

# **New Science** A new economic reality for innovation and growth

New Science. Novel Technologies. Better Patient Outcomes.



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# A new economic environment is demanding change in biopharma—especially as New Science grows in prominence

New Science has the potential to make medicine vastly more precise and effective, but will its price tag keep it out of most people's reach?

COVID-19 affected millions around the world, sent many countries into an economic downturn and saw massive social tension and nationalism. It also forced the biopharma industry into unprecedented action. The global scientific community collaborated in exceptional ways and public-private partnerships drove innovation to address a common need. Two highlights stand out: technology and science. Technology enabled people to make

the shift and work from home, reconfiguring supply chains and enabling contactless transactions. Science enabled multiple COVID-19 vaccines to be developed in record time despite the remote working shift.

The question is: do we need a global crisis, or can we continue to step up to create new pathways for innovation, access, and affordability? How can we use the lessons of the last year to help us address system—and patient-level affordability issues, while still powering the discovery, development, and delivery of new treatments for all health conditions?

New Science (novel life science mechanisms, modalities and platforms addressing significant unmet patient needs using a unique combination of advanced science and technology) is delivering more precise and effective treatments—but often at a higher price tag. The resulting economic environment is pressuring profitability, affordability, and sustainability.

But what if we could find opportunities to redefine manufacturers' economic relationship with customers, tailoring access strategies to the unique challenges of a specific asset, market, and customer?

The burden of investment in scientific innovation is born by all stakeholders but felt most deeply by patients. The goal must be maximizing return on that investment for patients, too. There are better ways to deliver innovation—2020 proved that. Today's economics demand it and society needs it. Our research revealed three key findings:

01

New Science is more important than ever, driving more growth than predicted, revitalizing operations and revealing new opportunities to innovate.

O2 A new economic reality is challenging profitability.

OS Success requires a future-fit enterprise to address both sides of the profitability equation.

# New Science is more important than ever, driving more growth than predicted



Scientific innovation capabilities drive the biopharma sector both to develop treatments and manage global health. But science has changed—so how we innovate must also change. The way we measure benefits for patients and populations is going to shape the future.

In 2019, Accenture identified and defined <u>New Science</u>: a dynamic combination of the best in science and health technology that is filling unmet needs with more precise and effective treatments. New Science is Accenture's global analysis of regulated scientific treatments in both the pipeline and the market. It classifies science using different dimensions to better understand its dynamics for patients, companies and markets. New Science is classified as treatments that feature high on the indices of scientific novelty, unmet need and technology convergence.

## New Science: Evaluating global medicines across three dimensions

Dimension		Hypothesis	Measure
	Scientific novelty	Measuring scienti'c novelty in speci'c terms will enable us to better understand future areas of growth in disease and overall therapeutic areas, and better manage portfolio risk.	New mechanis
			New treatment
			New scienti'c p
	Unmet need	Measuring treatments that qualify as achieving current unmet need ensures development of medicines for patient impact.	Previously-untr
			Signi'cant impr
			Signi'cant redu
	Technology convergence	Given recent policy shifts and technology's impact on product development, measuring medicines that coexist with technology in the near-term and future ensures a better understanding of science's growing dependence on tech.	Digital medicin
			Reliant on com
			Joint approvals
			Availability of c

- sm/mode of action
- nt modality
- platform
- treated population
- provement in effectiveness
- uction in complications
- ne
- mpanion diagnostic
- ls of treatment and tech
- direct to consumer testing

### 01. New Science is more important than ever

Prescription Rx rev forecast for New Science



New Science is projected to drive

### Source: Accenture Research New Science Model August 2020

1. New Science Model informed by Evaluates Consensus Forecast | Initial Forecasts taken in Feb 2020 had more conservative numbers which predicted growth of New science ~69% between 2020 - 2026. Forecast updated August 2020. 2. New Science Model Analysis April 2019.

