EXECUTIVE INSIGHTS

Cash Preservation in the Biopharmaceutical Industry: Navigating Uncertainty

Setbacks happen. A clinical trial that does not hit, a Food and Drug Administration complete response letter, a delayed manufacturing scale-up or a disappointing first product launch — all are examples of events that often require additional funding in order for an emerging biopharmaceutical company to move forward.

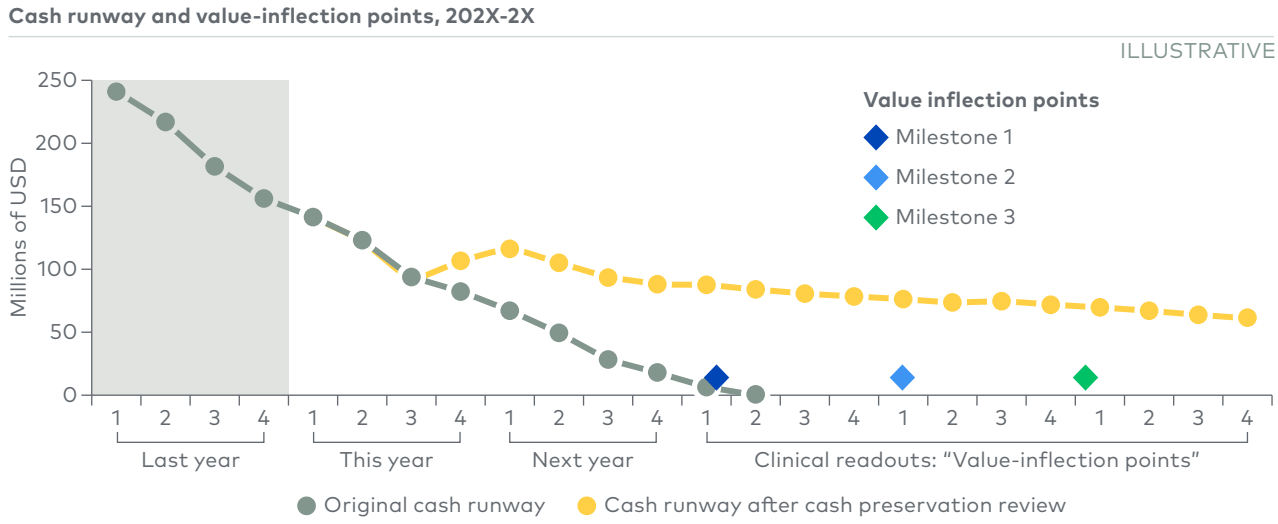
When funding is easily available and interest rates are low, as witnessed during 2020 and 2021, companies can bounce back from the negative news flow following asset setbacks. But in today's capital environment, such setbacks can be detrimental to the viability of biopharma companies, as access to capital is severely constrained. These conditions have resulted in layoffs at approximately 200 biopharma companies from January 2022 to May 2023, many of which are currently trading at a negative enterprise value.

Given these market conditions, biopharma executives need enough capital to reach the next value-inflection point and transform their progress into improved valuations. In this edition of *Executive Insights*, L.E.K. Consulting outlines how biopharma companies can extend their cash reserve to ensure operations past value-inflection points (see Figure 1).

Seeking financing options

Capital-constrained companies should explore a diverse range of options to fund their portfolios. These include traditional financial cash management options (e.g., optimize accounts payables/receivables and engage with debt stakeholders regarding payment terms and schedules) as well as sources of capital such as at-the-market (ATM) financing, private

