

March 15, 2021

The Honourable François-Philippe Champagne
Minister of Innovation, Science and Industry
C.D. Howe Building
235 Queen Street
Ottawa, Ontario K1A 0H5

RE: Considering the creation of new biomanufacturing capacity for Canada

Dear Minister Champagne,

The COVID-19 pandemic has revealed serious deficiencies in Canada's domestic supply chain of vital medicines required to keep our citizens safe and our economy functioning. The resulting impacts of vaccine nationalism on Canada's ability to procure critical vaccines from its allies highlights the importance of a strong domestic biomanufacturing industry as a matter of both economic and national security. In parallel, the COVID-19 pandemic has also demonstrated the strength of Canada's R&D institutions which have made critical contributions to the global innovation response. Outside of crisis periods, soaring drug prices and more advanced biologic therapies coming on to the market are placing enormous cost pressure on healthcare payor systems. Domestic multi-product manufacturing capacity to cost-effectively and sustainably supply provinces with complex medical therapies should be in the best interest of the Canadian Government's investment considerations.

In response to the consultation request, Alberta stakeholders in the life sciences value chain have collectively synthesized a response. **We believe that Alberta is uniquely positioned to play a key role in enhancing domestic biomanufacturing capacity and recapture Canada's leadership position on the global stage.** Poised for economic growth and transition, economic diversification is at the forefront of the agenda in Alberta. Biomanufacturing presents a powerful opportunity to build off the chemical and manufacturing expertise from our traditional sector and magnify the value generated by the life sciences innovation engine in the province. Alberta provides an opportunity to augment existing capacity (described in detail below) and ideal greenfield development opportunities in close alignment with the network of world class post-secondary institutions (research and talent), single health care system (patient access and application areas for biomanufactured technologies and products), airports (distribution), and industry partners (innovation). This includes Campus Alberta, which provides a comprehensive ecosystem including all 21 publicly funded post-secondary institutions and the apprenticeship and training system.

Municipal and Provincial governments in Alberta are well positioned to leverage a Canadian Government investment and are actively engaged in supporting Alberta enterprises through programs like the Alberta Innovation Employment Grant, the Opportunity Calgary Investment Fund, and notably, the Government of Alberta's recent vaccine development and manufacturing call for proposals. There exists a collective voice with aligned priorities to elevate and evolve Alberta's traditional sectors into advanced manufacturing sectors.

The future of biomanufacturing lies in adopting a user-friendly, modular approach that allows for flexibility of design. Development of plug and play, modular, multi-product facilities that can scale up in times of need effectively, while during non-pandemic times, allow companies to access and leverage the state-of-the-art equipment and expertise to drive innovation will be critical to Canada's international leadership role in the biomedical sector. There exists a teaming pool of regional SMEs and large-publicly traded companies in Alberta that have demonstrated their ability to respond to pandemic (Entos Pharmaceuticals, Providence Therapeutics, Gilead, Resverlogix, all developing COVID-19 solutions). A public-private infrastructure enterprise that will remain nimble in response to current and future pandemic needs but remain a sustainable fixture to the ecosystem in support of development and innovation is well aligned with Alberta's innovation agenda.

If the Canadian Government is serious about its intentions to double the number of companies and high growth firms in the life sciences sector by 2025, as targeted by the Canada's Health and Biosciences Economic Strategy Table, decisive action and large-scale federal support in Alberta will be essential to achieving this laudable goal. Canada should work towards developing a robust supply chain model by investing in a more collaborative approach leveraging regional clusters of expertise across the country's key economic zones. Alberta is well positioned to partner with the Government of Canada on growing our country's biomanufacturing industry and we look forward to bringing this opportunity to market.

Contributions made by the following stakeholders: Genome Alberta, Calgary Economic Development, Edmonton Global, BioAlberta, Providence Therapeutics, Northern RNA, Entos Pharmaceuticals, University of Calgary, University of Alberta, Innovate Calgary, Life Sciences Innovation Hub, Applied Pharmaceutical Innovation, and The Government of Alberta Ministry of Jobs, Economy and Innovation.

