and delays in the regulatory system. These elements present major hurdles to investment and the biomedical environment overall."

A couple of SME said IP is also one of the major issues facing their company and a previous OBIO consultation noted that the ability to fund patents with insufficient investment is a concern for many companies.

On the positive side, a number of CEOs commented that Canada's approach to IP has come a long way, that the EU trade agreement would help to complete the process and that it is not a barrier for investment

by their companies. Despite some positive remarks in this study, Canada ranked 12<sup>th</sup> on intellectual property protection In the Global Competitiveness Index<sup>11</sup>.

#### Industry Perspectives:

- "Canada has the shortest patent life, the appeal process lags other countries and the patent term restoration has not been implemented yet." MNE
- "Think in terms of broader global harmonization. Be consistent with the best in the world to attract investment. Need IP protection, data protection, rare disease protection." MNE
- "IP isn't overly problematic but further reform can only help." MNE

#### 7.4 Ecosystem

Canadian CEOs are passionate about the Health Science Industry and about Canada. The health sciences industry is seen as a major part of the healthcare system, providing equipment, treatments, services and multifaceted solutions for use by providers and patients. It also is a source of high calibre jobs, research and manufacturing investment and partnerships for research institutions. The industry is a global source of health innovation and the vehicle by which Canadian innovations get to patients. It is also viewed as an important contributor to the Canadian economy.

The strengths in the ecosystem have been discussed previously; science, clinical trial capabilities, talent and Canada's key opinion leaders. Additionally CEOs remarked on Canada's stability and a sound, if overly slow, regulatory environment.

Connectivity, networks and collaborations were seen as key to capitalizing on scientific expertise and skill sets. One recommendation from industry CEOs was for Canada to create an ecosystem for scientists to connect and compete with proposals for global participation. Currently the STIC report<sup>2</sup> states that within Canada the highest collaborations were in clinical medicine, biomedical research and biology. At the same time, figures presented in the section of the STIC Report<sup>2</sup> on Knowledge Transfer suggest that 24% of Canadian university researchers' publications were co-authored by at least one researcher from another sector but only 2.6% were co-authored by industry. Canada's higher education institutions were creating approximately 16 licenses per institution for every 35 created in the US and the value created by licenses from Canadian institutions was estimated at \$2.2M versus \$13.5 for US universities.

The present study found that connections between industry and academia are not as strong as they could be and this may be reflected in the numbers above. Within the Health Science Industry, the move to common institutional reviews in Ontario was seen as positive but both MNE and SME CEOs still expressed frustration with costs and time delays for contracting and execution of collaboration or contract research projects and clinical trials.

#### Industry Perspectives:

- "Difficulties with university/hospital Tech Transfer offices that do not move quickly enough, or are not nimble enough, to support academic spin-offs in a meaningful or competitive manner." SME
- "Lack of infrastructure or access to biomedical equipment and tools needed for small biotech. Dealing with academic institutions is not easy and is a slow process." SME
- "It used to be most products were discovered in house but now most come from partnerships. This requires science, know-how and infrastructure in a country. The international group ranks Canada high on science but struggles with the overall ecosystem." MNE

Industry CEOs commented that Canada doesn't see innovation in healthcare, only cost containment and further, that it is very difficult to find physicians willing to participate in the development of innovative technologies from small companies with little money to spend.

#### Industry Perspectives:

 "Finding local early adopters that are actively looking to improve their practices and willing to invest (not only money, but resources in general such as staff, facilities) in pre-market innovative solutions is difficult." SME

Receptivity to innovation and the pervasiveness of risk aversion across all levels and stakeholders were seen as having an impact on many things: laying the groundwork for the future, investment, R&D, development, commercialization and competitiveness. Much has been made of Canada's 26<sup>th</sup> ranking in company spending on R&D but other rankings of Canada's innovation capacity from the Global Competitiveness Index<sup>11</sup> are also worthy of note. In the same study, Canada ranked 23<sup>rd</sup> out of 140 countries on capacity for innovation, 18<sup>th</sup> on quality of scientific research institutions, 19<sup>th</sup> on university-industry collaborations, 55<sup>th</sup> on government procurement of advanced technology products, 10<sup>th</sup> on availability of scientists and engineers and 19<sup>th</sup> on PCT patents, applications/million population. These scores also suggest important areas for consideration when assessing the ecosystem. Canada's ranking on government procurement is of particular concern given our public healthcare system.

