Life sciences ecosystem: building capacity in Canada supporting biomanufacturing in a post-pandemic world.

On behalf of the over two hundred and forty member companies, BIOTECanada welcomes the opportunity to contribute to the government's biomanufacturing consultation. This is clearly an important and timely opportunity for Canada to identify and build upon its strategic assets in preparation for a future pandemic-like crisis. In this context, the industry offers the following perspectives.

- It is both prudent and strategic to develop domestic capacity to address a future health crisis akin to the current pandemic;
- Knowing that we cannot predict what form the next health challenge will take, it is important to develop a holistic response capacity;
- Canada's diverse biotech ecosystem provides the competitive advantage and a strong foundation upon which the government can build a holistic response;
- Accordingly, the government is strongly encouraged to focus on and augment existing areas of strength and expertise;
- Address some of the important existing gaps requiring government investment (eg: investment capital and manufacturing);
- Recognize that for the initiative to be effective and flexible, it must be commercial and connected globally to the multinational pharmaceutical industry; and
- The design should provide not only an emergency response capacity but also a means for economic growth, particularly during non-crisis periods;

Considerations

As the world begins to emerge from the severe human and economic impacts of the global pandemic, Canada has an opportunity to build from a position of strength in determining the next generation of solutions for healthcare and pandemic emergencies. With a vibrant, regionally strong life science ecosystem across Canada, drawing from both public and private global networks, the potential for life sciences to drive long term sustained economic growth is unprecedented. Canada's networks of research and academic institutions, startup companies, skilled expertise, private investments and commercial leaders have established a globally recognized level of scientific and research excellence.

The COVID-19 pandemic has illustrated the vital role Canadian life sciences has played in helping to address the global requirements of solving the current COVID 19 pandemic. Canadian biotechnology companies and organizations such as AbCellera, Acuitas Therapeutics, IMV, VBI Vaccines, Precision Nanosystems, Medicago, VIDO-InterVac, are developing specific

technologies and products which have placed Canada at the forefront of international efforts dedicated to combatting COVID 19. Indeed, as a result of its vibrant and diverse ecosystem, Canada has clearly been I apposition to make significant and impactful contributions to fight against this virus. In addition, several Canadian biotechnology companies have combined forces with multinational companies to combat COVID-19. For example, Canadian biotechnology companies such as Acuitas in Vancouver partnered with global pharma company Pfizer and BioNTech to develop the first COVID-19 mRNA vaccine; Abcellera also in Vancouver partnered with Lilly to bring an antibody treatment for COVID; and Medicago in Quebec City working with GSK on a COVID-19 vaccine candidate. Additionally, dozens of Canadian start-up companies have worked to pivot their research and development work into early-stage potential therapeutics and new vaccine candidates. All this expertise has established a path towards the recovery, economic growth and sustainability and involved thousands of jobs created for highly skilled Canadians.

The Canadian government recently initiated a national consultation designed to capture the vast potential of biomanufacturing in Canada to build capacity to address pandemic preparedness and other health emergencies. The entire life sciences ecosystem must be the foundation for determining the success of this public policy commitment. From academic research to small start-up companies to multinational commercial interests, a continuum of capacity building is the essence of how success for this initiative will be realized. The consultation document clearly identifies the issue of existing gaps and limitations in Canada's ability to produce at required scale, the lifesaving vaccines and medicines needed in times of public health emergencies like COVID-19. The challenge for Canada is to build a sustainable system to respond to current and future health emergencies.

The life sciences industry in Canada has called for a national strategy to capture the vast economic potential as part of the rebuilding required in the post pandemic economy. Understanding the goal of the government is to grow critical biologic based technologies, therapies and supply chains, the industry and partners stand ready to trigger the full life sciences ecosystem in order to build on the strategic investments made to date while ensuring a secure, long-term state of readiness designed to respond to future public health emergencies and needs.

As evidenced by the vast national network already actively responding to the current needs for vaccines and therapeutics, there remain serious gaps in capacity which have been long standing challenges to realizing the full potential of the ecosystem. The government, in its call for input towards a biomanufacturing strategy recognizes the need and opportunity to address the potential of aligning public investments with academic, clinical, investor and private industry potential.

The Opportunity for Readiness and Economic Growth

Throughout 2020, the public investments made by ISED into the sector have been targeted and valuable towards building the framework for the bio-manufacturing potential in Canada. The investments made by the Strategic Innovation Fund and the Industrial Research Assistance Program (IRAP) have supported pivotal milestone activity throughout the sector. These investments are impacting the sector via specialized technology research and development, direct job creation and physical infrastructure. These examples build on the expansive multi-year investments into the academic and research community the federal government and private sector has made for many years.

