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PURCHASING A PIPELINE

Perils, pitfalls, and priorities in asset acquisition

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Checkpoint inhibitors. Genetic therapies. Biomarker therapies. To hear big pharma tell it, we are living in an age of medical wonders.

The problem? In some patients, they make a huge difference. In others, they don't work at all.

From a bench-science standpoint, that's fascinating. But if you're a pharmaceutical executive thinking seriously about pipeline asset acquisition, translating large-molecule science into high-profit marketability is fraught with complexity.

In this White Paper, we will look at new and changing trends in pipeline acquisition, discuss difficulties inherent in the current marketplace, and offer worthwhile perspectives on pitfalls and opportunities based on our experience offering strategic guidance to pharmaceutical companies on a global scale.

[1] https://www2.deloitte.com/uk/en/pages/press-releases/articles/pharma-rd-returns-continue-to-slide.html

[2] https://www.bmiresearch.com/articles/global-pharmaceutical-rd-spending-to-drop-marginally

[3] Elsevier 2017 https://pharma.elsevier.com/pharma-rd/mergers-acquisitions-pharma-industry/

Big pharma pipelines are not what they used to be

The majority of new drugs measure their success in increments.

Orphan drugs and tightly targeted MOAs offer the most exciting breakthroughs, but they offer them to smaller and smaller groups of patients. New cancer drugs are launched with great fanfare even when their pivotal studies suggest they offer a scant three months' improvement over the competition. Small molecules are languishing. Biologics, once heralded as an arena of unbounded promise, are nearing the end of their patent lives, negotiating payments worth millions to keep biosimilars off the market.

All of this translates into smaller financial returns for pharma companies. But anyone with a passing familiarity with the business knows that bringing a new drug entity from bench to bedside has always been a risky process, fraught with high costs and a strong possibility of failure. Several sources peg average developmental costs of an approved and launched drug, including early-stage failure, at around $2.6 billion. In order for drugs this expensive to be successful, anything less than yearly sales of $487 million represents negative net present value, or NPV.[1]

A very high bar indeed. New drugs with MOAs that represent real and substantial improvement over the standard of care have little to fear, as the success of the recent Hepatitis C breakthrough drugs has proven.

Given the advanced state of the science, one would think that previously intractable disease states would be ripe for first-in-class modalities. But, in fact, the number of untreated indications is rapidly falling, and R&D budgets are trending downward.[2]

The resulting attrition to teams, and to the institutional core knowledge on which pharma companies rely, does not bode well for many - and many familiar - pharma companies.

All of this impacts ROI. In 2017, it was projected that the top 12 pharma companies saw a 3.2% return on investment, the lowest level in 8 years. Combine this with expiring patents and the constant pressure to do whatever is necessary to meet the expectations of shareholders, and it becomes clear: the advantages of buying an existing pipeline for a finite amount of money are surer than spending a near-infinite amount to build one.[3]

