Unleashing Pharma from the R&D Value Chain

The industry’s innovation crisis will not be solved by quick fixes. Reconfigured value chains will give rise to new business models.
Executive Summary

A cure for the pharmaceutical industry’s innovation crisis has yet to be found. During the past decade, new molecules output decreased steadily from ~30 NCE per year to ~25 NCE per year while R&D costs more than doubled. Many of the attempted remedies may even be responsible for the high attrition rate of pharmaceutical R&D projects. Open innovation, currently trapped in an unsustainable coexistence of both end-to-end in-house capacities and extensive partnering, has yet to deliver its promise. What will future pharma business models look like? In this study we take a fresh look, with a focus on the R&D value chain, and offer five key insights gained from the study’s analyses:

1. **Quick fixes, such as outsourcing R&D services, have not saved productivity.**

   While the contract research organization (CRO) industry has grown by 10 percent per year since 2001 as a result of extensive outsourcing, capacities are still maintained for almost every step. Make-or-buy decisions appear to be opportunistic and cost driven. This is no basis for long-standing innovation partnerships—such as those between industry and academia, for example.

2. **Constant changes in R&D portfolio prioritization reduce creativity—and destroy pipeline value.**

   Up to 50 percent of all decisions to terminate projects have no scientific or medical rationale, but rather occur for financial or “strategic” reasons. But strategic management decisions require long-term tactics, to align with pharma’s characteristically long development time. As a result, creativity is reduced and potential pipeline value is destroyed. Talented, passionate “drug hunters” are essential for success, but volatile portfolio decisions are not conducive with their needs and as a result they have all but disappeared in many big pharma companies over the past decade.

3. **There is a clear breakpoint in the R&D value chain between front-end discovery and late-stage development.**

   The clinical proof-of-concept stage separates high-risk, front-end innovation projects from well-planned, achievable development programs. Planning and execution require distinct capabilities; some pharmaceutical companies already recognize this and adapt their internal organizations according to the capabilities and risk profile of the two value-chain stages. We predict significant movement toward a clear separation of the two models—for example, via spin-offs and carve-outs. Pharma companies focused on a successful future of profitable growth will have reconfigured value chains, new equity stories, and new business models.

4. **Pharma value-chain reconfiguration will result in two main new business models.**

   - “Discover Molecules”: Pharma companies embracing this model will cease launch and marketing activities and focus their business model on technologies delivering clinical candidates for as many indications as possible—similar to today’s biotech companies, but with a much better ability to scale. Indeed, their business model is infinitely scalable, as they develop new drugs for global markets. Creative drug hunters are likely to be found and better nurtured in this environment.
• “Implement Therapies”: Other companies will perform market-driven development and launch programs. They will source their entire pipeline externally, manage regulatory complexity on a country-by-country basis, expand their market access capabilities, and introduce new, value-based offers—for example, in e-health. In addition, thanks to the highly capable CROs and contract service organizations (CSOs), the outsourcing boom has produced, new alliances will be forged. In niche and specialty markets, where capabilities are present or affordable, hybrid players can be expected to cover end-to-end value chains.

5. **Pharmaceutical companies will need to actively select and sharpen their business model before uncontrollable market forces drive the change.**

Pharma companies that focus on one of the two business models will stand the best chance of success—trying to adopt both at the same time will invite a high risk of failing in both. The business model decision should be guided by a clear understanding of their competitiveness along the value chain, and its implementation should be based on sound, individual strategy. Only by adhering to these principles will a compelling equity story—a prerequisite for profitable future growth—be created.

For companies that adopt a wait-and-see approach, the combined and increasing difficulties in both market access and R&D will bring margins down and create much bigger problems in the years to come. In other words, the time to act is now.

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1 NCE is new chemical entity.
With years of prize-winning research, lucrative growth, and strong profits from new proprietary drugs, the pharmaceutical industry has been a role model for translating cutting-edge science into economic success. However, a dramatic slump in research and development (R&D) over the past decade has left the industry in a drug innovation crisis.

In response, the R&D value chain is about to be broken up with a sharp focus on distinct steps by industry players, and a complete, rather than partial, outsourcing of others. This restructuring will bring about new business models and open the door for new entrants and new alliances. It will also increase the risks for established players.

