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Pharmaceutical Portfolio Development: Strategic Rationale, Challenges & Solutions

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ABSTRACT

Seeking revenue growth has always been one of the key strategic priorities of business entities in the biopharmaceutical industry. The path to such growth can take diverse forms shaped by factors such as business context, strategic and operational capabilities, asset profiles, resources and competition. Developing assets (whether organic or acquired) with a strategy that seeks to build, maintain, optimize and grow a portfolio of assets offers a reliable path to reducing risks presented by organic development or through mechanisms such as partnering, mergers & acquisitions. The benefits of achieving profitable growth with a portfolio strategy span the asset life cycle continuum, from influencing asset development programs, shaping investment decisions, determining commercialization choices, informing launch planning and driving corporate priorities. This article outlines rationale for crafting and adopting a portfolio strategy since it improves the design of corporate, development, commercialization and lifecycle management strategies. Through cases based on the author's engagements, this article highlights common challenges and creative solutions that lead to the development and execution of viable portfolio strategies implemented by firms of diverse sizes and corporate objectives.

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BACKGROUND

The pharmaceutical and biotechnology industries serve critical societal needs in every region of the world. All too often, demands to sustain basic healthcare needs with supplies of proven medicines for large afflicted populations are overwhelming. But, more often than not, the demand for innovation rises to the fore as about the most important requirement for sustaining businesses, laying the foundation for growth, and making available to society options that serve their medical needs in better ways than ever before.

It is rational then for a pharmaceutical business to set aspirations that are in keeping with such a mission, unlike that of entities in most other industries. Taking pride in making new products for treating afflictions with no cure, developing therapeutic advances that offer significant new benefits, finding better ways to make drugs safer and to work more effectively or devising radical new approaches to how they are administered are some of the key elements of vision guiding leading edge businesses that strive to innovate as a means to business success. According to the Pharmaceutical Research & Manufacturing Association (PhRMA), member companies have invested nearly $1 trillion dollars in pharmaceutical R&D since 2000, establishing the biopharmaceutical sector as the most R&D-intensive industry in the U.S. economy.

Internal Innovation

Innovating through internal R&D is challenging and expensive. For example, man studies estimate that it costs approximately $2B to bring a single pharmaceutical/biotechnology product to market. Other studies have included time costs, i.e. expected returns that investors forego while a drug is in development, and costs for post-approval studies,

which bring the total estimated R&D costs incurred for bringing one product to market to be between $2.6B & $2.9B [1,2]. Such costs are incurred over a timeframe of six to ten years with about a ten percent probability of success.

Bringing a developmental asset to market fruition carries considerable risk as well. Such risk requires astute management and adequate funding. Much of this risk is spread over successes and failures. In essence effective development calls for smart management to generate adequate realization of business return from successful assets to cover for those that fail. Developmental costs among PhRMA members routinely average 20-25% of actual revenue from saIes. 17-20% of an asset's sales are further expensed for costs related to its commercial activities and management.

While the monetary cost of bringing a pharmaceutical asset to market is high enough, ancillary risks, opportunity costs, market launch and management costs are additional, necessary and vital sources of expense. Such costs need to be amortized appropriately, such as through revenues accrued from the sale of successful products. Sustaining a successful business that develops, manufactures and markets pharmaceuticals is at least as challenging as the science behind discovering them. Adding to the aura of challenge is the all too real fact that the relationship between spending on innovation and successful return in the form of new medicine is murky at best. There is little evidence to suggest that spending more on R&D, for example, will lead to more innovation [3].

Partnering, Mergers & Acquisitions

External sourcing of promising developmental and in-market assets through mechanisms such as partnering, mergers and acquisitions (M&A) is an alternate and often used route to realizing the benefits of pharmaceutical innovation.

