



Realising a biotech's potential

What is required to scale successfully?

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Booming biotech sector at the centre of innovation

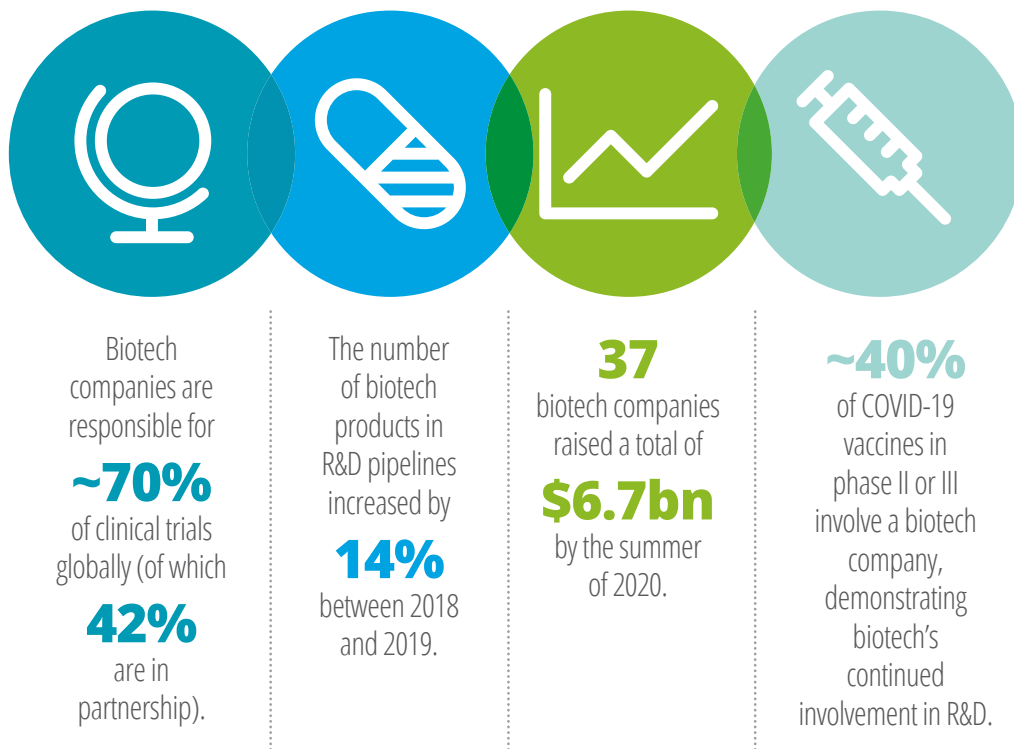
WHILE MANY SECTORS have struggled during COVID-19, the biotech sector has continued to grow and attract high investment. By the summer of 2020, 37 biotech companies raised a total of \$6.7 billion through US IPOs, compared to \$5 billion in all of 2019 across 51 IPOs.¹ The Nasdaq biotechnology index rose to a five-year high in December 2020 – up more than 25 per cent since the start of the year.²

Biotech's presence in biopharma research and development (R&D) has also been increasing

in recent years. In 2019, the number of biotech products in the R&D pipeline increased by 14 per cent from a year earlier – from 4,751 products to 5,422.³ In particular, more than 300 next-generation therapies, such as gene and cell therapies, are currently in biotech's late-stage pipeline, three times more than in 2009,⁴ and between 2018 and 2019 the number of these therapies in pipelines rose by more than 20 per cent.⁵ In addition, biotech companies continue to play a leading role in developing, alone or in collaboration with other players, COVID-19 vaccines or treatments.

FIGURE 1

The biotech sector is booming



Source: Deloitte analysis, 2020.

What is required to scale?

AS BIOTECH COMPANIES attract fresh investment, they need to consider how they can scale up and what is required, in order to deliver on their promise of providing innovative medicines to patients. Early in the life cycle, a biotech company's management team typically grows the business through a few core assets and limited programmes, focusing its resources where the most value can be gained such as differentiation in manufacturing, understanding of disease and biology, or drug chemistry. As the company grows, however, and attracts significant capital (including from IPOs), management needs to consider the following:

- Do we need to build a commercial organisation or can we remain an R&D company as we scale?
- What pipeline or portfolio will be required to support our growth into a mature biotech business?
- How many products/candidates does it take to 'win'?
- How many therapeutic areas should we enter?
- To what extent should we collaborate or go it alone, and in which geographies?

One of the core drivers of longer-term success is to build a portfolio of products to sustain growth – this research seeks to identify which portfolio approaches have enabled biotechs to scale, brought innovation to patients and created financial success for investors and founders.

