

Preparing Biopharmaceutical Start-ups to Navigate the Critical Stages of Their Development

Key Challenges and Opportunities for Action

Authors and Affiliations: Juliette Sabbatani, Ph. D.^{1*}, Cameron Black, Ph. D.^{2*}, Fanny Guimont-Desrochers, Ph. D.¹, Véronique Dugas, Ph. D., MBA¹

¹ CQDM ² CQDM Scientific Advisory Board * Equal contribution

Executive Summary

Quebec has strong assets to support the emergence of high-performing, world-class biopharmaceutical companies: research excellence, cutting-edge infrastructure, highly qualified talent and a well-established support ecosystem. However, turning a scientific discovery into a fundable company remains one of the most fragile steps in the innovation chain. Many promising projects struggle to cross this “valley of death.” Better support of this transition and the creation of conditions conducive to the development of high-potential innovations is essential to maximizing the economic and societal benefits of discoveries arising from Quebec research.

Drawing on a mapping of support programs and on consultations with more than sixty ecosystem stakeholders, this white paper highlights seven recurring challenges faced by Quebec's biopharmaceutical start-ups. These include asset differentiation, roadmap development, definition of decision milestones, building credible leadership, integration into specialized networks, access to infrastructure and scientific capabilities, and the negotiation of university licences in a way that is conducive to private financing.

Based on these findings, this white paper explores several avenues for action that build on capabilities already present in Quebec. It aims to raise awareness of learning pathways and networking opportunities, and make the support landscape easier to navigate. It proposes to strengthen biopharmaceutical expertise within companies, particularly as they approach Series A financing. It also contemplates better access to existing infrastructure and scientific capabilities, different ways of engaging pharmaceutical companies in start-up development, and harmonizing university licensing practices.

Introduction

Quebec has a long tradition of biopharmaceutical innovation, driven largely by the strength of its biomedical research institutions. Its life sciences sector now comprises more than 750 companies and nearly 40,000 jobs, and generates \$4.2 billion in exports¹. Yet turning scientific breakthroughs into profitable biopharmaceutical companies remains difficult. Many start-ups fail to raise the capital needed to advance their projects and realize their therapeutic potential. This difficulty limits the development of promising innovations and Quebec's ability to maximize their economic and societal benefits over the long term.

Recent reports have examined the role of Canadian research ecosystems in the formation of clusters and anchor companies² the importance of investment capital for the Canadian life sciences sector³, and the difficulties involved in turning discoveries into venture-backed biotechnology companies⁴. This white paper builds on that work and focuses on the critical early stages of biopharmaceutical company creation.

The Quebec Life Sciences Strategy 2025–2028 earmarks nearly \$271.5 million to strengthen the financing continuum, support the growth and anchoring of companies, foster the emergence of new leaders and improve access to advisory services, training and mentorship. It thereby recognizes that the sector's growth depends on capital, talent development and the support provided by the ecosystem¹. These initiatives create a significant opportunity to accelerate the sector's development.

For Quebec start-ups to navigate the critical stages of their development, it must be recognized that biopharmaceutical research is governed by realities distinct from those of other sectors. Developing a therapeutic product, from discovery to market, generally takes ten to fifteen years^{5,6}. The risk of failure remains high: once they enter clinical trials, only 13.8% of development programs result in marketing authorization, or roughly one in seven⁷.

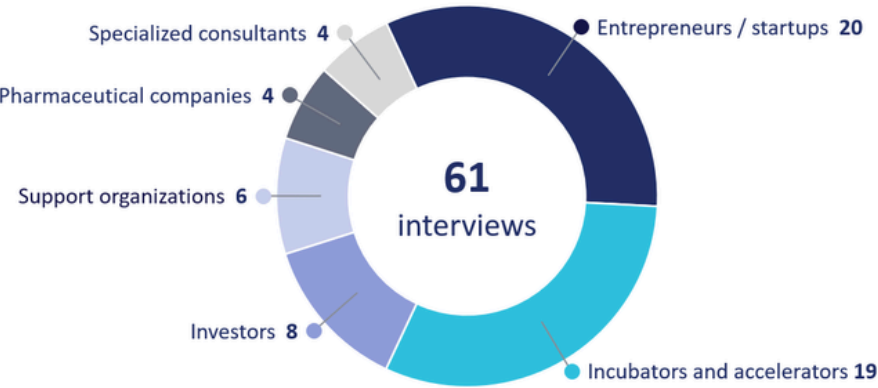
A biopharmaceutical company typically generates no revenue for most of its existence. Its value depends on reaching milestones that progressively increase the probability of success. Specialized investors accept a level of risk that few sectors could tolerate and seek returns commensurate with that risk⁸. The investment thesis, the team’s composition and the sequencing of experiments therefore become as decisive as the science itself. Building a company in this sector is a discipline in its own right, whose needs often go beyond the scope of support models designed for other technology sectors.