In the present study, the quality of the relationship between industry and government was mentioned repeatedly in discussions of future issues, attracting investment, leading jurisdictions and policy recommendations.

#### Industry Perspectives:

• *"There is a trust issue. Neither can live without the other but there is a need to update the trust relationship. It is not where it should be and lacks action from the top." MNE* 

- "What does government really mean about partnerships with industry? MNEs bring new tech to Canada from other places. We must understand Canada can't get special treatment. Need to discuss what the ultimate goal is. If it is better treatment outcomes we are doing the wrong thing. Would love a chance to chair a meeting with politicians and bureaucrats to work on this. Industry can play an important role in getting to better healthcare efficiencies and outcomes e.g. through risk sharing but right now there is no appetite or mechanism. This is slowly killing innovation. Need incremental change that will add up to a real difference." MNE
- "The relationship between government and industry is non-existent." SME

The 2013 OBIO report "Realizing the Promise of Healthcare Innovation in Ontario"<sup>20</sup> identified trust as a fundamental barrier to moving forward to innovation adoption by the healthcare system. Within the current study, CEOs have identified trust as a barrier to building a successful healthcare industry and for meeting the future needs and challenges for Canada's healthcare system and economy. Relationships between government and industry have been identified as strengths in competitive jurisdictions and as providing a mechanism to share the risk of ensuring the high cost technologies of the future deliver the outcomes and cost savings promised in a complex system where gathering metrics and sharing rewards across siloed budgets is highly problematic. It should be noted, responses in this report were obtained during the high profile US investigations of drug price increases and a number of CEOs commented on the industry's image and the challenges with getting public support and recognition for the health and life solutions they provide.

#### 7.5 Policy

The 2015 BCI report<sup>19</sup> states that "a growing body of data suggests that on top of market size, demand and costs, economies' competitiveness for biomedical investment is positively linked to the local policy environment – all of the laws, regulations and initiatives in place affecting biopharmaceuticals. The overall scores exhibit a relatively clear division by income and development. All high income economies bar Russia score above 70 out of 100, with six of these seven achieving at least 75% of the total possible score. Having said that, some economies exhibit significant weaknesses in critical areas. For example, Canada represents an outlier among developed high-income economies. Although Canada has attractive aspects to its biomedical environment (such as robust regulatory system and generally international standard manufacturing capacity), what is notable is how far below other high-income economies its overall score falls, despite in some cases having a much larger market. Canada's relatively low score is primarily due to a mediocre life sciences IP environment that deviates from international norms in important aspects of patenting and enforcement, an overly restrictive pricing and reimbursement environment, and delays in the regulatory system. These elements present major hurdles to investment and the biomedical environment overall".

The lack of an industrial policy and strategy for the healthcare industry was raised by many SME's but also by MNEs who see the missing components of the health-science ecosystem when they make comparisons to other global jurisdictions. There were comments on the overall misalignment of policy with stated goals. For example, if stated goals include job creation and growth, CEOs asked questions on: why SR&ED criteria are linked to ownership and why much of the provincial research funding goes to academic centres instead of research jobs in industry? Why do government officials focus more on manufacturing and discount the creation of jobs in industrial R&D? Why doesn't the Canadian Institute for Health Research support clinical trials by local industry? Finally, if Ontario is investing in the future through genomics and individualized medicine, why is there no reimbursement framework for the molecular diagnostic tests that exist today and are reimbursed in other countries, including tests that were invented here?