New Science's revenue growth continues unabated—in 2020 it far exceeded our expectations in terms of momentum. New Science is projected to drive 81 percent of biopharma revenue growth and 61

percent of all revenues between 2021 and 2026. This outpaces Accenture's previous forecast of New Science driving 54 percent of all revenues from 2017 to 2022. This is despite the clinical trial slowdown caused by the pandemic with 1,479 New Science and traditional trials suspended or delayed between February and August 2020—resulting in a \$391 billion decline in forecast revenue for New Science from 2020-2026.<sup>1</sup>

New Science net present values (NPVs) are expected to outshine traditional treatments. Of the 893 treatments most likely to launch through 2026, the average NPV of New Science treatments to be launched from 2022-2026 will exceed traditional counterparts by 69 percent, reinforcing the fact that while New Science is driving revenue growth, it is also important to overall profitability. New Science treatments with leading NPVs expected to be launched in this period include Eli Lilly (Tirzepatide), Allakos (AKOO2), Amgen (AMG 510) AstraZeneca (DS 1062).<sup>3</sup>

Immunology, and cardiology are central to growth in New Science over the next five years. We expect oncology to continue leading other therapeutic areas in New Science, hovering at around 90 percent growth from 2021 to 2026, with a potential decline of two percent from the previous period (2017-2022). At the same time, immunology and cardiovascular are expected to grow by more than 15 percent.<sup>2</sup>

New Science will also be central to deal-making. Based on our analysis, which covered greater than **80 percent** of reported value in the industry, New Science deals grew 216 percent from 2010-2014 to 2015-2020. More recently, in the last five years, of all deals intended to create entirely new therapies, 76 percent were New Science-driven. Biopharma deal-making is evolving rapidly as data and technology exert ever increasing influence on New Science.<sup>4</sup>

Scientific novelty and unmet patient needs have been the primary drivers of New Science treatments, but technology convergence is expected to make the largest contribution in the future. Of the three dimensions of New Science, technology convergence is expected to grow from **21 percent** in 2019 to **31 percent** in 2026 (see chart). Meanwhile scientific novelty is forecast to grow by six percent from **83 percent** to **89 percent** for the same period. This indicates that the New Science being developed in the next five years is more likely to require technologies for improved clinical outcomes.<sup>5</sup>

New Science dimensions	% change in # of New Science treatments by criteria 2019 vs. 2026	Running 10
Scientific novelty Treatments that apply innovative scientific paths, modalities, and mechanisms beyond being a new molecular entity	+6%	
Unmet need Treatments that solve patient need in unaddressed indications or where significant unmet need as determined by regulatory bodies	-10%	
Technology convergence Treatments that rely on technology either to be discovered, prescribed or delivered to a patient. Including those which augment the clinical impact of the therapeutic, or are technologies approved as a therapy	+10%	

**10-year avg. (by product)** 



56%

26%

# OZ A new economic reality is challenging profitability



### **02.** A new economic reality is challenging profitability

COVID-19 has heightened a new economic reality. Accelerated and irreversible private sector forces and the looming threat of policy and regulatory change have coalesced around the biopharma industry. The pandemic has further challenged affordability for the system, and profitability for manufacturers.

### **Case in point:**

Biopharma executives we surveyed expect margins to decline in nearly every therapeutic area over the next five years (including leading categories like oncology). The only exception is cell and gene therapy. This decline is expected to be over six percent on average, with antiinfectives expected to experience the largest decline at 11.6 percent.<sup>6</sup>

The average tenure for a marketleading treatment in a therapeutic area has dropped by 51 percent from 10.5 years in 2000 to 5.1 years in 2017.8

Our analysis also yielded an expected one to two percent decline in Net Price Growth in the US over the next five years, significantly below the historical 4.3 percent growth.<sup>7</sup> This is occurring even as list prices go up, emphasizing the growing gross-to-net bubble—the gap between cumulative sales at list prices versus net prices—which the Drug Channels Institute now estimates at \$175B annually in the US alone. Globally, this trend is consistent with other developed nations projected to have net price declines.

# The shift to value—after a slow start, it's speeding up

The shift starts slowly with the passage of the Affordable Care Act in 2010, incentivizing steady and measured horizontal consolidation of payers and providers.