If there was ever a time for big pharma to sharpen its business model with a clear understanding of competitiveness along the R&D value chain—it is now.

Sluggish R&D is Cause for Alarm

The translation of biomedical science into medicine has scarcely been questioned as a business model. Images of laboratory research still figure prominently in the annual reports of big pharma companies, but it has become increasingly clear that what those images show—scientific discovery being converted into high-value medicine—has become a matter of concern rather than of pride.

The dramatic decrease in productivity of pharma R&D over the past decade has not gone unnoticed. While some optimism returned in 2011, thanks to the 30 new molecular entity (NME) approvals recorded by the Food and Drug Administration (FDA) which represented the highest number since 2004 when 36 NMEs were approved, it is quickly dampened by the price tag.

A Tale of Three Mergers

An equity story sparing R&D expenses from cost synergy targets is not likely to get investor support today as more investors expect R&D cost cutting. This certainly differs from yesterday’s pharma industry where building critical mass in R&D was often the number one reason for consolidating. For example, in 1996 when Ciba and Sandoz formed Novartis, there were no immediate R&D cost savings and the first site consolidations did not begin until five years later. In 2000, Glaxo Wellcome and SmithKline Beecham formed GSK. The company planned to consolidate R&D operations to reduce operating costs by $370 million and capture another $1.8 billion from cost synergies—all of which would be reinvested in a new R&D spend of approximately $3.6 billion. More recently, in 2009, Pfizer’s acquisition of Wyeth promised operating cost synergies worth $4 billion, more than 30 percent to be delivered by R&D.
From 2009 through 2011, $128 billion was spent annually on drug R&D, compared to $78 billion spent per year from 2002 through 2004. The outlook appears no better: In 2011, 29 new filings for approval—tomorrow’s drug hopefuls—were received, compared to 32 in 2004. This marks the end of a decade in which the money spent on R&D and the number of companies active in drug R&D more than doubled (see figure 1).

The capital markets do not expect pharma R&D to recover quickly. Its market value, reflected in a $42 market capitalization of big pharma per R&D dollar spent in 2001, was almost halved to $20 in 2011. As a result, R&D budgets have become subject to cost cuts in the same way as other operating expenses have been. Researchers working for big pharma companies confirm that cost-cutting initiatives are ongoing, but the trend becomes most striking in mergers and acquisitions (M&A) where reducing R&D costs has become the rationale for many deals—replacing the creation of critical mass or consolidation of operations as the main reasons for M&A (see sidebar: A Tale of Three Mergers on page 4).

Yes, the pharmaceuticals industry has learned to economize in R&D with a round of cost-saving and efficiency improvement programs—from stringent portfolio management and concentration on a smaller group of therapeutic areas to the outsourcing of R&D services to contract research organizations (CROs), many of them operating from low-cost countries. But none has changed the industry for the better (see sidebar: No Rescue in Sight on page 6).

Figure 1
**R&D activity has more than doubled in the past decade, but new molecule approvals have dropped**

<table>
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<tr>
<th>Year</th>
<th>Number of companies</th>
<th>Global R&amp;D spending by world’s top 500 pharma companies (US$bn)</th>
<th>Number of companies performing pharma R&amp;D</th>
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<td>1999–2001</td>
<td>42 (49%)</td>
<td>59.0</td>
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<td>131.7</td>
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<td>2009–2011</td>
<td>44 (51%)</td>
<td>131.7</td>
<td>2.455</td>
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Note: FDA is the U.S. Food and Drug Administration. Percentages may not resolve due to rounding.
Sources: Parexel Sourcebook Biopharmaceutical R&D Statistical Sourcebook 2011/2012, Food and Drug Administration Center for Drug Evaluation and Research

2 FDA Center for Drug Evaluation and Research (CDER)
3 EvaluatePharma, Parexel
The pharmaceutical industry has gone through a round of cost-saving and efficiency improvement programs, but none has transformed the industry for the better. For example, portfolio management processes now make R&D projects compete for funding based on commercial attractiveness and feasibility of development rather than just allocating funding by area or department. While this barred even more money from being spent on projects with little chance of success, estimates of a strategic attrition rate of more than 50 percent mean that half of the R&D efforts are lost not to biomedical complexity but to deficiencies in the planning process. Given that the planning process should focus all of R&D’s creativity on addressing biomedical complexity, this is not good news (see sidebar: Strategic Attrition: A Hidden Value Killer on page 11).