The study underlying the findings presented in this document initially sought to identify the priority challenges of companies in the RNA-based therapeutics field in order to guide the evolution of the AReNA initiative. As many of the challenges identified were common to the entire biopharmaceutical sector, its scope was broadened to all Quebec biopharmaceutical start-ups. In particular, the study sought to understand how Quebec biopharmaceutical start-ups move through their stages of development, what obstacles they encounter between discovery and the main development milestones, and which levers could be mobilized more effectively to meet their needs and improve their chances of success.

The approach is based on consultations with over sixty ecosystem stakeholders, including entrepreneurs, investors, pharmaceutical company executives, heads of support organizations and biopharmaceutical development consultants. These semi-structured interviews made it possible to address common themes while considering each participant’s particular experiences and priorities.

Comparing the challenges faced by start-up leaders with the expectations of those who finance, support or contribute to their development brought seven recurring challenges to light. Five findings concern the start-up’s ability to optimally steer and execute its therapeutic project, while two relate to the conditions the ecosystem must bring together to effectively support the maturation of both the technology and the company.

Figure 1 – Profile of stakeholders consulted



PART 1 | WHAT THE CONSULTATIONS REVEAL

Challenges specific to start-up development

Establishing a differentiated product profile

The investors consulted frequently raised the lack of differentiation in the technologies presented to them. The scientific quality and novelty of a discovery are not enough to establish its therapeutic relevance. The technology must show which problem it will solve better than available treatments and competing assets in development, and why that advantage will still be relevant when it reaches patients. As one participant put it: *"This project is a scientific solution in search of a problem."*

Establishing this differentiation requires an in-depth analysis of the competitive landscape. This analysis must cover marketed products and clinical programs, but also, as far as possible, preclinical assets likely to transform the standard of care during the many years needed to develop a therapy. A well-positioned competitor can jeopardize an asset's development unless the asset can demonstrate a specific advantage, such as superior efficacy, better safety or more convenient administration.

Teams do not always see what is missing from their analysis. Specialized databases and the capability to interpret an evolving competitive landscape are generally restricted to investment professionals, and less so to the teams that need them to guide their own project. A lack of differentiation can thus remain invisible until an investor, an industry partner or a biopharmaceutical expert brings it to light.

First-in-class and best-in-class strategies can both be viable, but they have different theses and do not necessarily appeal to the same investors or partners⁹. The experts consulted stressed the importance for teams to provide early clarification of the chosen approach, the therapeutic advantage sought and the evidence needed to demonstrate it. Otherwise, the asset risks being perceived as a me-too¹⁰ product that could reduce interest from potential investors or partners, particularly in an already crowded therapeutic space.

With limited resources, the absence of a differentiation strategy can steer work toward experiments that are scientifically sound but of little use in establishing the asset's therapeutic relevance. The project then accumulates data, with the associated time and costs, without reducing the uncertainty that threatens its success. Defining the intended differentiation early instead makes it possible to focus resources on decisive experiments, inform the choice of indication and redirect the project before its key decisions are locked in.

INVESTOR PERSPECTIVE

"The technology must demonstrate a clinically meaningful therapeutic advantage in the target indication and defend that advantage against assets already in development."

Integrating clinical, regulatory and manufacturing considerations

A project's roadmap must specify the data needed to reduce the main risks and reach the next value inflection point while preparing for the subsequent stages of development. However, the consultations show that projects often move from one scientific stage to the next without sufficiently anticipating clinical, regulatory and chemistry, manufacturing and controls (CMC) considerations, which are often associated with later stages of development and integrated too late. In such situations, key experiments may not consider the requirements of subsequent stages, leading to delays and additional costs. The consultations also highlighted weak clinical strategies early in development and inconsistent access to relevant experts. Yet these dimensions should be considered from the outset to inform which preclinical studies to prioritize as well as the feasibility of the intended development path.

This early integration is particularly important for emerging modalities, to which the established frameworks for small molecules do not necessarily translate. Depending on the modality, requirements related to biodistribution, immunogenicity, characterization, comparability, toxicology or manufacturing can profoundly alter the development program and the order in which studies must be carried out¹¹. For new modalities with limited precedents, early discussions with regulatory authorities make it possible to validate the main assumptions before starting pivotal studies.