Figure 1
Impact of cash preservation review — extension of cash runway



Source: L.E.K. research and analysis

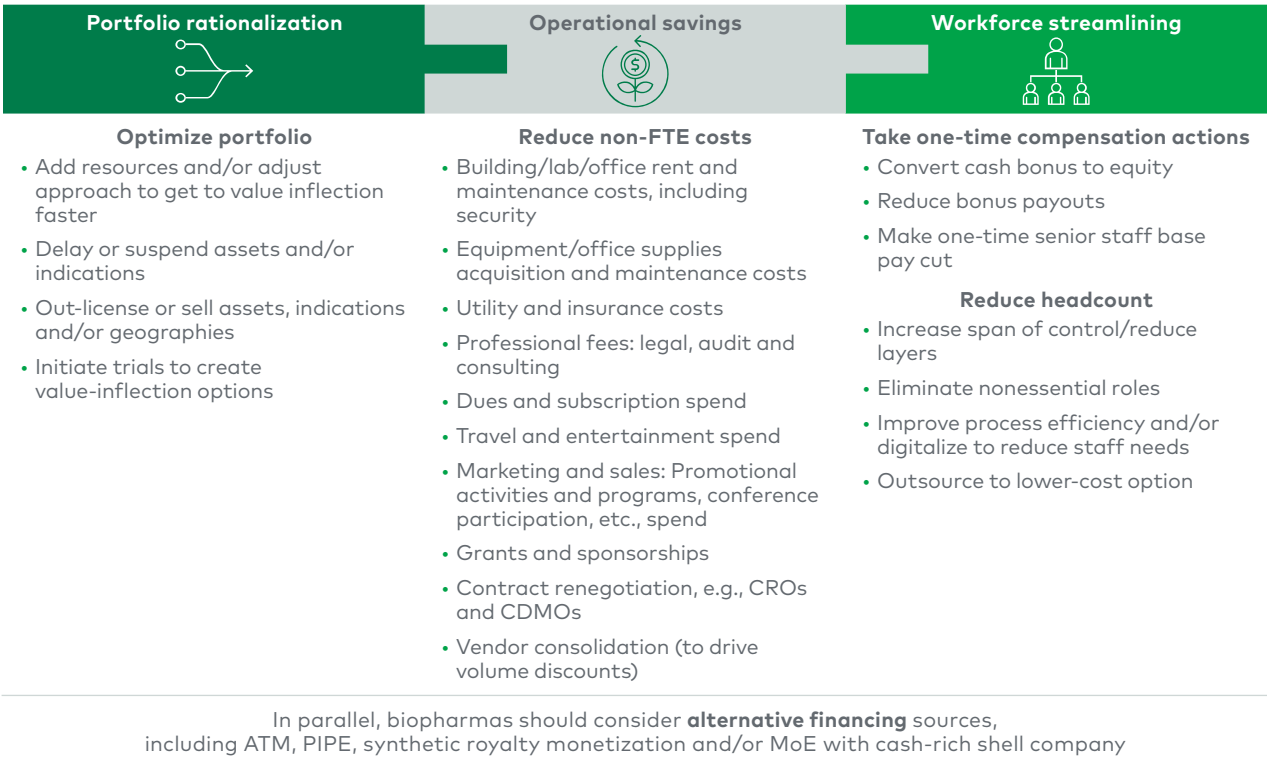
investment in public equities (PIPEs), debt financing, synthetic royalty monetization or mergers with cash-rich shell companies.

There are pros and cons to these different options, which should be carefully considered. For instance, ATM financing and PIPEs can provide faster, more flexible and opportunistic options to generate equity financing; however, depending on company and market conditions, they run the risk of diluting existing shareholders. Royalty monetization or mergers with cash-rich shell companies can provide non-dilutive capital but can take more time to execute and may relinquish potential upside. Ultimately, exploring these avenues in parallel with cash preservation options increases the likelihood that biopharma companies can avoid cash shortfalls and effectively navigate unforeseen challenges.

Implementing cash preservation

Without access to sufficient capital, biopharma executives need to migrate toward cash preservation options. The first step in this process is to determine the number of months of cash runway the company has under different portfolio scenarios, by understanding how long the cash on hand can cover the expected burn rate of the portfolio. Drawing on our experience supporting biopharma companies that "right size," L.E.K. has identified three main categories of cash preservation strategies: portfolio rationalization, operational savings and workforce streamlining — whether one-time compensation actions or headcount reductions (see Figure 2).

Figure 2
Three cash preservation categories to consider



Note: FTE=full-time equivalent; CROs=contract research organizations; CDMOs=contract development and manufacturing organizations; ATM=at-the-market financing; PIPE=private investment in public equity; MoE=merger of equals
Source: L.E.K. research and analysis

Portfolio rationalization

To make "no regret" portfolio choices, the management team — in consultation with the company's board — should confirm its corporate vision and strategy as a foundation for making portfolio decisions. At the same time, alignment on portfolio choices is an iterative process that needs to balance direct R&D investment decisions with concurrent operational savings and organizational restructuring initiatives. With this context in mind, biopharma executives can consider four alternative investment options for each program/asset in their portfolio:

1. Accelerate asset development timeline and value-inflection points
2. Delay development of an asset or indication(s)
3. Partner on an asset or a group of assets
4. Divest and/or terminate an asset or indication(s)

Delaying, partnering or divesting an asset can help free up cash but does so at the expense of reducing long-term portfolio value. As a result, before pulling these levers, biopharma

companies should first identify opportunities to accelerate the development timeline and near-term milestones for their lead asset. Examples of such accelerated clinical development strategies include:

- Negotiating a surrogate endpoint for an indication that significantly reduces the length and complexity of its clinical development program
- Exploring breakthrough designations with the regulatory agencies to shorten both the development and review periods for an asset's development
- Designing adaptive trials to speed dose optimization, adjust sample sizes and use interim analyses to rapidly assess safety and efficacy

In more financially distressed situations, biopharma companies may have to break up their portfolio by out-licensing or divesting assets in exchange for upfront cash and near-term milestones. These moves, though painful, help refocus investment on more advanced and attractive assets, preserving cash and enabling the company to survive in case of future clinical delays or setbacks.

