

# editorial



**Patrice Talaga**

## Open Innovation: share or die...

*'It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change,'  
Charles Darwin (1809–1882)*

The drug discovery industry starts transforming again. It is now well accepted that R&D productivity is declining, and will thus no more be sufficient to drive future growth of the drug discovery industry, as highlighted in a recent report from Deloitte [1]. The overall productivity gap of the pharmaceutical industry can actually be attributed to numerous factors [2] including:

- the fact the spring of the 'low-hanging fruits' (mainly in terms of targets) has now dried up,
- technologies (e.g. HTS) and/or methodologies (e.g. combinatorial chemistry) that have not delivered as originally expected,
- poor clinical validations of genomic targets,
- an excessive reductionism of our drug discovery approaches (e.g. focus on single targets to cure complex disorders such as Alzheimer's or Parkinson's disease),
- the inability to demonstrate significant efficacy,

- poorly innovative management of an evermore complex drug discovery process, etc.

Moreover, increasing R&D costs, decreasing revenues due to patent expirations, impact of generics competition, reimbursement driven by medical and economic outcomes, enhanced regulatory hurdles and rapidly evolving standard of care have thus forced drug discovery organizations to adopt new strategies and business models to improve productivity and innovation of R&D.

Mergers and acquisitions have become traditional ways to increase the number of pipeline candidates, technologies and therapeutic areas. The creation of such mega-organizations will, in any case, not help to solve the problem of the so-called innovation gap. Such strategy does not really deliver breakthrough drugs, but instead often induces a loss of motivation amongst the industrial scientific community because of associated reorganization and downsizing [3]. Sometimes a partial, if not total, extinction of the 'acquired' partner's drug discovery culture can even happen. But what is actually needed? I guess innovative products rather than bigger and bigger companies!

Biotechs are currently considered to be a major source of innovative products. Integrating a Biotech into a Pharma company may actually not be the best solution to generate a successful outcome for both partners. On the contrary, by collaborating whilst maintaining autonomy, each partner could make the best use of its specific strengths – innovation, fast decision-making of the Biotech; financial, resources and drug development experience of the Pharma. This should create a more challenging but friendly environment to discover breakthrough medicines successfully. As recently reported by Ted Torphy, CSO at J&J, 'the future of Research and early Development will have to rely on new business models that should emphasize on capital efficiency, lean infrastructure, flexibility, financial risk and reward sharing, and Open Innovation (OI) as well' [4]. To co-develop innovative breakthroughs with partners like Biotechs, academic groups or drug discovery centres, Pharma companies should start using OI along with new business models reflecting a real mindset of 'sharing is winning', to win the battle of the innovation gap [5].

Open Innovation has been defined as a paradigm that assumes companies should use external as well as internal ideas, paths to market to advance innovative technologies, products to markets via a spectrum of traditional and new business models, for exam-

ple licensing in or out, spinning in or out, joint venturing, setting-up Pharma-Academic consortia, etc. [6]. More recently OI, in the field of drug discovery, has been increasingly implemented through 'corporate venturing', equity investments in university spin-offs, or via governmental funding through Public Private Partnerships (PPPs). PPPs actually constitute an attractive OI business model for Pharma companies to address major issues in the field of R&D, combining expertises from various research communities like Academia, Biotechs and/or drug discovery solution providers [7]. A gradual switch from closed innovation, referring to processes focusing essentially on internal know-how, to OI is currently changing our drug discovery business. It actually started within various business areas ranging from Informatics (e.g. IBM), food industries (e.g. P&G and Nestlé Co.) to drug discovery companies, first exploring this new type of paradigm in the field of neglected diseases [8]. Other potential partners like drug discovery Contract Research Organizations (CROs) should soon enter the scene, which may offer new interesting partnership opportunities.

