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Redesigning for speed: Addressing life cycle compression in biopharma

Biopharmaceutical companies that make bold moves to address life cycle compression, including reshaping portfolios and operations for agility and decisiveness, can capture value from innovation.

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The commercial life cycles of drugs have compressed significantly. In the past two decades, top biopharmaceutical companies have seen a decrease of almost two years (from 11.7 years to 9.8 years) in the average time it takes for products to earn 50 percent of lifetime sales.[1] To earn 80 percent of lifetime sales, there's an even greater decrease of 35 months.[2]

This trend can be defined as asset life cycle compression—that is, a decrease in both the available time to capture value and the overall value that can be captured from a pharmaceutical product (in other words, a reduction in the "area under the curve" of an asset's sales curve). While compressed life cycles reflect innovations reaching more patients earlier, they also reduce the amount of time that biopharma companies can earn sales from their innovations.

Since our last industry report in 2022,[3] increased competition, rapid advancements in treatment, increased biosimilar adoption, and pressure from payers are increasingly requiring biopharma companies to find innovative ways to mitigate risks and capture emerging opportunities. They must also account for the influence of new policies—notably, the US Inflation Reduction Act (IRA)—on their portfolios in the coming months and years.

In this article, we aim to answer three questions:

1. How have asset life cycles evolved in the past two decades?

2. How might the IRA affect asset life cycles?

3. What are the implications for biopharma companies?

Specifically, we discuss the four most prominent forces driving life cycle compression in more depth and use a hypothetical scenario based on our analysis to highlight the impact of the IRA on life cycle compression (see sidebar "Methodology").

Methodology

There is still substantial uncertainty about how the Inflation Reduction Act (IRA) will manifest—for example, the extent of discounts and the impact of single-asset negotiation on the broader class. This article is focused on the "as written" negotiation provision. All estimates of financial impact are based on the Congressional Budget Office's assessment of the IRA and do not include potential second-order effects on classes and commercial business.

Our research was based on analysis of data from Evaluate Omnium, which provides a global view of past, current, and projected sales by asset. Included assets represent products from the top 36 assets launched between 2001–05 and 2021–25. Revenue curves were plotted over the life cycle of the asset to assess the percentage of total sales captured year by year, with a minimum requirement of 18 years of sales data. The data was accessed in March 2023.

We then look at the implications for assets, portfolios, and companies, and discuss how leaders can quickly and proactively address them.

Evolution of asset life cycles

Our analysis of assets that the top 36 biopharma companies have launched since 2001 found a clear reduction in the average time for assets to accrue 50 percent of their lifetime sales. The reduction in average time for assets to accrue 80 percent of their lifetime sales is even greater at 35 months, with "long tails" of revenue shortened due to payer controls and continuous clinical innovation.[4]

The impact on asset life cycles varies between small-molecule products and biologic products and between single- and multi-indication assets

[1] EvaluatePharma, accessed March 20, 2023. Calculated for the first 22 years of an asset's life cycle and includes analyst consensus forecast revenues.
[2] Ibid.
[3] "The Helix report: Is biopharma wired for future success?," McKinsey, October 27, 2022.
[4] EvaluatePharma, accessed March 20, 2023. Calculated for the first 22 years of an asset's life cycle and includes analyst consensus forecast revenues.

(Exhibit 1). The life cycle sales curve for single-indication small-molecule assets has remained largely unchanged, with a modest reduction in average sales. In contrast, biologics and multi-indication small-molecule assets have seen more than two years of compression to reach 50 percent of sales, with a substantial decrease in average sales per asset. The industry-wide effects are driven by shifts in portfolios, with single-indication small-molecule assets making up 66 percent of new molecular entities between 2001 and 2005, compared with only 30 percent between 2021 and 2025.[5]

Forces driving life cycle compression

Beyond evolving portfolio composition, four primary forces appear to be driving the compression of product life cycles: increasing competitive intensity, rapidly evolving clinical practice, policy and payer pressures, and the advent of biosimilar interchangeability.