Likewise, strategies for CMC and clinical trials should not be put off until they become rate-limiting. The main manufacturing issues must be anticipated before scale-up, while the choice of indication, population and clinical endpoints should guide the generation of preclinical data. The goal is to avoid upstream decisions compromising downstream development milestones.

INVESTOR PERSPECTIVE

"The roadmap must be as credible as the current data. It must show how the asset will reach the next milestone, which risks will be reduced and what evidence will be required."

Defining milestones that inform decision-making

In developing therapeutics, a company must reduce uncertainty early enough to guide the allocation of resources, even if that means terminating or redirecting a project. The consultations revealed contrasting perceptions of the value of stop decisions. Several participants observed that in some ecosystems, notably the United States, terminating an unpromising avenue to redirect resources toward a better opportunity is considered normal development practice. This fail fast logic is also common in large pharmaceutical companies, where stopping a program early can be seen as a success when it avoids further investment in a dead end. However, the consultations suggest that in Canada this decision is more often associated with failure. Yet invalidating a hypothesis provides decisive information for the rest of the project.

The decision to continue, pivot or stop is more robust when the criteria are set before the results are analyzed. Without this framework, a partial signal may be interpreted as sufficient to continue, thereby postponing a key decision without reducing the main risk¹². A milestone should therefore not simply mark the completion of an activity, but the decision informed by the results obtained. Indeed, the interviews show that some projects keep accumulating data without reducing uncertainty or informing upcoming choices. A stop decision may impact an indication, a formulation, a biomarker or an experimental approach without condemning the entire project. Negative data can close one path while clarifying which ones remain viable.

Some serial entrepreneurs openly share invalidated hypotheses and the resulting pivots, but this type of learning remains largely invisible in ecosystem discussions. Yet knowing when to end an approach is often as important a decision as choosing to pursue it.

ENTREPRENEUR PERSPECTIVE

"Ending a hypothesis does not erase the experience gained. Rather, the decision preserves resources, the ability to pivot and the team's value for the next opportunity."

Building a credible leadership team

The consultations show that in young companies spun out of academia, scientific and leadership responsibilities often remain concentrated in the hands of the principal investigator.

An outstanding academic career does not necessarily prepare someone to lead the development of a therapeutic asset, raise financing and establish strategic partnerships. The scientific founder brings irreplaceable knowledge of the discovery, its biological rationale and the data that support it. However, turning a discovery into a development program requires setting priorities, building the team, raising capital and negotiating with partners. Defining and sharing these responsibilities early makes it possible to preserve the founder's scientific contribution while adding the skills needed for the project to progress¹³.

INVESTOR PERSPECTIVE

"The project interests me, but the team will need to evolve before I invest."

At the very earliest stages of company development, available resources rarely allow a full leadership team to be assembled. Some functions can nonetheless be filled by seasoned professionals acting as advisors, independent directors or fractional executives who bring hands-on experience in biopharmaceutical development and knowledge of the expectations of prospective investors and partners. That said, these contributions must eventually become clearly assigned internal responsibilities. As a major financing round approaches, business development, partnerships and execution should no longer rely on peripheral contributions.

This transition may be difficult because the consultations point to a scarcity of leadership profiles with hands-on experience in biopharmaceutical development, particularly among the next generation. Strengthening this pool will depend on the advancement of talent within start-ups, the transfer of experience and openness to career paths developed in other ecosystems.

Building a biopharmaceutical network

For researcher-entrepreneurs, building a company means joining an industry-affiliated biopharmaceutical community distinct from the scientific setting in which the project originated.

This community relies largely on relationships of trust built through collaborations, transactions and shared experiences. Experts, executives, investors and partners are often identified through referrals. The interviews highlighted how difficult it is for founders who have not yet worked in this environment to identify the first points of entry, even when they actively take part in networking activities.

ENTREPRENEUR PERSPECTIVE

“A conversation with a patient, an experienced entrepreneur or another young company can reveal a poorly articulated need, a different priority or an unexpected complementarity.”

Industry events are often a first point of entry into this community. However, their concentration in Montreal, their frequent overlap and their more limited presence elsewhere in Quebec do not always make it easy to establish those first connections. Yet these connections are decisive: once trust is established with a few relevant contacts, the network expands through successive referrals to the experts, executives, investors and partners the company will need as it matures.

