The impact of external market conditions on R&D valuation

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Abstract

Traditional real options models regard the idiosyncratic risk of a project as the main value driver. Beyond the specific risks embedded in the project, i.e., both its technical and idiosyncratic risk, our model captures the interactions among different market, economic and social forces and their impact on R&D project valuation. Using Fourier series, our model aggregates external forces that play relevant roles in the process that determines the cash flow structure. Consequently, the posited model provides managers and policy makers with a powerful yet flexible tool to stress test several economic scenarios under which the project could develop. In a practical case, we apply our novel model and methodology to the valuation of a pharmaceutical R&D project and examine the impact of external forces on the optimal time to launch the project. The real options approach also allows for the possibility of optimally abandoning a project before completion whenever the investment cost exceeds the expected net cash flow stream after considering the impact of market conditions.

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1. Introduction

Productivity, technology diffusion and innovation driven by R&D have been of major interest for academics and policy makers since the early seventies. However, research progress has been made since the seminal framework of Griliches (1979), which assumes a linear relationship between R&D and firm productivity. Kancs and Siliverstovs (2016), for instance, report a non-linear relationship between productivity growth and R&D expenses. In a recent contribution, Ugur et al. (2016) investigate the firm-level and social impact of R&D and identify conditions for knowledge spillovers. Given these potential economic and social repercussions, R&D spending remains an issue of the utmost relevance for practitioners, academics and policy makers. Specifically, Brautzsch et al. (2015) study the macroeconomic effects of R&D subsidies during the economic crisis of 2008-2009 in Germany, while González and Pazó (2008) analyze the effects of public financing on private R&D investment.

R&D decision making relies heavily on the accurate valuation of the project. In this regard, a widely accepted valuation method is the real options approach. Option-like features allow the incorporation of considerable flexibility into the valuation process, i.e., the project can be optimally abandoned or delayed. In contrast to the discounted cash flow (DCF) method, the real options approach successfully captures the value of the managerial decision-making process.

An uninvestigated issue in R&D valuation is the extent to which such valuation is affected by external economic conditions and the optimal time to launch a project. Indeed, both methods fail to incorporate the contributions of external forces, such as market conditions, economic forces, public opinion, and political influence. Recently, several examples have demonstrated the impact of external conditions on the value of an R&D project. For instance, the 2014 Ebola outbreak revealed the lack of resources and effort allocated by the pharmaceutical industry to combating this virus while it was limited to or contained within African borders. The pharmaceutical industry's interest only increased when the virus crossed European and American borders and "opened a new market".

The aim of this paper is to provide a comprehensive methodology for valuing R&D projects because they are subject not only to technical uncertainty but also to external factors that contribute to the valuation process. This enables the use of stress testing around the optimal market launch based on economic conditions.

To address the above-mentioned gap in R&D valuation research, we propose a model that is able to capture the interactions among different market, economic, and external forces. Fourier series are a simple and flexible mathematical tool to represent a function as the sum of a set of simple sines and cosines. Such a representation allows us to aggregate all the forces that impact the generation of a project's cash flows.

The posited model allows managers and policy makers to stress test several scenarios under which a project may develop. Hence, it can be used to depict any extreme economic and social situation and properly value an R&D project targeting such a market. Furthermore, since some projects are developed with contributions from the public sector —see, for instance, Cockburn and Henderson (2000)—this model can be implemented to determine the appropriate amount of taxpayer money to allocate to a specific project, to analyze strategic interactions, or to incorporate the factors affecting R&D spending. Recently, Hammadou et al. (2014) analyze the determinants of public spending in R&D accounting for several factors such as international context, GDP, or openness. Note that public opinion is a strong force than can substantially affect the value of a project. For instance, the pharmaceutical industry has divided public opinion in several controversial areas, such as animal testing, drug prices, the lack of interest in research on certain diseases, and public funding. However, industries such as nanotechnology benefit from remarkably positive reputation based on their potential benefits and applications in transportation, energy, and environmental science, among others. Hence, we might expect external forces to make different contributions during the R&D processes of pharmaceutical and nanotechnology projects. In this paper, we claim that these effects can be modeled by using appropriate terms in the Fourier expansion.