Small and early clinical development stage firms represent vital sources of assets that can create, enrich and revitalize the product portfolios of established pharmaceutical firms. As explicated in [4], tried and tested processes spanning the clinical development pathway can increase chances of successful partnering. Key to such ventures is finding opportunities to collaborate early, including at stages where targets are identified, molecules matched and optimized for them, animal toxicity/efficacy studies are designed and pre-clinical, indication-specific studies are planned. A portfolio view encapsulated in the corporate strategies of larger firms can facilitate and often expedite scan processes that identify potential partners at various stages of such asset development. Equally important to the shaping of strategy and ensuring mutually productive partnering outcomes are factors such as constructing a shared vision, thinking through questions about cultural compatibility and streamlining a plan of execution during the diligence process [5]. Successful partnering is often the best way to guaranteeing a licensing, merger or acquisition deal. While partnering as a bridge to M&A is a key aspiration toward structuring optimal portfolios, outright M&A plays are much more likely to satisfy more urgent corporate value generating goals. In 2021, Biopharmaceutical M&A activity totaled $145B in value, generated from 165 transactions [6].

Key reasons for spending on M&A have not changed fundamentally from years' bygone. Solely relying on internal R&D engines to spawn assets that can flourish in their respective markets over a full lifecycle of ten years or more is a risky proposition at best, influenced as it is by vagaries of achieving clinical trial success, securing regulatory approval, wide access and full reimbursement, and dealing with competition.

Strategies to acquire and commercialize assets via collaborative development or commercialization deals, licensing or partnerships have fast become a necessary corporate mandate in sustaining or achieving growth corporate growth targets. While growth continues to be a key motive for firms looking for external opportunities, realizing supply chain efficiencies, tax benefits and organizational consolidation are other lesser benefits that also represent potential goals [7].

The all too real consequence of M&A as a value generator, however, is not borne out in fact. Like the facts surrounding R&D productivity, learning from analyses of M&A casts doubt on its reliability as a panacea to stem declines in (or accelerate) growth and enhance corporate value. Several studies have estimated the failure rates of M&A as being anywhere from 70-90% [8,9].

As elaborated in [8,9], desirable consequences of M&A can, and ideally should, be achievable by focusing on vital basics such as

- Customer-focused innovations in products and services within the current portfolio

- Enhancing the quality and depth of resources required to deliver such innovations

- Adopting differentiated business models that represent unanticipated, profitable disruptions to the status quo, and

- Leveraging excess capacities to improve customer satisfaction and expand the customer base.

In this context, it is worthwhile to note that of the 27 biopharmaceutical M&As in 2021 that met or exceeded $1B in value, the top area of interest in terms of both volume and value was the purchase of contract development and manufacturing organizations (CDMOs) and contract research organizations (CROs) [6]. This fact highlights the increasing importance of the manufacturing supply chain, which is no less critical to corporate success than R&D productivity and commercial performance.

A Portfolio View

It is this author's view that debating the pros and cons of investing in organic, R&D driven assets versus externally focused, opportunistic strategies as a path to realizing business revenue growth and profitability is worthwhile when framed in the context defined by key factors vital for success. Such factors include a pharmaceutical organization's corporate objectives, its propensity to assume various risks, the ability to access sufficient capital and the broad array of organizational capabilities necessary for success. When pursued this way, it is likely to shed light on the viability of corporate priorities, strategies and resource allocation rationale per se. It is less meaningful when the desired outcome of such debate is a clear answer to questions about making investment decisions for advancing or curtailing the development or commercialization of a specific asset. When - as is frequently the case - corporate strategists are tasked with developing rational arguments that support or refute a business case for one or more assets, taking a portfolio view in the context of owned assets and / or what may be available externally offers a pragmatic and more practical framework to enable effective executive decisions.

Developing assets - whether homegrown or acquired - with a strategy that seeks to build, maintain, optimize and grow a portfolio of assets offers a reliable path to reducing risks presented by organic development or through external mechanisms such as mergers and acquisitions. The benefits of achieving growth with a portfolio strategy span the asset life cycle continuum, from influencing asset development programs, shaping investment decisions, determining commercialization choices, informing launch planning and driving corporate priorities [10].