# 2018

The shift is accelerated by the private sector. While initial regulatory shifts were meaningful to the market, their scope and impact were dwarfed by the private sector driving vertical consolidation across the value chain. CVS Health had a \$77 billion acquisition<sup>12</sup> value—the single largest healthcare deal in history—with 93 million plan members, covering an additional 39 million with broader pharmacy insurance coverage,<sup>13</sup> This represents a foundational shift in the marketplace, and while it is the largest, it is just one among many with industry-disrupting potential.<sup>14</sup>

Looming policy changes threaten pricing and value delivery. While private market forces (like competition and customer leverage) drive change and challenge manufacturer profitability, biopharma executives we surveyed expect system-level pressures such as policy change and public scrutiny on pricing to pose the greatest threat to margins five years from now. (see Profitability Pressures chart).

# Profitability concerns outside of the United States



## **European Union**

The five biggest markets in Europe still reimburse the high cost of some new treatments and are pursuing measures to limit the impact of coverage decisions on health care budgets. Higher list prices in Europe are coming with a higher rebate.

Unlike the US, introductory prices for new drugs seeking reimbursement are subject to explicit negotiation in France, Italy, and Spain. Manufacturers are free to set their own launch prices in the UK, though they will hit access hurdles if they do not satisfy the National Institute for Health and Care Excellence's (NICE) cost-effectiveness criteria, while in Germany companies may sell drugs containing new active substances at higher list prices for 12 months, after which prices negotiated by manufacturers and statutory health insurance funds apply.<sup>9</sup>



## **Emerging Markets**

Typically, as far as drug coverage is concerned, public healthcare programs focus on the provision of free or subsidized generics. As a result, patients are still heavily exposed to pharmaceutical costs in most emerging markets, and measures to cut outof-pocket spending on medicines are often an integral feature of reforms designed to improve access to healthcare.<sup>10</sup>



China's healthcare system is undergoing a series of major reforms to regulatory and reimbursement policy. These reforms are aimed at closing the demand gap for novel and cost-effective therapies, particularly those developed and available in the western countries which have not reached China's growing domestic market due to approval hurdles. In November 2018, the State Medical Insurance Administration (SMIA) of China officially launched the National Drug Centralized Procurement Pilot Scheme, commonly known as the 4+7 Scheme, aiming to slash generic drug prices and encourage the consolidation of a fragmented national drug procurement system. Of the 25 generic drugs impacted, tenders were won by only two multinational manufacturers, suggesting that it will be increasingly difficult for multinational generic manufacturers, who are usually less willing to compromise on prices, to survive in this changing environment.<sup>11</sup>

# Biopharma at an inflection point with pressure from all angles

Biopharma has traditionally passed increased costs to consumers, but this is no longer sustainable. There is significant and growing pressure from governments, people, and corporations to reduce costs. There simply isn't enough money in the system to pay for more patients with more expensive personalized treatmentseven if they're more effective.



# Here's what those pressures look like

# Government

Healthcare spending reached **\$3.8 trillion** in 2019–17.2 percent of US GDP accounting for 24 percent of government spending.<sup>12</sup> As of 2019 over 35.4 percent of Americans are on Medicaid, Medicare, or Military plans.<sup>13</sup> An aging American population will exacerbate the problem.

Government Accountability Office's (GAO) 2019 report shows expenditures increased by **13** percent from 2014-2016 (from \$103.2 billion to \$116.1 billion) for Part D alone (this is the most recent data available).<sup>14</sup>

There is a misalignment between government health system capacity for prescription drug spending and the anticipated pharmaceutical company revenue. If we look across developed markets around the world, there is an estimated **\$300 billion** affordability gap (by 2028).

# ប៉ឺក៉ឺប៊ឺ People

In the US, the average premium for family coverage has increased 22 percent over the last five years and **55 percent over the last** ten years. That's five times the rate of average wage growth experienced over the same period.<sup>15</sup>

Of the **\$3.8 trillion** spent on healthcare in the United States last year, 11 percent (\$406.5 billion) was paid for by patient out of pocket costs.