Input from each with respect to the mandate, scope of operations, role within the ecosystem, sustainability, and governance of a future biomanufacturing capacity development program was captured and synthesized in the following document by the signatories of this letter of support.

Yours truly,

Mary Moran
President & CEO
Calgary Economic Development



Malcolm Bruce
President & CEO
Edmonton Global



David Bailey
President & CEO
Genome Alberta



Robb Stoddard
President & CEO
BioAlberta



Defining the Biomanufacturing Opportunity in Alberta

Alberta's Research and Bioinnovation Expertise

Alberta is home to two top-10 U15 research institutions in Canada and world-class expertise across life sciences, medicine, engineering, and artificial intelligence. Complementing the Universities of Alberta and Calgary is the entire Campus Alberta network that includes community colleges, polytechnics, and universities with unique capabilities to contribute meaningfully to the bio-ecosystem. For example, the University of Lethbridge is within the top 6% of global institutions for research performance and was ranked 2nd in the primary undergraduate university classification by Maclean's University Rankings. The talent pipeline from Alberta institutions provides a robust pool of highly qualified personnel that could be retained and employed in a growing biomanufacturing ecosystem. The collective provincial academic capacity makes Alberta well-positioned to be a national and international leader in biomanufacturing. Additional coordinated investments in the industry will be key to the retention of local life sciences talent by providing more job opportunities for graduates.

The major post-secondary institutions house core facilities that support biomanufacturing and biopharmaceutical research and innovation. The University of Calgary's transdisciplinary Engineering Solutions for Health: Biomedical Engineering research strategy is a consortium of over 330 researchers from six faculties—Engineering, Medicine, Kinesiology, Veterinary Medicine, Science and Nursing, working to solve the most pressing health challenge. The Snyder Institute for Chronic Disease, houses a Biosafety Level 3 facility and leads the International Microbiome Centre, including the world largest germ-free facility, and the deep expertise in large-animal research at the University of Calgary School of Veterinary Medicine, provide key resources for pre-clinical drug development. A new Centre for Cell Therapy Translation will marry veterinary, engineering, and medical infrastructure with leading edge stem-cell biomanufacturing technology to deliver a globally unique resource in advancing cell therapies into new medicines. Collectively, these facilities enable scientists to continue research into vaccines and treatments for COVID-19 and other highly infectious diseases, providing an R&D hub to develop viable health technologies to combat future emerging pathogens.

In Edmonton, the University of Alberta houses complementary facilities such as the Li Ka Shing Institute of Virology (LKSloV), and the adjacent translation and commercialization hub, the Li Ka Shing Applied Virology Institute (LKSAVI). Together, these institutes research, develop, and transition technologies with clinical application into the life sciences sector. The LKSAVI is home to Canada's most recent Nobel laureate, Dr. Michael Houghton, who co-discovered the hepatitis C virus and has contributed 30 years of research towards treatments and vaccines. The institute also houses a GMP-certified center to produce pharmaceutical-grade biomolecules.

Adding to the University of Alberta's capacity is the Alberta Cell Therapy Manufacturing (ACTM) facility, which helps researchers working on cell-based therapeutics advance their technology by aiding in technology transfer, process, and assay development, and GMP manufacturing for clinical trials. The center is one of its kind in Western Canada and has proven its capacity to respond to emerging challenges, such as its partnership with Entos Pharmaceuticals to generate COVID-19 vaccine components for clinical trials.

Experts in biomedical engineering agree with current industry leaders that adopting a modular and complementary approach for biomanufacturing will provide Alberta with a strong provincial network to best leverage existing expertise, pipelines, and resources. Combining strong research

capabilities, trainee talent, and local infrastructure, there exists a critical mass to respond for a future biomanufacturing industry in Alberta.

