THE CRITICAL PATH TO PRODUCT SUCCESS

A STRATEGIC FRAMEWORK TO MAXIMIZE THE VALUE OF A PRODUCT THROUGHOUT ITS LIFECYCLE

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Pharmaceutical companies are facing new challenges at every stage of the product lifecycle. On the development front, companies are experiencing a general lack of R&D productivity, spending too much money, and taking too long to get products approved and onto the market.

The commercial landscape is also changing, as competition increases and payers put pressure on pricing in an effort to control healthcare costs. The stakes for a successful product launch, meanwhile, have never been higher, as companies that do not prepare well for launch suffer delays and suboptimal results.

As a result of weak R&D productivity, increased competition, and pricing pressure, pharmaceutical companies find themselves with fewer opportunities to successfully commercialize products that will grow the company. Therefore, it is vital that companies find ways to maximize the lifecycle value of the products they bring to market.

To this end, we have created a strategic framework designed to increase the odds of success at every stage of the product lifecycle. This framework leverages the key lessons we've learned helping our clients develop, commercialize, and optimize their products through more than 500 projects in the past five years.

To help development and commercialization teams navigate each stage of the product lifecycle, this article provides an overview of the lifecycle stages, the objectives associated with each stage, and the three strategic themes that cut across every lifecycle stage: Prepare the Product, Ready the Organization, and Engage the Market. This article will also show how these strategic themes evolve across the product stages.

Lifecycle Stages, Objectives, and Strategic Themes

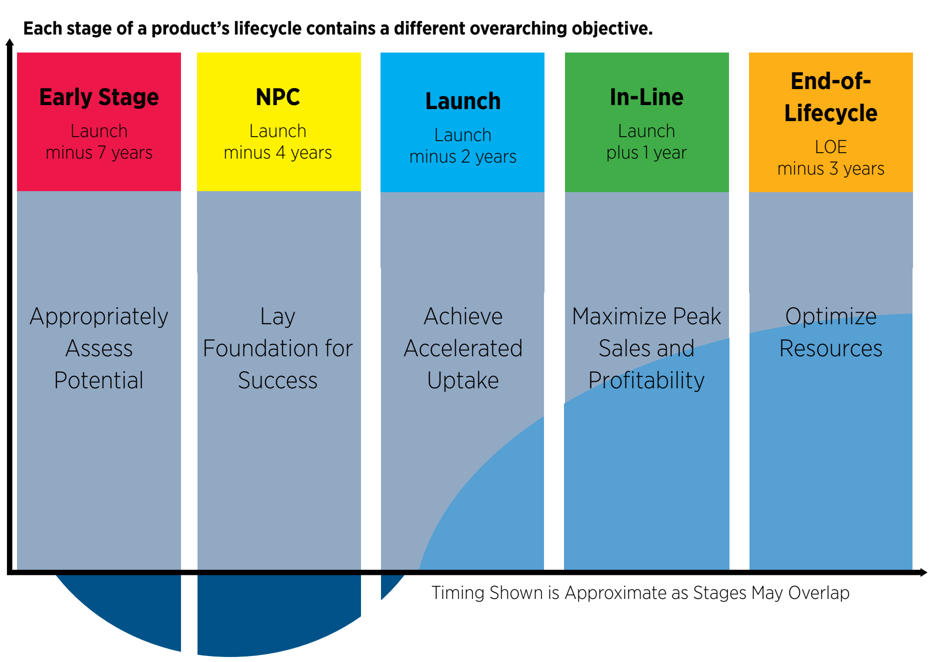
Every company works differently, and the triggers to move an asset from one stage to the next differ significantly, sometimes even within the same company. Many companies look at the stages of the product lifecycle by development phase, but that can oversimplify how things work in reality. For example, in orphan diseases, products may skip phases altogether or the launch period may be extremely fast.[1]

For the purposes of this series of articles, we have attempted to minimize those differences by defining the following five stages of the product lifecycle and their related objective:

- Early Stage: Appropriately Assess Potential
- New Product Commercialization: Lay the Foundation for Success
- Launch: Achieve Accelerated Uptake
- In-Line: Maximize Peak Sales and Profitability
- End of Lifecycle: Optimize Resources

These five stages correspond to typical points where there is a major shift in the strategic objectives for the asset or there is a transfer of ownership from one group to another within a company. They represent fairly standard groupings, and though the terminology may differ from one company to the next, they should nonetheless be universally recognizable.

