GREATER ZURICH AREA

Transitioning from local R&D to global commercial in BioPharma

Whitepaper based on a roundtable

blue | matter

About the whitepaper

A selected group of life sciences executives sat down with seasoned commercial launch executives and industry experts from Blue Matter Consulting, Korn Ferry, Alexion, and the Canton of Zug in Fall 2023 to discuss key success factors for organizations transitioning from R&D to commercial, as well as pitfalls to avoid when expanding outside the US.

The guest speakers shared their experience and expertise and stimulated an open debate on options for US biotech companies seeking to commercialize and expand abroad. The discussion is summarized in this white paper.

Speakers:

Nicola Heffron
Global Head of Commercial, Alexion

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The journey from R&D to commercial: The Blue Matter perspective

Why to think commercially early

Thinking commercially is more than just “sales & marketing”

A good “commercial perspective” centers around deeply understanding:

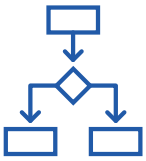
Who are our customers?

What are their roles?

(prescriber, patient, payer, other stakeholders)

What do our customers need?

How do our customers make decisions?



How will our product fit into what our customers are currently doing?

What is required for them to change their current behavior?

It is never too early to begin thinking commercially!

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Pitfalls of emerging innovator companies

1. Resources

Many emerging companies don't have the resources to hire experienced commercial launch teams, whereas larger organizations have built-in integration between commercial and clinical with roles like "life cycle leader."

A key success factor is collaboration and communication between the commercial and clinical teams. A lack of collaboration can significantly reduce the ability to realize an asset's full commercial potential.

2. Commercialization focus

Science-focused founders may overly focus on development.

Smaller organizations operating with the mindset of "just get through phase 2 and then it's someone else's problem to commercialize" can run into challenges down the line when it becomes time to commercialize.

3. Founder syndrome

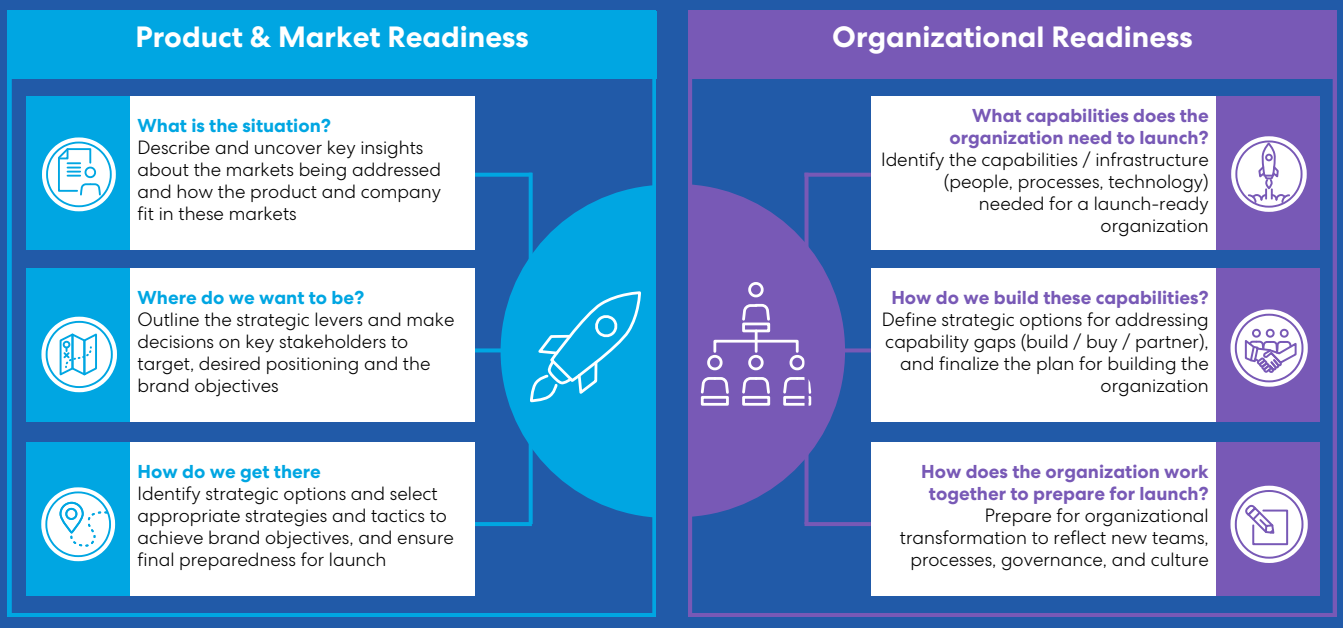
"Founder Syndrome" can cause friction between the newly hired commercial leaders and the founding development team.

Founders that are too attached to their science can reject skepticism from new hires with commercial experience.

Setting your product and organization up for successful launch

As an emerging company, shaping the product and the market while building the organization is key. Understanding the environment that you will be launching the product into early in the development process will allow you to tailor the product to the market.