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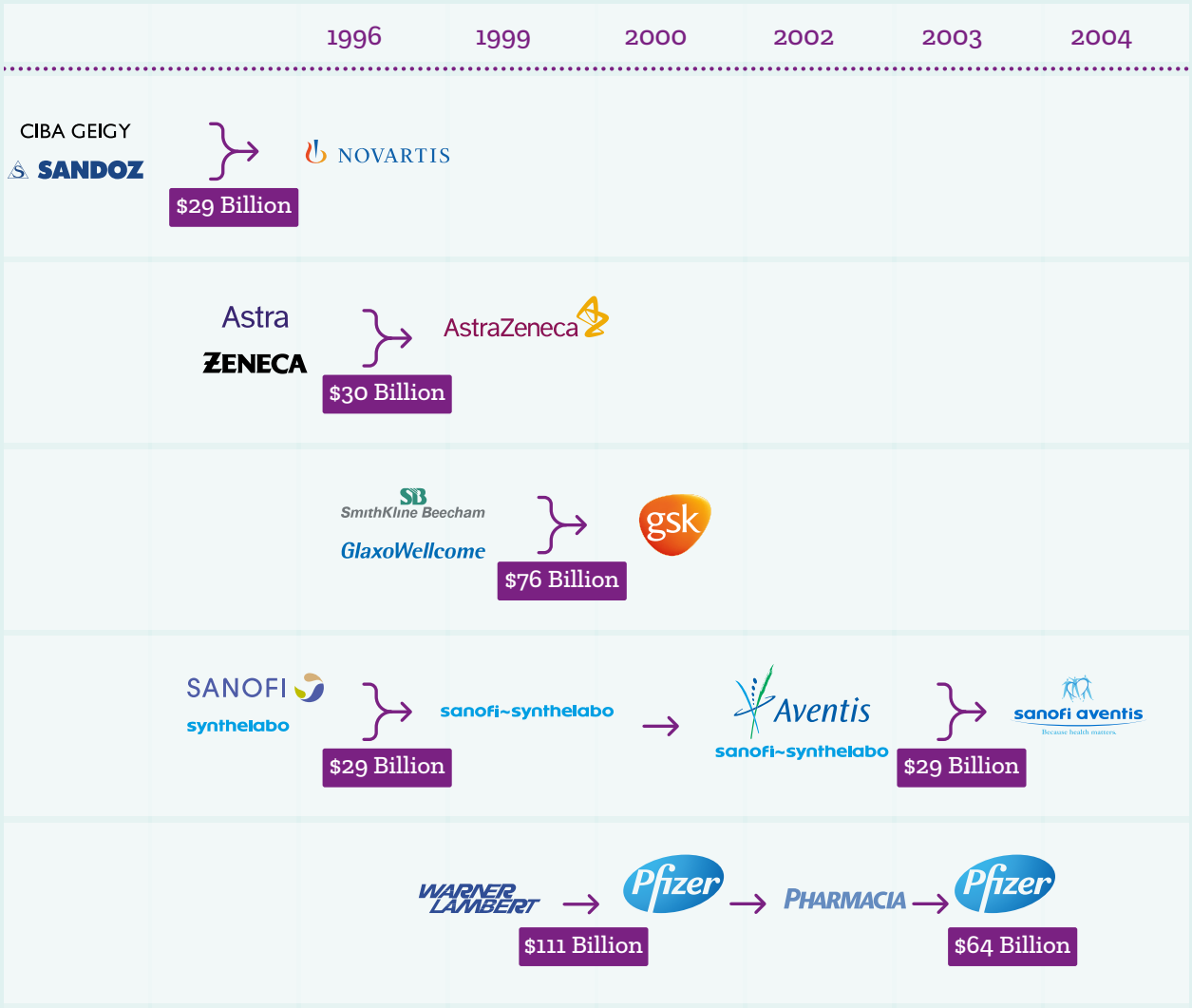
There was a time when bigger meant better

Future historians may someday pin down when the phrase "R&D investment strategy" stopped describing funding streams for internal labs and started applying to the purchase of, or merger with, companies doing promising research.

Certainly, by the 1980s it was in full flower. That decade saw such intense merger and acquisition activity that the term "mergermania" crept into the headlines, and droves of law students began looking for jobs in "M&A."[4]

Many pharma companies were large enough that they could see the economies of scale vertical integration would bring. Those facing patent cliffs sought out companies that would diversify their portfolios. In 1985 the top 10 global pharmaceutical companies together accounted for 20% of overall pharmaceutical sales. Over the next decade, multibillion-dollar mergers and purchases became routine. By 2002, sales for the top 10 had risen to 48%, and the trend was far from over.[5]



[4] https://scholarship.law.duke.edu/cgi/viewcontent.cgi?referer=https://www.google.co.uk/&httpsredir=1&article=6441&context=faculty_scholarship

