Russell Reynolds Associates

Innovation Leadership

Enhancing Scientific Acumen in the Pharma Boardroom

Introduction

Developing new drugs always has been difficult and high risk, but current trends in the overall healthcare market are making research and development (R&D) in the pharmaceutical industry even more challenging. Longer product development cycles, ever more stringent approval requirements and greater scrutiny of pricing mean most pharmaceutical companies struggle not with a lack of good science but with how to deliver that science in the form of effective and affordable medicines.

DRIVING CHANGE FROM THE TOP

The pharmaceutical industry continues its high commitment to address and solve unmet medical needs and to provide access to healthcare around the globe. However, to adapt to the changing market realities and ensure long-term value creation, pharma companies will need a new generation of confident, innovative, adaptable leaders. Functional and business executives will have to have the learning and decision-making skills to evolve business models, move away from the process culture that governs many organizations today, and put the delivery of science center stage [Ref 1].

Fundamental changes are necessary at the highest levels of leadership in the pharma industry. R&D professionals and their science groups cannot create a new innovation paradigm alone—they will require an integrated and balanced leadership team at the very top of the company, including at the board level, to be part of the solution.

Conventional R&D Models Under Threat

The recent surge in product approvals has been welcome news for the pharma industry. In 2014, the U.S. Food and Drug Administration approved a record 50 novel new drugs (new molecular entities and biologicals), well above the annual average of 33 over the past decade [Ref 2].

However, the cost of bringing a product to market also continues to rise. According to a 2014 report by Deloitte, the average cost of developing a new medicine has risen for the fifth consecutive year and now sits at over US$1 billion [Ref 3], and other studies have estimated the average costs to be as high as US$4 billion for every drug that is approved [Ref 4]. Not surprisingly, this has created even more pressure and focus on developing medicines that will achieve blockbuster status, a status that less than one in every three new drugs ever achieves.

RETHINKING THE R&D MODEL

As productivity in pharma R&D has struggled, there has been a tendency to blame the science. However, a key factor to improving productivity is avoiding failures in the final, most crucial and expensive Phase III development stage.

Not surprisingly, the priority for many pharma companies has become more about managing risk. For decades, the traditional approach to mitigating the risk of clinical failure in the pipeline has been either to diversify or to expand "shots on goal." But recent moves by some of the industry's major players suggest that firms are starting to change or at least vary their tactics, along the lines of two major archetypes:

- **Buying a pipeline.** There has been a tremendous surge in merger and acquisition (M&A) activity among pharma firms as one way to rapidly and materially augment their pipelines. In 2014 alone, deals topped US$200 billion—well over twice the average volume over the past decade [Ref 5 and 6]. However, the nature of these deals also has changed. Companies are increasingly focusing on the therapy areas in which they have or want to build core capabilities, and are either bringing external assets completely in-house or are partnering with other parties in innovative deals to harness their expertise.
- **New approaches to R&D.** Pharma companies have also made changes to their own approaches to R&D. For example, over the last few years, between a third and a half of pharmaceutical companies have reorganized their R&D function, and this trend does not seem to be slowing down. Other pharma companies have pursued a strategy of outsourcing. A 2014 PwC report foresees that at least 40% of large pharma R&D spend will be outsourced in the next years and for instance, clinical operations, may even be outsourced entirely [Ref 7]. Finally, there has been a distinct proliferation in the development of drugs targeting the orphan and rare disease space, which for the moment seem more immune to pricing concerns.

MOVING THE NEEDLE

Despite these trends, it is difficult to predict what tweaking the traditional R&D model or buying new assets will do to "move the needle" on innovation and productivity overall. There is an acute need to address the key operational issues of organizational complexity, inefficient decision making and incentive systems that seem to be more aligned with activity and process milestones rather than real results.

To address these challenges, pharma company executives will have to have the courage and the competencies to make bold, strategic decisions, and drive fundamental change through their teams.

Major Archetypes of Change—Some Company Examples

BUYING A PIPELINE

The recent asset swap between Novartis and GlaxoSmithKline (GSK) is a good example of the new trend in more innovative business transactions. In March 2015, Novartis finalized the sale of most of its vaccines business to GSK for around US$5.3 billion and agreed to combine its over-the-counter medicines business with GSK's under the British company's management. In return, Novartis agreed to buy GSK's cancer unit for around US$14.5 billion [Ref 8].

