Early strategic planning for Biotechs:

How to overcome future commercialisation challenges through effective planning

Written by: Oliver Spray & Richard Ogborne

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Biotechs face a challenging commercial environment despite recent scientific advances

Scientific innovation is flourishing. In recent years, new technologies have emerged, such as cell therapy, mRNA-based therapeutics, and genome editing leading to a sharp increase in the number of university spinouts and pre-revenue biotechs[1]. This trend has fundamentally altered the dynamics of the life sciences industry. It is now the science-focused biotech firms that are the key contributors to the R&D pipeline and not the big pharma companies. Indeed, in 2022 companies with an R&D spend of under $200M contributed 66% of molecules in the global pipeline up from 51% in 2017[2].

Despite this surge in R&D activity, biotechs are facing an increasingly challenging commercial environment. This is reflected in the finding that 60% of biotech startups fail within the first 5 years of their inception[3]. We see three key challenges for biotechs in this area:

- **Increased R&D cost –** average cost to develop a single therapy from discovery to launch has increased from $1.3bn in 2013 to $2.3bn in 2023[4].
- **Increased enrolment time for clinical trials –** Clinical trial enrolment durations from trial start to patient enrolment have increased by 26% from 2019 to 2023[5].
- **Lowering success rates –** the percentage of therapies progressing from IND to approval has decreased from 15% in 2014 to 10.8% in 2023[6].

Early strategic planning is a critical success factor for biotechs

Considering these trends, biotech founders are confronted with the pivotal question of how to prepare their science-focused organisations for commercial success. An important success factor for biotechs is creating comprehensive strategic plans which pre-empt future commercial challenges. Analysis shows that companies which plan early and effectively are both more likely to win investment, and deliver a successful product launch:

- A 2021 survey of biotech investors carried out by Industry Standard Research (ISR) highlighted the importance of strong commercialisation analysis in driving investment decisions. 78% of respondents mentioned that detailed commercial analysis is extremely important, with a majority of the remainder saying it is somewhat important[7].
- A recent survey of biotech leaders showed a correlation between the success of product launches and planning start times[8]. On average, companies that delivered successful launches initiated planning 4 months earlier than companies with unsuccessful launches.

[1] https://www.ibisworld.com/industry-statistics/number-of-businesses/biotechnology-united-states/#:~:text=There%20are%202%2C363%20Biotechnology%20businesses,over%20the%20past%205%20years%3F
[2] https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-trends-in-r-and-d-2023/iqvia-institute-global-trends-in-rd-2023-forweb.pdf
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/
[4] https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-rd-roi-14th-edition.pdf
[5] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/rethinking-clinical-trial-country-prioritization
[6] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2024-activity-productivity-and-enablers
[7] https://healthadvances.com/application/files/5016/8996/5469/health-advances-biotech-investment-22.pdf
[8] https://www.mckinsey.com/industries/life-sciences/our-insights/making-the-leap-from-r-and-d-to-fully-integrated-biotech-for-first-launch