The R&D process is extremely complex, and the interactions of external factors depend heavily on the industry and project under consideration. However, the approach proposed in this paper can accommodate very specific situations. Our practical case covers a pharmaceutical R&D project; however, the model and methodology used can be easily extrapolated to any industry, for instance, projects in the car industry.

The remainder of this paper is structured as follows: Section 2 is devoted to the literature review. Section 3 presents the valuation model, technicalities, and implications. In Section 4, we perform a stress test analysis to determine the impact of exogenous forces and the optimal launching of a pharmaceutical R&D project. Finally, Section 5 concludes by citing the contribution of our model to the literature and its implications for practitioners and policy makers.

2. Literature review

The extant literature on the use of real options models for valuing R&D projects treats the successful completion of the R&D phase as exogenous variable. Some examples follow. Majd and Pindyck (1987) use a geometric Brownian motion to model the evolution of a project's market value after market launch and conditional on a successful R&D stage. The authors show that the arrival of new information might lead the firm to depart from its original spending plan. Therefore, traditional DCF methods, as they do not capture managerial decision flexibility, are inadequate for properly valuing projects where spending decisions and cash outlays occur sequentially over time. Assuming that the gross project value follows a geometric Brownian motion, Trigeorgis (1993) analyzes the valuation of flexible capital budgeting projects as a collection of real options and investigates the impact of the interactions among these options. Pennings and Sereno (2011) value a compound R&D option while assuming a geometric Brownian motion process for the underlying value of the project and a Poisson random variable for the technical failure probability. Berk et al. (2004) model the cash flows generated by a single R&D investment

project using two distinct stochastic processes. One process models any possible catastrophic event, and the other models the conditional cash flows the project would have produced if it had been completed. The authors assume that the cash flows last forever, thereby allowing them to value the completed project using a continuously compounded version of the growing perpetuity formula. Finally, Schwartz (2004) implements a simulation approach for valuing patents and patent-protected R&D projects. He assumes two stochastic differential processes, one for the cost of completion and another for the cash flows generated from the project, and the probability of a technical failure is introduced as a Poisson probability.

In our model, we consider the net cash flow as the underlying variable. In this sense, our approach is closer to the work of Berk et al. (2004) and Schwartz (2004). Similar to the literature, we will use a Poisson process to model technical risk and start modeling a project's cash flows under the assumption of a market launch. As in Alexander et al. (2012), however, we assume that the net cash flow of a successful project is given by an arithmetic Brownian motion process. This captures the fact that the underlying variable could yield a negative cash flow stream if one considers the production and marketing costs.

An important feature of R&D projects is their uncertainty related to the cost of completion. For an in-depth examination of this topic, see for instance, DiMasi et al. (1991) and Hansen (1979). In particular, DiMasi et al. (2003) perform a thorough study of the R&D costs for 68 randomly selected new drugs produced by 10 different pharmaceutical companies and estimate the cost of pharmaceutical innovation. Pindyck (1993) also studies investment decisions when projects are subject to two different sources of uncertainty, technical uncertainty and cost uncertainty. Although the sources and amounts of cost uncertainty vary greatly across projects, cost uncertainty is shown to have a deeper impact than technical uncertainty on the value of the investment opportunity. Different sources of uncertainty might also play a key role in R&D decision making; for instance, Garcia-Quevedo et al. (2014) show that uncertainty over product/service demand has a substantial impact on the amount of investment

and the likelihood of engaging in R&D projects.

Other relevant studies of real options valuation include Childs and Triantis (1999), who examine dynamic R&D investment policies and the valuation of R&D programs in a contingent claim framework. The authors study interactions among multiple R&D project cash flows and analyze how the firm alters its funding policy over time. Smith and Nau (1995) compare the classical DCF approach (or risk-adjusted discount-rate analysis), options pricing analysis, and decision tree analysis approaches to valuing risky projects. Posner and Zuckerman (1990) determine the optimal time to abandon an R&D project under the assumption of a stochastic process for expenditures. McDonald and Siegel (1986) compare the optimal timing of investments and assume a geometric Brownian motion for the future net cash flows (with and without jumps) and another geometric Brownian process for the cost of completion. Brown et al. (2017) analyze the financial market rules and the effectiveness of domestic policies to promote R&D.