Operational savings

Operational savings target non-full-time equivalent (FTE) cost reduction and should focus on investments that will not impact revenue-generating activities (e.g., core supply chain and commercial activities) or clinical development activities. Cost categories to consider include, for instance, office space, overhead, sales and marketing, and travel and entertainment, among others.

Operational savings need to happen across functions and subfunctions, with a focus on identifying quick wins. When prioritizing these quick wins, executives need to consider the timing of the impact of these cost reductions. Some expense line items such as travel and entertainment can be reduced immediately, while others such as a reduction in office space to save on leasing costs may require several months to realize.

Workforce streamlining

Outsourcing mix is an important lever for streamlining costs related to FTEs. By strategically identifying which functions can be effectively and economically outsourced, biopharma companies can preserve cash without compromising essential operations. There are no one-size-fits-all solutions, but often functions such as manufacturing and supply chain, clinical operations, information technology, human resources, and legal can be outsourced to access cost savings, specialized expertise and streamlined processes. These outsourcing initiatives

enable biopharma companies to optimize their resource allocation around the most valuable internal activities while preserving valuable talent and expertise.

Beyond outsourcing more actively, biopharma companies may have to consider reducing the scale of their organization to preserve cash in order to reach the next value-inflection point. In doing so, executives need to take a systematic approach to evaluate how many FTEs to reduce and determine where FTE reductions should come from. To determine the number of FTEs by function to include in a reduction in force (RIF), biopharma companies need to combine external benchmarking to provide insights on required FTE ranges with a bottom-up, iterative internal organization assessment. Using these different inputs, leadership can set RIF targets by function and communicate final targets to each functional head, with an eye on preserving the talent pool and maintaining company morale through the restructuring. Once it has been verified that budget targets are met and the company can still deliver on its revised portfolio investment strategy with planned FTE reductions, implementation planning should begin.

Implementing cash preservation initiatives

The final and most challenging step of a cash preservation effort is implementing cost reductions with the least amount of disruption to ongoing operations. It is key to preserve the link between the enterprise strategy and the forthcoming cost-reduction actions to avoid too much disruption in the equity narrative of the company and investor expectations.

Successful execution requires elements of traditional change management to maintain company performance. To ensure alignment and timely execution of cost-reduction actions, instituting a project management team is a critical step. This team should be composed of cross-functional individuals who can accelerate implementation and drive ownership of the following activities:

- **Deliver direct and consistent messaging:** Clearly define the desired end state and share objectives broadly with consistent messaging and anticipation of questions
- **Identify interdependencies:** Different cash preservation options/initiatives can impact each other. For example, too-steep headcount reductions could impact the ability to move a pivotal trial forward or delay a tech transfer. The project management team needs to identify these linkages before selecting the recommended initiatives
- **Follow a detailed plan:** Leverage preprepared material to minimize communication hiccups
- **Prioritize talent planning:** Identify talent at risk, and review retention options

- **Establish implementation metrics:** Organize function efforts to align with key value drivers and establish key tracking metrics as well as key functional interdependencies
- **Identify and mitigate key risks:** Work to mitigate risks to the organization's image or potential cultural risk from an RIF, e.g., resentment if there is a perceived different impact by function or geography

As implementation begins, a detailed tracker should be maintained to ensure effective execution and facilitate providing progress updates to leadership.

The way forward

In these uncertain times it is critical for biopharma executives to consider the following questions:

- How much cash is needed to reach near-term inflection points?
- What are the financing options to extend the cash runway of the company?
- Are there portfolio rationalization options that save cash while preserving value?
- Which operational savings and workforce streamlining options could be considered?
- How does the company execute and track progress on these cash preservation initiatives?

We hope that the recommendations outlined in this *Executive Insights* will enable biopharma leaders to address the questions above (and others) in order to adopt the right strategy to build a bridge to less-dilutive future equity offerings after reaching transformative clinical milestones.

For more information, please contact lifesciences@lek.com.

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