Increasing competitive intensity

Competition across a range of asset classes has increased substantially over the past 20 years, with more assets in each class that come to market sooner. We selected a few large classes across oncology, endocrinology, immunology, infectious disease, and pain to analyze how quickly competition came to market. Prior to 2003, the average time until three products were available within a class was around 15 years; for products with first launches after 2013, this time frame was shortened to about two years.[6]

This increase in competition is fueled by the "herding" effect (that is, the tendency of drug development efforts to focus on previously successful targets or therapeutic approaches), which we have seen across industry pipelines. A recent paper found that the number of assets per investigated target increased from three to seven, with even larger increases in oncology assets.[7]

Rapidly evolving clinical practice

Continuous innovation is a hallmark of the biopharma industry; today's standard of care can be quickly replaced by improved therapies that strengthen outcomes for patients. This increased pace underscores the importance of reaching patients early in the life cycle and seizing the value from enhanced therapies before they are replaced. One proxy for this "replacement effect" is to analyze the changes in oncology guidelines over time. For example, our analysis of first-line treatments for

[5] Ibid.
[6] EvaluatePharma, accessed March 20, 2023. Calculated for the first 22 years of an asset's life cycle and includes analyst consensus forecast revenues.
[7] Julie Cannon et al., "Herding in the drug development pipeline," *Nature Reviews Drug Discovery*, April 28, 2023.

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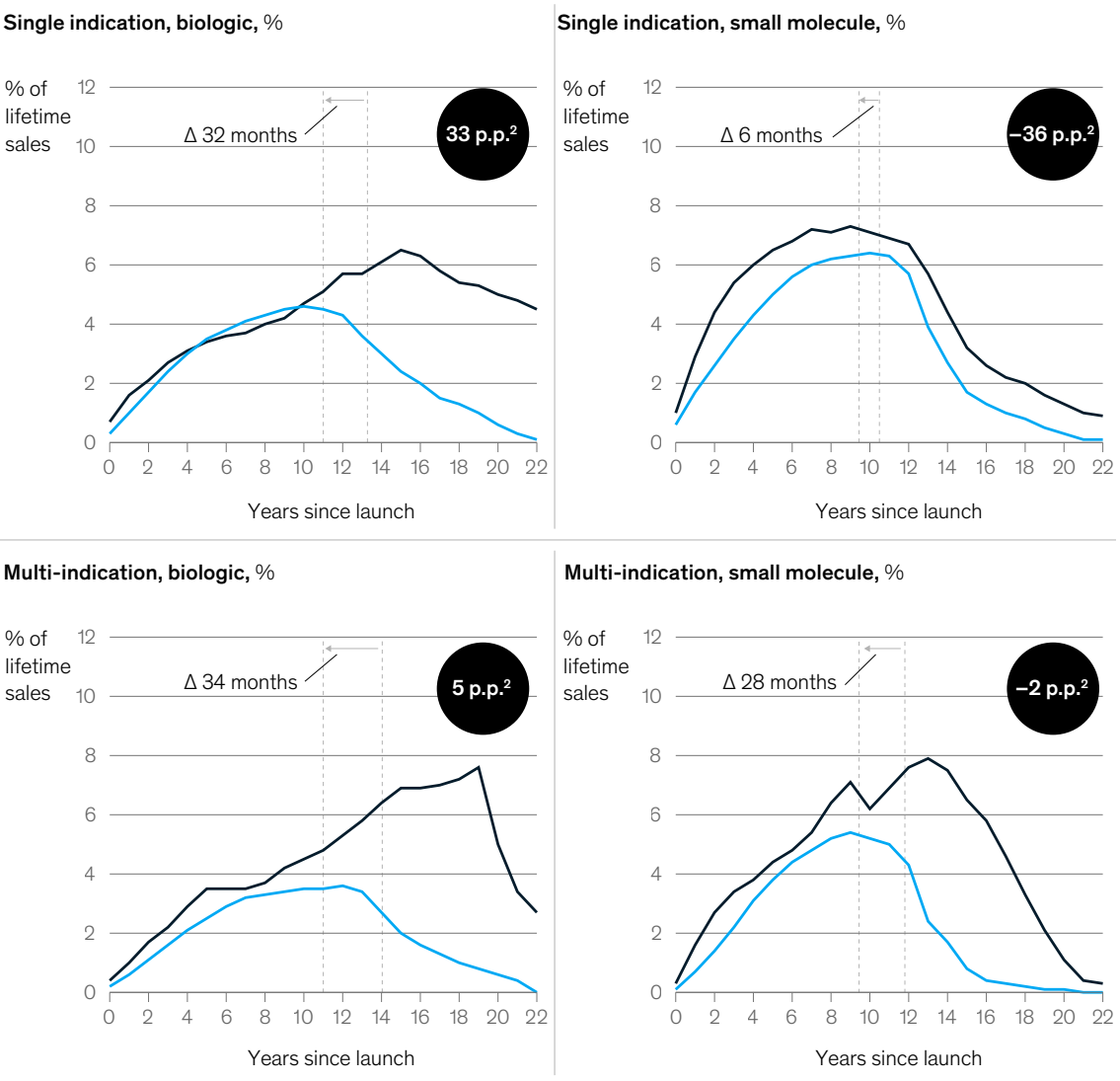
Exhibit 1