Additionally, R&D is increasingly concentrated on fewer therapeutic areas, both in response to reduced resources and to sustain (or reach) critical mass, leading to about €1 billion being invested on average per year in a single therapeutic area. This alone is not a sign of productivity. Yet, focusing on therapeutic areas has not only failed to rein in R&D costs, but also decreased innovation performance in all areas except the big four: oncology, anti-infectives, central nervous system, and cardiovascular (see figure A).

Further, to allow for more flexibility in managing operating costs, companies have outsourced some services such as DNA sequencing, chemical synthesis, and safety pharmacology testing. Here, contract research organizations (CROs) gained the advantage, capturing a rising pharma services outsourcing market that grew 10 percent per year from 2003 to 2011—faster than the 7 percent yearly R&D spending rise by the world’s top 500 pharma companies in the same time frame. Based on scale effects and a lower cost base by CROs operating from low-cost countries, outsourcing has the potential to save pharma companies 20 percent per year on average.³

But the larger and still growing CRO market has not helped increase overall innovation in the past decade. So it is difficult to believe that the projected 5.2 percent annual growth of the CRO market until 2015—again higher than the projected 2 percent growth in global R&D spending—will rescue R&D productivity (see figure B).
Open Innovation: Can it Materialize in the Current Business Model?

In addition to outsourcing R&D services to emerging market-based CROs, pharma leaders began establishing their own R&D sites in these countries. The intent has not been to recreate the big U.S. or Europe-based organizations but rather to gain access to innovation now emerging in Asian science and research clusters. Biopolis in Singapore is a good example.

This desire for external innovation—“innovation sourcing”—is not restricted to emerging countries, and goes beyond outsourcing R&D services. While services outsourcing operates mainly on a fee-for-service basis, innovation sourcing operates on a contract basis with external R&D players—companies or academic institutions—that feed the product pipeline. These contracts specify license fees, milestones, and royalty payments in the case of successful drug development.

Today, hardly any announcement of R&D restructurings and savings comes without aspirations to increase the proportion of externally sourced pipeline assets. In the past three years, this share grew from 35 to 40 percent in the pipelines of the top pharma companies.\(^5\) Open innovation initiatives, known mostly from the consumer goods industry, have been adopted by pharma companies, for example Eli Lilly’s Phenotypic drug discovery program (PD2) and target drug discovery initiative (TargetD2). Both programs reach out to a community of scientists for new target or lead compound ideas, a community that consists of biotech companies and researchers around the world. The idea is that small players, start-ups, and biotechs are, as a whole, more efficient and innovative than a big central research laboratory.

Has innovation sourcing actually led to a more efficient capacity reallocation in the marketplace? The short answer is no. Generally speaking, big pharma companies that employ open innovation have not taken the strategy to the next level and adapt their internal structures accordingly. For example, much target and lead discovery continues in-house.

In addition, the researchers seem not to use the capacity freed by innovation sourcing to pursue other ideas in other areas. The majority of biotech licensing deals and active projects in pharma R&D still focus predominantly on the big-four therapeutic areas served during the last decade: oncology, central nervous system, anti-infectives, and cardiovascular, although the latter are rarer in the pipeline than in recent approvals, as mentioned above. Pharma companies, it seems, are a lot like people—far more comfortable in their areas of interest and expertise.

However, it is highly doubtful that the buildup of target and lead discovery capacities by biotechs and academic laboratories to serve big pharma’s R&D in a few therapeutic areas is sustainable when, at the same time, big pharma continues to operate its own research centers serving the same therapeutic areas. These old R&D habits will likely not solve the innovation crisis.