### Almost **30 percent**

of patients report not taking their treatments as prescribed—due to cost.<sup>16</sup>



and system-level affordability challenges abound. While the scope and scale of proposed regulatory and legislative reforms differs by party, the levers are largely consistent. Among those commonly included in proposals are: international reference pricing **models**, allowing the government to negotiate directly with manufacturers for Medicare pricing, caps on price increases year-over-year, drug importation, and shifts in cost-sharing burdens to manufacturers for public payers.

In the US, legislation proposals to address patient-

The UK has tightened their policies using new budget impact model policies and even delayed access to new lifesaving treatments until prices were managed down. Other examples abound—with China negotiating drug pricing down an average of **44%** and novel reference pricing models proliferating across the world.

several years.

An increase in utilization management based on financial (as opposed to clinical) considerations is causing significant friction between Pharmacy Benefit Managers (PBMs)/payers, HCPs and patients. Formulary exclusion lists identify drugs that payers do not cover: the rationale is that formularies lower overall insurance costs by forcing patients to use lower cost drugs, or drugs that provide the best value for money. ESI and CVS Health have used formulary exclusions aggressively and publicly in the recent past. CVS health developed a formulary specifically with a **\$100k** per Quality Adjusted Life Year (QALY) cost effectiveness threshold. Patients and physicians are increasingly frustrated by payer and PBM constraints on their ability to choose what they consider to be clinically optimal treatment paths.

This **OALY** model has been in implementation across the world-championed by international bodies such as ICER and leveraged by many HTAs and countries such as NICE in the UK for

# **Payer executives anticipate a** diversification of contracting models, opening the door for innovation in reimbursement and access

With more than half of industry revenues coming from the US and the growing pressure on pricing in the US specifically, we dove into the US market to explore how the economics and reimbursement models will evolve. Accenture conducted a survey among 40 payers and Pharmacy Benefit Managers (PBMs) in the fall of 2019 to understand whether they foresaw changes in contracting—and what those would look like. The results were profound, with broad shifts anticipated in reimbursement models, embracing a much more diversified approach than we see today.

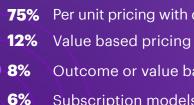
The rebate model: currently dominates across payers and PBMs, but by 2025 senior executives at payers and PBMs expect their portfolio of contracts to dramatically diversify.

Shift to value: just a fraction of payers currently report that outcomes—and value-based contracts represent a quarter of their portfolios. But in five years, 38 percent of payers believe at least a guarter of their contracts will be value—or outcomesbased, and 31 percent believe that a guarter of contracts will be built on value-based pricing.

## **Contracting models are changing**

What 40 Payers and Pharmacy Bene't Managers told us

Today, the rebate model dominates across the industry, but novel contracting models-and even novel partnerships (e.g.,direct-to-provider) -are emerging.



In 2025, customer executives expect to employ a diversity of models at scale including dramatic growth in value—and outcomes-based arrangements.

**31%** Value based pricing

- **75%** Per unit pricing with discounts applied as rebates
  - Outcome or value based contracts
  - Subscription models

**58%** Per unit pricing with discounts applied as rebates **38%** Outcome or value based contracts

- **10%** Indication based pricing

Biopharma executives see policy change and public scrutiny as the greatest future threat to profitability

The threat of policy and regulatory change looms over profitability. In fact, the biopharma executives we surveyed in the US, view regulatory and policy change as well as public scrutiny on pricing as the highest threat to profitability in five years—a very different picture than we see today (see chart Profitability Pressures).



For example, in the US there are discussions between industry and the Food and Drug Administration (FDA) about the "upcoming reauthorization of user fees for prescription drugs, biologics and generic drugs."<sup>17</sup> Discussions are around FDA post-market processes, how they impact "health disparities and representativeness and how new information and additional research affects FDA review of black box warnings." In that context, what are the implications of anticipated policy and regulatory change, broadly?

Regulatory change can potentially have a far greater impact on manufacturers than incremental private market shifts because it happens at scale and can impact how patients access and afford treatment for decades. There are also global implications to US policy shifts. For example, a potential US government reference pricing model could affect profitability and drive manufacturers to rethink global launch strategies and market presence.