[5] http://www.eiiff.com/merger-acquisition/pharmaceutical/

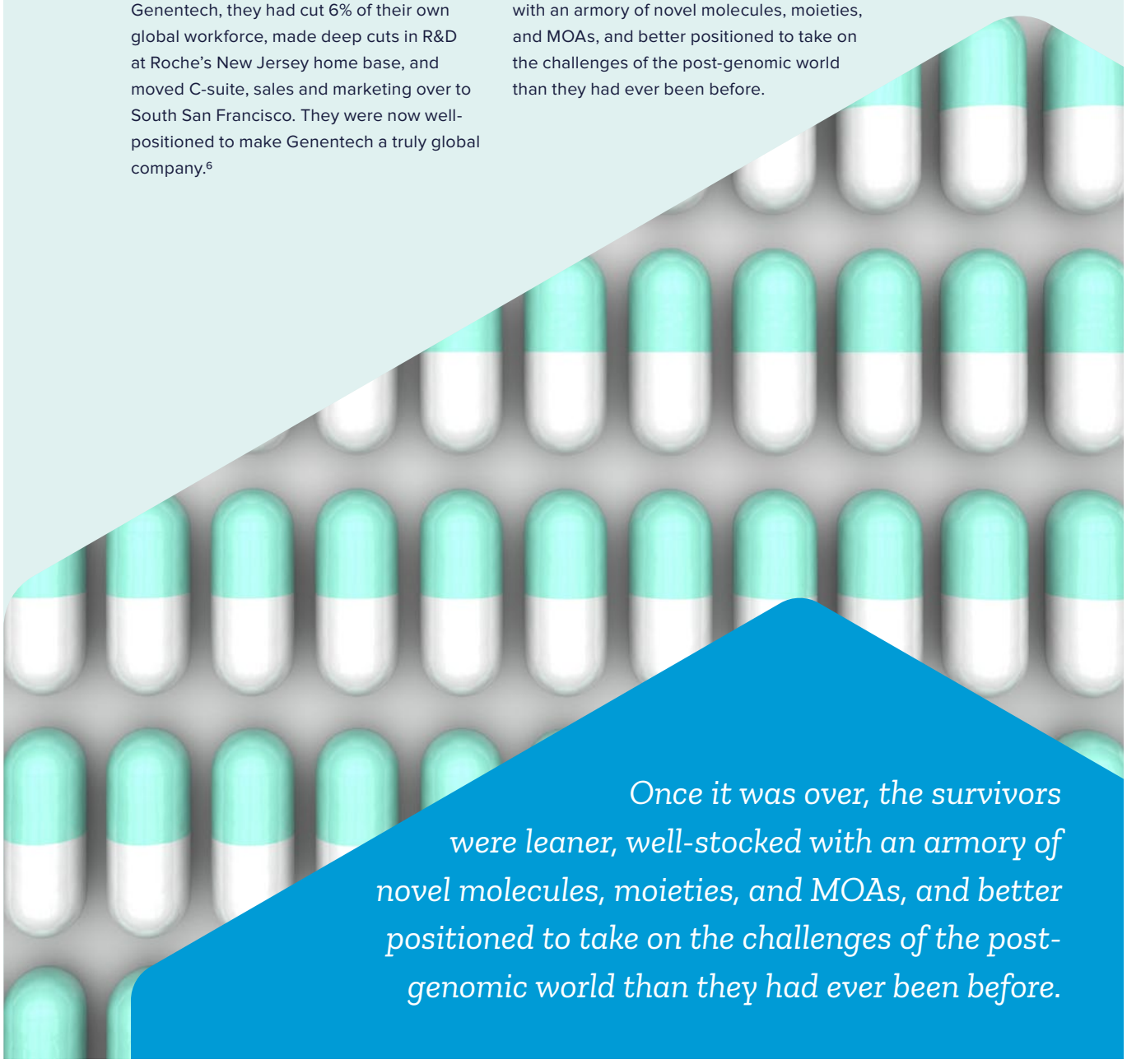
[6] https://www.genengnews.com/news/three-years-after-merger-genentech-rd-outshines-that-of-roches/

Predictably, this era of expansion by consolidation left companies with bloat, redundancies, and inefficiencies. Differing corporate cultures, disparate locations, overlarge workforces - all predicated a shift to leaner, more sharply focused C-and D-suite oversight, as areas of weakness were uncovered and promising molecules gained resources and support.

Some companies used this fertile moment of marketplace disruption to grow exponentially smarter. Three years after Roche acquired Genentech, they had cut 6% of their own global workforce, made deep cuts in R&D at Roche's New Jersey home base, and moved C-suite, sales and marketing over to South San Francisco. They were now well-positioned to make Genentech a truly global company.[6]

Meanwhile, AstraZeneca, having completely recreated itself through M&A, then divested their infectious disease franchise, created a neuroscience unit, and slimmed down to four core areas: oncology, inflammation and autoimmune disease, cardiovascular, and metabolic disease.