In its essence, a portfolio view of corporate strategy:

- Treats individual assets as parts of a collection of assets that evolves in value over time

- Focuses on identifying and creating synergies among portfolio assets, so that their combined value is higher than the sum of their values

- Includes assets in all stages of a product lifecycle such as discovery, development, commercialization, and in the market

- Holds the potential for enabling superior returns on investments compared to when individual assets are treated separately

A portfolio view of R&D strategy executed well also promises an alignment of seemingly disparate R&D goals under the rubric of corporate strategy, key parts of which mandate corporate success as a direct function of R&D achievement. Approaching R&D decisions through the portfolio prism holds the promise of

- Clear, non-overlapping and simultaneous development paths for multiple assets in a variety of stages

- Effective development of complex asset offerings, some of which may be in the process of external clinical testing – such as the development of theranostics, i.e. a therapeutic plus a diagnostic (e.g. a biomarker test)

- Developing a regimen of complimentary products treating sequentially severe stages of a chronic disease - such as advancing multiple sclerosis, osteoporosis or HIV

- Effective resource allocation across multiple developmental and commercial assets according to transparent criteria that is

meaningful to the organization, rather than specific departments alone

- Effective design and management of clinical trials that
    - Avoid redundancies in samples representing targeted sub-populations
    - Increase representativeness and overall respondent quality through proactive, portfolio based controls,
    - Increase the effectiveness of site selection processes,
    - Enhance depth and breadth of subpopulation study without increasing duplication, overlaps and repetition
- Laying the foundation for an organization to establish a unique corporate brand on the basis of one or more portfolios

A portfolio view of strategy can (and in the best of circumstances should) influence the design and execution of commercial strategies. For example, an organization with in-market brands that are part of an optimized portfolio can expect to:

- Eliminate (or at worst reduce) revenue losses due to product cannibalization
- Streamline customer outreach through operational efficiencies in sales force customer targeting, sales force sizing, structure and call planning
- Develop clear, simple and effective brand positioning platforms in line with a portfolio thematic that further reinforces a singular corporate brand
- Enable brand cross-selling to common targets and de facto create new opportunities with customers who may not otherwise be using other brands in the portfolio
- Provide leverage with large customer accounts (such as insurers, hospitals, ACOs, GPOs) through purchase contracts that offer differential, brand level discounting and incremental service benefits in exchange for terms favoring as many products in the portfolio as may be of use to the account, particularly as alternatives to competition
- Using assets in the portfolio as a springboard to assuring a ready market for future, yet to be launched assets – reducing the need to incur additional expense related to new product launch, while building up on portfolio level equity

In the author's experience, a portfolio view encompassing effective development and commercialization also addresses operational and organizational barriers to corporate success. Not pursuing a portfolio view (as a guiding principle) has been known [11,12] to result in a host of otherwise manageable problems such as the following:

- Too many projects are trivial and represent updates or modifications. A broader portfolio view recognizes overlaps and duplications before long and instills tendencies to look for synergies
- There are clear disconnects between spending on projects and strategic priorities. A myopic, functional view encourages localized project design and execution that at best only partially fulfill strategic priorities
- A "turf mentality" pervades the process of resource allocation by project or function, eventually leading to the realization that resources are scarce and require rationing
- Project design and execution - often delegated to external consultancies - are tied to realizing narrow objectives manageable by specific role players, thereby calling for a needless bureaucracy of teams and managers overseeing multiple disparate projects where portfolio driven efficiencies could have led to effectiveness
- Lack of consistency and accuracy in data, insights and ultimately strategies that are advocated - not necessarily because of inherent and authentic differences in the issues under study - but more so due to overlaps in project objectives, differences in design considerations, data collection methods, analytics, modeling approaches and

multiple, sometimes contradictory and subjective interpretations

In this context, there is merit to the argument that adopting a portfolio view at all levels of a hierarchical corporation will enable the realization of a flatter organization that seamlessly (and thus effectively) operates with common, known and transparent purpose.

Case: Optimizing Portfolio Composition & Performance

Consider this situation fairly typical of portfolios created as a result of mergers and acquisitions driven by valuations that factor for, but are not necessarily shaped by or limited to portfolio considerations.

A large pharmaceutical firm known for developing innovative cardiovascular (CV) treatments acquires a firm with a good line of next-generation, early-stage compounds, some of which would launch in the same indications as its in-market brands, while others would represent novel, first-in-class treatments.

Over a five-year window after the acquisition, there is a high chance that the combined company would launch four new products while continuing to manage the lifecycles of eight in-line products.

- How would the firm best manage this portfolio of 12 products so that the opportunity was maximized in terms of financial and market performance?
- What would constitute a CV portfolio optimized for value, considering top line revenue projections, potential and realized synergies, costs, profits and profitability?
- How could the portfolio best realize inherent synergies?