Regulatory change is less predictable, harder to mitigate, and manufacturers need to be prepared for a wider variety of scenarios to address.

While the US is seeing a pronounced focus on pricing—these trends persist across the world, with regulators willing to delay or deny access to novel drugs until or unless prices are negotiated downward. For example, in a study by MDPI<sup>18</sup> novel anti-cancer drugs have taken on average 242 days longer to get marketing approval in most European markets compared to the US, often due to a focus on pricing negotiation (not exclusively).

Further, when biopharma companies are not meeting pricing objectives, regulators are showing willingness to fully deny access—such as Sarclisa in the UK. China's overhaul of regulations in recent years brought a fast-track approval process and a potential local study waiver for treatments targeting rare diseases or diseases with substantial unmet needs. Since then, China has experienced exponential growth in new approvals and a significant reduction in drug lag, compared with the US and the European Medicines Agency (EMA).

### **Anticipated profitability pressures** today versus 5 years from now Ranked from most impactful to least impactful

Competitive entrants

Bargaining power of insurers

Patient affordability

Regulatory & policy change

Public scrutiny on pricing

Shifts to #1 in 5 years

Shifts to #2 in 5 years

# O3 Success requires a future-fit enterprise to address both sides of the profitability equation



### **03. Success requires a future fit enterprise**

In light of this new economic environment, the biopharma industry needs to consider a shift in how it creates, captures and shares value. Many of the pressures we have outlined are not new, but the continued profit erosion by the private sector coupled with policydriven disruption create a new catalyst for change. So, what should biopharma's do?



## We believe biopharma companies should approach this challenge from both sides of the profitability equation:

Improve the way treatments are discovered and developed while lowering costs from billions to millions by riding the wave of innovation across development and commercialization strategies and operations that produced a COVID-19 vaccine in record-breaking time.

Identify opportunities to redefine biopharma companies' economic relationships with customers, capturing and sharing trapped value where it matters most for the ecosystem.

This two-pronged approach will evolve biopharma companies' healthcare ecosystem role and facilitate patient access to novel, more affordable treatments without stalling the research and development engine that's creating the next generation of innovation.

# Improving the way treatments are discovered and developed while lowering costs from billions to millions

The pandemic has shed light on our ability to turn old ways of operating into new ways of discovering, developing and commercializing treatments. For example, in response to the crisis, virtual **clinical trials grew by over 50 percent in 2020**,<sup>19</sup> and are expected to triple next year, improving access and reducing inequities.<sup>20</sup> Our research revealed 65 percent of pharma sales representative meetings were held virtually across therapeutic areas, and increased engagement was reported.<sup>21</sup> Across the lifecycle, there are opportunities to integrate lessons learned from the past year of disruption, adaptation and acceleration. The cost **of bringing a successful treatment to market lies between \$2.6 billion<sup>22</sup> and \$6.7 billion**<sup>23</sup> (including the cost of capital and cost of failure). To succeed in the new economic environment, biopharma companies should seek opportunities to speed and improve research and development and commercialization of these new treatments while lowering the cost to do so.

The cost of bringing a successful treatment to market lies between \$2.6 billion and \$6.7 billion (including the cost of capital and cost of failure).



# 5 Key Levers

Our research on technologies, protocols and services leveraged in the response to COVID-19 identified five key levers that can rebalance the treatment-cost equation. These are greater adoption of:

01	02	03
Data-led drug discovery	Efficiencies of New Science	Virtual, hybrid and decentralized clinical trials
04	05	
Regulatory innovation	Virtualized selling	

Of the five levers, the greatest progress has been made on levers 1, 2, and 3. These three provide an immediate opportunity to shatter traditional biopharma research and development approaches and open the gates of New Science brought to market faster and at a lower cost. We explain some of the benefits of these three levers here, however, we will share a more in-depth analysis of how research and development has a pivotal role to play in improving how treatments are discovered, developed and delivered and lowering the cost to do so from "billions to millions" in a future publication.

# ()

### Data-led drug discovery is primarily influenced by advanced biomarker discovery capabilities with deep learning and predictive models.