Integral to the capacity and expertise of the life sciences ecosystem are the partnerships framed not only with public sector institutions including research hospitals and academia, but with global commercial companies. In 2018, Sanofi invested $500 million into vaccine manufacturing, October 2020 saw Roche Canada announce $500 million for a new global operations facility; in February 2021 Novo Nordisk announced it was investing $20 million into a joint project with University of Toronto in diabetes and population health; Zymeworks in Vancouver has announced 10 research and development partnerships with global pharmaceutical companies; Novartis Pharmaceuticals and the Mila Institute announced in October 2020 the creation of the Biome Digital Innovation Hub; Pfizer Canada and AdMare have created a national executive training program for SME Corporate Executive leadership; and, Amgen is in a strategic partnership with Toronto Innovation Acceleration Partners (TIAP) to co-fund and advance early-stage health technologies. These partnerships and investments underscore the strategic importance of the multinational pharmaceutical industry within the biotech ecosystem. An initiative designed to improve Canada's ability to leverage its biotech ecosystem for both economic growth and health crisis preparedness must recognize this important relationship.

The expertise and portfolio of knowledge these investments have created is a crowning achievement for Canada. Today, if the goals of a national bio-manufacturing strategy are to be realized, it is vital to both keep creating the next round of start-up companies, while pulling the existing portfolio of vaccine and therapeutic candidates, into the development and commercialization cycle. The opportunity to leverage the years of previous government investments into immediate commercial value, create thousands of highly skilled jobs and turn Canadian innovations into global operational companies in Canada is here today.

The need to unlock this potential has been recognized by numerous reports and evaluations, most recently including the government's own Health and Biosciences Economic Strategic Table report (September 2018) and the recently published Deep Centre report (2021). Dedicated

investments into the sector will help to ensure Canadians are protected during future pandemics. The next health crisis or pandemic could be cancer, diabetes, viral, bacterial, fungal, and those threats are well documented. Emerging companies like Adapsyn, Bright Angel Therapeutics, Aspect Biosystems, or Turnstone Biologics are working on the next generation technologies including stem cells that could be called upon in the next health crisis. Ensuring Canada has the domestic capacity to manufacture the variety of solutions on the horizon is vital to the potential success of any biomanufacturing strategy. They will also bring desperately needed economic benefits including skilled job creation, help to attract investment proposals from vaccine developers and allow for existing and new start-up companies to keep building operations here in Canada.

The success of any public policy framework designed for capacity and commercialization will be determined by a full continuum of program alignment.

It is with this in mind, BIOTECanada is highlighting 3 fundamental building blocks:

1. Attracting venture capital
2. **Technology transfer, incubators and accelerators**
3. Infrastructure investments

These building blocks are essential and interdependent – a piecemeal approach will not work. Together, these building blocks create a vibrant ecosystem establishing in Canada long-term high-quality, inclusive jobs, open to all Canadians, a strengthened R&D pipeline, SME's capable of building operations in Canada, and ultimately a secure supply chain supporting the biomanufacturing and life science innovation system. Additionally, improved SME financial returns, allowing investors to continue supporting the sector and providing fiscal revenue to the government.

We are competing in a global innovation race and cannot afford to be complacent. Our biotechnology sector operates in a hyper-competitive and everchanging world for investment and talent, not only with biotechnology companies but a broad range of business sectors. As global forces reshape the post pandemic economic landscape, new strategies and models are needed to boost productivity and competitiveness.

Prior to the pandemic, countries such as the U.S., China, U.K, France, and Israel, were already significantly increasing their support of innovation systems. This competition has only heightened as the grip of the global pandemic hit and challenged nations to capitalize and translate expertise and knowledge into rapid fire development cycles.

1. Attracting Venture Capital:

Venture capital, and later public markets, are the fuel required across the entire value chain, from seed stage to expansion capital, growth and public listings. It is ultimately what will realize the creation of foundational biomanufacturing companies. Success with previous investments into venture capital even on the limited basis into life sciences from the Venture Capital Catalyst Initiative (VCCI) and Venture Capital Action Plan (VCAP) programs, has helped to spur on unprecedented levels of investment attraction and commercial growth for leading Canadian life science companies including StemCell, Aurinia, Abcellera, Repare, Fusion, Zymeworks. Additional medical device company success was also realized—another key component to the biomanufacturing sector.

A dedicated Life Sciences VCCI would be a national, dedicated life sciences investment envelope in the amount of $500 million, within the well-established VCCI framework. Each federal dollar dedicated in this envelope has the potential to be leveraged with two (2) other dollars. This envelope should be committed rapidly – within six to 12 months – to capitalize on global investments into the life sciences sector and to ensure maximum impact so that recipient organizations and companies can then deploy it over the next three years.