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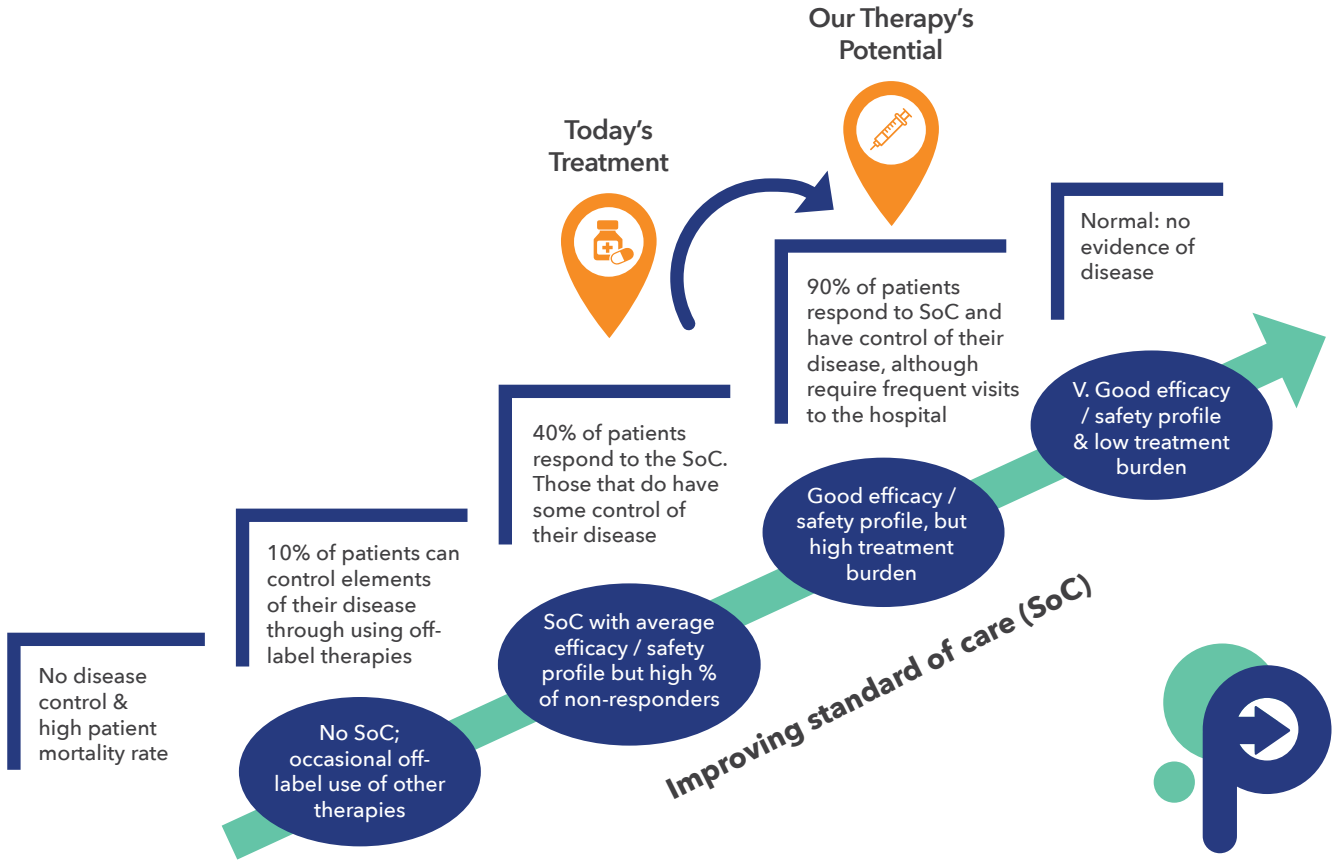
In this white paper, we present four key themes which should be addressed in a biotech's early strategic planning:

I. **Building backwards from an end goal**
II. **Developing strategic plans focused on improving patient outcomes**
III. **Leveraging technology**
IV. **Establishing effective leadership**

I. Building backwards from an end goal

Defining an asset's purpose allows a company to build backwards from a clinical objective to ensure that daily business activities are moving the company closer to that objective. A good purpose statement demonstrates an understanding of how the standard of care addresses its patient population, what medical unmet needs remain, and how your products or technology will address that need (Figure 1.). This exercise should be carried out on an ongoing basis. As the external and internal environments change companies need to reassess their end goal and correct their strategy accordingly. For companies with multiple assets in similar indications, identifying treatment positioning is particularly important to minimise market attrition between assets and prevent confusion from future customers.

Figure 1. Companies should have clarity on how their products will address an unmet medical need



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Companies which embed their purpose within the company culture can see behavioural and motivational improvements. Jazz Pharma is one of the few pharma companies to make it to +$1bn annual cash flow in the last 10 years. CEO & Founder Bruce Cozadd attributes a large part of the company's success to its highly patient-centric culture which has led to a resilient and innovative workforce[9].