OI is actually based on networking and several solution providers are offering relevant tools to help partners to increase their business connections [9]. Examples include InnoCentive (<http://www.innocentive.com>), NineSigma (<http://www.ninesigma.com>), YourEncore (<http://www.yourencore.com>), etc. Such open networks, harnessing the collective talent accessible through the Internet, actually enable organizations to more rapidly search out the most appropriate partners for their projects. For example, the business networking platform LinkedIn (<http://www.linkedin.com>) hosts an interesting network (<http://www.linkedin.com/groups?homeNewMember=&gid=54595&trk=>), which allows more than 700 members to share their ideas and thoughts about OI. There is actually room for innovation to identify and attract the best partners. Interesting examples of recent OI platforms include the one from Lilly, a champion of open-source R&D initiatives. Lilly's open collaboration platform 'PD2' (Phenotypic Drug Discovery initiative) uses Lilly's disease-state assays to evaluate the therapeutic potential of compounds coming either from universities, Biotechs or CROs (<http://www.pd2.lilly.com>). Lilly provides the partners a complete biological profile of the compounds tested in four phenotypic screening assays. In return for the data, Lilly has first rights to exclusively negotiate a collaboration with the submitters of the compounds that demonstrate interesting biological activities. SciClips (<http://www.sciclips.com/sciclips/>) is another interesting platform where scientists are invited to submit ideas aimed to identifying novel disease targets or to develop low cost screening assays. Sage is another open-access platform aiming at building complex, predictive models of disease using logistics and data from Merck and seed money from private sources (<http://www.sagebase.org>). Another interesting way to attract potential partners consists in setting-up internal web portals, for example Procter & Gamble's, P&G 'Connect + develop' where people are invited to submit their innovative ideas and commercial opportunities based on P&G's needs (<https://www.pgconnectdevelop.com/pg-connection-portal/ctx/noauth/PortalHome.do>). Even more transformational models are starting to appear within the landscape of OI. For example, the Open Innovation ecosystem built by Philips some years ago, the so-called high-tech campus near Eindhoven in the Netherlands, hosts more than 40 companies and institutes working together in the

development of new technologies (<http://www.hightechcampus.nl/>). Such concept may radically change the way Pharma companies, Biotechs and CRO's work together, allowing scientists to collaborate under what I would term a sort of 'international proximity' paradigm.

### The set-up of (open) innovative partnerships in the drug discovery arena

Transitioning to OI is not an easy task. OI is still in its infancy as far as the drug discovery business is concerned and thus there is no real proof of benefits today. In the early days, research funds dedicated to incentive-based projects, were often provided with little expectation of a return on investment. Engaging into OI should be seriously prepared (see Box 1 for some key points to think about before starting OI) to avoid further disappointment. First of all, an integrated internal process to develop, manage and implement such type of alliances should be set-up before entering into the field of OI. In particular, the management of OI collaborations should be performed in the same manner Pharma industry is actually managing its internal project portfolio. The example of Nestlé's experience in this area nicely illustrates the way to go to change mindset successfully within a company whose innovations came essentially from 'inside' [10]. The basic model which was adopted to start with OI is described in Fig. 1 (adapted from [10]) and may serve as a template for setting-up OI in other companies. The first general principle to adopt, whatever the stage of the partnership, will be to bring together the needs and requirements from one group with the competencies and solutions from the other.

Early stage ideas should fit into what Nestlé called 'benefit areas' simply reflecting the needs of the partners. At more advanced/mature stages, OI will need a clear business focus with goals defined and agreed via risk sharing partnerships agreements. In this regard, business model innovation is crucial to sustain OI! A major issue, especially for newcomers, is actually related to the evaluation of the risk and the costs that such business models will imply, at each phase of the process. For example, for mid- or late-stage collaborations, where risk decreases (as value increases), no or very little cash investment should be requested as the investment needed would mainly rely on expert resources. This may constitute a major hurdle for CROs as existing resources dedicated 'for free' to such collaborative schemes may not be perceived as a successful deal by senior management. OI in principle should ideally lead to co-created values and thus early financial invest-

#### BOX 1

##### Considerations before engaging in the Open Innovation business

- Set-up a clear (open) innovation strategy.
- Exactly define your requirements or needs.
- Get internal business engagement.
- Get an aligned internal view on how to handle IP.
- Explore all kind of OI service providers.
- Make sure your partner meets your expectations.
- Make sure your partner shares the same business philosophy.
- Respect the needs of your partner.
- Allow some failure to build trust.