\(^5\) Citeline, Inc
Overhauling the R&D Value Chain

The most frequent answers to the sputtering pharma R&D engine are to add fuel (more open innovation) and reduce weight (trim costs in all standard processes). Yet neither of these solves the problem. We believe the pharma engine needs a complete overhaul, and thus a fresh look at which parts are core, which are supportive, and where the power conversion—in this case from science to medicine—takes place. Still, many people in pharma R&D believe that the discovery of the molecule, that is, the new chemical entity, made proprietary by a composition-of-matter patent, is where the value is generated.

Our strategic analysis of the R&D value chain focuses on answering two questions: Where are a company's unique capabilities in the value chain? How relevant are these capabilities to building a competitive position?

In pharma R&D, most steps require distinct, hard-to-imitate capabilities, given the inherent difficulty of a process characterized by high levels of attrition. But attrition is not evenly distributed along the pipeline. For instance, projects in lead discovery have almost no chance of entering the marketplace but a reasonable probability of entering the next phase (see figure 2).

Most attrition occurs in the early clinical phases. Once a project survives phase II, it has a reasonable chance of reaching the marketplace. Thus, the critical step that transforms a project from a high-risk vision into a product in development with realistic timelines and success

Figure 2

Patent application is far from being a value-critical step in drug R&D

Note: The entire process typically takes 10 to 15 years.
Sources: Parexel, Morgan Stanley, A.T. Kearney analysis
probabilities occurs long after the molecule has been discovered and the patent filed. This overall picture is true across therapeutic areas: While development times vary widely between therapeutic areas and acute versus chronic indications, the overall clinical success rate in all therapeutic areas from phase I onward is in the 7 to 15 percent range.

The belief that the molecule front end constitutes a strategic innovation step—where all projects have a 90 percent likelihood of failure in spite of all scientific advances—is inconsistent with observations and can be explained only with the chemistry heritage of pharma companies. So far, no company has demonstrated a reliably consistent quality of its biological targets or a magic bullet approach that reduces the attrition rate between the time a patent is filed and the clinical proof of concept where most projects die.

Why then assign strategic importance to preclinical candidate molecules and keep them in-house? All that is known about projects at this stage is that they will, with 90 percent probability, never contribute a single dollar worth of sales. At the same time, the performance of the back end (developing and registering drugs) is not only expensive but becomes increasingly crucial. Even clinically successful phase III trials can signal losses if they fail to convince healthcare payers to reimburse an innovation premium on a new drug.

It is time to take a fresh look at the key steps in the R&D value chain and define competitiveness from there.

A Fresh Look Finds New Business Models

Imagine a pharma company that identifies late-stage clinical development as a distinct core competency, compared with other steps along the value chain. The next question should not be how to make the other steps cheaper or more efficient, but rather whether it makes sense to exit them altogether. Exit becomes an attractive option once assets no longer produced in-house are available in the marketplace, which seems to be the case for pre-clinical drug candidates. The early steps of the R&D value chain are likely to be commoditized as access to biomedical knowledge increases.

Take, for example, target discovery: Since the human genome sequence was published more than 10 years ago, all companies now share the same knowledge about the sequence of the 23,000 human genes. There will be no new targets to be cloned or discovered. As for disease correlation, biomedical researchers worldwide are linking genetic information with disease biology, and much of this information is in the public domain. Consequently, the number of academic labs and startups performing early and preclinical drug R&D is on the rise.

Will it be feasible from an organizational standpoint for an established big pharma organization to exit certain research activities? In doing so, will the company lose critical skills that are needed in other value chain steps and thus endanger its success?
A look at the current management setup of big pharma R&D units shows diverse organizational designs converging on the same transition point: A science-driven discovery organization takes projects to the early clinical phase, where a business unit- and franchise-driven development process takes over. Each unit is equipped with the necessary know-how to perform its part of the value chain. Figure 3 illustrates this. Company A has separate research units focused on specific diseases, while Company B assigns pre-proof-of-concept research to its science-driven drug discovery organization. Novartis Institutes of Biomedical Research (NIBR) is a case in point for this model. At NIBR, Novartis carries out pre-proof-of-concept discovery based on biomedical signaling pathways independent of its pharmaceuticals commercial organization.