Objectives By Stage



Strategic Themes

Regardless of where a product is in its lifecycle, companies must focus on three overarching themes to drive value within that stage.

- Prepare the Product: Ensure that the product is appropriately prepared to compete in the marketplace by finding the right balance between a "product-out" strategy and a "customer-in" approach
- Ready the Organization: Align the organization behind goals and timelines, while building an infrastructure according to the strategic imperatives
- Engage the Market: Ensure that the customer-facing teams are able to effectively engage the market with a consistent set of messages and activities

While these strategic themes cross every product stage, the relative importance of each theme differs across stages, and the specific business questions associated with each theme evolve from one stage to the next. That being said, stages can and will overlap, and moving from one stage to the next doesn't give a company a free pass to skip any unanswered questions within the stage they are exiting. In fact, it often just speeds up the need to answer those questions as the questions build upon one another. The next section of this article will examine each stage and the interplay of the strategic themes within those stages.

Bringing It All Together: A Walk Through the Stages

Early Stage

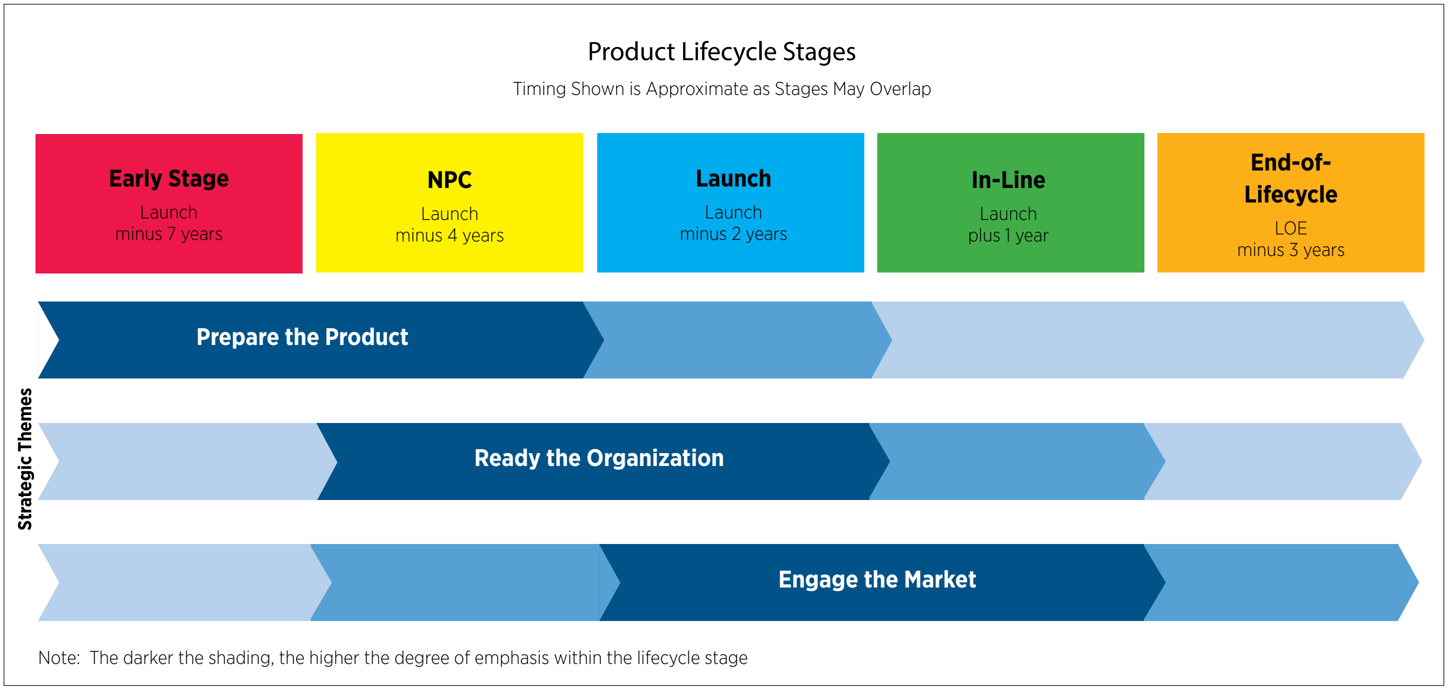
We define Early Stage generally as launch minus seven years. The key objective of this stage is to appropriately assess the potential of the product being developed, and therefore the most important key questions are related to the Prepare the Product theme.