The literature summarized above does not, however, provide a real options framework able to capture a project's flexibility in terms of abandon options and the impact of economic conditions on the project's specific risks. The model built in Section 3 allows us to perform a stress test analysis with the objective of timing the launch of the project after taking into account the impact of external forces, while considering both technical and idiosyncratic sources of risk. McDonald and Siegel (1986) and Posner and Zuckerman (1990) already consider the optimal timing of investments. However, their framework does not unveil the impact of exogenous forces. To account for these external forces, we assume that the net cash flow of a successful project is given by an arithmetic Brownian motion process plus a time-dependent component depicted by a Fourier series. For illustrative purposes, this time-dependent component captures the interaction between the business and volatility cycles.

3. R&D valuation model

It is well established in the literature—see, for instance, Brealey and Myers (2000)—that an R&D project faces two major sources of risk, economic and technical. Technical or technological risk takes into account the inherent uncertainty over the successful completion of each stage during the drug development phase; for instance, an extreme side effect during clinical testing could lead to failure. By contrast, economic risk addresses market uncertainty around sales volumes, pricing levels, and market competitors. One part of this risk is idiosyncratic in nature, and the other part is instead systematic and can be related to external economic factors such as interest rates, inflation rates, and growth rates. To effectively value research and development projects, we need to properly capture both sources of risk at the appropriate time.

3.1. Technical uncertainty

Technical or technological risk is the primary source of uncertainty during the development process. For instance, regarding pharmaceutical R&D projects, most drugs in the preclinical and clinical stages do not obtain the regulatory authority's approval. Since each stage must be preceded by the successful completion of the previous one, the failure of one stage leads to overall project termination. However, we assume that once the project successfully passes every test and stage of the R&D process and finally achieves regulatory approval, technical risk virtually vanishes. In this regard, the use of a Poisson process to model technical or technological risk is widespread—see, for instance, Pennings and Sereno (2011) and Schwartz (2004). The Poisson probability mass function (PMF) is given by

$$f(k;\lambda) = \frac{\lambda^k e^{-\lambda}}{k!} \tag{1}$$

where $\lambda > 0$ is the Poisson parameter, and $k = 0, 1, 2, ..., \infty$ defines the number of events. Generalizing $k = 1, 2, ..., \infty$ as any possible technical event and $k = 0$ as no technical event, we have

$$\text{Probability of success} = e^{-\lambda} \tag{2}$$

$$\text{Probability of technical failure} = \sum_{k=1}^{\infty} \frac{\lambda^k e^{-\lambda}}{k!} = 1 - e^{-\lambda} \tag{3}$$

Hence, the expected project value *conditional on technical risk* is given as

$$E\left[V_t|\text{Technical Risk}\right] = V_t(k=0) \cdot e^{-\lambda} + V_t(k=1,2,...,\infty) \cdot \left(1 - e^{-\lambda}\right) \tag{4}$$

where

- $V_t(k=0)$ is the value of a successful project
- $V_t(k=1,2,...,\infty)$ is the residual value of a failing project

Although a failed project might still increase a company's stock of knowledge, it is common to assume that the outcome of a failure is a worthless project. Under this assumption, technical risk translates to a premium over the risk-free rate. During the development process, the discount factor is given by $e^{-r_d t} = e^{-(r+\lambda)t}$, where λ represents the annual rate of failure, and r is the risk-free rate. Note that, as stated above, technical risk vanishes after the regulatory authority's approval; hence, this premium is only valid during the drug development phase.