To anyone paying attention, a generation of mergers, acquisitions, dizzying deals and crashing realities seemed like cut-throat capitalism at its most rapacious. Once it was over, the survivors were leaner, well-stocked with an armory of novel molecules, moieties, and MOAs, and better positioned to take on the challenges of the post-genomic world than they had ever been before.



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Current challenges in the world of asset acquisition

Despite - or perhaps because off - all the mergers and new-company spin-offs of the last two decades, the number of pharmaceutical companies with active pipelines has roughly tripled.

In 2018, 3,807 drugs entered official pipeline status. In 2017, 54 new active substances were launched, a 32% increase from 2016.[7]

There are a growing number of players. Some may be well-funded recombinations of merged entities, and some may be small companies focused on one or two ideas, pushing forward in the hope that a larger company will see their worth and absorb them.

But whatever their origins, they all face the same current market dynamics:

The **shift to value- and outcomes- driven payments** has been a significant market change in the US, with ripples that have extended to other markets.

More varied pathways to market, resulting in diversified stakeholders and decision-makers.

The **rise of health economics outcomes research** and real-world evidence (HEOR and RWE) have forced a level of transparency into discussions of cost and efficacy.

The **rise of biosimilars**, currently more of a force in Europe than in the US due to aggressive deal-making on the part of companies facing biologic patent expiration.

The continuing pressure of mature-market government regulation and control of both pharma products and corporate growth has not been lost on players in the **emerging markets**.

Spotlight: Emerging markets

It may be argued that all these trends offer opportunities to both big pharma and little startups alike. Granted, big pharma may be better positioned to make use of them. But if a smaller-company drug was shown to have superior safety, efficacy, or both, and backed by a strong HEOR narrative, several avenues toward profitability exist. The right drug at the right time with the right narrative could be a giant-killer - or it could be taken up by giants, who would be in better position to launch and market it with their full force and weight.

Many emerging-market countries offer relaxed taxation, a permissive attitude toward growth, a highly educated workforce, capabilities for building and infrastructure, and an enormous population to call upon for every aspect of clinical trial testing.

Accordingly, countries such as Japan, Brazil, China, and India have made a point of offering more favourable commercial, regulatory and innovation-friendly environments.

In 2017, global deal activity stayed generally the same as in previous years, but the location of these deals continued a trend of greater deal activity in the emerging markets than in the US.

[7] https://www.ft.com/content/cb456228-4d5b-11e7-919a-1e14ce4af89b

The hazards of pipelines

Currently, many pharma companies rely on internal business development analysts to collect and evaluate asset data. These tend to utilize standard market analysis tools - ad hoc primary and secondary research, solicited opinions from stakeholders, and deferral to medical teams to do due diligence on clinical trial data.

Unfortunately, the vested interests of many companies may well promote a corporate culture capable of ignoring assumptions in data valuation, personal and institutional biases, and invalidated decision making. Untested assumptions often lead to an overoptimistic view of potential financial synergies an asset acquisition might bring.

Common blind spots in pharmaceutical asset acquisition include:

- Underestimating the competition
- Overestimation of data showing incremental or near-incremental improvement
- Bias in considerations of cost
- Insufficient understanding of upcoming changes in treatment pathways to accommodate new MOAs, products, and technologies
- Insufficient consideration of patient unmet need
  - What does the patient dislike or fear about their illness and the drugs currently in play to combat it?
  - What concessions has the patient been forced to make in the past that they would gladly take back?
- Limited consideration to the chain of customers leading to the patient
  - What is the value of a drug - or its competition - to a pharmacy benefits manager? To a pharmacist? To a hospital quality department head?
  - HEOR studies may compound these differences
  - Private organizations such as the Institute for Clinical and Economic Review - ICER - may influence press, payer uptake, and access

The ability of a company to acquire high-value assets requires 360-degree foresight and depth of vision to correctly analyze and weigh all these elements and many more. Business development analysts have comfort zones. Sometimes the correct answer lies beyond them.