Also in March 2015, Ignyta, a precision oncology biotechnology company, announced its acquisition of the worldwide rights and assets relating to four of Teva's targeted oncology development programs in exchange for 1.5 million shares (6%) of Ignyta's common stock.

Disappointment in the outcome of their own pipeline over the past few years has encouraged other large pharmaceutical companies to take an alternative approach by buying small, innovative firms with promising ideas. For example, in 2014, Merck announced its intention to acquire biotechnology firm Idenix for US$3.9 billion to step up Merck's research pipeline for hepatitis C treatments. Similarly, one of Merck's main rivals in this area, Gilead Sciences, paid US$11 billion for a relatively small company, Pharmasset, in 2012.

NEW APPROACHES TO R&D

GlaxoSmithKline pioneered a new approach to R&D some time ago, focusing on empowering and incentivizing the performance of individual research units in an effort to increase productivity. However, in 2014, they went back to the drawing board, made deep cuts to R&D, and revisited the overall structure.

Roche has been through one of the largest R&D reorganizations following the buyout of Genentech, exiting its historical location in Nutley, New Jersey, and establishing the gRED and pRED focal points within its R&D organization.

Novartis has limited itself to some minor tinkering as it pushes ahead with some major new franchises, while Eli Lilly has resisted the reorganization trend in R&D but has chopped US$1 billion out of its R&D program.

Pfizer has also made big cuts to its R&D program, and has a thin pipeline as a result. In an attempt to address this, the company has been pursuing a previously discredited mega-merger strategy, including proposing an ultimately unsuccessful tie-up with AstraZeneca, which is in the middle of reorganizing its own R&D operation.

Finally, some other pharma companies are focused on optimizing their R&D footprint, centralizing the function (e.g., Bayer, Takeda) and/or moving to locations which allow for better access to science and technology such as Boston/Cambridge, Massachusetts (e.g., Amgen, Baxalta) and Cambridge, United Kingdom (e.g., AstraZeneca).

What is Required?

BRINGING SCIENTIFIC ACUMEN INTO THE FOLD

A number of key pharma industry trends identified above—consolidation, regulatory uncertainty and changing product portfolios, among others—have raised serious questions about the conventional pharma R&D model. In addition, the challenge of growing shareholder value means that the effectiveness of a company's leadership in terms of delivering on innovation is more critical than ever before.

We believe that more effective decision making regarding R&D and, more important, the visionary strategies necessary to drive innovation require greater scientific experience and expertise among the industry's senior leadership. In fact, in our view, this is the only way to drive the industry onto its next growth curve.

I) R&D LEADERSHIP—EXTENDING A COMPETENCY SET

Arguably, the traditional technical-based skills of R&D leaders are becoming more of a commodity with respect to the success of pharma companies as they seek to deliver more innovation. Now, factors such as the ability to develop strategy, deal with ambiguity, make complex, multi-dimensional decisions, and inspire and drive change will become the mission-critical qualities of senior R&D executives.

In order to facilitate successful innovation, top-level R&D leadership must have the relevant scientific know-how as well as the ability to:

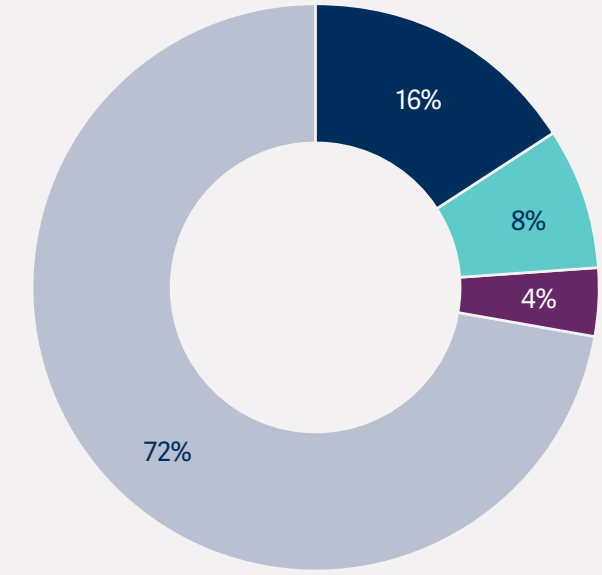
- Lead and inspire innovative teams with the right analytical skills in order to form a more global, integrated and streamlined organization.
- Face and influence internal and external stakeholders concerning the vision for the overall portfolio, as well as throughout a product's life cycle.
- Foster a truly strategic mindset in the R&D team to collaborate with other parts of the business such as Finance, Strategy, Business Development and Commercial to deliver on the pipeline's full potential.