Lifetime revenue distribution has compressed since 2001, especially for multi-indication products and biologic products.

Share of lifetime sales[1] by years since product launch, %

— 2001–05 — 2021–25 Δ Change in months since launch to reach 50% of lifetime sales XX Change in share of new molecular entities, 2001–25



[1]Calculated for the first 22 years of a product's lifetime.
[2]Percentage points.
Source: EvaluatePharma, accessed March 2023

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metastatic melanoma found that there have been disruptive shifts in the past decade alone, with eight molecules removed from the guidelines between 2013 and 2016 and another three molecules removed between 2019 and 2023.[8]

Policy and payer pressures

Volume is becoming the predominant sales growth lever as net prices for brand-name drugs are deflationary industry-wide; we have not seen industry-wide net price increases since 2017.[9] In the United States, this trend will continue to be exacerbated by recent increases in mandatory rebates in Medicare Part D, inflation penalties, and IRA negotiations, as we will discuss in further detail. In international markets, the access landscape has tightened as multiple pricing reforms have passed. Examples include Japan's implementation of "off year" price revisions in addition to biannual price adjustments[10] and Germany's new legislation, which reduces the free pricing period from 12 to six months and increases manufacturer rebates to payers through mandatory discount increases and volume-based pricing models.[11]

The advent of biosimilar interchangeability

Loss of exclusivities in biologics are increasingly becoming like those of small molecules. In Europe, biosimilar adoption has accelerated significantly; for example, biosimilars to Adalimumab (a drug targeting autoimmune diseases) have captured more than 50 percent of the EU market.[12] In the United States, biosimilars have rapidly eroded medical benefit biologic shares: a 2021 article found

[8] McKinsey analysis of the number of molecules and unique regimens added or removed from the National Comprehensive Cancer Network guidelines.
[9] "Brand-name drug prices fell for the fifth consecutive year—and plummeted after adjusting for inflation," Drug Channels, January 4, 2023.
[10] Annabelle Brough et al., "Japan's latest drug pricing policy updates: Off-year revision and other anticipated changes in 2023," Trinity, February 27, 2023.
[11] *Inside EU Life Sciences*, "Germany significantly tightens drug pricing and reimbursement laws," blog entry by Adem Koyuncu, Covington, October 26, 2022.
[12] Ying Chen, Alex Monnard, and Jorge Santos da Silva, "An inflection point for biosimilars," McKinsey, June 7, 2021.