#### Industry Perspectives:

- "Absence of coherent policy that would foster the growth of start-ups towards forming anchor corporations in healthcare." SME
- "Need a business plan at the federal level to change our dependence on the commodity world." MNE
- "Government looks at small companies too much and needs to invest in building a big player here. Work with global players to build a big domestic pharma company in Canada." MNE
- "Canada needs more stakeholders with experience and wisdom who could weigh in to the process and augment decision making." SME

Within the concept of a national strategy for building a successful, competitive Health Science Industry, there were specific mentions related to: incentivising investment and maximising companies' abilities to stretch each dollar; improving market access conditions; improving government funding programs; building an experienced workforce; and meeting international standards for health science-related IP (*Figure 10*). Governments were also encouraged to identify healthcare priorities, unmet medical needs and to devise a strategy for tendering projects to industry to solve priority challenges. Finally CEOs emphasised the need for Canada to address the problems of timelines, predictability, consistency and transparency, and to look to the future when designing and delivering new policies.



Figure 10: Industry had several Recommendations for Policies to Build Canada's Competitive Position

## 8 Recommendations

#### 8.1 National Industrial Policy for the Health Science Industry

In order to derive both economic and health system benefits from competing in a \$9 trillion market, Canada needs a national strategy to build our health sciences economy. Government policy makers must work in partnership with industry stakeholders to develop a sustainable and prosperous Canadian health sciences industry and must embrace innovation as a means to delivering efficient, outcomes-driven healthcare.

A national strategy for building a strong domestic health sciences industry must be established to recognize the fundamental role of industry in bringing health care solutions to patients and providers and to achieving a sustainable health sciences economy. This strategy must address the need to build local companies that will develop and deliver innovative health products to both domestic and global markets and must adopt globally competitive standards of assessing value, partnering with industry and protecting IP.

A coherent and consistent set of industrial policies anticipate the future and ensure:

- Canada is ranked highly on innovation, system efficiency and value and commercial success.
- A national focus on building an environment for success.
- An industry that has the capital and expertise to compete.
- An economy where the Health Science Industry is making a valued contribution.

#### Policies to encourage development and growth of Canada's Health Science Industry:

#### 1. Policies to address procurement and innovation adoption

# Build the environment for industry to thrive through market access policies targeted at growing, attracting, and ultimately retaining globally competitive companies to provide innovative products and solutions for the Canadian health system.

Access to Canadian markets is estimated to take more than two years longer than in other developed nations. The process is not well understood, predictable or transparent and both local and multinational companies are considering not registering new products in Canada or not seeking reimbursement to make them available. Canada is being left out of global conversations on solving the price versus benefit equation and is in danger of failing to build the infrastructure and processes that would enable shared risk and give Canadian patients access to advanced health solutions.

Policies to build the environment and enable market access should include:

• Aligning Canadian intellectual property rights with those of other advanced countries.

- Value based pricing and procurement policies that put a value on innovation, with shared risks and benefits for all stakeholders.
- Technology infrastructure policies, that will ensure that Canada is equipped with the required electronic medical records and databases that industry requires for big data analytics.
- Adoption and reimbursement policies, that streamline a predictable and timely path to market and that favors early adoption of locally developed technologies once approved by Health Canada.

#### 2. Policies to attract and retain investment in Canada's Health Science Industry

Access to the right capital and maximising its deployment for growth and success is local industry's number one priority and biggest challenge. Canada's R&D tax incentives are at risk of becoming non-competitive with other jurisdictions creating challenges for academic hospitals to attract research here and missing an opportunity to provide SMEs with additional runway.

Tax policies can influence the decision by a foreign investor to move a company or leave it where it is headquartered and should be used strategically to address Canada's competitive performance on measures of business enterprise and industrial R&D and to create more opportunities for companies to stay here and grow.