These capabilities will revolutionize the way research is done and improve disease understanding to better and faster identify, validate, and optimize targets that are at low risk of failing during development. For example Exscientia, an AI drug discovery company, uses algorithms to compare a target protein against a database of protein interactions to generate a manageable list of compounds that are favorable drug candidates. According to Exscientia, this process can reduce discovery costs by 80 percent and cut the time spent in discovery from four-and-a-half years to as little as a year.<sup>24</sup>

### The efficiencies<sup>25</sup> of New Science include a greater likelihood of success, smaller patient cohorts, and overall genomic efficiencies.

These efficiencies can be realized by shifting the portfolio to be more heavily weighted on New Science. In our research, cost savings distributed on the total treatment calculation. Our analyses modeled the cost savings of the improved Probability of Technical and Regulatory Success (PTRS) for each New Science treatment and the cost saved from smaller population trials—and this amounted to about \$134 million in additional savings per treatment.

The next two levers can lead to a lean development engine that streamline drug development processes, improving clinical and regulatory outcomes.

# 03

Virtual, hybrid or decentralized clinical trials leverage in silico and digital twin capabilities and enable near-to-patient trials using digital technology to accelerate the operational timeline across many aspects such as patient identification, recruitment, and enrollment. We evaluated the impact of virtual components of clinical trials with our research partners that cover over 100 new trials across 30 countries and found that virtual components improve patient enrollment, retention and overall time to trial completion such that they would save approximately US\$146M per treatment.

Regulatory innovation creates clear opportunities to leverage more efficient protocols, find new ways to balance safety/risk profiles of treatments and allow for different pace of regulation given the nature and variation of medicines. The U.S. Food and Drug Administration held a public meeting in July 2020 to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA VII) and continues holding industry discussions. Proposals include increased use of innovative drug development tools such as complex innovative designs, model-informed drug development and patient-focused drug development.<sup>26</sup> Regulators see the overall benefit of accelerating the process for emergency use and essential treatments, however, we do not expect upheaval in the regulatory process for all treatments.

Lever 5 brings in opportunities, but not directly to the cost of treatments.

Virtualized selling and removing the excess from sales forces will bring savings and greater customer engagement, however, this savings may be rebalanced by broader digital marketing efforts.

# Changing the economic relationship with customers

How do biopharma companies best optimize net sales and increase revenue? We believe it's by redefining economic relationships with customers, demonstrating value, and sharing in outcome-based risk.

Understanding how to quantify, communicate, and capitalize on the better health outcomes delivered by scientific advancements will be critical to biopharma' success—especially in the context of increasingly costly New Science.

This starts with changing the financial relationships with customers, stakeholders, and markets. The aim is to diversify and tailor contracting models to the needs of treatments, markets, and customers. This includes everything from how players set value-based prices to how they work with agencies, develop evidence, and so forth. The focus should be on targeted tactics and strategies for specific treatments. That said, historically, biopharma companies have had limited success in doing this.



## Actions biopharma companies can take to succeed in the new economic environment:

### Know where and when to apply and scale new economic

arrangements with customers: The subject of value-based contracts and innovative arrangements is not new and has not fully lived up to its promise—yet. The path forward does not require a wholesale shift in contracting strategies away from the rebate model. Some treatments will not be economically "worth it" to pursue innovative models for the payer or the manufacturer. In such cases, simple rebate-based contracts will remain the most efficient and effective means of engaging customers.

Biopharma companies should seek targeted opportunities to pursue innovative contracting models where it matters most—in cases where a treatment will be access-constrained--and where there is meaningful shared value that can be unlocked for manufacturers, ecosystem players across the value chain, and patients. In those instances, half measures will not be enough—biopharma companies must invest early in the lifecycle and fully in development and deployment of the new model. The model can't be in addition to the overall brand strategy, it must be a core part of it.



40 payer and PBM executives surveyed in the fall of 2019 said that customers expect significant diversification of contracting types in the next five years, with dramatic expected growth in value- and outcomes-based contracts and value-based pricing.

