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# Open innovation: A real option to restore value to the biopharmaceutical R&D

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ABSTRACT

The pharmaceutical landscape has changed, and new business models, based on alliances, are increasingly being adopted in this industry. Biotechnology advances have pushed this development, and pooling complementary resources coming from incumbents and newcomers is a key skill to succeed: these are the premises for a quick spread of the open innovation (OI) paradigm in this industry. R&D portfolio selection needs R&D project evaluation, and Real Options Analysis (ROA) is acknowledged as a powerful tool to evaluate uncertain projects that have an intrinsic flexibility. The present research aims to foster the use of ROA in the OI field in order to encourage firms to undertake this innovation model; to achieve this goal the authors propose a closed-form model that is easy to implement, to evaluate the OI initiative for selecting an optimal R&D portfolio. The study wants to support managers in optimal R&D portfolio construction in terms of choosing the most promising products, the means by which the related project has to be undertaken (in an open or closed manner; i.e. licensing-in or not) and the self-financing policy. The proposed model can be easily implemented into a spreadsheet, and the inputs needed to run it are usually requested to evaluate projects using the most used net-present-value-based methods. Moreover, some parameters of the model allow strategic aspects to be considered: for example the nature of the project (core/non-core), the impending project phase, and the risk-sharing opportunity.

The results of the developed numerical example show that the selected portfolio is well balanced in terms of development stages, core/non-core therapeutic areas and, licensing-in (an inbound open innovation solution), is preferred in the case of products at their early stages of development.



## 1. Introduction

Recent studies find that the pharmaceutical industry has faced a problematic period (2000–2010) resulting in an increase in R&D investment achieving a 16% of sales with a 60% increase on the previous decade. This effort does not match the forecasted returns; nevertheless, big pharmaceutical companies cannot avoid relying on R&D, and continue to make it a strong contributor to value creation. Thus, decision-makers should select projects accurately, being sure to choose the most promising, and must consider new paradigm solutions including next-generation licensing and effective precompetitive collaboration with other companies (Dhankhar et al., 2012), without neglecting interdependencies among products and strategic goals. These suggestions imply a proper evaluation of every single project, the enrolment of an open innovation (OI) paradigm in the manager's agenda, and the adoption of a portfolio perspective that is able to incorporate strategic issues into the R&D decisions.

As a matter of fact, the pharmaceutical industry has experienced an advent in biotech newcomers that foster the OI solutions because of the increasing need for collaboration in order to exploit the complementary resources of incumbents and newcomers: Biotechnology innovation has, in fact, been largely pursued through collaborative arrangements between biotechnology firms (newcomers), who accomplish the discovery and preclinical tests and established pharmaceutical companies (incumbents), which typically undertake clinical trials and marketing (Gupta et al., 2007).

Specifically, the adoption of OI in the biopharmaceutical industry has been systematically documented by Bianchi et al. (2011), who point out that biopharmaceutical companies enter into relationships with different types of partners (such as large pharmaceutical companies or product biotech firms) to acquire (inbound OI) or to commercially exploit (outbound OI) technologies and knowledge (Chesbrough and Crowther, 2006).

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The governance of these inter-firm relationships can vary from market to hierarchy-like solutions depending on the characteristics of the partners and of the transaction to be completed (Lo Nigro et al., 2012b); at any rate, these agreements represent an operationalization of the OI paradigm in the drugs R&D field. A key element in the agreements signed between pharmaceutical/biopharmaceutical and biotechnology companies is flexibility. Real Options Analysis (ROA) is acknowledged as a powerful tool to evaluate uncertain projects that have an intrinsic flexibility (Dixit and Pindyck, 1994; Trigeorgis, 1996). In addition, the pharmaceutical R&D process has a long and dynamic life, and further investments depend on the success/failure of previous ones, which then also represent an ideal field of application for ROA.

On the other hand, unlike the closed innovation model, the open innovation paradigm highlights the spectrum of alternatives open to firms during the R&D process; indeed, at any phase of the process, they can decide to start, to continue, to collaborate with others or to abandon the project.

Therefore, as Vanhaverbeke et al. (2008) state, it is surprising that scholars do not pay attention to the existing synergy between ROA and OI. Furthermore, a portfolio perspective is needed to properly allocate the annual budget and to consider the interdependencies among projects. Finally, in order to obtain a balanced portfolio, the objective function has to take into account different aspects, including the possibility of adopting OI solutions to develop each project, as well as a self-financing policy. These considerations underline how important it is for pharmaceutical companies to select a balanced R&D portfolio, which is composed of products almost on the shelves – i.e. at the latter stages of development – and compounds still in the earlier phases of development.