Volume is becoming the predominant sales growth lever as net prices for brand-name drugs are deflationary industry-wide.

that oncology biosimilars captured approximately half of a drug's total sales within 12 months of launch.[13] Pharmacy benefit drugs lag behind medical benefit biologics; however, we expect faster uptake in the future as the industry responds to updated FDA guidance on interchangeability.[14]

The IRA as an accelerator of life cycle compression

Several new policies could substantially accelerate the life cycle compression trend—most notably, the IRA in the United States, where a large and growing share of global biopharma revenues are earned (see sidebar "The impact of the Inflation Reduction Act on drug pricing"). The top 15 global biopharma companies have increased their share of revenue from the United States by a median of 12 percentage points over the past ten years (from 41 percent to 53 percent),[15] and the share of revenue from the United States is tightly correlated with company profitability. Similar legislation on the horizon in other markets could have a comparable

[13] Ibid.
[14] Sarah Yim, "Updated FDA labeling recommendations for biosimilar and interchangeable biosimilar products," US Food and Drug Administration, January 16, 2024.
[15] EvaluatePharma, accessed March 20, 2023. Calculated for the first 22 years of an asset's life cycle and includes analyst consensus forecast revenues.

The impact of the Inflation Reduction Act on drug pricing

The Inflation Reduction Act (IRA) of 2022 contains a set of drug pricing proposals that will reduce US federal spending by $288 billion over ten years.[1] The following are the three main provisions in the legislation.

1. Medicare Drug Price Negotiation Program

The Centers for Medicare & Medicaid Services (CMS) will directly negotiate prices for ten drugs accounting for high Medicare Part D spend. This first round of drugs was selected for negotiation in 2023, with prices going into effect in 2026.[2] The number of negotiated drugs will increase to 15 per year in 2027 and 20 per year in 2029.[3] The negotiated price will also affect Medicaid best price. Medicare Part B drugs will follow an analogous but delayed timeline, with the first negotiated prices available in 2028.[4] Drugs become eligible for negotiation once they have been on the market for a fixed number of years—seven years for small molecule and 11 years for biologics—and there is no marketed generic drug or biosimilar available.

2. Part D redesign

Out-of-pocket costs for patients with Medicare Part D plans are capped at $2,000 per calendar year, with existing coverage gaps eliminated. The reduction in patient exposure to cost and CMS catastrophic liabilities will be covered by health plans and manufacturers.

3. Price increase inflationary rebates

CMS will require biopharma companies to rebate drug price increases greater than inflation using 2021 average sales prices and average manufacturer prices for Part B and Part D drugs, respectively, as benchmarks. The penalty will be calculated on the total volume of drugs sold in the Medicare market starting in 2022. Part D rebates apply to 12-month periods beginning in October 2022; Part B rebates apply to calendar quarters starting in January 2023.

Future legislation has the potential to affect drug pricing further. For example, the European Union's 2023 revision of pharmaceutical legislation shortens minimum drug exclusivity from ten to eight years[5] (with an additional four years granted upon meeting certain criteria), and various legislative proposals are in the works to expand on the IRA.

[1] "Estimated budgetary effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation, as posted by the Senate Committee on Finance on July 6, 2022," Congressional Budget Office, updated July 13, 2022.
[2] "Medicare Drug Price Negotiation Program: Selected drugs for initial price applicability year 2026," CMS, August 2023.
[3] "HHS selects the first drugs for Medicare drug price negotiation," US Department of Health and Human Services, August 29, 2023.
[4] *Medicare Drug Price Negotiation Program: Revised guidance, implementation of Sections 1191 – 1198 of the Social Security Act for initial price applicability year 2026*, CMS, June 30, 2023.
[5] "EU pharma overhaul favours access over innovation," Economist Intelligence Unit, July 14, 2023.

effect on product life cycles, further prompting urgency to formulate proactive strategies.