The consultations also highlighted the value of practical experience that circulates through these relationships and that programs or formal documentation have more difficulty conveying. These exchanges help teams frame their questions better, test their hypotheses and identify earlier the decisions that call for an outside perspective. Exchanges with patients, physicians, investors and other companies can thus change the understanding of the clinical need, reveal a complementarity or open access to expertise, a scientific capability or a decisive partnership.

The challenge, therefore, is to find the points of connection that allow gradual entry into the biopharmaceutical community and access to the relevant relationships while they can still shape the project's trajectory.

Ecosystem-level challenges

Accessing affordable infrastructure and scientific capabilities

The interviews highlighted a central constraint: biopharmaceutical start-ups must generate the data needed for their next milestone while their capital and experimental capabilities are still limited. This constraint, however, arises at different times depending on the company's origin.

Projects that originate in academia can generally continue their work in the founding laboratory early in their maturation. This access becomes harder to maintain as the company gains autonomy and its activities, staff, data and intellectual property must be clearly separated from those of the university laboratory. Start-ups created outside this setting, for their part, must access experimental capabilities from the outset.

In both cases, companies must eventually operate their own laboratory or outsource their work to public laboratories and platforms or to contract research organizations. However, even though laboratory supply has grown in Quebec, and Montreal has the lowest occupancy costs among the main North American life sciences markets^{14,15}, a laboratory remains out of reach when a company cannot yet bear its recurring costs. Outsourcing reduces fixed investment, but can be costly and slow down iteration when protocols are evolving rapidly.

Collaborative project funding programs can offer a complementary solution by allowing a company to carry out certain work with a public research centre. This route, however, requires that the project lend itself to collaboration, that a university team meet the company's needs and that the company be able to provide the required financial contribution - conditions that are not always met at the early stages of company development. The ARENA initiative, for example, also offers flexible, direct funding to companies developing enabling technologies relevant to the development of RNA-based therapies¹⁶. This funding helps reduce the costs associated with maturing early-stage, high-risk technologies, whether carried out in-house or outsourced through collaborations or service contracts. At present, however, this funding tool remains highly targeted and is not available to all start-ups in the biopharmaceutical sector.

ENTREPRENEUR PERSPECTIVE

“I need data to get funding, but funding to generate that data.”

Negotiating the transfer of university intellectual property without compromising private financing

The terms governing the licensing of university intellectual property were among the issues most frequently raised during the interviews. Negotiation timelines, financial terms and the complexity of sharing rights can limit a young company's ability to attract private capital. In particular, participants described a possible mismatch between certain institutional commercialization practices and the conditions needed to finance and develop a therapeutic product.

It is important to note that technology transfer policies vary considerably from one institution to another. In the absence of a common Quebec framework governing the sharing of intellectual property and university licensing, founders and investors must deal with processes, expectations and negotiating parameters that differ by institution¹⁷. This unpredictability is particularly challenging in the biopharmaceutical sector, where development spans long periods and requires several financing rounds. The interviews show, however, that negotiations move forward when the institution and the company share a common goal: bringing together the capital, skills and partners needed to advance the technology. One entrepreneur described a turning point when the institution recognized that an independent, fundable company could be a powerful way to promote the university's reputation.

This alignment does not require the university to give up its rights. Rather, it involves evaluating the licence as a whole: equity participation, royalties, milestone payments, rights to improvements, development obligations, sublicensing terms and flexibility for future transactions. A favourable term taken in isolation can reduce the overall value of the agreement if it discourages investment or complicates a later partnership or acquisition.

Finally, participants suggested that the company's progress should be an integral part of assessing the impact of university commercialization. The indicators typically used by technology transfer offices, such as patents, licences, licensing revenue and companies created, say little about these companies' ability to raise capital, reach their development milestones and secure partnerships^{18,19}. The time taken to grant the licence, the financing obtained and the company's subsequent progress would provide a more complete picture of the value created.

INVESTOR PERSPECTIVE

"When an institution's practices are known to be lengthy or difficult to reconcile with venture capital financing, some investors may choose not to look at the project."