METHODOLOGY

To understand the portfolio required to scale into a maturing biotech company and capture what high-performing companies are doing differently, Deloitte has collected and analysed data from 20 biotech companies between 2012 and 2019 which have successfully scaled their business following an IPO. Deloitte has made a comparison of their portfolio and pipeline composition at the time of the IPO versus that at maturity. We also analysed the data at the product and company level and supplemented the quantitative inputs with qualitative research.

DEFINITIONS

- **Biotech:** emerging innovative life science company focusing on developing therapeutics
- **Maturity:** when biotech business reached a \$5 billion market cap
- **Asset:** new molecular compound/entity in development by the biotech (including both clinical and pre-clinical ones published by the company)

As biotech companies attract fresh investment, they need to consider how they can scale up and what is required.

Supporting growth with licensing and product sales

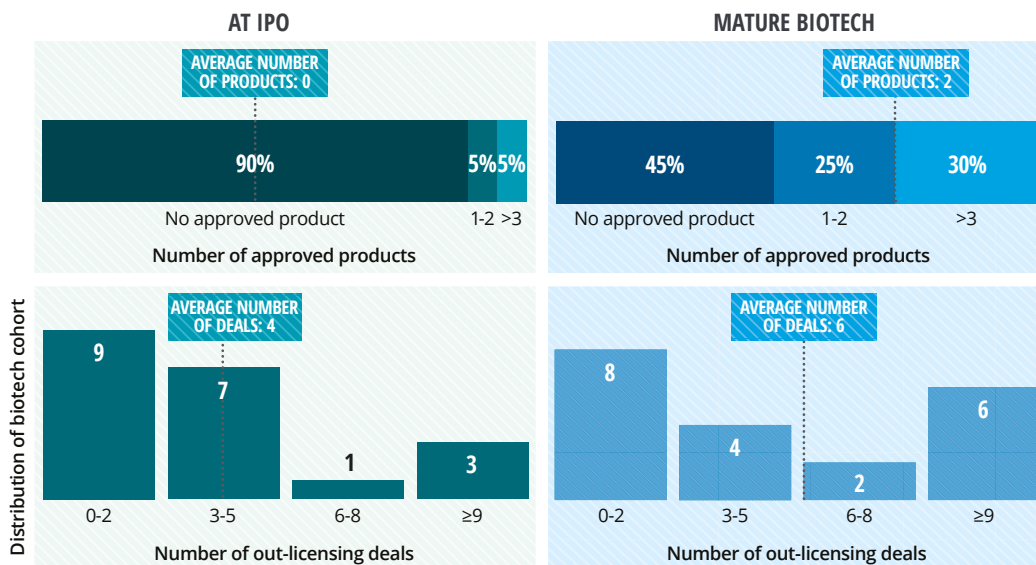
COMMERCIAL SUCCESS COMES from revenue generated by effectively and efficiently launching one or more products across key markets. A product approved by regulators is both a key driver of a company's valuation and often a hallmark of maturity. But this approach to revenue generation is not the only path a company can take. Almost 50 per cent of the biotech cohort studied achieved maturity without an approved product. Instead, management teams in these companies relied on their R&D pipeline profile and strategic collaborations or alliances with other players for revenue.

In the majority of cases, these collaborations and/or alliances are with similar-sized or larger players. Thus, by granting their partner potential commercial rights, these biotechs are able to gain access to the capital and the expertise required to enable them to take their clinical programmes to the next milestone. About 50 per cent of agreements reviewed were tied to discovery programmes and pre-clinical research, with the majority of the remaining being used to support Phase 2 trials. Within the cohort analysed, only one company reached maturity in the absence of any reported deals. In this case, its lead drug targeted a large therapeutic area and life-limiting disease producing positive phase III clinical study data.

FIGURE 2

Revenue generation

Not all mature biotech companies have marketed products – close to 50% are still in the R&D phase with income being generated from licensing deals.



Source: Deloitte analysis, 2020.



Diversifying pipeline through assets, clinical programmes and therapeutic areas

IN ADDITION TO revenue generation, the R&D pipeline profile is also crucial to being able to scale. Biotech companies that have scaled successfully have managed to diversify their R&D pipeline and de-risk their business while sustaining innovation. Analysis of the cohort of 20 companies we looked at highlights this (figure 3). Mature biotechs drove diversity by increasing their drugs assets and clinical trials, not only in terms of absolute number but also in the number of trials which progress to the later stages of clinical development (figure 3). To ensure that this pipeline diversity continues, biotechs should make efforts to ensure their pipeline is sustained.