Policies to address the chronic challenges with accessing capital for Canadian SMEs and to ensure Canada can compete for global R&D investment in the health science space should include:

- Creating health science specific investment funds to address the timelines and needs of this industry.
- Capital gains tax credits/exemptions for investors in health technology companies.
- Wage tax credits or subsidies to enable job creation and the building of an experienced workforce.
- Talent attraction and retention policies or programs that will provide direct funding support or tax relief for companies to competitively develop experienced personnel.
- R&D tax credits that recognize:
  - Investment in scientific development to meet regulations and commercialize.
  - MNE investment in local companies.
  - Work and jobs in Canada rather than ownership.
  - The need for refundability for pre-revenue companies.

- Industry-focused government programs that are nimble, streamlined, reward corporate investment in technology development and are unbundled from academic partnership requirements.
- Ensure the health technology sector is included in any consideration of extending the Flow Through Share regime to other tech sectors to avoid biasing sources of risk capital away from health technology.
- Incentivize technology exports without penalizing companies that have sales in international markets but without significant revenues in Canada.
- Eliminate program requirements that SME companies have sales in Canada to offset challenges with gaining access to the Canadian markets.

#### 8.2 Building a Strong Health Science Industry in Ontario

#### 8.2.1 Addressing Barriers to Scale-up for Ontario Companies

A sustainable, successful Ontario Health Science industry capable of solution-driven R&D and product commercialization represents significant potential for Ontario's economy. Enhancing Ontario's attractiveness as a jurisdiction for investment and growing companies can be achieved by investing in specific programs and incentives for Health Science Industry growth and competitive success. These programs and incentives will attract investment, fuel revenue and support knowledge economy job growth.

#### Key recommendations for Ontario include:

- Attract Health Science Industry investment to Ontario by addressing procurement and market access barriers and addressing clinical trial costs and delays.
- Improve access to capital for Ontario Health Science Companies by creating a health science innovation capital fund, streamlining government programs and eliminating arduous matching fund and academic partnership requirements.
- Deploy tax credits to incentivize investment, extend runway and create jobs by introducing wage subsidies or tax credits for SMEs, removing non-Canadian companies from the associatedcorporations category in the taxable capital test and/or increasing the \$800 limit for taxable income and the \$50 million taxable capital cap.
- Modernize tax credit eligibility criteria to allow companies to stay and grow in Ontario by including commercial development research activities, allowing research activities that are not available in Canada to be eligible for tax credits, and revising the associated-corporations rules as described above.
- Build an experienced workforce through job creation within industry and by using the Provincial Nominee Program to accelerate the immigration of experienced healthcare industry personnel who can transfer knowledge through on the job mentoring and training.

## 9 Discussion

Following the 2015 Federal election, Prime Minister Trudeau issued mandate letters to each of his ministers. These letters are publically available and provide insights into what the Government is planning. While many industries are mentioned for specific investment or policy initiatives to strengthen their role in the Canadian economy, the Health Science Industry is conspicuously absent as a contributor to economic growth and is only tangentially mentioned in discussions of the need to adopt digital health and of a national formulary for pharmaceuticals. The Health Science Industry is not mentioned in the innovation agenda nor as a place for job creation for Canada's well educated work force. Instead it might be assumed to be captured under the broad term "science" within academia and proposed co-op programs and possibly under initiatives for incubators and accelerators or regenerative medicine investment. There is no mention of strategies or policies to strengthen Canada's Health Science Industry or to prepare Canada to assume a leading or even successful role in the global bioeconomy of the future.

As recently as January 2016 the Globe and Mail released an article<sup>21</sup> on Canada's "non-innovation innovation policy" based on a brief to the Minister of Innovation Science and Economic Development obtained through Access to Information. While the article quotes people like Jim Balsillie and Dan Breznitz as calling for change and for long-term industrial policies to help foster the growth of successful domestic technology companies, there is no mention of health technology as one of the sectors. These oversights need to be addressed to meet the needs of Canadians for leading edge, affordable healthcare, quality jobs and for a growing economy.