A program of systematic stakeholder research, customer insight generation from market research with current and future product prescriber targets, patients, insurers, distributors and pharmacists provided a foundation of data and information required for analyses. Key analytical steps included:

- In-depth asset and portfolio reviews driven by brand & portfolio managers
- Customer insights - such as learning about brand / portfolio perceptions, utilization, choice drivers, brand levers and intent to use asset(s) - in comparison to competition as measured via share metrics
- Calibration of future behaviors based on normative models of competitive product choices as a function of product features and assumptions about marketing (including promotions, pricing, access), sales force and medical affairs activity
- Measurement and prediction of product use within the portfolio in comparison to external competition under scenarios simulated to represent alternate portfolio composition and inputs representing product characteristics, marketing, sales force and medical affairs expenditures
- Financial models of present value as a function of alternate portfolio composition and supporting development, commercialization, launch and life cycle management assumptions

The cumulative benefit of such insight and analyses - highlighting the advantages of taking a portfolio view - could be summarized as enabling

- A detailed understanding of
    - How products in the portfolio were perceived by its customers,
    - How such perceptions would change under alternate assumptions of portfolio composition and commercial effort as summarized by marketing & sales activities,
    - The sensitivity of product and portfolio sales as a function of such effort, and ultimately
    - The best combination of portfolio composition, commercial expenditure and other cost inputs that would result in the highest present value over a window of 5-10 years
- A detailed assessment of the type of developmental effort required to populate

the optimized portfolio with assets that were not yet approved, including overviews of potential clinical, competitive and regulatory challenges that needed to be overcome prior to successful launch

- A rational framework for the engagement sponsor to use in other therapy areas to identify portfolio inefficiencies, justify salient results of product licensing scans, support potential portfolio divestments and inform product commercial strategies (e.g. repositioning, marketing / sales force budgeting strategies) supported by financial considerations.

It is worth emphasizing that such a framework, when adopted and supported by senior management, encouraged the leveraging of portfolio perspectives at all levels of the organization, stressing inherent advantages over single brand-focused approaches.

Case: Building a high value portfolio of pipeline assets

Firms this author has worked with have also actively explored the strategic option of building from scratch a high value portfolio of assets in therapy areas of particular interest. The major difference between this and the case previously discussed is the absence of an in-market asset around which to anchor the new portfolio. This can be a blessing in disguise depending upon characteristics of the market for the intended portfolio, the availability of potential assets, the degree of scientific and clinical development acumen required to advance such assets and the cumulative novelty and beneficial innovation offered in a cost-effective manner by assets in such a portfolio.

Consider this situation: *A biotechnology firm is actively pursuing the development of a portfolio of assets serving unmet needs in the therapy area of metabolic disorders. While there is no asset in the market indicated for treating metabolic disorders, alternatives with narrow, niche indications do present potential ways to serve patient needs, albeit in limited ways. The biotech acquires an early stage asset with a broader promise, and seeks to create a viable, synergistic portfolio with it in combination with its nascent, in-house developmental program of two other Phase 1 assets. Key questions of strategic interest include the following:*

- What are the feasible target indications for each asset so that they each serve complementary, non-overlapping patient segments within the metabolic disorder therapy area?

- What are the key value propositions for each asset (and the firm's metabolic disorder portfolio) that highlight opportunities to use them as stand-alone products as well as in a sequence aligned with the patient treatment paradigm?

- What may be the best clinical development path for each asset that would allow for parallel, efficient and synergistic indications?

- What are the commercial hurdles and perceived benefits that would define success for the portfolio of three assets?

A program of strategic research provided the foundational data to initiate analysis addressing such questions. Specifically, the research centered around gathering data from –

- Scientific leaders spearheading each of the three early stage assets, including those in charge of discovering the sole in-licensed asset

- Potential thought leaders with expertise in the clinical development of assets in therapy areas analogous to metabolic disorders, such as Type 2 Diabetes, Cardiovascular Diseases, Obesity and Dyslipidemia

- Stakeholders in the market for treatments addressing such diseases, including physicians, patients, health insurers, health technology assessors, pharmacists and key actors in the supply chain

- Internal documents encapsulating results of pre-clinical experiments that provided signals about potential hypothetical, targetable indications for each asset

A series of analyses resulted in answers to key questions in the form of –

- A list of potential target indications for each asset that could be pursued as part of a stand-alone, asset-based developmental pathway