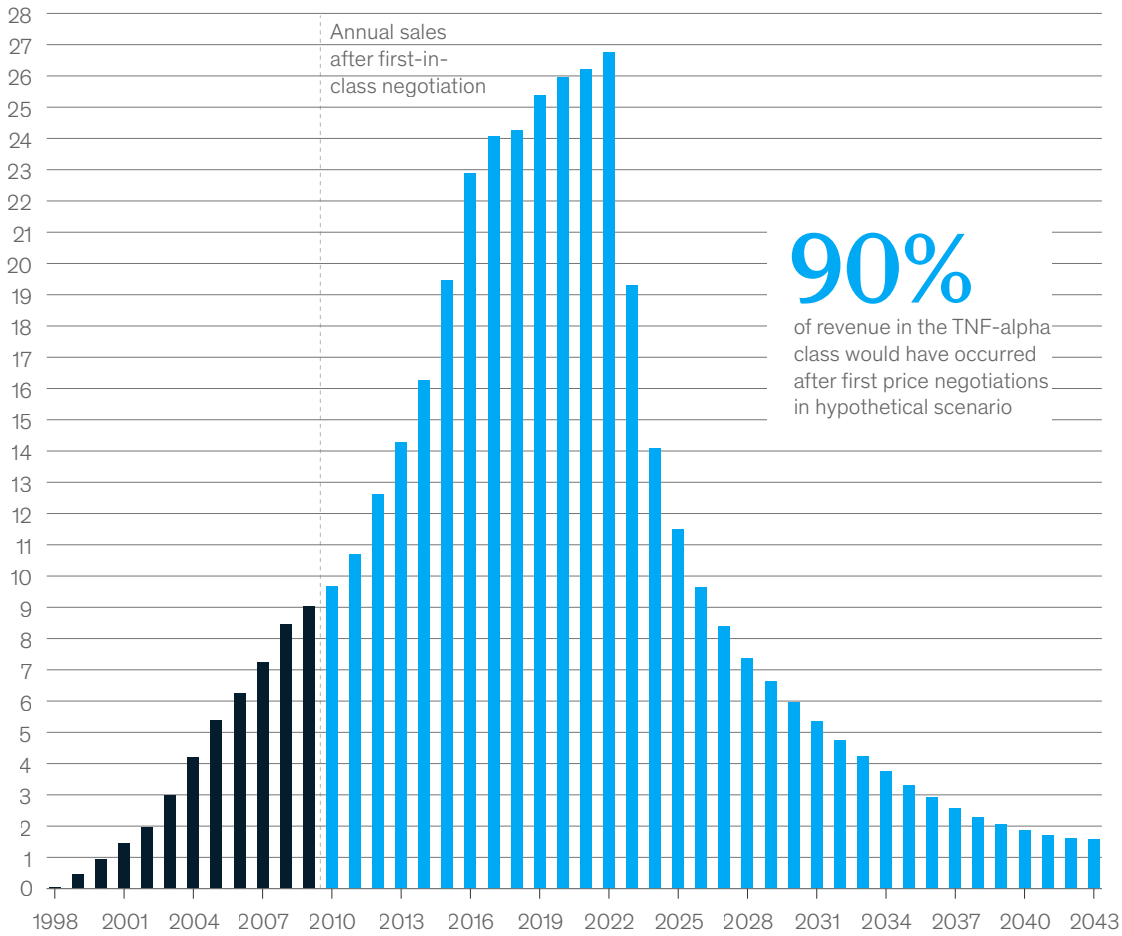
To illustrate the potential impact of the IRA on business as usual, we created a hypothetical scenario in which the IRA negotiation provision was put in place in 1980. We examined a selection of drug classes to understand how much asset revenue would have occurred after negotiation.

The results are striking (Exhibit 2). In one example, 90 percent of sales from tumor necrosis factor alpha (TNF-alpha) therapies would have occurred after the negotiation of Remicade (the first TNF-alpha on the market). Any impact on pricing across the class could easily change the business case for subsequent products in the class.

Exhibit 2

If the Inflation Reduction Act had been in place since 1980, many drug classes would have had substantial revenue after first-in-class negotiation.

Hypothetical scenario: Annual sales from tumor necrosis factor alpha (TNF-alpha) therapies,[1]
$ thousand



[1]Including Remicade (1998), Enbrel (1998), Humira (2003), Cimzia (2008), and Simponi (2009).