Canada has been described as having fallen behind and as underperforming in the areas of innovation and productivity. Industry is vital to the process of translating research into treatments, skills and processes and to closing the circle on knowledge transfer. In order to build a new economy, we need to build a new environment and we need to focus on building industry. This requires parallel effort not sequential steps to maximise returns to Canada in the shortest period of time.

There has been a clamour of voices in reports, op-eds, studies and white papers urging policy makers at every level to make change. Some go back several years and some have been commissioned by policy makers themselves. While it may be tempting to say there is nothing new, the current report reflects the experience of industry in 2015 and clearly shows that while there is opportunity in the global health market, Canada is not in a position to compete for it yet and may lack the basic infrastructure to hold its current place. Further, this report points to specific fixes and makes recommendations to implement them. First, the health-science industry must get on the agenda as an industry and as a critical part of the ecosystem. While we can't change the size of the Canadian market or the arising needs in our aging population, we can change who and how we bring participants to the table to find solutions. We can look to other jurisdictions with identical challenges on the cost side but with dramatically different answers, or at least risk sharing experiments, on the solution side.

In some ways we are fortunate. We are not starting to build an industry from a base of no knowledge, no education, poor infrastructure and no history. We have an industry that contributes to our economy and to the prosperity and health of Canadians. We need to address policies and processes and to work more effectively together to make our industry successful and competitive in the future and to ensure Canada is an attractive place for the health-science industry to invest, stay and grow.

10 Appendix 1:

Demographics of Ontario Health Science Companies The following demographics information on Ontario health sciences companies comes from a survey conducted by OBIO with over 80 companies participating. The number of company respondents is specified for each dataset, as not all companies answered every question.

#### **Basic Demographics of Ontario SME's**

The majority of Ontario health sciences companies are privately owned (91%). Only a few Ontario companies (9%) have been able to access the public markets for capital. Public companies tended to be clinical stage and in the therapeutic space. In terms of companies that are generating sales, and expanding to global markets, only 25% are at the stage of revenue generation. However, OBIO has noted from previous internal survey data that in the last four years there has been a slight increase in the proportion of companies generating revenues. At the same time there has been a slight increase in the proportion of early stage companies, while the number of clinical companies has dropped. This makes R&D incentives an important incentive for companies remaining in Ontario.



#### Figure 11: Basic Demographics of Ontario SME's:

Most Health Sciences companies are privately owned in Ontario (91% privately owned, 9% publicly owned, N=70). Majority of companies in Ontario are at pre-cinical developent (31%), followed by clinical

development phase (20%), market ready (17%), generating sales (16%), market expansion (9%), research (7%) (N=70).

#### **Employment Among Ontario SME's**

Most Ontario health science companies (68%) have fewer than ten employees (*Figure 12*). Among medical device company respondents, this number increased to 80%. CROs, diagnostic and manufacturing companies showed a trend toward larger companies. By comparison, in 2011 56% of companies had fewer than ten employees. Job creation in 2016 is projected to grow, with at least 82% of responding companies planning to hire one or more new people in the next year compared to 40% of companies in 2012 who said they planned to hire.



Figure 12: Employment for Ontario SME's

#### **Revenues and Domestic Sales for Ontario SME's**

The majority of Ontario companies (68%) earned less than \$5 million last year and about half said their revenues were the same as in the previous year (*Figure 13*). Of the companies with sales, one third said they have no sales in either Ontario or Canada. For medical device and Health IT companies, this number was closer to half.



Figure 13: Revenues and Domestic Sales for Ontario SME's

#### **Runway and Sources of Funding for Ontario SME's**

The 2012 OBIO consultation found that companies reported an average of fourteen months of runway (*Figure 14*). Now, for 2016, more than half the companies have fewer than twelve months of fiscal sustainability. Only 25% of companies responded with confidence that they had thirteen or more months of funding remaining.