- A list of potential indications unique to each asset, as well as another list representing potential indications common to any two (and all three) assets

- A risk analysis with specifications of clinical success probabilities by developmental phase, for combinations of key indications and asset configurations

- An options model analysis that yielded present value financial estimates of pursuing select possible development paths for the same asset-indication combinations

- An explication of potential positioning planks that could conceivably describe each asset to its market in and of itself as well as part of a larger target portfolio targeting metabolic disorders

- A description of key hurdles to commercialization at the asset and portfolio level, including potential requirements for successful regulatory filing

- Inputs, insights, measures and metrics that fed a five-year global portfolio development plan for assets in the metabolic disorder treatment space

In essence, the engagement resulted in defining a clear path forward to advance each asset through development, but as a portfolio holding forth promises of serving patients with assets indicated for treating a sequence of conditions, even as patients advanced along the treatment paradigm from early diagnosis through stages of increasing severity associated with metabolic disorder.

Other ancillary benefits accrued as a result included increased and sustained organizational collaboration, efficiencies in clinical operations and more effective commercial planning than what would have occurred had each asset been treated as a stand-alone entity [13].

Value Enriched Portfolios

In recent times progressive pharmaceutical firms have increasingly relied upon the development and optimization of product portfolios as a central component of strategies that emphasize value generation. Some of such action can be attributed to astute, forward-looking thinking that anticipates corporate benefits due to a portfolio orientation.

A few firms, on the other hand, often have found themselves faced with the onerous task of managing, by default, a portfolio of products that was formed through well intentioned opportunity, but which now has grown and matured - with little portfolio insight and management over time.

Some firms find that developmental assets that evolved into standalone products and provided good returns on their investment for a finite time now need to be managed for longer life cycles through a viable portfolio strategy. In such situations lifecycle management of mature brands through a host of actions such as launching line extensions, dosing & delivery enhancements, engaging in extended customer contracting laced with financial discounts and seeking new geographic markets are common strategies with incremental returns at best.

It is also not uncommon for mergers and acquisitions to result in the creation of an inefficient portfolio of products that seemingly compete with each other for resources rather than generate sales in excess of what they could as separate, stand-alone entities. Such situations call for the application of strategic analysis and pursuant action that bring back meaning and purpose to a modified portfolio.

In the author's experience [14] too much internal competition and inadequate financial returns resulting from holding on to an inefficient portfolio can

- Permanently damage the equity inherent in successful brands, which may also be threatened by internal competition from one or more new line extensions or an acquired product

- Dampen the true sales uptake path of a new version of a successful product in the portfolio, thereby reducing the net potential realizable from both products, also making it easier for an outside competitor to make inroads into the same market

- Raise the cost of resources needed to support comparable products within the portfolio in terms of personnel, as well as total sales, general and administration (SGA) costs. Each of the internally competing products can also

likely realize less of its potential now than before when it had the market to itself.

- Over the long term, harm the image of a firm as a responsible corporate citizen, making it seem less interested in offering genuine innovation and more interested in profits stemming from selling multiple, similar products (or higher priced, incremental improvements of existing products) to the same customer.

Across multiple portfolio strategy engagements in therapy areas of importance to primary and specialty care, a key question of interest posed to this author by executives revolves around what in principle constitutes an effective and valuable pharmaceutical portfolio. When addressed in the context of a firm's assets (both in development and inline) an answer to this question can lay the foundation for significant corporate, brand, operational and organizational changes. Mining insights from multiple engagements a few key guiding percepts come to the fore. Specifically, pharmaceutical product portfolios that generate more value than when its constituents are sold alone share the following traits:

1. The portfolio has a clear theme

such as a portfolio of assets that collectively provide a range of supportive care to patients across multiple types of cancers, or a collection of medicines addressing successively advancing stages of disease in chronic conditions - such as post-menopausal osteoporosis, chronic pain or multiple sclerosis.

2. The portfolio includes a mix of mature and new, innovative assets.

Such portfolios are especially attractive to large, business-defining customers, whose patient flow mix represents a wide swath of multiple, related conditions as well as sequentially severe conditions of the same disease. The availability of a portfolio with a product mix that lines up well with the patient mix allows customer accounts to realize efficiencies such as uninterrupted supply from a single manufacturer, quality guarantees agreed under a commonly understood, mutually agreed upon set of standards that apply to all products in the portfolio, and first-look, preferred supplier arrangements to review upcoming add-ons, product and service innovations.