3.2. Idiosyncratic risk

It is common to model the evolution of a project or the evolution of its cash flow as a stochastic differential equation

$$dC_t = \mu(C,t)dt + \sigma(C,t)dW \tag{5}$$

where the process can take the form of a geometric Brownian motion, an arithmetic Brownian motion, or an Ornstein-Uhlenbeck process. We can use a more realistic and sophisticated framework, such as that proposed by Schwartz (2004), in which both the cash flow and the cost of completion are modeled by stochastic differential equations. In this paper, we consider the evolution of the net

cash flow over time. The net cash flow stream takes into consideration the production and marketing costs; consequently, it could yield a negative rate. Thus, an arithmetic Brownian motion is a suitable representation of the underlying process.

As long as we consider only one stochastic factor, all these models have a single source of uncertainty that comes from a random walk weighted by $\sigma(C,t)$, that is, the diffusion term.[1] It seems fairly obvious that a simple diffusion model cannot account for a realistic variety of forces affecting the project's market phase. In particular, none of these models can properly account for seasonal components. For instance, seasonality plays a primary role in influenza outbreaks. These models also do not consider the effects of the business cycle or other relevant forces. At this point, it is worth considering whether such models are oversimplifications and identifying which forces really make an impact in terms of project valuation. The next subsection addresses this issue. Of course, there is no one right answer, as each project must be analyzed to determine the appropriate set of relevant forces. However, it seems fair to conclude that a simple diffusion model is a naive simplification of the market structure.

3.3. External conditions and forces

In this sub-section, we introduce the contributions of external factors and conditions affecting the valuation process defining the cash flow structure of a successful project, which gives rise to the project's abandon option. These are economic factors (both macro- and microeconomic) driving the systematic component of cash in- and outflows. Note that we intentionally use the phrase "successful project" because we have divided projects into two major phases, the R&D phase and the market phase. During the R&D phase, technical risk is the dominant source of uncertainty, which vanishes once the project successfully completes each stage in the development process and finally achieves approval.

[1] The options pricing literature has been very fruitful in terms of models with two and even three stochastic factors — see for instance, Chen (1996) —.

Projects reaching the market phase are successful projects. Once the project reaches the market phase, several forces play a significant role in what we call the external force contribution; however, it is important to remember that only a successful project will be affected by the contributions of these external forces.

We consider the net cash flow stream C_t of a successful project given by a latent variable Y_t and depicted by an arithmetic Brownian motion process and a time-dependent component described by a Fourier series, that is

$$\begin{aligned} C_t &= f(t) + Y_t && (6) \\ dY_t &= \mu dt + \sigma dW_t && (7) \\ f(t) &= \text{Fourier Series} && (8) \end{aligned}$$

where $\{(\mu,\ \sigma) \in \mathbb{R}\}$. Note that in applying Ito's lemma to equation [6], the net cash flow dynamic is depicted by

$$dC_t = \left(\mu + \frac{df}{dt}(t)\right) dt + \sigma dW_t \tag{9}$$

In this framework, the solution of the underlying process and the net cash flow at any given time t under the risk-neutral probability $\mathbb{P}^Q$ is represented by

$$\begin{aligned} Y_t &= Y_0 e^{rt} + \sigma \int_0^t e^{r(t-s)} dW_s^Q && (10) \\ C_t &= \Big(C_0 - f(0)\Big) e^{rt} + f(t) + \sigma \int_0^t e^{r(t-s)} dW_s^Q && (11) \end{aligned}$$

where W_t^Q is a standard Wiener process under the risk-neutral measure $\mathbb{P}^Q$.

As in Schwartz (2004), the cash flow stream starts at market launch. Before this stage, the process describes the net cash flow that the project would have produced were it successfully completed. Once the project is launched in the market, its value depends exclusively on the net cash flow generated. Hence, using the Merton (1973) no-arbitrage technique, the project value $V(C_t, t)$ must

satisfy the following partial differential equation:

$$\frac{\partial V}{\partial t} + rC\frac{\partial V}{\partial C} + \frac{\sigma^2}{2}\frac{\partial^2 V}{\partial C^2} - rV = 0 \tag{12}$$

subject to the appropriate terminal condition $V(C,T)$, where T represents patent expiration.