On average, companies reported that 75% of their funding was from Canadian sources. Research and preclinical companies are least successful at attracting foreign capital and rely most heavily on Canadian sources of funding



#### Figure 14: Runway and Sources of Funding for Ontario SME's

#### **Funding Sources for Ontario SME's**

Ontario companies rely heavily on private individuals and government for their sources of funding (*Figure 15*). Health IT, CRO's and manufacturing companies account for the highest percentage of revenues while venture and public markets are most associated with clinical stage companies in the therapeutic, device and diagnostic spaces.

About half of Ontario based companies have received funding through a federal program and only 42% from a provincial program.



Figure 15: Funding Sources for Ontario SME's.

11 Appendix 2:

Case Studies of Ontario Health Science Companies

#### 11.1 LEO PHARMA A/S

Spokesperson: Xavier Bertin, President and CEO

#### **Investing in the Canadian Health Science Ecosystem**

LEO Pharma A/S is a leading global pharma company specializing in dermatology and thrombosis. Headquartered in Denmark, the company has operations in 61 countries world-wide and sales in 100. LEO Pharma A/S is owned by the LEO Foundation which is an independent, private institution. Xavier Bertin, CEO of the Canadian affiliate, explains that being owned by a foundation provides the stability needed to plan focused, long-term research and development programs that address unmet patient needs.

In 2015 the company invested in the establishment of LEO Innovation Lab — headquartered in Denmark, with locations in France, the UK and Canada — to ensure the company is well positioned to fulfill the corporate mission to improve patients' lives. The LEO Innovation Lab has been established with non-profit requirements and is part of a long-term strategic decision by LEO Pharma to put people at the center. As announced, on January 27, 2016 Canada became the company's first Innovation Lab in North America, headed by Miron Derchansky.

LEO Pharma Inc. (Canada) was established in 1983. Mr. Bertin explained that the decision to invest in an Innovation Lab here was because Canada is positively perceived and that Ontario has a reputation for innovation. There are opportunities to pilot patient centered trials here and the plan is for ideas generated in the Innovation Lab to be tested in the Canadian marketplace. Canada will be a key country involved in this global initiative. To keep attracting global investment, Canada needs to facilitate access to innovation and establish predictability and interpretation of criteria for reimbursement. Criteria for reimbursement and pricing must be clear and consistent and not solely focused on cost containment. There should also be agreement across all provinces on what the criteria are.

The LEO Innovation Lab is backed by \$100M CDN in funding and will partner with the start-up community to foster innovation in non-drug advanced technologies. Along with the Innovation Lab, LEO Pharma announced a LEO Ventures initiative addressing access to capital; the number one issue for SMEs in Ontario. LEO Innovation Lab is prepared to invest in and give grants to start-ups to find and develop solutions that focus on all the areas of peoples' lives that can be impacted such as stress, diet, nutrition, family, fitness, beauty and relationship with the doctor.

#### 11.2 SPARTAN DIAGNOSTICS

#### Spokesperson: Charudutt Shah, Business Development Officer

#### Molecular Diagnostics and Individualised Therapy in Canada: Is there a Future?

By many metrics Spartan is a successful company. Located in Ottawa and employing fifty-five people, Spartan has developed a rapid on-demand DNA diagnostic test that identifies potential drug metabolism issues for patients undergoing treatment with medications that are metabolized by the Cytochrome P450 2C19 gene system. One in three people carry CYP2C19 mutations that can impair drug metabolism, leading to waste, treatment failure, increased adverse events and delays in getting effective therapy. The Spartan RX CYP2C19 test is small, non-invasive and can help clinicians in real time select the most appropriate drugs and dosages for patients undergoing treatments for conditions such as coronary angioplasty, heart disease, epilepsy, depression and pain related diseases.

The company's innovative technology has attracted the attention of Canon USA resulting in a strategic investment. Spartan has been supported by US cardiologists who view the system as enabling individualised anti-platelet therapy. The system carries 100% specificity and reliability and was approved by Health Canada in 2014. However, as a molecular diagnostic, there is no clear, affordable path to adoption and it is not reimbursed by Ontario or other Canadian healthcare systems.