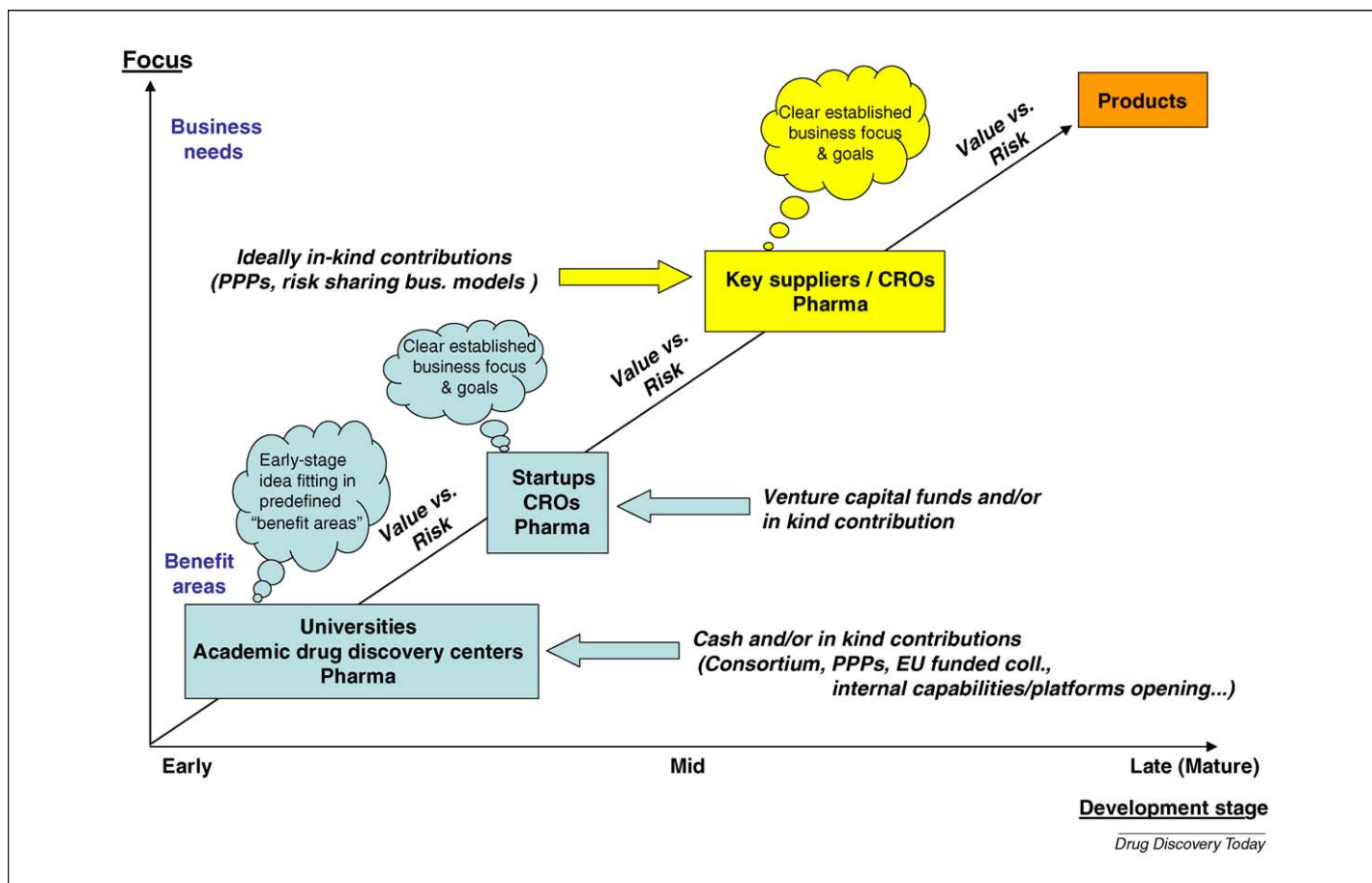


FIGURE 1

Innovative partnership stages (adapted from [10]).

ment, as in typical fee for service or FTE-based agreements, should be delayed until value has been established by the successful accomplishment of a joint project. Cultural and commercial differences between partners may constitute a serious hurdle in the negotiation process towards a successful risk sharing agreement in an OI frame. People will have to trust each other, to see the potential value and to share risks, costs, IP to maximally decrease cash investment at the start of the collaboration. Its actually IP rights which more and more will become the currency that will fuel OI, as noticed by B. Munos, advisor in corporate strategy at Lilly [11]. Partner reward will obviously have to be clearly defined via milestones, royalties' payments, market rights, etc., before starting the partnership, thus providing a clear vision of what can be the return on investment in case of success.

Industry–biotech–academic–CROs–drug discovery centres–collaborations will continue to be of utmost importance in the discovery and development of breakthrough therapies. Most importantly, the OI alliances should be managed in a similar way to how Pharma is managing its project portfolio to allow its successful implementation. But will it be sufficient to make a great leap forward? It is my hope that the global integration of breakthrough ideas, knowledge and expertise from world-wide sources via Open Innovation will significantly contribute to solve the 'innovation gap' issue, and thus to enable the launch of

breakthrough medicines that will be of real benefit to the entire healthcare community.

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