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Although assets today face a more compressed timeline, a significant amount of their lifetime revenues occur after the negotiation window. On average, McKinsey analysis suggests that small-molecule drugs capture 51 percent of their revenue after IRA-negotiated prices take effect (after year nine) and biologics capture 29 percent (after year 13).

The IRA could have implications far beyond Medicare sales of the negotiated drug. Negotiated assets have the potential to set a new pricing standard for their classes, particularly in classes with lower clinical differentiation between assets. Commercial payers and pharmacy benefit managers may also use IRA-negotiated prices to anchor commercial negotiations. Novel drug classes that compete with negotiated classes will also face a higher bar for cost-effectiveness.

Implications for industry leaders during increased compression

In a world of compressed life cycles, speed is imperative. We see three levels for acceleration.

At the asset level, leaders will need to embrace a new risk calculus for development and launch planning. At the portfolio level, leaders will need to maintain portfolios that are oriented toward clinical differentiation and patient impact. Finally, at the company level, leaders will need to revisit what capabilities will drive competitive advantage across the enterprise.

Asset: Embrace new risk calculus for development and launch planning

Multi-indication therapies (small molecules and biologics) have opened new avenues for patient impact, often bringing a series of indications to market more than five years after the original asset launch.[16] These assets have proved attractive given their long periods of exclusivity and ability to expand to new patient populations without the risk, cost, and timelines associated with bringing a new molecule to market.

Our analysis shows that multi-indication biologic assets are experiencing the most life cycle compression (defined by time to 50 percent of lifetime sales),[17] creating increased pressure to

[16] EvaluatePharma, accessed March 20, 2023. Calculated for the first 22 years of an asset's life cycle and includes analyst consensus forecast revenues.
[17] Ibid.

In a world of compressed life cycles, speed is imperative. We see three levels for acceleration.

capture more value from each asset earlier in the life cycle. The increased competition resulting from multiple assets in a class coming to market within months (not years) after the first launch will increase the pressure to accelerate time to market.

While it takes two years on average for a multi-indication asset to launch half of its indications, it takes six years to launch 80 percent of indications.[18] With compression from increasing competition and policies that could truncate asset life cycles, there is increased pressure to capture more value from each asset earlier in the life cycle.

To ensure continued patient value creation while reducing financial risk in scenarios in which late–life cycle indications drive minimal business value, biopharma leaders must rethink their development strategies by investing earlier in development (for example, running clinical trials in parallel) and launch planning. Despite the increased risk, running clinical trials in parallel can help recapture some of the value lost in a compressing life cycle.

Portfolio: Clinical differentiation and patient impact remain the North Star

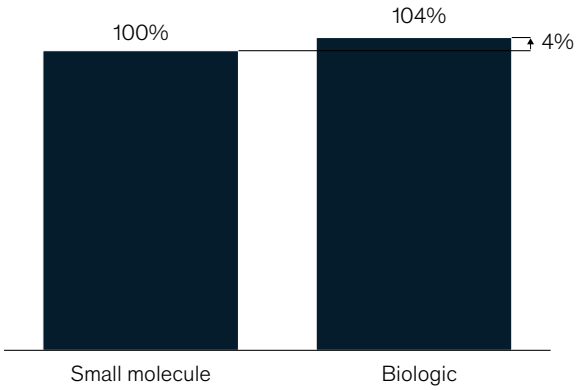
The IRA has initiated a debate on how the longer exclusivity for biologics compared to small molecules could affect portfolio decision making. We considered a hypothetical asset to compare the commercial potential for a small-molecule product with that of a biologic product, holding all other variables (indication, price, and market share) constant (Exhibit 3). While there is marginal incremental value for the biologic, it likely will

[18] Ibid.