By contrast, the Spartan CYP2C19 system was reviewed and approved by the FDA in October of 2013 and accepted for Medicare/Medicaid reimbursement in early 2014. The rationale behind both approval and reimbursement in the US is being accepted by other international markets and Spartan has obtained a CE IVD mark and a Korean MFDS License where the test will also be reimbursed. Further, the fact that Spartan manufactures in Canada opens up the possibility of fast tracking their technology in many countries.

The incidence of heart disease and the prescribing of anti-platelet therapies in Canada is as high as in these other countries and Canadians are equally likely to have the genetic mutation that interferes with metabolism of anti-platelet and other common medications. Ontario has invested heavily in genomics research and has publicly identified personalised therapy as a priority for the future, yet OHIP doesn't cover the Spartan system and Canadians cannot pay privately in Ontario for such genetic tests.

Spartan is not the only company in this space whose sales are 90% from international markets. There is a perception within industry that there is no framework for the successful commercialization of molecular diagnostics despite discovering, researching, developing and manufacturing the technologies here. To be the first to get reimbursement and adoption would take a "monumental effort which is better expended elsewhere" where the outcome data accepted by US Medicare is consistent with requirements and there is no additional need to do local trials.

Companies like Spartan are still in Ontario because their founders and founding technology experts are here. Given time and the opportunity for knowledge transfer, there is a real risk they will be lost to jurisdictions where innovation is embraced and the deployment of genetic testing for personalising medical treatment is more than an academic exercise.

#### 11.3 NOVADAQ

Spokesperson: Arun Menawat, CEO

#### Slow Innovation Adoption: Regulatory Approvals Fail to Translate into Canadian Sales for Novadaq's Proven Imaging Technology Products

Since its founding in 2000, Novadaq has developed and launched four different imaging systems specifically designed for different surgical specialities. Each incorporates Novadaq's SPY® technology, a real-time fluorescence imaging technology that enables surgeons and wound care specialists to image blood flow and tissue perfusion in real-time during complex procedures including reconstruction, colorectal surgery, surgical oncology and cardiac and vascular surgery. Over 175 publications attest to the compelling health and costs benefits associated with the systems' use.

Since then, the company has grown from three employees in Toronto to 340 worldwide.

However, growth outside of Canada has been much quicker and is a reflection of faster technology innovation adoption beyond our borders. Canadian hospitals and healthcare facilities are not adopting the products as quickly as U.S. or foreign institutions.

In a 2013 OBIO case study, Novadaq detailed the vast difference in its success between selling into both the US and Canadian markets. At the time, more than 850 hospitals in the U.S. had adopted its technology compared to just ten in Canada.

There has been little traction in Canada since then while other jurisdictions quickly adopt the technology. Even though Novadaq has only been selling into the international market for just over a year, it expects units in China, India and Japan to all exceed those in Canada by year's end. As a result, Novadaq is increasing its salespeople in all other current jurisdictions except Canada.

Canadian hospitals lack the necessary capital to invest in new technology, and often only have the funds to replace current technology. There is no mechanism to invest money up front for future savings. And working through hospital foundations to access capital is often slow and bureaucratic.

Novadaq suggests the development of a fund to facilitate acquisition of new technology. Either provincially or federally funded, this capital allocation would eliminate the need to apply for research funding in which the equipment is purchased as part of a research-focused initiative. It would also eliminate hospital foundations as middle-man when it comes to purchasing new equipment. Optimally, the fund would also cover operating costs, including service, repairs and disposables, for the first two to three years while the user builds a business case for cost reduction.

Tax breaks for purchases of Canadian manufactured products would also provide additional incentive for the purchase of leading edge products such as Novadaq's. Right now, there is no such incentive and as such, Novadaq has no advantage selling into the Canadian market. Policy changes such as the development of a fund for the purchase of new technology and tax breaks for Canadian manufactured goods, could help increase technology innovation at Canadian hospitals and provide better care for patients.