In almost all cases studied, project handovers take place at the clinical proof-of-concept stage. When a pharma company separates these two tasks—discovery of molecules that work in patients and development of therapies based on these molecules—into two organizational units, is there any reason not to expect this separation to appear in the marketplace?

The logical conclusion drawn from this analysis is for a pharma company to exit the pre-proof-of-concept phase completely, and leave the front end—let’s call it the discover molecules business model—to others and focus on the critical steps closer to the market, which we call the implement therapies model. The viability of the discover molecules business model is demonstrated every day by biotech startups, including the venture capital-funded university spin-offs that are rich in science but not equipped to perform late-stage clinical development.

Yes, a pharma company without molecular biologists and medicinal chemists seems radical. But when Chris Viehbacher, chief executive officer of Sanofi, said, “My goal as CEO is never to
inaugurate a new R&D center,” it suggested that the separation of these two business models could be just around the corner (see figure 4).

Figure 4
What will the innovation landscape in pharmaceuticals look like?

Notes: CRO is contract research organization. CSO is contract sales organization.
Source: A.T. Kearney analysis

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6 Parexel Biopharmaceutical R&D Sourcebook 2011/2012
Shaping a New Business Model

We expect to see a more consistent focus on the implement therapies business model, with a subsequent demand for small molecules and biological drugs creating a broad, transparent marketplace for drug innovation candidates. This will provide an opportunity for both biotech startups and individual research-based pharma companies to develop into full-scale discover molecules powerhouses. Specialty areas will need hybrid business models, which might be called niche-focused hybrids, while an innovation marketplace will continue to create opportunities for new players. What will the advantages for the new players be, and how to seize them? Let’s take a closer look at each business model and the companies that adopt them:

**Discover molecules powerhouses: turning scientific vision into products**

Companies that adopt a discover molecules business model will be more efficient as they are liberated from strategic attrition (see sidebar: Strategic Attrition: A Hidden Value Killer). Because the major incentive of a science- and technology-driven company is to bring clinical candidates to the licensing marketplace, imagine how much more productive preclinical researchers will be without strategic attrition.

The chance for success will be higher as drug candidates are systematically probed across therapeutic areas. For example, sildenafil, the active ingredient in Viagra, was developed to treat angina pectoris, a type of chest pain. Unsuccessful studies for its primary treatment paved the way to another use, which made it a blockbuster. A discover molecules company would not leave its potential next Viagra story to serendipity or allow it to be prevented altogether by

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**Strategic Attrition: A Hidden Value Killer**

All innovation project portfolios are subject to attrition rates. For example, technical or clinical attrition occurs when a compound fails to demonstrate efficacy or safety and will not be approved as a new product. Strategic or financial attrition occurs when a project is stopped because the commercial outlook changes. This is largely independent of project progress and often the result of R&D strategies being shorter lived than R&D projects.

Project terminations are not published in early or middle stages, but recent estimates show that up to 57 percent of all pharma project terminations between 2001 and 2010 were the result of nontechnical (that is, financial or strategic) reasons. In other words, had the commercial strategy been more stable in the first place, half of these projects would not have claimed resources at all. Another view is even less flattering to portfolio management: Assuming equal technical attrition rates for strategic and nonstrategic projects, R&D output would double if the nonstrategic projects were given their chance to succeed in other companies.

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7 Citeline, Inc., Parexel
the narrow therapeutic area focus of today’s big pharma R&D departments. It would simply be offered to another therapy developer interested in different indications.

In addition, the equity story will be sharper as capital markets understand the high-risk, high-return nature of investing in discovery molecules. Research capabilities are gauged by discovery performance rather than discounted due to issues of a mature business. This risk-conscious selective investment seems to be an increasingly attractive option for big pharma R&D, evident in AstraZeneca’s search for alternative sources of funding for its projects as one example. An alternative source of funding for the R&D portfolio may emerge—and with it a new business model.

**Implement therapies companies: developing, registering, and marketing medical treatments**

Companies in the implement therapies business will see costs fall due to an improved risk profile. Although their Profit & Loss (P&L) statements will show higher milestone payments and licensing fees, R&D costs for sunken projects will be much lower. It is more attractive to pay a license on a successful product than to maintain preclinical R&D organizations that spend 90 percent of their resources on products that will not make it. The implement therapies companies can turn the not invented here syndrome to their advantage as external pipeline assets will be analyzed certainly more objectively than the internal projects.