II) CEO LEADERSHIP—FILLING THE INNOVATION GAP

Much has been made of the shortage of scientific expertise at the chief executive officer (CEO) level in today's pharma industry. Our analysis of CEOs of the top pharmaceutical companies endorses this view and demonstrates a clear lack of scientific backgrounds and specific pharmaceutical industry R&D experience. Among the top global pharma companies [Ref 9], more than 70% of CEO seats are held by non-scientists* (Diagram 1), and 80% have had no industry-specific R&D experience (Diagram 2).

Despite their lack of personal, hands-on R&D experience, innovation remains high on the strategic agenda of the top pharma CEOs. The dominant approach today is to rely heavily on their top team for the proper scientific guidance. Our analysis shows that all 25 top pharma companies have an R&D seat on the executive committee, albeit with varying job titles such as head of innovation, chief scientific officer or head of R&D. By comparison, only half of companies viewed to be innovation leaders in a recent PwC studies have an R&D or scientific seat on their executive committee [Ref 10]. Despite the presence of R&D on the executive committee in the pharma industry, the approach appears to remain too silo'd for real breakthrough to occur. The question remains: What more do pharma companies, and their CEOs specifically, have to do to advance the innovation agenda effectively?

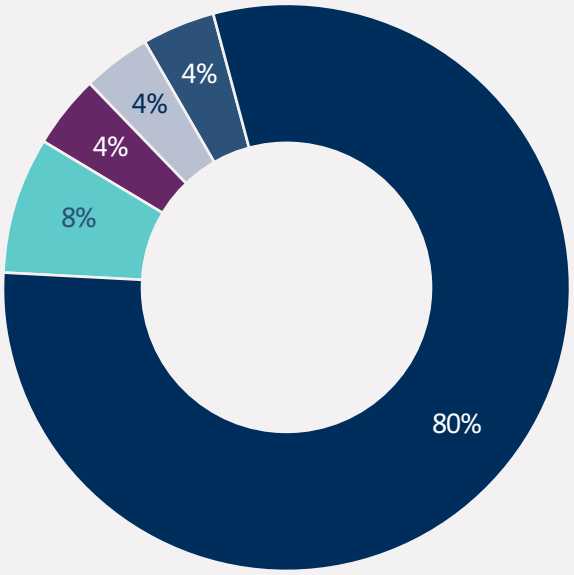
DIAGRAM 1: POSTRGRADUATE QUALIFICATIONS OF CEOs AT THE TOP PHARMACEUTICAL COMPANIES



Scientific Postgraduate qualification
Medical Doctor
Veterinary Doctor
Non-scientific qualification*

* Non-scientists refers to those with no postgraduate qualification and those with a non-scientific postgraduate qualification (e.g., chartered accountant, juris doctor, M.B.A., non-scientific master's degree or Ph.D.).

DIAGRAM 2: PHARMACEUTICAL INDUSTRY R&D EXPERIENCE OF CEOs AT THE TOP PHARMACEUTICAL COMPANIES, UPON APPOINTMENT TO THEIR ROLE