#### 11.4 VBI VACCINES

Spokesperson: Adam Buckley, V.P. Operations and Project Management

#### SR&ED Modifications Could Improve Canadian Health Science Company 'Stickiness'

Variation Biotechnologies Inc., or VBI, is working to develop technologies that expand vaccine protection using its eVLP vaccine platform. Its lead asset is a prophylactic Cytomegalovirus vaccine which the company is getting ready to put into preclinical and Phase I trials.

Founded in 2006, VBI started with five employees and has since grown to twenty-two. However, as the company expanded and began to attract U.S. investment dollars, it lost its status as a Canadian Controlled Private Corporation, or CCPC. As a result, it no longer qualified for the Federal SR&ED tax credit and the resulting dollars that would make keeping jobs in Canada more economically viable.

Now headquartered in Massachusetts, VBI Vaccines has maintained research facilities in Ottawa; as a cross border company, it regularly reviews the maintenance of its R&D site in Canada as part of updating its business strategy. For VBI's foreign investors, the loss of SR&ED makes it difficult to justify continuing Canadian operations and makes the idea of moving jobs south more tempting.

As such, the SR&ED CCPC requirement undermines Canadian companies' ability to create and keep quality health care jobs in Canada.

Other jurisdictions such as Australia, faced with a drain of high potential early stage companies such as VBI, responded with changes to tax credits that reward where the R&D work is done and where jobs are created.

A similar change here would allow an entity located and conducting research in Canada to be eligible for the SR&ED tax credit regardless of ownership. This would increase Canada's attractiveness to foreign capital and free up Canadian companies to raise funds outside Canada and grow, creating revenues, jobs and wealth for Canada.

A further incentive to increase 'stickiness' for companies such as VBI would be to extend SR&ED eligibility for expenditures for scientific research and experimental development to R&D that cannot be conducted in Canada.

#### 11.5 SYNAPTIVE MEDICAL

Spokesperson: Cameron Piron, CEO and Maia Jones, Director of HR

#### Mission Critical: Attracting and Retaining Talent for High Growth Health Science Companies

The lack of a deep pool of experienced individuals required to effectively scale up and support later stage biopharma companies like Synaptive is one of the industry's greatest challenges. And while Canada may have a wealth of talent, it is not always the right talent needed by growing device companies like Synaptive Medical.

Synaptive has found there simply aren't enough qualified people within Canada that have experience with the specific skills they require. Canada needs programs to bring in people with the right industry experience; people who can build the talent pool on the job and provide knowledge transfer once they are here.

The neurosurgical technology development firm started in 2012 with two employees. Since then, it's grown to 210 employees. Positions have been difficult to fill. As a result, more than fifty positions remain open as the company navigates the uncertain immigration process as it looks to the U.S. to meet its needs.

In two specific instances, Synaptive has had trouble securing the go-ahead to hire U.S. candidates because it must first prove there is no one in Canada with the right experience and skills. The current process involving the Federal Job Bank Board is not suited to high tech, skilled positions, and in Synaptive's experience leads to inaccurate matching of jobs with candidates.

Retention is also a challenge, as filling jobs from a limited pool of talent has also resulted in poaching, a common occurrence in the Canadian Health Science Industry where smaller companies can't compete with salaries, security and better benefits packages offered by larger firms.

Smaller firms need to be able to use stock options and share grants to level the playing field and companies are concerned these tools will be taken away by changes to policy. Job-related grants that pre-revenue companies like Synaptive are not qualified for are also a missed policy opportunity for Canada to stimulate growth in our research focused health science firms.

In the meantime, Synaptive supports a long-term view of Canadian talent development through job creation and retention within industry to develop seasoned employees with the global networks and experience required to take a product from science to manufacturing and revenues.

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