Emerging companies need to address multiple related business questions when preparing to launch their first product



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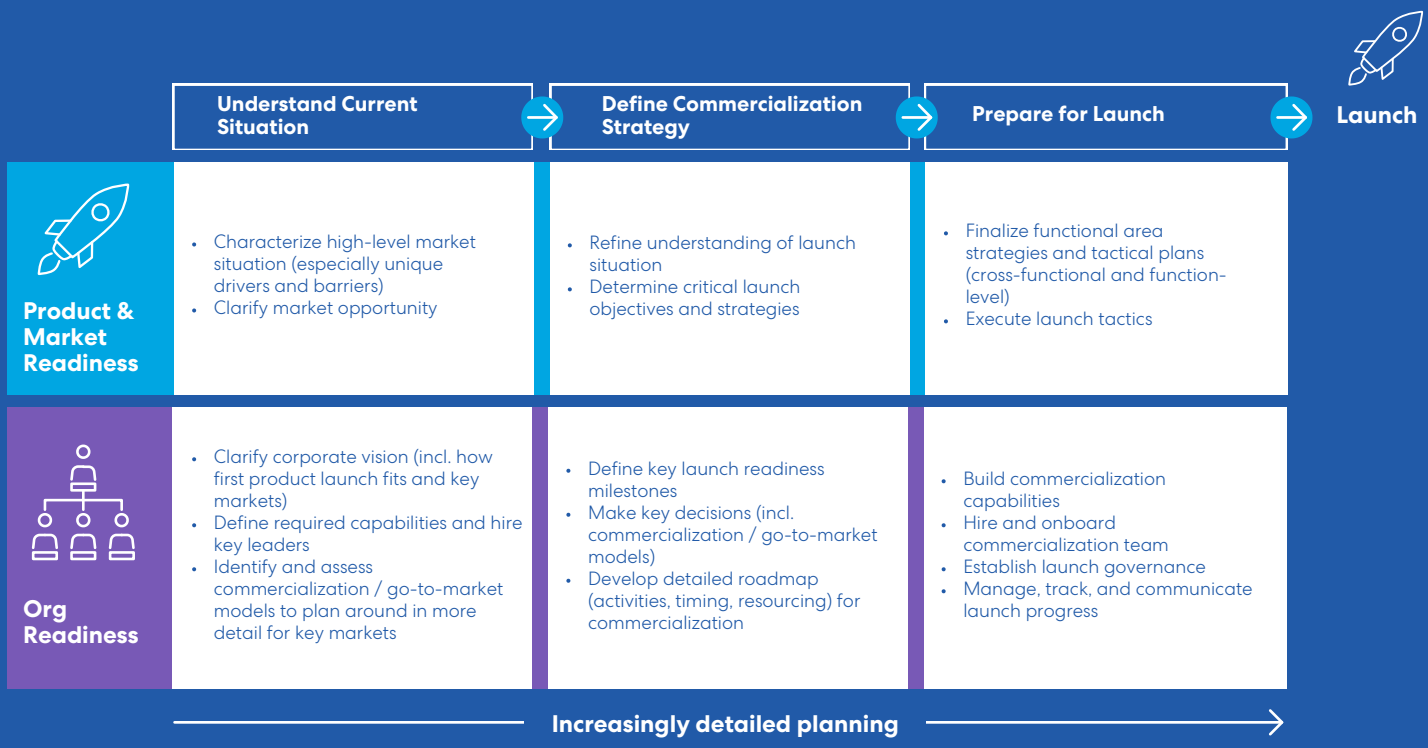
Key focus questions to guide your build-out include:

# 1	Once our product gets to market, what is that landscape going to look like?
# 2	Who is the competition?
# 3	What is the market access situation going to be?
# 4	What are the major barriers or challenges that need to be addressed in order to be successful?
# 5	Strategically, where do we invest versus not?
# 6	On the organizational side, what capabilities are we going to need in order to be successful in knocking down some of these barriers that we have previously identified?
# 7	Are we hanging-up our hat on our first launch, or are we using it to set up future molecules?
# 8	What do we need to be successful in the market?
# 9	What do we need to achieve from a positioning and differentiation standpoint, market access, etc.?
# 10	On the organizational side, what are the milestones that are going to trigger or unlock investment?

Launching a first product while building the organization is complex



Each company's journey is unique and may be iterative or non-linear

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Shifting the organizational mindset from clinical to commercial

An inflection point for many organizations is a shift in mindset away from a very cost-conscious clinical stage company that is tightly managing spend and runway into a company that is beginning to scale up and build commercial capabilities.

Leadership needs to be ready for this shift, as it necessitates major increases in investment that will not see return until product(s) hit the market.

Teams will often create a roadmap outlining the unlock-criteria for additional funds, which can include clinical, regulatory, or other milestones.