The capacity for deployment of an envelope of this size has never been more opportune for Canadian governments and investors. Canada's life sciences venture capital sector has seen significant growth over recent years. Between 2013 and 2019, the Canadian sector has experienced a 121% increase in the number of deals (53 to 117) and a 300% increase in dollars invested (CAD$271 million to CAD $1.085 billion). At least five Canadian funds entirely focused in the sector are seeking to raise CAD$ 800 million over the next 18 months. Importantly, this envelope would be a critical catalyst, providing the capital required to expand the Canadian venture capital sector to appropriately support the full Canadian life sciences innovation continuum.

To date, Canada has been very successful in starting companies but has not effectively retained those companies once created. Without an adequate domestic capital pool, most of these companies must eventually leave Canada in search of larger investment pools. In this context, a critically important aspect of the Fund is to establish a significant pool of investment capital which would enable Canadian VCs to be the lead investors in more Canadian companies. This will in turn significantly reduce the need for Canadian early-stage companies to leave Canada in search of larger pools of capital. Ultimately this will provide the necessary conditions for not only growing but also retaining more domestic companies.

This recommendation builds on the previous successful VCAP and subsequent VCCI funds created by the federal government. The proposed dedicated Life Sciences VCCI envelope

mirrors the fiscal opportunity for deriving investment returns for the Federal government's economic stimulus and growth targets. As of the end of 2018, the impact of VCAP was to create through further leverage more than $331 million dollars of investment capital directed into the life sciences sector, despite being a minority portion, which helped create 51 life science companies and created or supported more than 4,300 highly skilled jobs.

National Canadian investors, of a large enough size, are required to drive value with international investors for investment power can be shared, more companies can grow into anchor companies, and financial returns flow back to Canadians. Traditionally, Canadian funds in this sector are too small to play a lead role, thereby limiting capacity to secure operational growth within Canadian borders. The large Canadian pools of capital (e.g., pension funds, VCCI funds) are largely absent from life sciences leaving start-ups and potential foundational companies in the biomanufacturing sector vulnerable to moving outside of Canada to grow.

Recommendation

The federal government invest $500 million to establish the *Life Sciences Capital Catalyst Initiative (LS-VCCI),* a life sciences venture envelope with the critical capital necessary and incentives to attract private capital (from Canadian institutional investors Canadian Pension Plan (CPP), OMERS etc. as well as international sources) in order to grow the availability of capital to domestic life science venture funds, top performing later stage companies, as well as key seed stage initiatives.

To maximize the return to government on its investment, the proposed "Life Sciences VCCI" would have three (3) major functions, namely:

I. **Finance seed and early-stage funding vehicles**: These vehicles will support company creation and early-stage growth of innovations/companies emerging from Canada's leading academic institutions;
II. **Grow Canadian venture capital fund capacity**: Strengthen and grow the Canadian venture capital investment pool by facilitating the collaboration of Canadian venture capital firms and attract investment from larger domestic investors and investors from outside Canada; and,
III. **Create Canadian-based anchor companies**: Provide later stage companies (private or public) access to investment capital to support their ability to grow in Canada and ultimately mature into domestic anchor companies with biomanufacturing in Canada.

2. Technology Transfer, Incubators and Accelerators Recommendations

Canada has in place a diverse national network of clusters, many with a range of incubator and accelerator capacity. These have served as a vital component of the technology transfer process from academic and research institutions. They have also in many cases, leveraged provincial government support to capture expertise and generation of start-up companies. These have served some objectives very well. The next stage of development within this network is vital to the goal of a national biomanufacturing capacity.
A pan-Canadian approach to technology transfer and company creation is essential to transfer academic discoveries into actual products developed by Canadian businesses. Access to quality commercial wet-labs, while identifying commercially focused translational expertise from throughout the accelerator and incubator networks, will help determine viable investments in universities & academia able to contribute specific projects to the strategy.

Recommendation

The biomanufacturing initiative should:

I. **Provide a long-term funding envelope of support to proven incubators to support their national alignment into contributing to the biomanufacturing commercial needs. Those organizations who have already established capacity in this space should be identified immediately and recruited into the national network while establishing common objectives and performance metrics used to determine appropriate funding needs; and,**

II. **Explore means of enticing life science financial angels to be drawn into the sector for truly early-stage potential, leveraging BC and QC angel investor incentives.**

3. Infrastructure Investment Recommendations

The lack of key infrastructure, specifically wet labs and biomanufacturing capability has been a missing element in the ability to attract domestic production of key COVID vaccines and ultimately new therapies writ large. This will not be solved with a single focussed approach. Any solutions to build this capacity is the function of the broader ecosystem of governments, private sector investors, academic and research collaborations key to driving rapid, targeted milestones. Early investments to date from the government in 2020 are a good start. They have already begun to generate additional private investment with the potential for more as product development milestones are met.