For some this means working closely with universities and institutions to conduct innovative research. For others an in-licensing approach is required to continue the development of pre-clinical assets. This way companies continue to demonstrate the strength of their R&D capabilities and pipeline, driving market confidence and the subsequent willingness of other players to collaborate and partner. For successful biotechs, collaboration remains an important element in scaling – on average, between 30 and 40 per cent of the trials are conducted in collaboration with other players at both IPO and maturity stages.

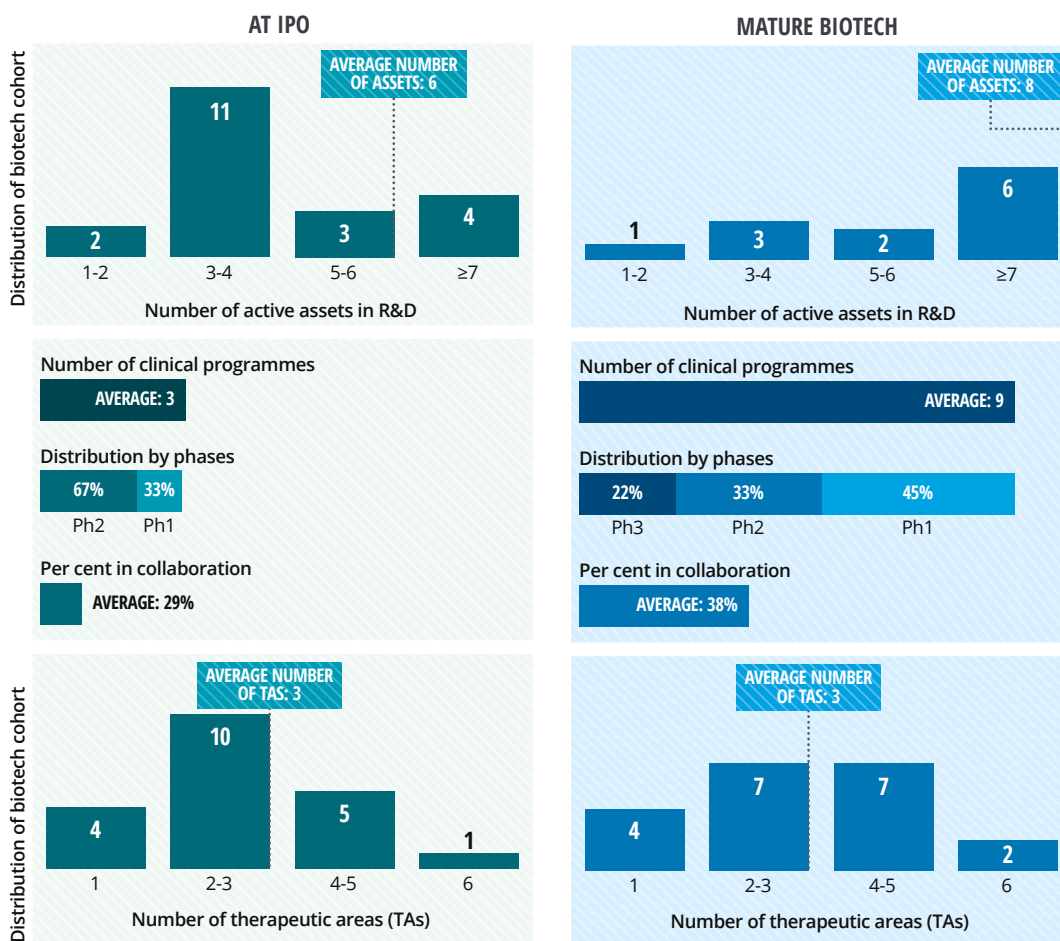
Naturally, as we see fluctuations in the average number of clinical programmes, collaborations between companies, and drug assets, it can be expected that the number of targeted therapeutic areas (TAs) will also fluctuate. However, our research shows that for scaling biotechs, this number remains constant – at three, on

average. Management teams should therefore make an early choice to focus on a limited number of TAs. A choice likely driven by the drug assets they have, a need to optimise the use of limited resources and, for some, the need to best prepare for commercialisation and health care profession (HCP) engagement.

FIGURE 3

Pipeline diversity

Mature biotech companies diversified their pipeline by expanding assets and clinical programmes, but remained focused on certain therapeutic areas.



Source: Deloitte analysis, 2020.

Biotechs should make efforts to ensure their pipeline is sustained.