Success in assets acquisition: inside and out

Different acquiring companies have differing values, visions, and historical realities. In the same vein, each company has different drivers in mind when purchasing an asset.

The desire may be to acquire desirable skills or technologies speedily, thus reducing cost. Or maybe to broaden products or service offerings, thus increasing revenue. The emphasis could rest on creating or increasing market access. Any and all of these benefits are considered in tandem with the internal needs that asset acquisitions could fulfill, such as:

- Consolidation to;
  - remove excess capacity, thus balancing demand and supply
  - restructure competition, thus reducing or maintaining price
- Recombining highly fragmented markets to a more viable size

Whatever the impetus for purchasing an asset, there are overarching strategic endeavors that must be met in order for success to materialize. To realize these key values and objectives, acquiring companies must be willing to understand their own needs and motivations as deeply as they understand those of the company under inspection. There must be a process that allows them to uncover blind spots - their own, those within the target company, and those within the market itself - and test and verify assumptions from which future-proof strategies are drawn.

External assessments

An ironclad **understanding of competitors and competitor intent**, whether they be traditional pharma companies or tech disruptors

A holistic **perspective on every stakeholder**, with a foundational understanding of the motivation behind their behaviors in any given situation

A thorough **exploration of the macroeconomy** surrounding the asset, sifting for market trends or disruptors as possible influencers for success

A **firm handle on the national and international regulatory environment** and an understanding of possible opportunities or barriers to entry

Assessment tools of value

The creation and population of a true competitive landscape

A deep dive into the fears, hopes, and capabilities of every competitor

Real-time primary and secondary insights into all possible stakeholders, including:

- Patients and patient caretakers
- Partners
- Prescribers
- Providers
- Payers
- Policymakers
- Professional societies

Secondary research into the market and market trends

Thorough and astute financial modelling

A fully immersive competitive landscape

Regulatory designations that can be leveraged

Regulatory barriers to be overcome

Externally...

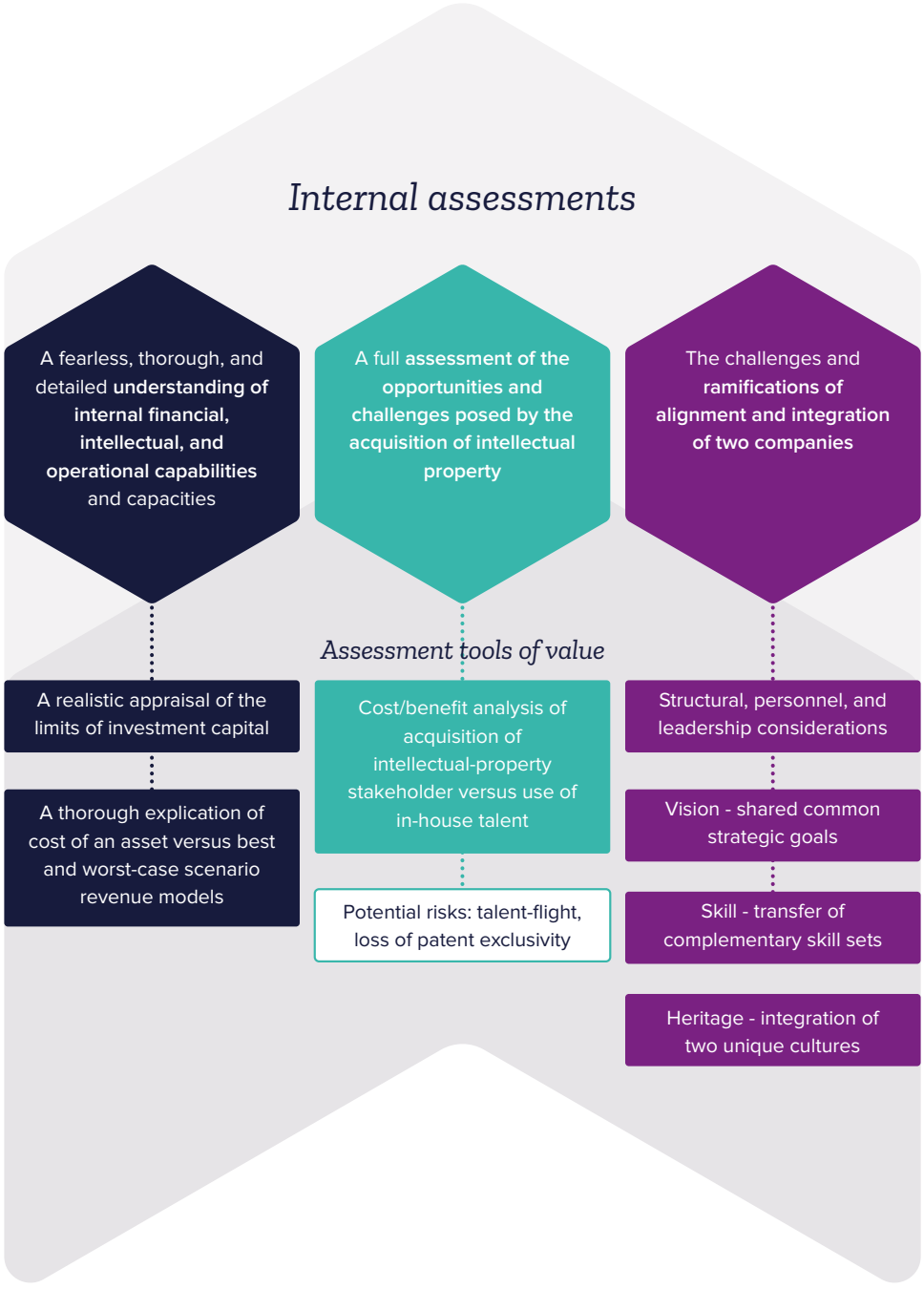
Assessments of external factors include an ironclad understanding of competitor intent, a holistic perspective on key stakeholders, a thorough exploration of the macroeconomy at play, and a firm handle on the influencing regulatory environment.