As illustrated in the next section, the literature fails to deal with these "needs" simultaneously, and managers have highlighted this lack (Hartmann and Hassan, 2006): Our research goal is to fill this literature gap, and to this end we propose a realistic real options model (Open OptFolio Light (OOL)) that is able to support pharmaceutical R&D decision-makers in the portfolio selection process by suggesting which projects should be undertaken, the best means by which to develop them (through an open- or a closed-innovation paradigm, i.e. licensing-in or not), and the cross-financing policy.

In the following section, a literature analysis will be conducted to highlight the scientific support of our research goal, and the need to fill the aforementioned gap. Section 3 will focus on the biopharmaceutical R&D project evaluation. The OOL model, which is based on OptFolio (a model available in the literature (Rogers et al., 2002)), is presented in Section 4; in Section 5 OOL is compared to other real options models that are available in the literature to highlight its characteristics, and in Section 6 OOL is applied to a numerical example. In Section 7, conclusions are drawn, the research findings are summarized, and further developments are anticipated.

## 2. Literature overview

Previous research acknowledges ROA as a powerful tool to evaluate biopharmaceutical R&D investments (Cassimon et al., 2004); nonetheless, the evaluation of a single project would not be consistent with a firm strategy that usually assumes a more comprehensive point of view. In order to overcome this limitation, the whole portfolio of R&D projects should be considered. This is especially important in the context of the biopharmaceutical industry, which is characterized by very high failure rates of new drug candidates, and by long time to complete the entire R&D process (Rogers et al., 2002).

Project portfolio selection is crucial in many organizations, which must make decisions on investments, where the appropriate distribution of investments is complex due to varying levels of risk, resource requirements, and interactions among the candidate projects (Berzinsh et al., 2006). In addition, R&D activities have become increasingly costly and risky; hence, measuring their performance and contribution to value is critical (Lazzarotti et al., 2011). While the portfolio management methods employed in different organizations vary greatly, the objectives that managers are trying to achieve are quite similar (Eilat et al., 2006). According to Cooper et al. (1997), an objective that usually dominates this decision process is that of obtaining a balanced portfolio, i.e. diversifying the projects in the portfolio in terms of various trade-offs such as high risk versus sure bets, internal versus outsourced work, etc. To the best of our knowledge, no model is available in the literature that is able to fulfill this multiple need for balance. This research therefore aims to propose a model that is easy to implement and makes it possible to answer this request.

On the other hand, OI is an incentive to integrate technology management and innovation management (Licthnthaler, 2011), and this reinforces the need to evaluate the entire R&D project portfolio, rather than simply considering a stand-alone project.

In addition, OI provides an invaluable tool by which to balance an innovation portfolio and share risk; in the meantime, an actively managed portfolio demands judgments calls. The judgments may well be based on quantitative values and careful measurements, but the shadow of false positive and false negative judgment persists (Bingham and Spradlin, 2011) and can be mitigated by adopting an evaluation method that is able to overcome the underrated problem inherent in the net present value-(NPV) -based evaluation method (false negative in the case of flexible alternatives) such as the ROA. Therefore, OI reinforces the usefulness of ROA in this context.

However, organizations, as pointed out by Hartmann and Hassan (2006), while recognizing the importance of the ROA, do not apply it because it is perceived as a complex concept.

The main contribution to the literature of the present research is to propose an ROA model that is easy to implement, in order to support two critical aspects: (i) R&D projects selection; and (ii) how to carry out the selected projects (internally or externally). Such a tool would represent an operative way to deploy OI. The targeted balance is multifaceted: behind open vs. closed means by which to decline innovation, the equilibrium between products able to produce cash flows and products that need financial sustain is pursued. The model also aims to contribute to the available models, considering the possibility to create a financially balanced portfolio, since it includes a self-financing policy (Enea and Lo Nigro, 2011a) and a tighter control of risk because it includes the option to license the R&D projects. The resulting model is named Open OptFolio Light (OOL). According to Kamien and Schwartz. (1978), the self-financing of R&D for a company is urgent for two reasons. First, external financing may be difficult to obtain without substantial related tangible collateral that can be claimed by the lender if the project fails; an R&D project that fails generally leaves behind few tangible assets of value. Second, the firm might be reluctant to reveal detailed information about the project that would make it attractive to outside lenders, fearing its disclosure to potential rivals.

The output of the model is the composition of the pharmaceutical portfolio, and for each selected drug it is able to suggest whether it should be developed in-house or through an alliance with a biotechnology company, and if (and to what extent) it will finance other projects in the pipeline when it is commercialized.