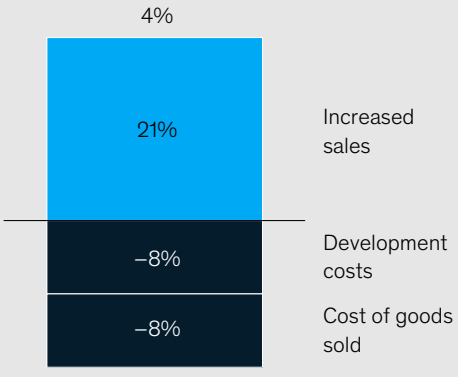
Exhibit 3

Additional revenue generated by biologic products may be offset by higher costs.

Hypothetical average asset comparing the commercial potential of a small molecule vs a biologic under current Inflation Reduction Act rules



Net additional value of biologic over small molecule



Note: Figures may not sum, because of rounding.
Source: EvaluatePharma, accessed March 20, 2023

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need to be more substantial to drive portfolio decision making.

However, the IRA might accelerate the trend toward developing products focused on low-prevalence diseases because a broader base of assets will be needed to achieve a similar overall revenue level. Faster development of next-generation assets will continue to be a winning strategy.

Company: Doubling down on sources of competitive advantage

At the company level, capabilities that accelerate time to market and manage risk across the drug development and commercialization value chain will become even more crucial. We anticipate that such capabilities will gain increasing importance across the enterprise.

Research and development (R&D). Leaders need to create a nimble and efficient R&D organization that can swiftly adapt to the changing market. Opportunities include the following:

- accelerating trial enrollment (especially in increasingly competitive areas)
- developing easily updated analytical models infused with changing payer or commercial insights to assess a wide range of development scenarios
- cultivating a culture in which teams can make difficult decisions confidently
- optimizing asset-to-indication process (for example, the potential to develop multiple assets and split indications based on relative efficacy)

Product supply. Product supply has a critical role in shortening the development time of pharmaceutical products and managing uncertainty in product demand. Key strategies to achieve this include the following:

- compressing chemistry, manufacturing, and controls development timelines by capitalizing on technologies such as platforms and in-silico modeling
- building a network that effectively leverages external partners to preserve flexibility in capital expenditures deployment
- fostering network flexibility and implementing robust business-continuity planning to manage demand volatility

Go-to-market approach. An analytics-driven, proactive, and agile go-to-market approach may enable biopharma companies to effectively respond to compressing life cycles through the following:

- ensuring faster clinician awareness and patient coverage by leveraging, for example, digital analytics for a personalized healthcare clinician engagement strategy
- generating early (prelaunch) evidence on the costs and outcomes of unmet medical needs for communication with medical teams, enabled by health economics and outcomes research and real-world evidence studies
- incorporating clear analytics to predict and proactively address crucial moments in the patient journey
- forecasting launch volumes in an agile way, enabling faster ramp-to-peak supply at time of launch, and managing increased uncertainty caused by a higher number of indications at launch

Cross-cutting issues. Given the many potential responses to meet demands for speed and flexibility, biopharma leaders will benefit from sharpening their perspective on what capabilities will drive competitive advantage and aligning investments accordingly. We've identified a few overarching priorities, including the following:

— rethinking models on how to fund asset development and commercialization

— deepening integration across functions to enable speed

— adapting cost and capacity variables to swiftly flex in response to uncertain market outcomes

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Despite the challenges posed by life cycle compression, those evolving at pace continue to have opportunities for growth and innovation in the industry. As individual players react to the IRA and other life cycle compression accelerants, the interplay among stakeholders will raise several second-order questions to monitor in the months and years to come:

— Will large biopharma companies establish scale or firepower as a source of competitive differentiation that in turn spurs consolidation?

— Will biotechs explore alternative deal models to unlock value-creation opportunities for multi-indication assets?

— Will companies require higher confidence in the degree of differentiation to invest in developing follow-on therapies?

Looking ahead, biopharma companies may benefit from carefully considering the strategic implications of life cycle compression and evolving regulations such as the IRA on their portfolios. Proactively addressing these considerations will be pivotal in navigating the dynamic landscape of the industry and ensuring sustained success in a dynamic biopharmaceutical environment.

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