Resources and Support for Biomanufacturing and Commercialization

Alberta's life sciences ecosystem is comprised of numerous support entities, several of which contributed input to this document with strong alignment on Alberta's opportunity for scaling up biomanufacturing capacity. Organizations like BioAlberta and Genome Alberta have acted as information conduits for stakeholders in the life sciences sector for 15 years. In different but complimentary ways, the two organizations serve life sciences researchers and business to help bridge connections, create opportunities, and support technology transfer. Genome Alberta's mandate is to support the development of genomics-enabled solutions with socioeconomic benefit for the province. The applied and translational research programs coordinated by Genome Alberta have helped facilitate strong relationships between academics and industrial end-users, and SMEs emerging from these programs would benefit from established local biomanufacturing facilities. Biomanufacturing of recombinant genetic vaccines and engineered macromolecule delivery systems are viewed as future drivers in the diversification and growth of the bioeconomy. Working with its members, BioAlberta has a mandate for advocacy on behalf of the life sciences industry in Alberta, engaging with government decision makers and senior business leadership domestically and internationally to promote Alberta as a partner of choice and a preferred location to invest and conduct business.

Calgary Economic Development works with business, government, and community partners to position Calgary as the location of choice for the purpose of attracting business investment, fostering trade, and growing Calgary's workforce. [Calgary in the New Economy](#) identifies key sector clusters with established advantages, strategic fit and the potential to create long term economic impact and prosperity in the region. An investment in biomanufacturing within Calgary's life sciences industry would accelerate the region's ability to attract international investment, create hundreds of STEM jobs, strengthen and diversify Canada's supply chain and position the region to compete globally. A robust manufacturing ecosystem will also strengthen the value proposition for the attraction of multinational enterprises which will catalyze future growth. Calgary is well positioned to partner with the Government of Canada on growing our country's biomanufacturing industry and looks forward to bringing this opportunity to market.

The University of Calgary's Life Sciences Innovation Hub (LSIH) supports research-intensive companies to deliver commercially viable products and services to market, by providing access to infrastructure, expertise, and startup services. The commercialization engine is further catalyzed by programming delivered by The Hunter Hub for Entrepreneurial Thinking. The Hunter Hub has a dedicated portfolio for the life sciences with programming designed to develop successful professionals in an industry that has deep technical and regulatory complexities. Further downstream, the BioHubX initiative is helping meet the demand for scale biomanufacturing regionally by lowering the barrier for SMEs to engage with ISO/GMP certified manufacturing facilities and training professionals with essential GMP-skills through their partnership with the Southern Alberta Institute of Technology.

Specific to Alberta's pharmaceutical network are critical players such as the University of Calgary's IMPACT program based out of the LSIH. This program connects the world-class pre-clinical research facilities on campus to industry partners, enabling the commercialization of health-related inventions and supporting the development of clinical trials.

The forthcoming Calgary Cancer Centre, the largest in Canada, will bolster this capacity by providing top-quality cancer care and acting as an innovation hub for advanced therapeutics in oncology.

The Edmonton landscape is supported by a similar initiative, the Applied Pharmaceutical Innovation (API). This interdisciplinary network based out of the Katz Centre for Pharmacy and Health Research supports researchers by guiding them on translating their work from the research bench to the patient's bedside. The network provided training and support in the following areas via both in-house services and connecting researchers to industry partners: business development, regulatory & patent strategy, compliant toxicology, synthesis & chemical formulation, PK/PD clinical trial design, and product scale-up.

Further support of the Edmonton economic community is provided by Edmonton Global - an economic development organization representing the 14 municipalities across the Edmonton Metropolitan Region and focused on investment attraction and trade. Edmonton Global has identified life sciences as a focus sector for investment attraction and promote pharmaceutical R&D and manufacturing as key investment opportunities for potential investors. The research and talent strengths along with supply chain and logistics assets make the Edmonton Region an attractive place to invest in biotechnology.

The underpinning thread to innovation and connections in Alberta's biopharmaceutical industry is the province's critical mass, single-payer health care system that is open to collaboration, clinical trial conduct, and innovation. There are substantial innovation support mechanisms for a future Alberta biomanufacturing ecosystem to benefit from and enhance the translational and commercial opportunities for the benefit of all Canada. With further federal investment and continued support from the local community partners, there is the potential to put Alberta at the epicentre of Canada's biomanufacturing and make it a world leader in this space.