In for the long-haul: Setting realistic expectations for biotech fundraising and launch

1. Highlight total market potential early on

- Emphasize the unmet need, differentiation, and total addressable market
- Get investors excited about the possibilities, sell the story of the product
- Avoid specifics that may not materialize

2. Be realistic

- Early-stage projections are often overly optimistic, make sure to ground projections in market research, data, and real-world adoption rates
- Model both upside and risks
- Showcase credibility first and foremost

3. Map the patient journey

- Understand the expected bolus and duration, how the individual will experience the treatment
- Size early capacity for the likely demand
- Plan for volatility following approval

4. Communicate transparently

- Realign messaging as understanding evolves
- Set expectations aligned with realities
- Show validity behind assumptions
- Build trust through honesty

Whitepaper:
«Biopharma expansions to Europe»

Identify go-to-market path early

Defining the roadmap is a key factor in setting an organization up for a successful launch. While some companies decide early on in development the route that they want to take, others don't immediately know what the best path forward is for their product or are weighing competing opinions on the go-to-market strategy.

Leaders in this position should clearly map out what it would take to go alone, what it would take to partner, and the downstream effects of each option on the organization.
From there, it becomes easier to make the initial decision of which path to take.

For companies that plan to launch and commercialize assets on their own (at least in some markets), a launch roadmap is key.
Developing an aligned perspective on the required capabilities/functions, decisions/activities, and resourcing in sufficient detail is essential to:

1. Align the organization on key milestones and the potential path forward towards commercialization
2. Inform near-term investments and/or fundraising needs
3. Provide a starting point and facilitate transparency for the cross-functional launch team

7 “make or break” factors for emerging biopharma companies

For emerging, R&D-focused companies that are exploring their strategic options and/or preparing for commercialization, there are 7 “make or break” factors that they must address.

For a detailed exploration, please download this Blue Matter e-book:

7 “Make or Break” Factors for Emerging Biopharma Companies.

“Make or Break Factors”	Common Pitfalls
# 1 Educating and Aligning Internal Decision-Makers	Leadership is not aligned on the importance of thinking commercially early, resulting in key decisions not being appropriately informed by customer/commercial perspective
# 2 Generating the Most Important Customer Insights Early	Company may only speak to a few friendly KOLs instead of prescribers who will use their product in practice or payers/HTAs who will manage access and reimbursement
# 3 Integrating the Commercial Perspective Into Clinical and Corporate Decisions	Registrational trial may not be designed with the patient population or comparator that helps prescribers understand how to integrate the product into the real-world practice
# 4 Knowing What it Will Take to Commercialize	Company may underestimate the amount of time and resources required to commercialize, resulting in a delayed and/or suboptimal launch
# 5 Choosing the Best Commercial Path Forward	Company leaves too many options on the table for too long, creating organizational swirl and risks to launching on-time while functions look for clear direction
# 6 Right-Sizing Your First Launch	Company either over-invests with a “big pharma” mindset (leading to inefficient use of resources) or under-invests with a “cost minimization” mindset (risking launch success)
# 7 Establishing New “Ways of Working”	Teams and individuals work inefficiently when there isn’t clear guidance on how to collaborate and/or make decisions

Launching in Europe: A tall order for a small biotech

Europe is a complex collection of markets that each have their own requirements. "Going it alone" in Europe requires significant infrastructure build-out. Although there is hope for a single European market under the EMA in the future, the current reality in Europe necessitates identifying and prioritizing key launch markets. Companies will often choose a blended approach, going alone in the "big 5" and partnering in smaller and more complicated markets.

Nonetheless, the opportunity in Europe remains immense for BioPharma companies launching novel and innovative products. Regulators and payers are eager and willing to work with companies that offer effective treatments to patients, and organizations that plan early and thoughtfully will set themselves up for success in the European market.

e-book

For a detailed exploration of the keys to success for launching into European markets, please download this Blue Matter e-book:

7 Keys to Success in Europe

e-book

For an overview of the most common mistakes companies make when entering European markets, download this Blue Matter e-book:

12 Pitfalls in Europe

World-class technology in Europe's most stable environment

As a global leader in innovation and talent attraction and with Switzerland's business-friendly, stable, and reliable environment, the Greater Zurich Area offers international companies real added value and peace of mind for their strategic expansion. Greater Zurich has evolved into one of the leading locations for biotechnology and pharmaceutical companies in Europe, thanks to the region's academic excellence, Switzerland's business-friendly regulations, IP protection, large international talent pool, and R&D collaborations between universities and start-ups, as well as large multinational corporations.

How we help

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Facilitating contact to potential research partners at universities and research institutes.

Building the business case, introduction to service providers, and advice on regulations.

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Greater Zurich Area Ltd (GZA) is the reliable Swiss business concierge for companies looking to grow internationally.
We help you create a convincing business case for setting up a strategic location in Switzerland. Moreover, we guide you through the business and technology ecosystems and network you with the relevant companies, universities and research institutes, investors and incubators, authorities, and service providers.

GZA is the official investment promotion agency of 9 cantons (states) in German- and Italian-speaking Switzerland. The public-private partnership is supported by 30+ partners from business and science.

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