However, established models of creating infrastructure unique to an immediate or imminent public need leaves the facilities vulnerable to irrelevance or in some cases, mothballing as technology evolves. Infrastructure in the form of multilocation wet labs can be developed as a commercial asset to encompass the full development of technologies over time if engaged with private sector and commercial interests. These can feed the perpetual state of readiness for additional biomanufacturing ability.

Recommendation

A national approach is needed in order to:

III. **Implement a strategy aimed at not only securing capacity to address pandemic needs of today and the future, but a business-focused one where facilities and plants are utilized and continuously upgraded over time to remain commercially relevant**
IV. **Identify mechanisms with provinces to build commercial wet lab space within three years**
V. **Facilitate clinical trial coordination across Canada, to reduce contracting and uptake time**

The New Bioeconomy-New Jobs, New Competitiveness

With the potential of a national biomanufacturing strategy so starts the economic recovery Canada sorely needs. The life sciences industry has had two years of unprecedented levels of growth-attracting billions into potential foundation companies from the public marketplace even during the overall economic downturn through the pandemic. This is clearly evidenced in record setting IPO's and private financings from AbCellera, Repare Therapeutics and most recently, Notch therapeutics.

With this newfound security for growth, comes the opportunity for Canada to generate even more positive returns intrinsic to a successful biomanufacturing industry. From this success comes the potential for a modern, effective regulatory environment ensuring safety, while encouraging the development and adoption of innovative new products and services.

The speed at which the government responded to the COVID-19 pandemic, whether to create and launch relief programs, simplify and shorten procurement processes or expedite clinical trials, shows us that we can and must aim higher. A high performing regulatory system should be predictable, efficient, consistent and transparent, so as not to present barriers to business

investment, innovation and ultimately, economic growth and values improved outcomes that benefit Canadians.

We have seen the incredible opportunity that new technologies like gene editing, artificial intelligence, and nanotechnology offer. Implementing modernized regulatory processes aligned globally will help ensure Canada has the regulatory capacity to draw the next generation of technologies into use for and by Canadians.

Recommendation

Canadian life science companies operate in a global marketplace making it vital the Canadian regulatory system be stringent but also aligned with other lead international jurisdictions, including the United States. Indeed, a strong and competitive regulatory system is a competitive advantage for Canadian manufacturers. Moreover, the industry urges the Canadian government to take steps to reduce regulatory burden and regulatory overlap, including the Canadian Environmental Protection Act (*CEPA)* and related regulations to attract and retain biomanufacturing in Canada.

Summary

Where other sectors were badly damaged by the pandemic and will take years to bounce back, life sciences is filling the void. The potential for long term sustainable job creation is abundant in this sector. The highly skilled, well paid jobs required to bring Canadian discovery into the market has never been more promising.

Medicago, Fusion, AbCellera, Zymeworks, Repare and dozens of others are currently recruiting new talent from within Canada and abroad. Combined with generating new roles for expertise amongst the incubator and accelerator network for researchers, life sciences is continuing to create good jobs, draw investment capital, and churn out innovations at a rapid pace. In every region of the country, thousands of highly skilled researchers and employees linked to the national ecosystem of expertise are dedicated to finding the tests, therapies and ultimately vaccines needed for COVID-19. This knowledge can be captured over the longer term to prepare for the future if public policy enables it. The sheer breadth of the sector and the seemingly endless opportunities for applications of the technology add up to a compelling value proposition.

The Canadian biotech ecosystem is an economic strength that positions Canada well to compete successfully in the global economic recovery. Accordingly, the recommendations of investment, technology transfer and infrastructure to build the life science ecosystem in Canada will ensure domestic preparedness for future pandemic responses and other health

emergencies. These recommendations can grow critical biologics and therapeutics manufacturing and life sciences capabilities as part of Canada's life sciences ecosystem. They need to be combined with strategic investments supporting research and development, recognition of the need to enhance relationships with multinational commercial partners in order to ensure future pandemic preparedness and security of supply associated with vaccines and therapeutic drugs.

About BIOTECanada

BIOTECanada is the national industry association with over 240 members located nation wide, reflecting the diverse nature of Canada's health, industrial and agricultural biotechnology sectors. In addition to providing significant health benefits for Canadians, the biotechnology industry has quickly become an essential part of the transformation of many traditional cornerstones of the Canadian economy including manufacturing, automotive, energy, aerospace and forestry industries.