Figure 2 : Seven challenges shaping start-up maturation

5 CHALLENGES SPECIFIC TO THE START-UP

- THERAPEUTIC DIFFERENTIATION**
A defensible project in the face of competing treatments and assets
- INTEGRATED ROADMAP**
Clinical, regulatory and manufacturing considered early
- DECISION-MAKING MILESTONES**
Clear criteria for continuing, reorienting or quitting
- CREDIBLE MANAGEMENT TEAM**
The skills required to drive the company forward
- BIOPHARMACEUTICAL NETWORK**
Good relationships established before needs become urgent



2 ECOSYSTEM CHALLENGES

- CAPACITIES AND LABORATORIES**
The infrastructure and expertise needed to produce the data
- UNIVERSITY IP LICENSES**
A transfer compatible with private capital

PART 2 | OUTLOOK AND OPPORTUNITIES FOR ACTION

Avenues for action to build stronger biopharmaceutical companies

Quebec has many levers to support biopharmaceutical start-ups: funding, entrepreneurship training, incubation, acceleration, sector networking and expert networks. These resources already contribute to the development of entrepreneurs, the structuring of their companies and their progress.

Despite this favourable environment, the seven challenges presented in Part 1 persist. This section therefore explores avenues for action that build on the initiatives identified during the consultations. It examines how certain resources or initiatives could be better connected, deepened or scaled up to support more start-ups through the most demanding stages of their maturation.

Increasing the visibility of training and networking opportunities

In Quebec, various training programs offered by educational institutions and support organizations equip researcher-entrepreneurs at different stages of their journey. They provide the foundations needed to move academic research into the industrial setting. Some of these programs offer cross-sector training applicable to all industries, while others are designed specifically for life sciences or biopharmaceutical innovators. For example, CASTL's BioInnovation Scientist program²⁰ offers an initial introduction to the therapeutic development continuum, while PERCER, led by Université de Montréal²¹ as part of the Millénum Quebecor initiative, offers a more in-depth entrepreneurial pathway in the life sciences. Other initiatives, such as QcSE²² and Nucleate Canada²³, introduce students and postdoctoral fellows to company creation, connect them with their peers and open access to industry networks. Raising awareness of these initiatives and clarifying how they complement one another would help founders identify the programs suited to their needs, from scientific discovery to the development of their company, and acquire reference points specific to the biopharmaceutical sector earlier.

Beyond training, networking plays an essential role in accessing peers, experts, investors and partners. Sector organizations and clusters such as Montréal InVivo, Québec VITAE or BIOQuébec, among others, actively animate the ecosystem through their events and networking activities. Relevant networking opportunities abound throughout the year, but new entrepreneurs may struggle to identify the events that will allow them to meet the experts or partners they are looking for. Sustained participation can also prove costly and lead to a degree of fatigue, especially when networking objectives are not clearly defined beforehand.

Better coordination among organizers, notably through a shared calendar, would improve the visibility and accessibility of these events while helping young companies target those best suited to their needs, based on the themes covered and the audiences targeted.

Strengthening biopharmaceutical support, from pre-seed to the run-up to a Series A financing

Quebec offers extensive entrepreneurial support programs. Incubators and accelerators play an important role in developing entrepreneurs and structuring their companies, notably through business coaching, mentorship, access to networks and preparation for growth.

These diverse resources can, however, be difficult to navigate, and start-ups are not always directed to the organization or organizations able to meet their needs. To help biopharmaceutical start-ups and researcher-entrepreneurs identify resources suited to their stage of development and their needs, a map of the sector's accelerators and incubators has been developed in close collaboration with the organizations listed. By bringing together the main support players, it aims to increase the visibility of these resources and match them with the needs, stage of development and objectives of each Quebec start-up.

It is worth noting that several programs already call on entrepreneurs-in-residence and specialized advisors to provide support tailored to the needs of the biopharmaceutical sector. However, because access to critical sector expertise remains difficult for Quebec biopharmaceutical companies, organizations would benefit from bringing in more professionals with hands-on experience in the drug discovery process, therapeutic development and biopharmaceutical company creation, or from forging collaborations with groups that provide access to such experts. Their contribution would help founders build a credible roadmap and identify their project's blind spots earlier.

Although access to specialized biopharmaceutical expertise is limited at the pre-seed stage, the situation becomes even more critical at later stages of company development. The skills needed to prepare a company for major milestones, such as a Series A financing, are particularly scarce in the local ecosystem. Yet it is precisely at this stage that companies must make some of the biggest decisions in their development. They must present a credible development strategy, rigorous milestones likely to create value, a leadership structure capable of executing that strategy and sufficient command of clinical, regulatory, CMC and operational risks. Although some Quebec start-ups manage to obtain this type of highly specialized support, it is more often found outside the province, raising a real risk of the gradual relocation of our most promising Quebec companies and the workforce that comes with them.

Quebec would benefit from strengthening support at this stage of company development by offering accessible resources that maximizes the number of start-ups successfully transitioning into biopharmaceutical companies attractive to local and international investors.