### **Tailor access and affordability models to meet the needs of the market and customer.** For those

targeted treatments where innovative models are necessary to unlock shared value, rethinking economic relationships with customers and the broader ecosystem requires that biopharma companies go beyond the bounds of traditional rebate models.

These are just a few examples of how companies can rethink their approach to access. All of them require novel types of evidence generation, early engagement of target partners and customers, and alignment of crossfunctional strategies and market-facing activities to deliver against these models.

# Practical steps include:

Find ways to share risk (upside and down) to demonstrate superior population or patient outcomes—especially for launch treatments, where manufacturers have traditionally been reticent to share in the risk on real world outcomes. For mature or wellunderstood treatments, create "positive uncertainty" with companion solutions or devices and contract against the combined outcomes of asset + companion.

Create consistency and predictability in budget impact for payers—especially for ultra-high cost therapies for rare diseases via installmentbased payments, subscription model

Think beyond traditional arrangements to find customers with aligned incentives—for example, engaging a large employer to ensure access to a medication that demonstrates improved workforce productivity or reduces sick days / disability. Include patients in the share of value by creating direct benefits for adherence (e.g., increased co-pay value) or reduce financial risk through reimbursement of out-of-pocket costs for nonresponders.

'n Is.	For low-cost, "commoditized" treatments, consider direct-to-consumer models that cut out payers entirely and offer a differentiated experience and degree of convenience.

### Identify treatments requiring innovative commercial approaches early in the lifecycle to get ahead of customer engagement barriers. Here are some ways to make that happen:



**Have a clear, risk-adjusted view to treatment performance** that considers not just PTRS, but also marketbased risks that challenge price and access. Build those risks into long range planning processes and forecasts as early as the start of Phase II trials to create a burning platform for development of alternative paths to market. Leaders must first have the courage to demonstrate the financial risks of maintaining the status quo in order to create organizational momentum to do something different and new.

### **Embed the innovative model into**

a holistic strategy. In order to be successful, the approach must be viewed as a core part of the overall strategy for the treatment, rather than an isolated market access pursuit. Development and deployment of the model should influence cross-functional activities such as evidence generation, market development, early phase customer engagement, and potentially even business development or alliance activities.

# Target investments in enabling technologies that reduce barriers to execution with customers at scale, i.e.,

blockchain solutions that enable a single source of truth to compliantly track and visualize population level outcomes for contract adjudication.

# Adopt specific operating model changes that optimize processes and use KPIs to drive change. Change efforts will

**processes and use KPIs to drive change**. Change efforts will stall unless operating models are modified to drive development of novel access models and leaders are incentivized to build and deliver innovative approaches.



These are near term changes that biopharma companies can make today not to drive wholesale change away from traditional models, but instead to develop the strategies that best suit a treatment or market where a new approach is necessary.

When considering a broader horizon, we believe biopharma should step forward to find opportunities to shape the market, not just react to it. The healthcare ecosystem is changing at an unprecedented pace. In addition to redefining economic relationships where it matters most, bipharma companies can and will continue to play an active role in shaping the future.

Appreciating that regulatory hurdles such as Best Price and Fair Market Value have constrained risk sharing arrangements and partnerships to date, how might biopharma companies engage with governments to define mutually beneficial reforms that promote innovation? Where PBM incentives are not aligned with disease-state-specific employer or patient priorities, how might biopharma companies engage those upstream stakeholders to either contract directly or put pressure on traditional customers? Biopharma companies can help determine their own future and should do so—especially in those instances where outcomes and impact to people's lives can be directly linked back to economic value.

# Closing thoughts

Biopharma CEOs have the mindset that bringing great new medicines to address significant unmet need means the revenue will take care of itself. We will continue to explore how biopharma companies can balance the need to reduce cost (billions to millions) while increasing revenue (net sales). A rebalancing of cost reduction and revenue growth could help to transform economic relationships with customers and realize more affordable and accessible treatments. Biopharma companies should also look at pathways to achieve new growth outside of traditional business models, brining an economic lens to the various choices. We've seen some amazing success stories—as well as a graveyard of digital health failures, and our upcoming research creates a framework to understand options and pursue them in a responsive-yet-responsible way.

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