More specifically, these questions focus on defining the product's technical viability and the company's development strategy. During this stage, the product is typically being shepherded by a cross-functional product team led by R&D.

Assessing the potential of a product requires striking the right balance between the science and the market. It comes down to the relationship between the company's product-out strategy versus its market-in strategy.

A product-out strategy focuses on the potential set of indications for a product and whether these indications are technically viable. The market-in strategy requires companies to step beyond the indications to get an understanding of the market opportunity for those indications to assist in prioritization.

Within the Ready the Organization theme, companies must start to think about whether they have the capabilities and funding to develop the product themselves. Key questions related to the Engage the Market theme focus on key opinion leaders (KOLs)



Key Questions Early Stage Launch minus 7 years		
Prepare the Product	• Which indications could be available from the platform technology? • What is the relative opportunity of the potential indications? How should they be prioritized?	• What is the appropriate development sequence and clinical trial strategy?
Ready the Organization	• What are the strategic and financial objectives of the company? • What are the best options to fund and structure the R&D program?	• What are the specific metrics that will inform go/no-go decisions?
Engage the Market	• How should the company engage KOLs and potential investigators to implement the clinical trial strategy?	• How should the company engage current investors and the financial markets?

Note: The darker the shading, the higher the degree of emphasis within the lifecycle stage

and investigators to help understand the potential of the product and investors/partners to build capabilities.

The challenge in the Early Stage is to bring often-limited resources to bear to understand and prioritize a product's potential indications and opportunities. Companies that do this effectively don't get lost in the science, but instead take a disciplined approach to development and investment.

New Product Commercialization

We define the New Product Commercialization (NPC) stage as approximately four years prior to launch. The key objective at this stage is to lay the foundation for the success of the product. The most important key questions fall within the Prepare the Product and Ready the Organization themes, and this stage represents the point at which commercial team members become heavily involved in decision making.

From a product standpoint, teams must understand the market dynamics in terms of disease management, competition, and market access/reimbursement dynamics in order to identify opportunities for the product. It is also critical that NPC teams define a product profile that will differentiate and resonate in the market, while also considering the broader lifecycle strategy.

From an organizational standpoint, companies need to define their commercialization objectives for the product and then determine the most appropriate commercial strategy (e.g., launch alone, partner, out-license) to achieve these objectives. This is also the stage at which companies need to define the capabilities required to commercialize the product, taking into consideration their commercial strategy. Finally, companies need to start to think about how they should engage key stakeholder groups in the market.

Launch

We define the Launch time frame as the two years leading up to the product's market debut. The key objective at this stage is to achieve accelerated uptake for the product. The most important key questions fall within the Ready the Organization and Engage the Market themes, as this is the stage where strategy transitions into implementation.

At the Launch stage, the company will need to clearly define the sources of growth for the product and prepare the company infrastructure to get ready for the launch. This includes training the sales reps, putting in place the distribution strategy and logistics for the product, and making sure that the market is aware that the product is coming. Physicians and advocacy groups also need to be educated about the product and its intended use.

Key Questions NPC Launch minus 4 years		
Prepare the Product	• How is the disease being treated/managed today? • Who are the stakeholders and their unmet needs? • Who are the current and future competitors? • What influences market access/reimbursement?	• Where is the opportunity for the product? • What profile will create product differentiation and what data generation is needed to support it? • What is the lifecycle management strategy?
Ready the Organization	• How large is the opportunity for the product? • Is the company aligned on objectives for the product? • What is the commercialization strategy for the asset (e.g., launch alone, partner, out-license)?	• What capabilities are required to support the product? • What are the specific metrics that will inform investment decisions?
Engage the Market	• How can the company begin to engage key stakeholders, including KOLs, providers, patients, advocacy groups, and payers?	

Note: The darker the shading, the higher the degree of emphasis within the lifecycle stage

Key Questions
Launch
Launch
minus 2 years

Prepare the Product	• How will the market react to the new product? • Which customer segments do we need to target? • How should the product be positioned in the market?	• What is the product's value proposition? • What additional studies are required to further differentiate the product?
Ready the Organization	• What are the likely approval scenarios and their impact on the forecast and investment required? • What is the launch sequence & market entry strategy?	• How can the company most effectively build and manage a Launch Playbook to achieve objectives? • What internal and customer-facing teams, operating models, and supporting infrastructure are required?
Engage the Market	• How can we optimize product distribution and access? • What are the core activities, services, and messages to deliver to key stakeholders?	• Is the company effectively deploying resources?