Matching start-ups with existing laboratory infrastructure and capabilities

In Quebec, some accelerators give the start-ups they support access to university research facilities, notably District 3 in collaboration with Concordia University²⁴. In Ontario, Capital BioVentures also mobilizes university and hospital space suited to the scientific needs of companies participating in its programs, at no cost to them²⁵. These models could inspire other partnerships between accelerators and research institutions to make available laboratory infrastructure accessible to more start-ups, in several regions of Quebec, without them having to bear these costs prematurely. A facility offering laboratory space for start-ups near research institutions and bringing various support organizations under one roof could also strengthen the ecosystem. It would encourage knowledge sharing, facilitate connections with potential partners, and improve access to critical expertise and resources.

Beyond laboratory space, several Quebec research institutions already offer, in a decentralized manner, access to their platforms, instruments and certain specialized services²⁶. These resources allow start-ups to benefit from cutting-edge expertise and, often, to access partnership funding programs that further reduce their expenses. In addition to the platforms distributed across Quebec's universities, there is significant capacity within public research centres, college technology transfer centres and the laboratories of the National Research Council of Canada. Generally speaking, these resources remain little known and underused. Raising awareness of them, for example by centralizing information and consistently promoting the available resources, would allow more start-ups to take advantage of them.

On an exploratory basis, Quebec could also mobilize its large pool of contract research organizations (CROs) and established biopharmaceutical companies to make it easier for start-ups to access the scientific capabilities they need. One proposal would be to create "golden ticket" programs that sponsor, in whole or in part, start-ups' access to turnkey laboratory environments operated by third parties. Depending on the participating organization's means, this contribution could cover laboratory space, time on an instrument or platform, technical services or service credits. International partnerships among CROs, incubators and shared laboratories illustrate the relevance of such models^{27,28}.

A second proposal would be to make better use of private capacity that is temporarily available. Subleasing laboratory space between biopharmaceutical companies already exists, as does the occasional sharing of specialized instruments among industry players. A CRO or a company could thus rent unused space or time on certain equipment to a start-up at an advantageous cost. This model would allow it to earn revenue from available capacity while giving the start-up access it could not otherwise afford.

This second path would, however, be more complex to implement. It would require rigorous protocols to protect confidentiality and intellectual property, as well as mechanisms to identify available capacity, select eligible start-ups and allocate space or equipment according to need. The tax, financial or other incentives likely to encourage companies to make capacity available would also need to be determined. A structured discussion bringing together biopharmaceutical companies, CROs, start-ups and public stakeholders would make it possible to assess the feasibility of this model and define the conditions and levers needed to deploy it in Quebec.

Engaging global pharmaceutical companies early in start-up development

In the context of international competition, where the commercialization of new therapies often depends on partnerships with major industry players, global pharmaceutical companies can play a decisive role by steering innovation projects to address real market needs. Early access to their expertise, advice and support can reduce timelines and costs by helping start-ups target the indications, modalities and experiments most relevant to their innovation. It nonetheless remains difficult for new entrepreneurs to connect with industry experts able to give them useful feedback.

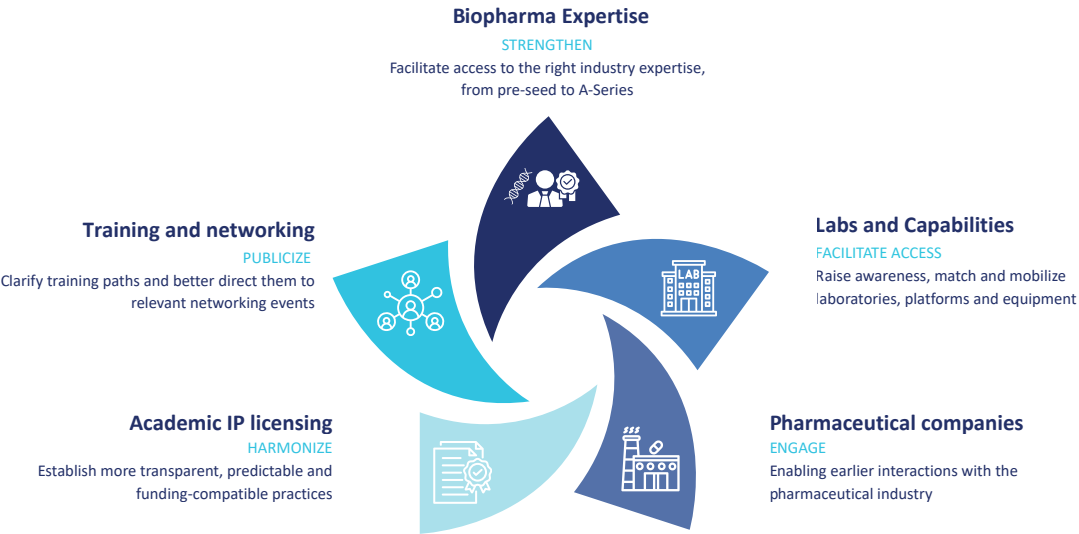
In Quebec, some targeted initiatives facilitate these interactions. The Merck Digital Sciences Studio, operated in collaboration with Centech, combines investment, scientific expertise and business mentorship²⁹. On a more occasional basis, the Pfizer "Masterclasses" offered at CQIB prepare companies for pharmaceutical partnerships³⁰. CQDM also fosters exchanges between biopharmaceutical companies and its eleven pharmaceutical members, notably through targeted calls for ideas and in-person events. New initiatives led by the pharmaceutical industry have also recently emerged. The AbbVie Biotech Innovators Award, offered in partnership with adMare BioInnovations, is one example: it funds a start-up's access to shared space, equipment and services for one year³¹. More generally, start-ups would benefit from building ties with the pharmaceutical industry from their earliest days.