Biomanufacturing Capacity and Infrastructure

The lack of Canadian vaccine development infrastructure has been widely noted as an impediment to the national response to the COVID-19 pandemic. Biomanufacturing capacity and existing infrastructure exists in Alberta that could be leveraged and positioned to not only respond to a future health crisis, but also support a value-added bioeconomic diversification. Alberta has been the Canadian home for the manufacturing facility of a multi-national biopharmaceutical entity, Gilead Science, Inc., since 2006, following the acquisition of a University of Alberta spin-off company. This flagship prairie site has undergone several expansions and demonstrates Alberta's potential for future pharmaceutical innovation and talent development.

Prior to the COVID-19 pandemic, several new entities had prepared to launch in this space, notably Entos Pharmaceuticals (Edmonton), Northern RNA (Calgary) and Providence Therapeutics (Calgary). Both Northern RNA and Providence Therapeutics were initially conceptualized around producing mRNA vaccines for cancer treatment before pivoting their capabilities and technology in a partnership towards developing a vaccine formula capable of protecting Canadian against COVID-19. Together Providence Therapeutics and Northern RNA have secured funding from the Next Generation Manufacturing Canada (NGen) supercluster to support the establishment of a manufacturing facility in Calgary that could support the production of COVID-19 booster vaccines by 2022. Providence Therapeutics has expressed their intention to continue developing Cancer vaccines in parallel and will be positioned to

redirect the facility usage when appropriate to maximize the benefits from existing infrastructure, leverage additional federal investments, and continue contributing to Alberta's growing biomanufacturing ecosystem.

Like others, Entos Pharmaceuticals was originally focused on cancer therapeutics using a DNA-based vaccine in combination with a proprietary delivery technology, *Fusogenix*. The company was capable of rapidly pivoting its capacity in response to COVID-19 and emerging variants. The company is expecting Health Canada's approval of a Phase I clinical trial of their COVID-19 vaccine, joining Providence Therapeutics as two Alberta-based COVID-19 vaccine developers in clinical trials. The company's ambitions extend beyond the current pandemic as they are seeking funding to establish a modular vaccine facility in Alberta. This facility would be focused on producing DNA and protein pharmaceutical products that would complement Providence Therapeutic/Northern RNA's capacity to produce mRNA products. Entos Pharmaceuticals envisions this facility as a collaborative endeavor and plans to work with several other ventures to quickly bring solutions to market, focusing on vaccines, neurodegenerative disorders, and diseases associated with cell senescence and ageing.

There are several small-to-medium scale production and pilot testing facilities available in Alberta that would allow for pre-commercial development in biomanufacturing. Outside of health and clinical products, there are significant opportunities in Alberta for manufacturing value-added bioproducts derived from plant, animal, and microbial sources. On the University of Alberta's south campus, the Agri-Food Discovery Place supports process optimization and scale-up platforms for natural health products, functional foods and ingredients, and microbial fermentations. This location is also home to several biomanufacturing entities, such as TerraVerdae Bioworks, a leading innovative company in biopolymers and bioplastics. Innotech Alberta, a subsidiary of Alberta Innovates, has two sites that offer modest biomanufacturing support for companies in the production of small molecule and fermentation bioproducts. Taken together, there is enormous potential for Alberta to become a biomanufacturing hub for high-value pharmaceutical or agricultural products. The facilities and current industry players have a willingness to collaborate, rather than compete, and de-risk investments into biomanufacturing in Alberta.

Decisive end-to-end federal support of the manufacturing infrastructure network is needed to ensure the success of Canada's start-up ecosystem and retain the economic benefits of the intellectual property grown through our institutions.

[The Alberta Ecosystem Advantage](#)

Alberta's emphasis on economic diversification provides opportunities for the biomanufacturing ecosystem to evolve and grow. The downward trend in oil prices observed over the last 5 years have decreased development pressure in the region, resulting in affordable real estate and greenfield development opportunities. Several tech ventures in artificial intelligence and data informatics have announced movement into the region. The expansion of the tech-sector in the Edmonton and Calgary regions adds to the case for pharmaceutical development as many companies look to incorporate advanced computational technology into small molecule screening processes.