The novel component of this model is the *ad hoc* incorporation of the Fourier series $f(t)$, which accounts for any economic, market, and specific forces affecting the project and not captured by the underlying stochastic differential equation. The Fourier series represents aggregate forces playing a relevant role in the process evolution and determining the cash flow structure. Note that the Fourier series provides a great deal of flexibility, as by Carleson's theorem, it converges almost everywhere for an L^2 function. Therefore, $f(t)$ allows us to properly define a scenario where a project will be developed, and such a scenario is tailored to the characteristics of each project, the influence of and exposure to certain forces, and other features. In this regard, we might not have a precise *ex ante* projection of such a scenario; for instance, we might know that the business cycle represents a risk factor, but we might not know how deeply it affects the cash flow stream. Hence, let us represent economic uncertainty by the state vector

$$\Phi^{(j)} \quad \text{with} \quad j \in \mathbb{N} \tag{13}$$

where each state defines a case scenario depicted by the concrete selection of terms in the Fourier expansion and represents the aggregate forces. It is important to stress that a state scenario does not attempt to replicate a precise future outcome but establishes an alternative future development. Each state determines the cash flow structure of a successful project and, consequently, the managerial decision to cease or continue the project. Thus, the expected patent value, conditional on a certain economic state, is given as

$$V\left(t, C_t, I_t; \Phi^{(j)}\right) = E\left[V \,|\Phi^{(j)}\right] \quad \text{with} \quad j \in \mathbb{N} \tag{14}$$

where C_t and I_t represent the net cash flow structure once the project obtains marketing approval and the investment structure during the R&D phase, respectively.

Note that the conditional patent value is constrained to the future development of each state, which is, of course, uncertain. Since Φ is defined as a discrete state vector, an essential piece of the puzzle is the appropriate definition of its PMF. In this regard, Huchzermeier and Loch (2001) define a one-dimensional parameter i to model product performance. The authors claim that this performance may unexpectedly improve with probability p or deteriorate with probability $(1-p)$. They generalize the binomial distribution by allowing both performance improvement and deterioration over N performance states. We can easily accommodate a similar PMF defining two states in the economic state vector, that is, $j = 1,\ 2$. However, as stated above, each state represents aggregate forces acting on the project and is therefore very project specific, so we will implement a Bayesian approach and assign a prior probability to each scenario. Note that each state can be defined in several ways; for example, we can tailor it to our expectations or define it based on analyst expectations. Hence, let us define the state vector PMF in general terms as

$$g\left(\Phi^{(j)}\right) = Pr\left(\Phi = \Phi^{(j)}\right) = p_j \tag{15}$$

where p_j represents the probability that the state $\Phi^{(j)}$ is real. Hence, under this framework, the patent value is determined by

$$\text{Patent Value} = \sum_j V\left(t, C_t, I_t; \Phi^{(j)}\right) \cdot g\left(\Phi^{(j)}\right) \tag{16}$$

4. Stress test and optimal market launch for pharmaceutical R&D projects

In this section, we focus on pharmaceutical R&D projects; however, the methodology can be easily extrapolated to any industry.

Developing a new medicine is a challenging endeavor, and the chances of success are extremely low. There are several complex forces, both economic and technical (idiosyncratic and systematic), governing the drug development process that are not entirely understood. The first obstacle arises during the early discovery stage when the company has to assign the appropriate amounts of financial and scientific resources. Although the total cost of developing a new medicine varies, it heavily depends on the type of compound, the drug under development, and the likelihood of failure. In terms of time to completion, a pharmaceutical R&D process can take, roughly speaking, between ten and fifteen years from the early-stage discovery of a new compound to the marketing approval and market launch of a product. Again, this timeline heavily depends on the drug or treatment. For some innovative drugs or treatments, both cost and time to completion are significant sources of uncertainty, and they constitute the cost of innovation. However, many "new" medicines or treatments are improvements on existing drugs. In this case, the cost and time to completion are quite standardized, and although there is some uncertainty, the financial and technological R&D costs are considerably lower.

Consider, for instance, a pharmaceutical R&D project to develop a new drug. The very nature of such a project and the potential impact on human health make the pharmaceutical industry unique and quite risky. There are several strict and well-regulated stages, spanning early-stage drug discovery to the marketing approval and market launch of a product. Fig. 1 illustrates a schedule for a generic pharmaceutical R&D project.