> **We start with identifying the basic need of the patient and work backwards around what's the best way to solve that problem**
>
> **Bruce Cozadd, CEO Jazz Pharma interviewed for a Forbes article in 2023**

II. Developing strategic plans focused on improving patient outcomes

Product launches will only have a positive impact on patients if those products are prescribed. As such, during early strategic planning companies need to pre-empt the future roadblocks to prescription and plan accordingly. In our view, early strategic planning should include three key dimensions: market access & pricing, regulatory affairs & clinical strategy, business development & partnerships.

- **Market access & pricing -** For many pre-clinical biotechs the prospect of engaging payers to understand their pricing and evidence needs may seem premature. However, the evidence shows that companies that develop comprehensive market access plans which address the future needs of payers have a strategic advantage. According to a 2020 report, 50% of the drug launches which failed to meet projected expectations did so due to inadequate planning for payer requirements[10]. A large part of this finding can be attributed to the fast evolution of the payer landscape in the US. Increasingly, payers are combining with primary healthcare providers and pharmacies leading to self contained healthcare ecosystems which have greater bargaining power in pricing negotiations. This shift is changing payers' reimbursement decision-making including a greater squeeze on drug pricing and a change in focus from inpatient treatment of chronic diseases to primary care and home settings. It is important for biotechs to stay abreast of these changes to ensure they are positioning their products accordingly[11].

[9] https://www.forbes.com/sites/chasefeiger/2023/12/05/how-this-ceo-built-a-top-50-pharma-company-focusing-on-culture-day-1/

[10] https://www2.deloitte.com/content/dam/insights/us/articles/6491_Commercial-launch-success-analysis/DI_Key-factors-to-improve-drug-launches.pdf

[11] https://clarivate.com/life-sciences-healthcare/blog/u-s-market-access-landscape-a-push-for-control-is-erasing-the-boundary-between-payers-and-providers-in-u-s-healthcare/

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> **You have to start as early as possible in clinical development... I think that the companies that are doing it most effectively are the ones that are actually incorporating that early into their clinical development.**
>
> **Gil Van Bokkelen, previous CEO of Athersys on the importance of engaging payers early**

- **Regulatory affairs & clinical strategy –** In recent years there has been a surge in the use of innovative and complex trials to support regulatory submissions[11]. Between 2010 and 2017 there was a fivefold increase in the use of novel clinical trial designs such as biomarker led trials and adaptive trials and a fourfold increase in the use of surrogate endpoints in FDA approvals. Regulators are driving this change to manage the increasing complexity and specificity of new therapeutics whilst encouraging innovation by keeping costs of trials low. Biotechs need to carefully consider the perception of regulators on the suitability of trial designs for different patient populations. This is a particular challenge for early-stage biotechs, which are often investigating novel modalities in previously unaddressed indications. In these cases, it is critical that companies engage early and often with regulators to understand their needs and to work together towards an aligned approach.

- **Business development & partnerships –** Companies need to decide how they are going to leverage deal-making to make it to market. Licensing deals worth $171bn were announced in 2024, which is in-line with annual deal volumes back to 2020, reflecting a sustained appetite for biotech assets [12]. Biotechs should consider two key factors when designing their partnership strategy.

    - Firstly, it is important to consider how future partnerships align with the company's capacity for risk across the pipeline. Biotechs should weigh up how deal value extraction (upfront payments versus milestone payments) allows the company to reinvest in its pipeline. In 2024, 7% of the total deal value was in upfront payments, which is a significant decrease from the 13% in 2019 and reflects big pharma's willingness to do larger deals by distributing risk throughout the development phases.