Harmonizing and simplifying university IP licensing

In the United States, the Bayh-Dole Act established a clear and predictable legislative framework for commercializing the results of publicly funded research, reducing uncertainty around intellectual property and promoting the transfer of university innovations to industry³². Although not directly transferable to Canada, this approach shows the value of clear rules and standardized practices. Closer to home, the University of British Columbia's Express License Agreement offers eligible spin-offs a standardized agreement with predefined financial terms³³. The Canadian SAIL initiative, for its part, offers a simplified framework for licensing the results of publicly funded research³⁴. In parallel, a pan-Canadian partnership of fourteen organizations, including Axelys, is also working on a common approach to intellectual property education³⁵.

Quebec universities and research institutions would benefit from drawing on the various existing models to establish harmonized and transparent expectations, standard terms where appropriate, target negotiation timelines and indicators that take into account not only the licences concluded, but also the company's ability to finance and advance the technology arising from publicly funded research.

Figure 3: Five avenues for action to better support the maturation of biopharmaceutical start-ups



Conclusion

Quebec has the assets required to give rise to and grow a new generation of innovative biopharmaceutical companies: world-class research, recognized expertise, cutting-edge infrastructure and a well-established support ecosystem. Yet the transition from a promising discovery to a company able to attract financing and reach its development milestones remains particularly fragile.

The consultation that led to this white paper brought seven recurring challenges to light. Five mainly concern start-ups' ability to steer and execute on their therapeutic project: establishing clear differentiation, integrating clinical, regulatory and manufacturing dimensions earlier, defining decision milestones, building a credible leadership team and building a relevant biopharmaceutical network. Two others relate more to the ecosystem: access to scientific capabilities and the negotiation of university licences compatible with private financing.

These challenges are closely linked. A scientific decision made without considering clinical studies, regulatory requirements, manufacturing, the market or intellectual property early enough can compromise subsequent stages. Likewise, a well-supported company remains limited if it cannot access the infrastructure, expertise and transfer conditions needed to generate the expected data and raise capital.

The consultation also highlighted the wealth of resources already present in Quebec. Taken together, these findings underscore the importance of a clearer progression between scientific discovery and the development of therapeutic innovations. By enabling start-ups to anticipate critical decisions earlier and mobilize the right resources at the right time, Quebec will be better able to turn its scientific excellence into strong, fundable companies capable of pursuing their path to commercialization for the benefit of patients.

Québec

This study was made possible through the financial support of the Government of Quebec. We would also like to sincerely thank the many organizations and stakeholders across Quebec's life sciences ecosystem who generously contributed to this initiative by participating in consultations and sharing their expertise. Their collaboration was instrumental in the completion of this work.

Statement on the Use of Artificial Intelligence

Generative artificial intelligence tools were used to support the linguistic review and refinement of certain sections of this document. All ideas, analyses, interpretations, and conclusions are those of the human authors, who reviewed and validated the entirety of the content and assume full responsibility for it.