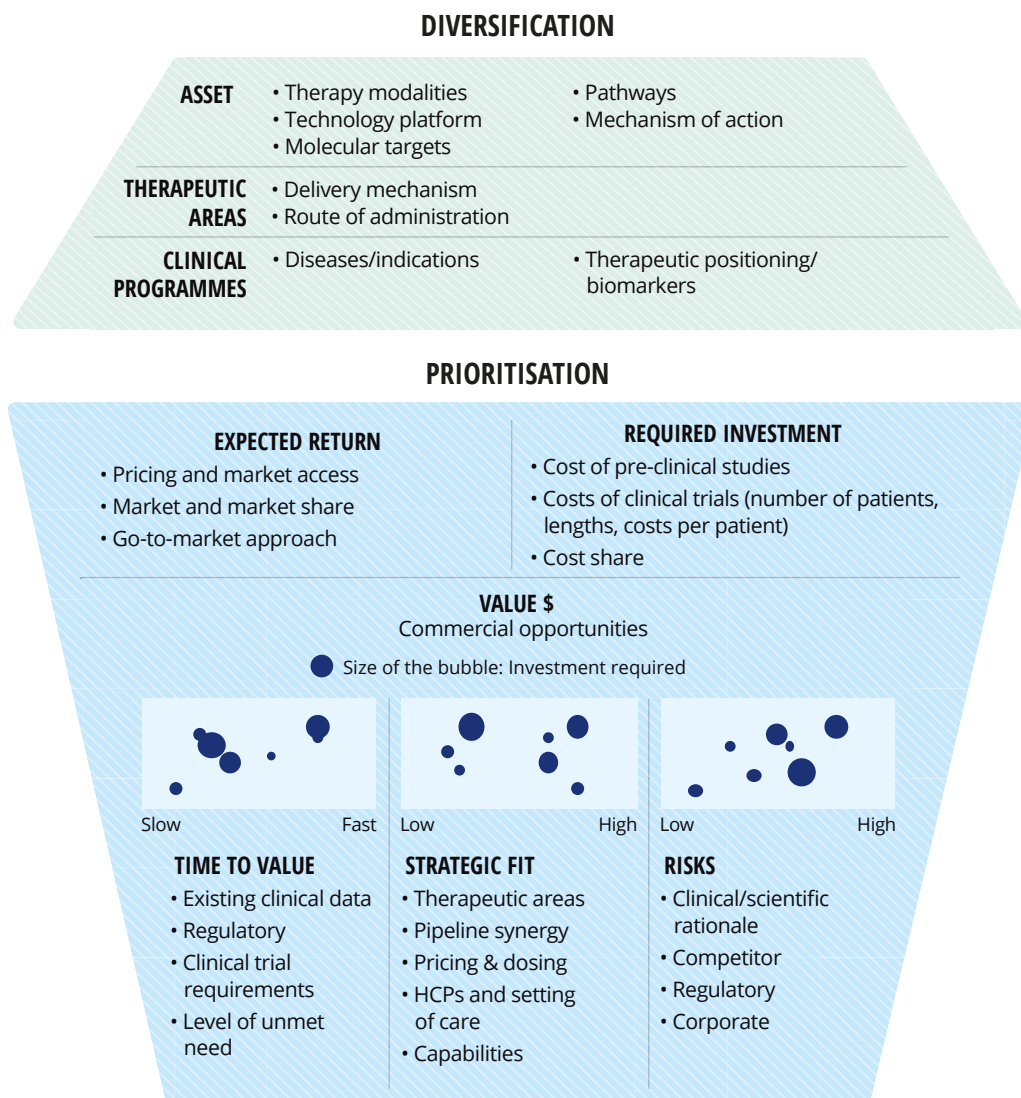
Determining the composition of a biotech’s pipeline in order to achieve sustainability and long-term growth requires management to balance multiple factors across diversification and prioritisation (figure 4). However, it is important to note that it is a challenging but critical exercise, which should balance

diversification and prioritisation. The process itself needs to be based on a rigorous fact-based assessment across different elements, including investment and return, timing to value, strategic fit and risks. And of course, it has to be based on excellent science.

FIGURE 4

Building a sustainable pipeline

Scaling a sustainable biotech requires a balance between diversification and prioritisation.



Source: Deloitte analysis, 2020.



Three scaling archetypes

THE WINNING 'BLUEPRINT' for scaling seems relatively homogenous: generate revenue through successful deals or R&D collaboration, and diversify the pipeline. However, to understand what the winning blueprint might be in more detail, we went beyond the aggregated quantitative analysis and further assessed each individual biotech. From this, three different biotech blueprint archetypes emerged: end-to-end, focus and diversify (figure 5).

Some successful biotechs look to build an 'end-to-end' entity from R&D to commercialisation, bringing their product(s) to market themselves.