3. The portfolio represents products with similar indications.

Similarity of indications across multiple approved products is a strong signal of a firm's expertise in the science, development, launch and life cycle management of products in the therapy area of interest. Research by the author has shown that If the firm also manufactures assets in the portfolio, it stands a much better chance of acquiring and retaining customers of the portfolio over longer time frames than otherwise. In essence, striving to manufacture, develop and commercialize a portfolio of products with similar indications holds the potential to enhance product, portfolio and corporate equity. For example, a pharmaceutical firm with an inline asset indicated for treating moderate to severe plaque psoriasis has worked with the author to develop and commercialize assets that treat mild to moderate forms of the disease - so that the same firm is perceived, justifiably so, as offering a portfolio of medicines that serve the entire patient disease spectrum. Another firm has developed a portfolio of cancer therapeutics and supportive care products that address key and unavoidable side effects stemming from the use of such offerings.

Strategies that proactively develop such portfolios encourage its owner to de facto develop a variety of disease specific, complimentary capabilities that work hand in hand to sustain and enhance long-term value. Such capabilities include broad and deep patient services expertise, a dependable access and reimbursement infrastructure, leverage with specialist physicians who know and recognize the firm's unique and differentiated capabilities within the disease area. With a portfolio of assets and capabilities, the firm is not simply selling a medicine; it is in fact anticipating and serving a broad and deep swath of patient, physician, insurer and institutional needs within a disease - with expert, disease specific capabilities that are, over time, unrivalled. Such factors are invaluable in building long term loyalty, while also laying the foundation for the success of future products that enlarge, sustain or otherwise optimize the same portfolio. Some firms who do this can also choose to assume unique corporate branding - driven by capabilities that perpetuate and build upon such equity consistently, while being perceived (justifiably so) as serving the full range of current and anticipated needs of patients, health-care professionals, health insurers, the supply trade and key institutional customers of the portfolio such as hospitals, IDNs and ACOs.

4. The portfolio offers products with a wide range of pricing options.

Flexibility in offering a portfolio with a range of product prices that are tailored to customer needs, affordability and perceived value, while providing the leeway to maximize customer revenue or profitability is a win-win benefit of a portfolio - in comparison to single product deals. A key advantage of offering multiple products in a portfolio over a wide range of prices is the ability to negotiate lasting, long term purchase contracts that balance relatively high prices for new and one-of-a-kind innovative brands with the flexibility to lower pricing on mature brands, conditional on portfolio purchases guaranteed over longer timeframes - insulated, as well, to the upcoming competition.

5. The portfolio comes with a significant, customer-centric service component.

The value of a portfolio is known to increase notably when it is offered with a customized service offering that is specifically tailored to its customer. Components of such an offering typically include physician/support staff education about portfolio assets; training for aspects such as appropriate use, patient follow up procedures, office administration, and digital support for maintenance, patient support services, ease of ordering, inventory management and swift problem resolution. Supporting the portfolio with a customer account management team at the manufacturer is an added value-enhancing option.

Conclusion

Seeking revenue growth has always been one of the key strategic priorities of business entities in the biopharmaceutical industry. The path to such growth can take diverse forms shaped by business context, asset profiles, strategic and operational capabilities, resources and competition.

Developing assets - whether home-grown or acquired - with a strategy that seeks to build, maintain, optimize and grow a portfolio of assets offers a reliable path to achieving such goals, while also reducing risks presented by organic development or through business mechanisms such as mergers / acquisitions. The benefits of achieving growth with a portfolio strategy span the asset life cycle continuum from influencing asset development programs, shaping investment decisions, determining commercialization choices, informing launch planning and driving corporate priorities.This article outlines rationale for crafting and adoption of a portfolio strategy inasmuch as it improves the design and execution of tasks vital to asset development, commercialization and lifecycle management. A portfolio mindset can spawn creative solutions that impact near term product development, commercialization and life cycle management strategies while, in parallel, shape a pharmaceutical organization and its priorities in ways that encourage common purpose and coordinated brand and functional strategies. Such endeavors can only make for a better, more productive firm poised to improve its market performance.

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