References

1. Government of Quebec, Ministry of Economy, Innovation and Energy. Quebec Life Sciences Strategy 2025–2028: Accelerating Innovation, Boosting Competitiveness (in French). December 2025.
2. adMare Institute. Canada's Evolving Life Sciences Industry: Exploring Ecosystems, Clusters, and the Need for Anchor Companies. 2023.
3. adMare Institute. Does Canada Own its Life Sciences Future? 2025.
4. Task Force on the Pharmaceutical and Life Sciences Sector. Report to the Ministers of Health and Industry. Government of Canada; 2026.
5. U.S. Food and Drug Administration. The Drug Development Process. Consulté le 22 septembre 2026.
6. Brown DG, Wobst HJ, Kapoor A, Kenna LA, Southall NT. Clinical development times for innovative drugs. *Nature Reviews Drug Discovery*. 2022;21(11):793-794.
7. Wong CH, Siah KW, Lo AW. Estimation of clinical trial success rates and related parameters. *Biostatistics*. 2019;20(2):273-286.
8. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics*. 2016;47:20-33.
9. Spring L, Demuren K, Ringel M, Wu J. First-in-class versus best-in-class: an update for new market dynamics. *Nature Reviews Drug Discovery*. 2023;22(7):531-532.
10. Aronson JK, Green AR. Me-too pharmaceutical products: History, definitions, examples, and relevance to drug shortages and essential medicines lists. *British Journal of Clinical Pharmacology*. 2020;86(11):2114-2122.
11. U.S. Food and Drug Administration. Cellular and Gene Therapy Guidances. Mise à jour en 2026.
12. National Institutes of Health. Milestone Driven Awards: A Go/No Go Proposition. 22 mai 2024.
13. Thomas VJ, Bliemel M, Shippam C, Maine E. Endowing university spin-offs pre-formation: entrepreneurial capabilities for scientist-entrepreneurs. *Technovation*. 2020;96-97:102153.
14. CBRE Research. Greater Montreal Lab Market: 2024 in Review (in French). June 2025.
15. CBRE Research. Montreal Lab Market Report 2025 (in French). July 20, 2026.
16. CQDM. ARENA: RNA Innovation in Industry. Accessed October 1, 2026.
17. Natural Sciences and Engineering Research Council of Canada. General Intellectual Property Considerations and Guidelines for Collaboration. Accessed September 22, 2026.
18. Association of University Technology Managers. AUTM Licensing Activity Survey. Consulté le 22 septembre 2026.
19. World Intellectual Property Organization. Knowledge and Technology Transfer. Accessed September 22, 2026.
20. CASTL. BioInnovation Scientist Program. Accessed October 1, 2026.
21. Université de Montréal, Faculty of Pharmacy. PERCER: Excellence Pathway for Building Entrepreneurship and Success Skills (in French). Accessed October 1, 2026.
22. Fonds de recherche du Québec. QcSE: Quebec Scientific Entrepreneurship Program (in French). Accessed October 1, 2026.
23. Nucleate Canada. Overview of the Canadian Chapter. Accessed October 1, 2026.
24. District 3, Concordia University. BioHub. Accessed October 1, 2026.
25. Capital BioVentures. Wet Labs and Services. Accessed October 1, 2026.
26. Médicament Québec. Industry Access to University Platforms (in French). February 2026.
27. Charles River Laboratories. Cell and Gene Therapy Incubator Program (CIP) and Accelerator Program (CAP). Accessed October 1, 2026.
28. BioLabs. Sponsorships. Accessed October 1, 2026.
29. Merck Canada. Merck Digital Sciences Studio: Program Description and Announcement of the 2026 Cohort. March 13, 2026.
30. CQJB. Pfizer Masterclass: Strategic Partnerships with Pharmaceutical Companies in Life Sciences. March 25, 2026.
31. AbbVie and adMare BioInnovations. AbbVie Biotech Innovators Award in Quebec. November 25, 2025.
32. United States. Patent and Trademark Law Amendments Act (Bayh-Dole Act). Public Law 96-517, 35 U.S.C. §§ 200-212. December 12, 1980.
33. Innovation UBC. UBC Express License Agreement (ELA) and Guide. Accessed October 1, 2026.
34. The SAIL Initiative. SAIL: Simple Agreement for Innovation Licensing. CanInnovate, MVIP and Action Potential; 2025. Accessed September 23, 2026.
35. Axelys. Pan-Canadian Partnership to Promote Intellectual Property Education (press release). September 15, 2026.



OCTOBER 2026

CQDM

465 rue McGill, suite 200,
Montréal (Québec) H2Y 2H1
Canada



info@cqdm.org



[@CQDM](https://www.linkedin.com/company/cqdm)

cqdm.org