    - Secondly, companies need to assess how attractive their asset's modality and stage of development is to future partners. Biotechs need to be realistic about the chances of successfully closing deals. For example, in 2024, just 11% of licencing deals were done on assets in Phase I, compared to 27% for assets in Phase III. In terms of modalities, biologics continue to be the most attractive modality for deal making, whereas gene therapy & gene editing technologies are still yet to garner large deal values, despite the extensive news flow[13].

[12] https://www.jpmorgan.com/content/dam/jpmorgan/documents/cb/insights/outlook/jpm-biopharma-deck-q4-2024-final-ada.pdf
[13] https://www.fiercebiotech.com/biotech/biopharma-dealmaking-continues-rise-ma-values-hold-steady-pwc

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III. Leveraging technology

Technological advancements in drug discovery and clinical operations have resulted in operational efficiencies and lowered development risks. Investors and their scientific advisory boards are increasingly evaluating how biotechs plan to leverage these tools when making their investment decisions. In our view, biotechs should consider two key factors:

- **Artificial intelligence (AI) –** The biotech industry has seen a wave of advancements in the field of AI across all stages of product development from drug discovery through to regulatory submission writing. In 2022 the FDA received 170 submissions that used AI for various elements of the submission including patient identification, identifying patient risk and assessing endpoints and biomarkers[14]. Other companies have used AI to fundamentally alter the way they discover and design their products. Biotechs such as the London based e-therapeutics are using biological datasets to produce insights that accelerate the discovery of multiple assets within a disease area[15]. Companies considering this path need to understand how to generate long-term value from their data – will their insights feed into an internal pipeline or will they bolster the drug discovery capabilities of other companies and rely on external partnerships? The answer will likely lie in the type of insights and the company's appetite for and expertise in external partnering.

> **We estimate that the analysis and tabulation process which took our medical writers an average of 20 weeks to complete manually can likely be cut in half**
>
> **Dr. Dylan Harris, Takeda Head of Medical Writing, writing for a Takeda blog in December 2024**

[14] https://www.raps.org/News-and-Articles/News-Articles/2023/7/FDA-sees-rapid-uptick-in-drug-and-biologic-submiss
[15] https://www.etherapeutics.co.uk/application/files/9017/1767/1448/ETX_Annual_Report_2024.pdf

- **Personalised medicine & biomarker detection –** The shift from a 'one-drug fits-all' to a more personalised approach places a greater emphasis on the identification of biomarkers. Many examples from industry demonstrate that the success of a therapy hinges on an ability to refine the target patient population to those that are most likely to respond to the treatment. One well-known example is the different launch trajectory's of the PD-1 inhibitors Keytruda and Opdivo. Both drugs are highly effective and were released to the market at similar times, and yet Keytruda's global 2023 sales were over double that of Opdivo's. Much of the difference can be attributed to MSD's decision to target a smaller group of PD-L1-expressing, first line NSCLC patients who responded best to the drug, whereas BMS targeted a broader patient group. The result was that BMS failed to show superiority to chemotherapy in the broader population resulting in delayed access to the first line patient population. There have been major technological advancements in biomarker identification and exploitation in recent years that biotechs should be aware of. Examples include the use of technologies to collect digital biomarkers such as the ones being used at Neurology AI firm NeuraLight, DNA sequencing work done by companies such as Illumina and Qiagen to reduce the cost of genome sequencing and the first biomarker-based AI-powered device for Covid-19 screening by Tiger Tech Solutions[16,17]. Biotechs need to generate a deep understanding of the disease physiology to identify relevant biomarkers and utilize external partners such as diagnostics or big data companies to identify how to use those biomarkers in the clinic.

IV. Establishing effective leadership

The biotech industry is a uniquely competitive and uncertain environment. It therefore requires excellent leaders who can inspire their team to navigate those challenges. However, many biotech leaders fall into the trap of devoting too much time on the science whilst neglecting their leadership duties. This can have serious, negative consequences on team performance and ultimately the company's chances of success.