Figure 1: This figure presents a general pharmaceutical process for the development of a new drug.

The overall project life can be divided into two major phases: first, the R&D phase and, second, the market phase. During the early stage of the R&D phase, a new compound, which may be developed into a marketable drug, is either discovered or designed. Once the compound is successfully identified as a potential drug and synthesized, the project moves to the next stage. During preclinical and clinical development, the drug must successfully complete a number of well-regulated stages. First, the preclinical stage covers laboratory and animal testing, and it is normally during this stage when the company applies for a patent. If and only if the drug successfully completes the preclinical stage does it proceed to the clinical stage, which can be divided into clinical phases I, II, and III. During clinical phase I, the drug or treatment is tested on a small group of healthy volunteers to determine the safe dosage, evaluate its safety, and identify possible side effects and toxicity. During clinical phase II, the drug or treatment is tested on a relatively large group of subjects (100-300) afflicted by the condition that the drug is intended to treat, with the objective of further evaluating its safety and efficacy. Finally, clinical phase III consists of large-scale trials, usually with a few thousand subjects, to confirm the safety and efficacy of the drug or treatment and to continue to monitor for possible side effects. The final stage of the R&D phase is marketing approval. Once again, if and only if the drug successfully completes each preceding stage does the regulatory authority decide whether the drug is approved for patient use. If marketing approval is granted, the project moves to the market phase, where an appropriate marketing strategy should be established. Finally, the product is launched in the market.

Over the life of the patent, the company is entitled to a set of exclusive rights protecting the project from market competition for a limited time. However, market competition is not the only force that jeopardizes the successful evolution of a project.

Economic conditions not only affect the number of investment opportunities available in the pharmaceutical industry but also play a key role in the cash-flow generation of a successful R&D project (i.e., with no technical risk). This

section is devoted to stress testing the impact of some economic forces on the overall project value and to determining the best timing for launching a project based on the interactions among these forces.

4.1. Economic forces

A vast number of economic variables can potentially affect an R&D project. For the sake of simplicity, in this paper, we analyze two major forces: i) the business cycle, defined as the cyclical movement of GDP around its long-term trend, and ii) the VIX index, which is a forward-looking measure of market volatility affecting the option market. It is used as a benchmark for the uncertainty governing market conditions. The objective is not to be exhaustive but to show that our framework allows us to take external forces into account.

i) *Business cycle*

The first variable under consideration is the business cycle, i.e., the cyclical movement of GDP around its long-term trend. The relationship between R&D and the business cycle and economic growth has been intensively studied in the academic literature—see, for instance, Pintea and Thompson (2007). In this respect, the first step is to disentangle the cyclical behavior from the long-term trend. To do so, we use a standard Hodrick-Prescott (Hodrick and Prescott, 1997) filter, the most commonly used tool for this task. We also perform a spectral analysis of the cyclical component of GDP using nonparametric estimates of the population spectrum, as in Hamilton (1994). The data set includes 278 quarterly GDP observations ranging from January 1947 to April 2016 obtained from the Federal Reserve Bank of St. Louis web page. Fig. 2 presents the cyclical component time series and the corresponding spectra.

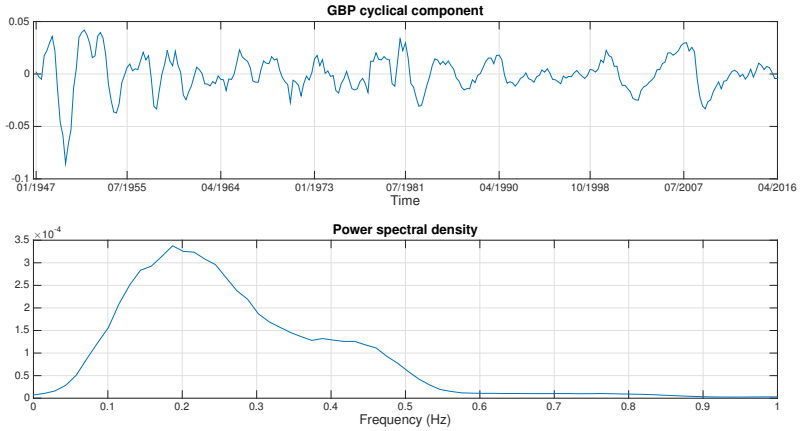

Figure 2: This figure presents the cyclical component of GDP and its power spectral density.