None
0-4 years
5-9 years
10-15 years
15+ years

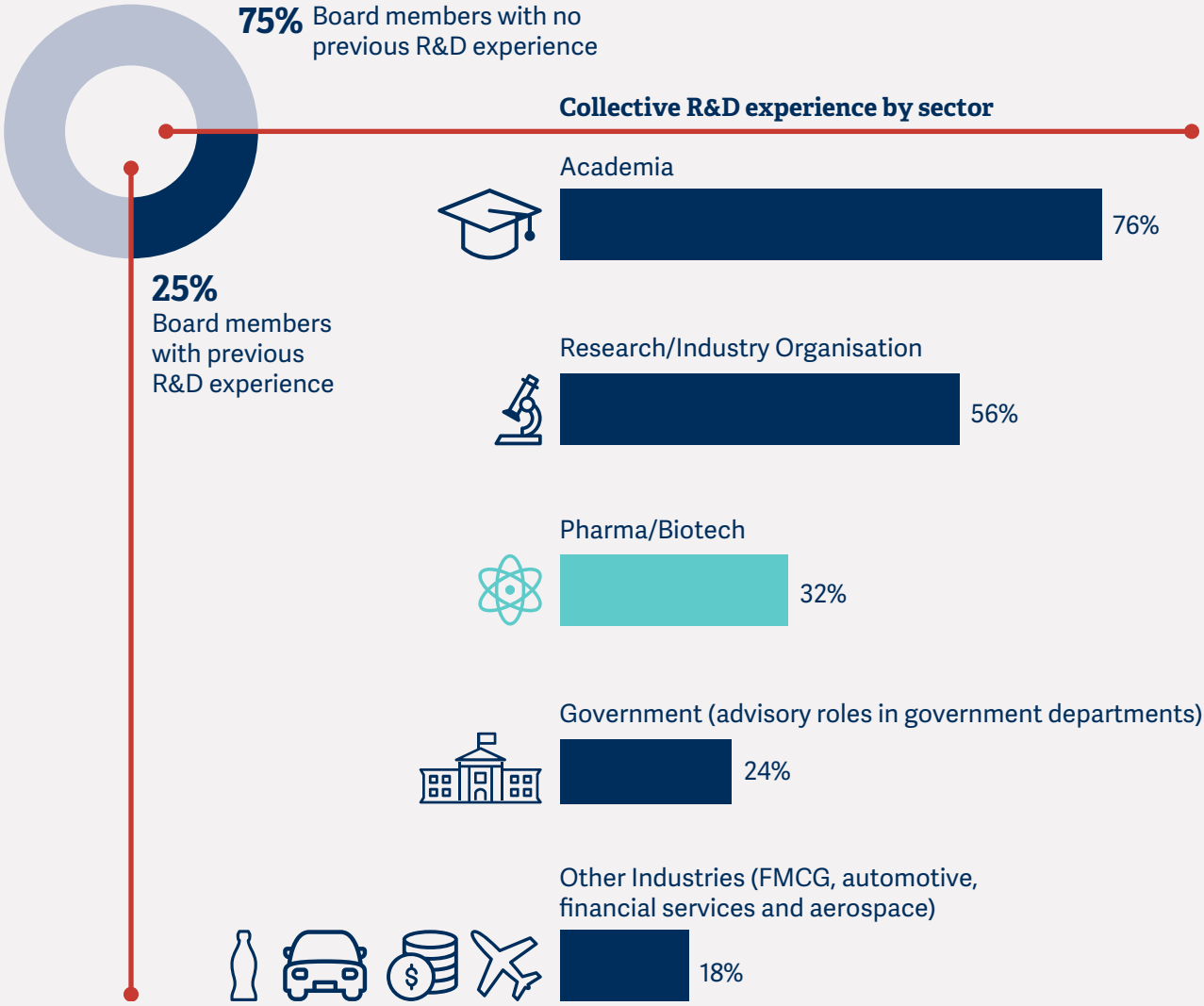
III) BOARDROOM LEADERSHIP—ENHANCING SCIENTIFIC ACUMEN

Pharma companies are under intense pressure to build a board with an optimum balance of domain expertise and multi-industry commercial knowledge in order to fulfill their fiduciary and strategic responsibilities to shareholders. If there is a dearth of scientific expertise among the board of major pharma players, how well-equipped are they to advise their executive management team on effective R&D models required to deliver innovation that addresses the emerging healthcare landscape sharply centered on affordable medicines?

According to our analysis, only 25% of board directors had some degree of R&D experience at the time of their appointment. Of these, a large proportion gained their R&D experience at an academic or research organization (or both), while only about a third (32%) had actual pharma industry R&D experience (Diagram 3) [Ref 11].

The need to increase scientific representation at the board level has evidently been playing on the minds of many organizations, illustrated by a spate of recent board appointments. For example, in the last two years, four out of the top 20 pharmaceutical companies have announced board appointments of directors with scientific, academic and medical backgrounds, including AstraZeneca, Bristol-Myers Squibb, Eli Lilly and Johnson & Johnson, and we anticipate this trend to continue.

DIAGRAM 3: R&D EXPERIENCE



Conclusion

The dynamics of the pharmaceutical industry are continuing to change fast, and the future of the conventional R&D model in particular is uncertain given the sharp focus on affordable care.

Our analysis in the current paper confirms that scientific acumen gained specifically within pharma R&D is lacking in the leadership at the very top of the industry's largest organizations. We believe this is a missing link that threatens the future of pharmaceutical companies.

It is vital for the industry's key players to ensure they have the right mix of the most relevant scientific expertise and experience on their executive teams and in their boardrooms.

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