Performance will improve thanks to a sharper focus on critical late-stage clinical development and market access. With increasing pressure from payers, a significant advantage will be the delivery of healthy economic outcomes in late-stage development. Furthermore, a successful late-stage developer will get better deals from the discover molecules side because researchers always want to see their discoveries translated into products.

Competitiveness will increase as resources are free to go beyond molecules to develop integrated solutions for the patients they serve—incorporating drugs, devices, diagnostics, services, and disease management information technology (IT) platforms. These resources will be far more competitive and harder to imitate than a single drug molecule. Sanofi, for example, offers diabetes patients everything from insulin pens to iPhone-compatible blood glucose measurement. Many more integrated offers can be created as the organizational focus shifts from molecules to patients. And, as described in “Pharmaceuticals Out of Balance: Reaching the Tipping Point,” the pharmaceutical company of the future will be fully connected—establishing an R&D value chain focused on freeing resources and attention to manage these connections and develop new therapies.

**Niche-focused hybrids**

In some therapeutic areas, companies will not gain immediate access to pipeline assets offered outside niche indications, such as inborn metabolic or infectious diseases with only local spread. Niche projects do not attract biotechs at the same level as the more prevalent oncology or neurodegenerative diseases. Hybrid niche-focused companies will need to keep parts of discovery in-house to establish new therapies for their niche hybrids, but are still likely to profit from a broader offer of drug candidates thanks to the discover molecules players.

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9 Pharmaceuticals Out of Balance: Reaching the Tipping Point, available at www.atkearney.com
New players

The emerging innovation landscape has options and implications beyond the business models already discussed in this paper. A restructuring will open the door for new alliances. CROs, generics, and mid-cap pharmaceuticals are part of today’s pharmaceutical landscape, but with the prospect of more innovative product candidates landing in the licensing marketplace, we will see more development alliances—or even mergers—in the implement therapies field.

Furthermore, downstream of the pharma R&D value chain, healthcare is rapidly evolving. Hospital chains are consolidating, telemedicine and managed-care networks are proliferating, and payers are becoming adept at orchestrating everything. For some players, such as large intensive-care hospital chains, a backward integration into the implement therapies space is conceivable. Imagine a hospital encounters a problem that big pharma is not interested in solving, a discover molecules business offers a potential solution, and a CRO has a feasible development project. Such alliances will be a by-product of the reformation.

From all of this comes the realization that operations must be untangled: From procurement, production, and distribution, to finance, IT, and human resources, the two basic models—discover molecules and implement therapies—have different needs and processes. Untangled, the operations of both will be free to focus on their value propositions (see figure 5).

Figure 5
Unbundling two ends of the R&D process allows a focus on value

Traditional pharma

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<th>Administration</th>
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Future pharma

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<td>Hire disease specialists and franchise managers</td>
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Source: A.T. Kearney analysis
The Time is Now

There will be no one-size-fits-all solution. Pharma executives will need to make some choices: Where in the innovation pathway is your company most competitive, and which business model will you pursue? Some therapeutic areas offer more options to externalize the front end than others. Distinguishing capabilities differ as preclinical R&D labs are crown jewels in some companies and under-deliver in others. Executives do not yet know whether their newly established market access department will be a competitive asset. Yet transformation always requires a sound understanding of one’s distinct capabilities and position in the future innovation landscape. Therefore, choosing a strategic position based on an unbiased analysis of the R&D value chain is vital.

The pressure on the current pharmaceutical model is too high, and the inconsistencies too obvious to believe in a recovery. Given the overall attractiveness of the healthcare market, new actors and alliances will emerge to play by the new rules and find new medical solutions. It is time to actively shape your business model rather than waiting for new value chains to grow around you.

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The signature of our namesake and founder, Andrew Thomas Kearney, on the cover of this document represents our pledge to live the values he instilled in our firm and uphold his commitment to ensuring “essential rightness” in all that we do.