For other biotech companies most of their attention remains on their R&D profile. Among those which are R&D focused, some take a 'diversify approach', expanding the number of assets significantly across multiple therapeutic areas and relying heavily on revenue generated through collaboration deals to progress assets past pre-clinical and Phase 1 stages. Drugs are often set to be co-commercialised with a partner. Others generate value in a similar vein but via a more 'focused approach', driving R&D forward with limited investment in diversification while creating optionality for a potential launch or out-licensing deals.

FIGURE 5

Biotech scaling archetypes

Three archetypes emerge from our cohort of 20 biotechs and single-case analysis.



Source: Deloitte analysis, 2020.

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Five key dimensions to succeed in the scaling journey



CLEARLY, AS RESEARCH shows, there is no single winning blueprint for maturing successfully, and blueprints alone cannot provide success. Instead, our experience and research suggests that biotechs that mature successfully are those where the management team make strategic and measured choices spanning across five dimensions:

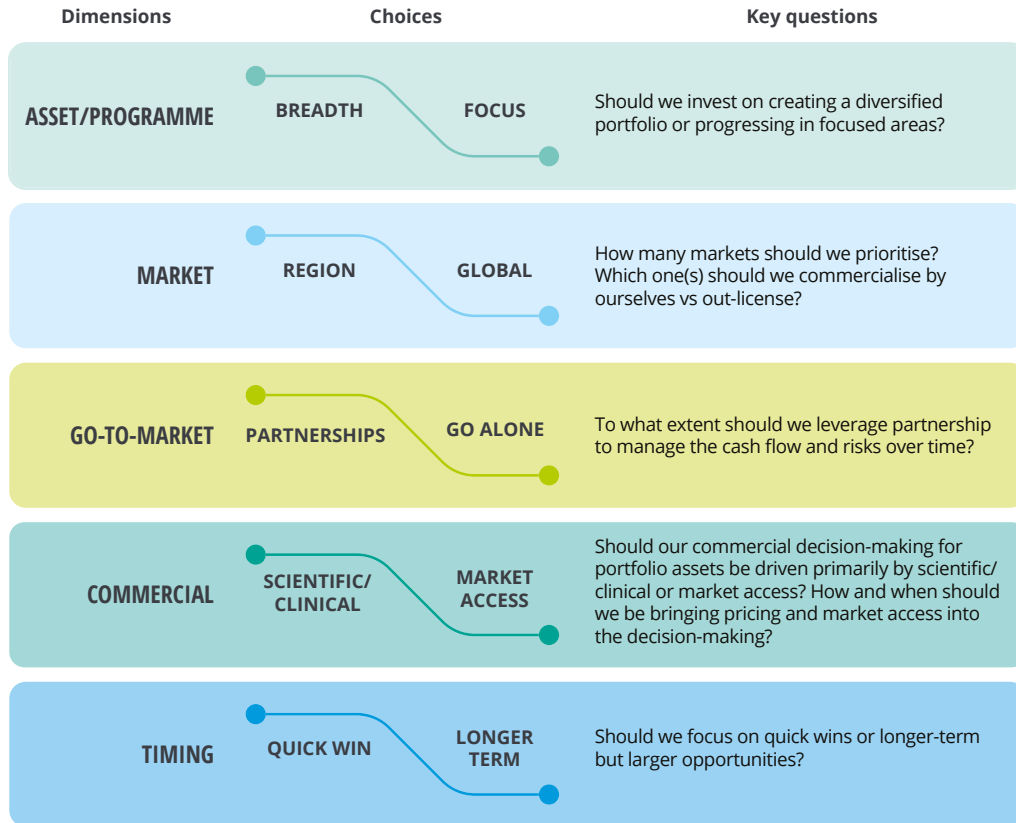
01. the breadth of assets or trials to develop
02. the prioritisation of markets
03. the extent of use of partnerships or collaborations
04. the balancing of scientific considerations with market access
05. the timeline to pursue.

By balancing these dimensions (figure 6) biotech companies are in a position to build the right capabilities and teams, galvanize the organisation and implement their chosen route to scale successfully.

FIGURE 6

Five key dimensions for scaling

Successful biotechs are those where the management team has made strategic and measured choices spanning across five key dimensions.



Source: Deloitte analysis, 2020.

It is not sufficient to just plan and implement a route to maturity; a biotech company’s management team must routinely reassess their position and decide when a change in path is needed.

A clear understanding of the choices to be made across dimensions and a blueprint matching the company’s profile and ambitions makes it possible to navigate the scaling journey successfully.

Endnotes

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