In our view biotech leaders should prioritise the following:

- **Cross-functional leadership –** A common challenge in the biotech industry is a lack of communication between functions. Indeed, in a survey of biotech executives, only 20% of respondents believed that the collaboration between the R&D and commercial departments was "seamless"[18]. To improve collaboration, companies should hire cross-functional leaders who can link functional activities to the overarching goals of the business. Typically, these are people who have had varied careers across multiple life sciences functions, they are strategic thinkers who do not get bogged down by tactical considerations and they have the interpersonal skills to handle sensitive situations and motivate change in other people.

[16] https://www.fiercebiotech.com/medtech/fda-authorizes-first-ai-powered-armband-for-covid-19-screening
[17] https://neuralight.ai
[18] https://knowledge.insead.edu/operations/how-biotech-firms-can-improve-cross-functional-collaboration

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> **It's the ability to stabilise teams and the communication across teams, up to the board down to the senior leadership team and across the organisation**
>
> **Jodie Morrison, a Venture Partner at Atlas Venture in an interview for Biotech Success.com**

- **Hiring people with diverse functional backgrounds –** Another common problem the biotech industry faces is functional biases driving hiring decisions leading to a lack of diverse thinking within teams. It is typical for biotech leaders to hire people with a similar functional background to themselves resulting in teams with little diversity in perspective and information processing skills. A lack of cognitive diversity in this way has been shown to result in weaker performance. Indeed, a study from the Harvard Business Review showed that higher cognitive diversity within teams leads to more efficient completion of tasks[19]. Leaders at R&D-focused biotechs should encourage the addition of people with commercial backgrounds to ensure other skillsets are involved in the decision-making process.

- **Taking the time to develop teams –** Biotech leaders are normally incredibly busy often having to deal with multiple competing priorities, preventing them from dedicating enough time to developing their teams. This can have significant negative consequences on the ability of leaders to shape culture and foster a high-performing work environment. In our view, time-pressed leaders should focus on three key objectives. Firstly, teams should be clear on their purpose. They should understand why they have been hired and the problems that would exist if they were not there. Secondly, team members should be empowered to trust one another. Great teams feel comfortable admitting their mistakes and their concerns without fear of reprisal. Finally, team members should be clear on how to deliver in their role. Good leaders take steps to guide teams on their roles and responsibilities through delivering trainings and sharing guidance materials. The best leaders are those that enact the expected behaviours themselves. By being the change they want to see in the organisation, leaders will maximise their chances of building high performing teams.

- **Aligning governance structure to an asset's development stage -** To succeed, biotechs need to successfully navigate the transition from a science-focused company to a commercial one. Leaders should pre-empt this transition by building teams which contain skillsets required for preparing an asset for launch. New departments – including Medical, Commercial and Market Access teams - need to be setup as early as the first clinical trials. In a survey of biotech executives, nearly half of leaders who oversaw less successful product launches reported that they hired for these roles too late in the launch timeline[20]. To manage this transition, biotech leaders need to have a strong understanding of the challenges that lie ahead in the route to commercialisation and be able to identify the right talent, at the right time to deal with those challenges.

[19] https://hbr.org/2017/03/teams-solve-problems-faster-when-theyre-more-cognitively-diverse
[20] https://www.mckinsey.com/industries/life-sciences/our-insights/making-the-leap-from-r-and-d-to-fully-integrated-biotech-for-first-launch

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How can Protagoras support?

Protagoras is here to help biotechs making the transition from science focused organisations to commercial companies. We place an emphasis on developing a deep understanding of our customers so we can create customised solutions. Our biotech services span 3 key areas including:

- Portfolio & product strategy
- Operating model improvement
- Capability building

Interested in speaking further?

Oliver Spray, Senior Manager, London
Oliver.spray@protagorasgroup.com

Dr Richard Ogborne, Executive Director, London
Richard.Ogborne@protagorasgroup.com