Without this in-depth knowledge to paint a holistic picture of the external environment as it applies to a pipeline purchase, acquisition plans won't foresee pivotal challenge or success factors in time to harness or mitigate them.

Internally...

But this external information is only half the picture. Alongside these insights lies a need for a complete, objective, and honest valuation of the acquiring company's capacity for such a purchase – what internal factors are at play that need to be assessed, stratified, and properly managed?

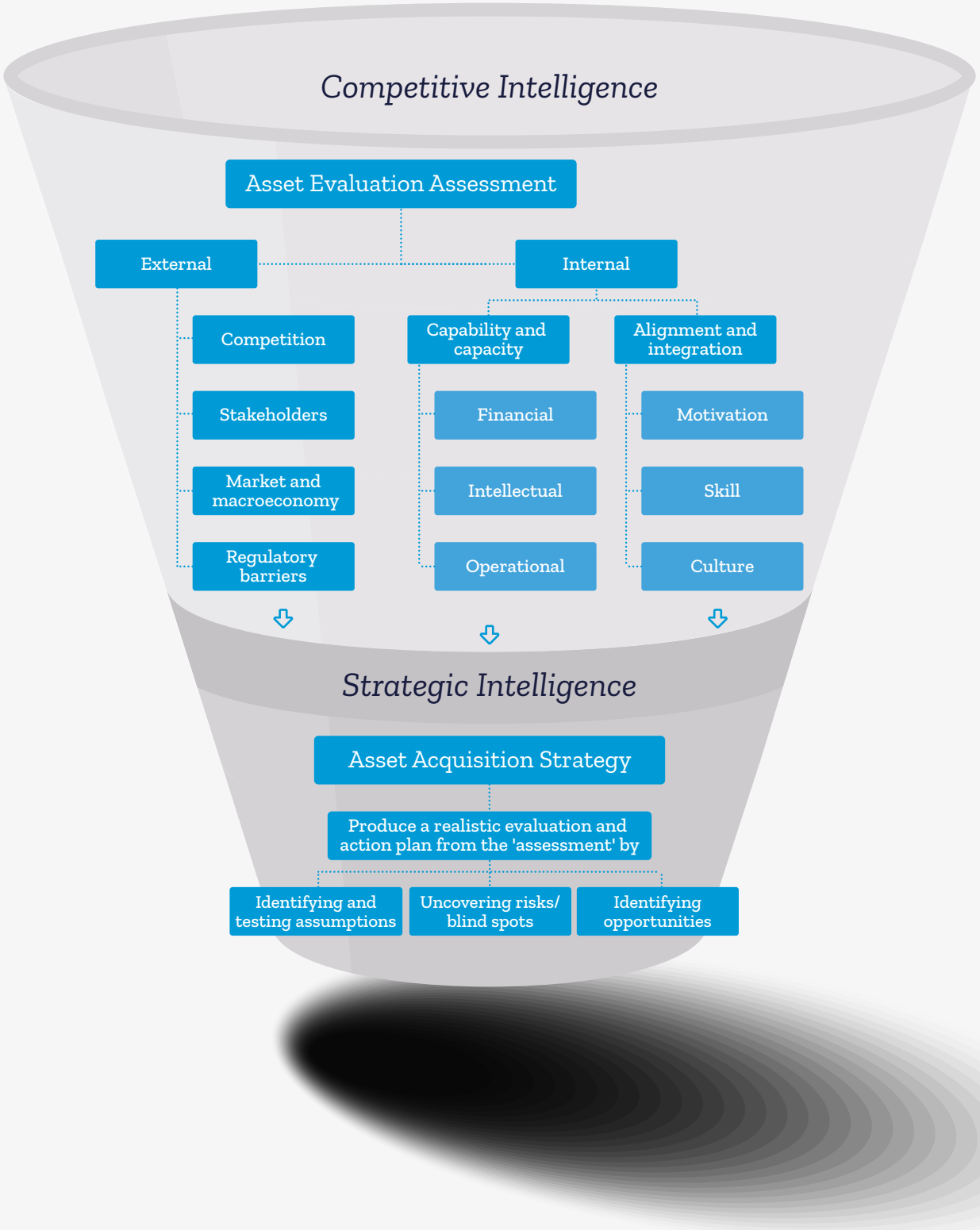
Internal assessments include an understanding of the acquiring company's internal financial, intellectual, and operational capacities, a full assessment of the internal opportunities as well as challenges posed by acquisition, and the possible ramifications of cross-company alignment and integration.



If this picture is incomplete, companies run the risk of acquisition failure from the inside out, with unforeseen internal challenges toppling chances for success and profitability.

Conclusion

Success or failure of any asset acquisition will depend on the extent to which any company is adept at critical self-analysis while simultaneously building a thorough understanding of every aspect of the target.



The difference between successful asset acquisition and those that run counter to expectation is information - the depth, the timeliness, the worldliness, and the overall quality of information with which a company arms itself as it considers an asset. This level of insight takes time, resources, and high-quality investigation requiring a powerful understanding of external realities and internal qualities. Only rarely is a company capable of doing this foundational work in the midst of the headlong rush into asset acquisition. Which is why many pharmaceutical companies have come to rely on the vision, experience, and candor of an outside consultancy well-steeped in strategic intelligence.

A partner rooted in a comprehensive and overarching understanding of pharma can uncover the risks, traps, and blind spots that accompany even the most straightforward acquisition. Such a partner may be invaluable in recognizing the untested assumptions that all too often prove devastatingly wrong. And they can also be constantly on the lookout for hidden opportunities, whether in efficiencies, economies of scale, or in the leveraging of intellectual property.

For many pharmaceutical executives grappling with pipeline acquisition in the current challenging environment, a true strategic intelligence company can offer invaluable perspective and insight that will create offer a more sure and secure platform for success and drive down the risk of failure.

About Deallus

Deallus is a unique strategic intelligence consultancy operating across the global life sciences sector.

Our mission is simple: to prepare you for the future by delivering the forward-thinking assurance you need in an uncertain and highly competitive world. The knowledge and clarity we provide helps life sciences companies shape future markets by making the right strategic decisions with confidence.

We create value across the product life cycle, from pre-clinical stages, through phases I, II and III, to launch and beyond, and right up to LoE. Our complete range of best-in-class services are built on the bedrock of our long-established and superior competitive intelligence capabilities.

With four offices across three continents, and over 25 languages spoken, we can offer global support as well as work as one global team, collaborating and sharing our expertise across geographies.

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