The Government of Alberta has recognized the biomanufacturing potential of the province and have launched a call for proposals from entities in this space. A large-scale investment to

overcome translation and scaling challenges in the province would only serve to enhance academic-industry partnerships and pique the interest of venture groups for future opportunities. The potential federal-provincial leverage of aligned investments could yield significant benefits to be deployed more rapidly than other Canadian jurisdictions. Contributing to this speed of rollout are other additional factors, including the recent surplus of talent in Alberta's labour pool. Highly skilled personnel from the oil industry, including engineers, trades workers, and scientists are ready to reapply their skills to new frontiers, with biomanufacturing being one of the most logistical transitions. The University of Calgary has numerous programs that would enable retraining and upskilling of these individuals. Additionally, Alberta's cities boast an affordable and high-quality of life (Calgary ranked highest in North America), providing an exceptional environment to attract top-tier talent from around the world.

Due to its geo-centralized location, and established expertise in importing and exporting goods. Both major Alberta cities have easy access by rail, road, and air, with notable companies in the GMP equipment space such as Spartan Controls and Engineered Air with headquarters in the region. Calgary's is western Canada's inland port providing a logistical advantage for rapid access to customers in global markets, building a commercial scale biomanufacturing supply chain. The city is geographically well-positioned with proximity to the U.S market and direct polar routes to overseas growth markets. YYC International Airport in particular handles over 135,000 tons of cargo goods per year and has infrastructure ready to manage transportation of temperature sensitive goods. Moreover, complimentary investments in Alberta provide strong potential for a cohesive network of biomanufacturing supply chain assets to be connected across Western Canada linking recent Innovation, Science and Economic Development Canada (ISED) investment locations in Vancouver (Precision Nanosystems, AbCellera) and Saskatoon (VIDO-InterVac).

Edmonton has already caught the attention of several national and multinational organizations as the go-to location for large-scale facilities due to the availability of land outside of the capital region. Amazon and Aurora are two notable players to capitalize on this space. Specific to biomanufacturing biopharma Polar Bear Genome Biopharma announced the development of production facilities just outside of in Leduc in 2019. The company who partners with SMEs to aid in production and scale-up of pharmaceutical and nutraceutical products, claims that at peak operations this production site will be able to process 200 tonnes of biomass for high-value product recovery.

The Edmonton International Airport (EIA) is also the only airport in Canada (and the most northern airport globally) to receive accreditation for the Center of Excellence for Independent Validators in Pharmaceutical Logistics (CEIV Pharma) from the International Air Transport Association (IATA). This is an advantage to biomanufacturing facilities in Alberta by providing direct access to an airport that can effectively manage temperature-sensitive products and ensure that products will arrive at their destination in good order. This certification is highly valued to European markets, priming products from the Alberta region for export. It also means that high value bioproducts imported from other jurisdictions for manufacturing purposes will in acceptable form, making it less likely for supply chains to manufacturing sites to be disrupted due to weather or other unforeseen events.

Conclusion

Alberta's economic landscape is changing, and Life Sciences is at the forefront. The province is home to over 300 life sciences companies (up from 230 in 2017), comprised of many start-ups and small businesses that complement an established set of mature companies. Responsible for over \$1 billion in revenues and employing over 15,000 Albertans in 2019, the industry is a significant contributor to Alberta's highly skilled, knowledge and innovation-driven economy.

We believe that Alberta is uniquely positioned to play a key role in enhancing domestic biomanufacturing capacity and recapture Canada's leadership position on the global stage. The signatories of this letter, and broader Alberta stakeholder community, would welcome an opportunity to continue the conversation with ISED and its partners Health Canada and the Public Health Agency of Canada as we collectively work towards expansion of domestic biomanufacturing capacity and related enhancements to the life sciences ecosystem.