The spectral analysis reveals a peak at a frequency of 0.1871Hz, representing a cyclical period of 5.35 years, which is consistent with similar studies—see, for instance, Groth et al.

ii) *Market volatility*

The second variable under consideration is market volatility. Here, we use 318 monthly observations of the VIX index from January 1990 to June 2016 downloaded from the CBOE web page. We apply the same procedure used for the GDP time series; that is, a Hodrick-Prescott filter disentangles the long-term trend from the cyclical component, and then, we perform a spectral analysis using nonparametric estimates of the population spectrum. Fig. 3 presents the cyclical component time series and the corresponding spectra.

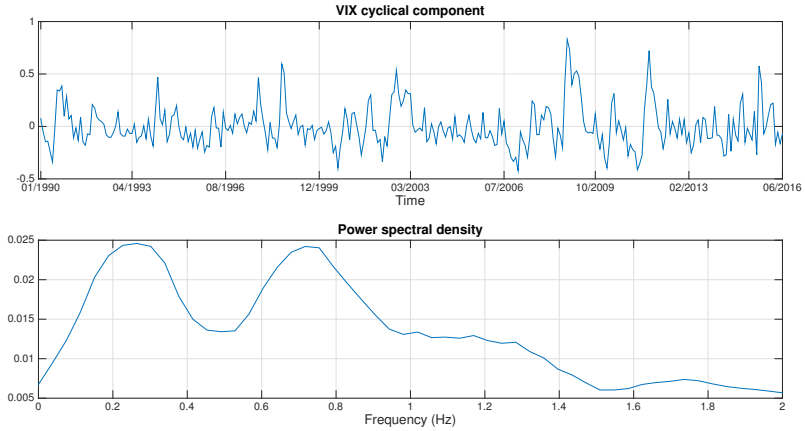

Figure 3: This figure presents the cyclical component of the VIX index and its power spectral density.

The spectral analysis reveals two dominating peaks representing periods of 1.4 and 3.8 years. Interestingly, in contrast to the GDP time series, the long-term component of the VIX series also exhibits cyclical behavior but over a much longer period. Fig. 4 presents the long-term fluctuations and the corresponding spectra.

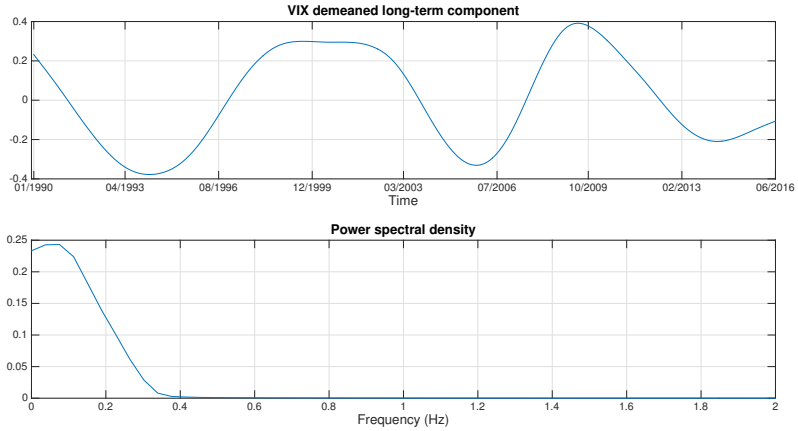

Figure 4: This figure presents the long-term fluctuation of the VIX index time series and its power spectral density.

Indeed, we can observe a peak at a rather short frequency (0.0755Hz), representing a cycle of 13.25 years.

Note that the parameters included in each term of the Fourier expansion and defining the behavior of the external economic forces, and hence of each factor, are the frequency (f) and phase (ϕ) parameters. The amplitude parameter defines the intensity of such a force or cycle over the net cash flow stream. This constitutes a project-dependent parameter.