Note: The darker the shading, the higher the degree of emphasis within the lifecycle stage

An important question under the Ready the Organization theme is around the development of specific metrics that will inform investment decisions. This is a critical component to launch planning. While it may not be possible to apply metrics to every tactic, metrics should be applied and used everywhere it makes sense to do so. Establishing metrics behind a tactic and measuring response are the only way to evaluate the success of that approach and ensure that money is being well spent.

As the plan is executed, the metrics established in the plan-building stage should be used to measure success throughout the duration of the launch period, beginning from one to one and a half years before commercial launch to one year after launch.

In-Line

We define the In-Line time frame as launch plus one year. The key objective at this stage is to maximize the product's peak sales and profitability. The most important key questions fall within the Engage the Market theme, which involves finding ways to open up a dialogue with KOLs, providers, patients, advocacy groups, and payers. Engaging the market is all about knowing who to go to and what to say at what time. Over time, the stakeholder mix will change, and so engagement tactics and messaging will also need to change and adapt.

Once the product has been in the market for a period of time, it is important to do self-evaluations and assessments to see how the product is performing. With the assessment made, there are two schools of thought on how to proceed. A company may choose to either begin making adjustments to the strategy right away or allow the strategy to play out a while longer.

Either way, the performance assessment is critical, and should it reveal that the strategy is not working, the company should be flexible enough to make changes and adjust as necessary. Key performance indicators will play an important role in this phase of monitoring and adjustments.

It will also be necessary to monitor the market in order to make adjustments as new competitors enter the space. Potential competitive blocking strategies should have been figured into the initial strategy so that they can be seamlessly rolled out as needed.

Key Questions
In-Line
Launch
plus 1 year

Prepare the Product	• What upcoming market events and trends are likely to meaningfully affect the product? • What impact will new generics have on pricing and market access strategy?	• Are there new leverage points for the product? • What are the potential patent extensions and lifecycle management opportunities?
Ready the Organization	• How is the product performing versus forecast? • How might the forecast change with new events? • Is the product supported with adequate resources?	• How effective are the resources that are deployed? • Is there a need to modify the resource mix?
Engage the Market	• Is there a way to more effectively engage key stakeholders?	• Is their adequate planning and coordination at the local level?

Note: The darker the shading, the higher the degree of emphasis within the lifecycle stage

End of Lifecycle

We define the End of Lifecycle time frame as beginning three years prior to loss of exclusivity. The key objective at this stage is to optimize resources, and, as a result, the questions around the commercialization strategy for the product and the capabilities required to support the product will need to be reassessed.

Key Questions
End-of-Lifecycle
LOE
minus 3 years

Prepare the Product	• Is there a pricing strategy that could mitigate the patent cliff factor? • (for biologics) Are competitors developing bioequivalent options? What is the likelihood of their success?	• Is there an opportunity to create combination products?
Ready the Organization	• What is the appropriate resource mix to support the product through loss of exclusivity? • Should the company redeploy existing teams to other assets or restructure?	• Can the company outsource risk to reduce fixed investment costs?
Engage the Market	• How can the physician and patient experience with the product be leveraged with new products?	• How can current customer relationships be leveraged?

Note: The darker the shading, the higher the degree of emphasis within the lifecycle stage

The important question for team leaders is to know when to break the inertia. A product that has been on the market for 10 or 12 years will likely have compensated for a number of new competitor entries in that time and thus may be able to continue seeing positive product performance up until the very last day of exclusivity. But at the same time, companies need to make an exercise of assessing whether they need to continue investing in the product at a high level and begin exploring options for the product in terms of what cuts can be made in education and promotion.

Summary

To maximize the value of products, companies can apply this strategic framework, which is designed to increase the odds of success at every stage of the product lifecycle. Throughout the lifecycle, companies must ensure that their product is appropriately prepared to compete in the marketplace, that their organization is ready to support the product, and that their customer-facing teams are able to effectively engage the market. This article showed how these strategic themes cross product stages and how the specific business questions that companies must address differ within each stage.

[1] Meekings KN, Williams CSM, and Arrowsmith JE. Orphan drug development: an economically viable strategy for biopharma R&D. Drug Discovery Today 2012; 17 (13/14):660-664.

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