4.2. Stress test analysis

Launching a project involves the decision of whether to launch it (with the embedded option to abandon) based on the technical and market risks involved and the choice of the optimal launch time. Timing the launch of a project corresponds to an option to delay. The objective of the stress test analysis is to jointly determine the optimal launch time and the impact of the option to delay on project valuation. Hence, we will simulate different scenarios for the phase parameter and estimate the change in the project value and the risk of failure

if the project is launched at different phases of each cycle under consideration. For instance, we will examine the impact of launching the project at the peak or the bottom of the business cycle. Note that we do not intend to price a specific project but rather to identify the optimal launch time; hence, we will use average market parameters for a generic R&D project, as described below.

Let us assume that the research team has already identified a compound that may be used to engineer a new medication. At this stage, the board has to face the first abandon option, that is, they have to decide whether this project constitutes a valid investment opportunity and apply for patent protection; otherwise, they abandon before any further development. They also have to decide whether to immediately launch the project or postpone it. For this purpose, we will stress test the launch date and establish the optimal timing considering the different stages of the business cycle and the market volatility. We assume that there is no uncertainty over the time and cost to completion if the project successfully overcomes every stage of the development process. Note that most of the investment cost is incurred in developing the drug, and it can be modeled stochastically following Schwartz (2004). However, for the sake of simplicity, we focus on timing the project kick-off rather than on development issues. The model could be easily extended to incorporate a stochastic process for the cost and time to completion. According to the Tufts Center for the Study of Drug Development—see DiMasi et al. (2014)—the total out-of-pocket cost per approved new compound is approximately 1,400 million (in 2013 dollars), although this figure can be heavily dependent on the development phase—see Archibugi and Bizzarri (2004). Based on this information, Table 1 presents our scenario for out-of-pocket investment costs and the yearly development phase schedule.

Table 1: Development phase schedule. This table presents the work schedule and budget for the whole development process, including regulatory approval.

Development stage	Preclinical testing		Clinical phase I		Clinical phase II		Clinical phase III			Regulatory review
Period	0	1	2	3	4	5	6	7	8	9
Investment	60	60	82	82	196	196	174	174	174	11

425 *4.2.1. Technical uncertainty*

In the previous section, we assume that during the development phase, the project can either fail or be abandoned. Technical risk accounts for the probability of failure for technical or technological reasons during the development phase, and we have generalized the Poisson distribution to allow for the probabilities
430 of technical success and failure. According to the "2015 biopharmaceutical research industry profile" report provided by PhRMA (Pharmaceutical Research and Manufacturers of America, 2015), the average time needed to develop a drug is approximately 10 years, and less than 12% of drugs entering clinical trials result in an approved medicine. Hence, assuming that only 12% of such projects
435 complete every stage of the development phase and a development period of 10 years, the annual rate of failure is given as

$$e^{-10\cdot\lambda} = 0.12 \tag{17}$$

$$\lambda = 0.2120 \tag{18}$$

We also assume that a failure results in a worthless project; hence, during the development process, the discount factor is given by $e^{-r_d t} = e^{-(r+0.2120)t}$, where r represents the risk-free rate.

440 *4.2.2. Economic and market uncertainty*

The net cash flow stream from sales revenues, marketing and production cost starts when the medication receives marketing approval and is launched,

which is expected to occur in period 10. Let us assume that a patent will be granted 4 years after the application and provides protection for a period of 20 years. When the patent expires, market competition forces sales to virtually zero, meaning that, based on the schedule, the company can only benefit from this project for 14 years starting at market launch. This assumption generates the boundary condition $V(T) = 0$ on equation [12], where T represents the patent expiration date. In addition, we consider an initial cash flow parameter C_0 in equation [11] of 100 million, while the process volatility σ is fixed at 20 million.

As for the economic variables, the previous section specifies the characteristics of each economic variable, that is, the frequency and phase parameters of the GDP and VIX cyclical components and the VIX long-term component. To initialize the conditions for the amplitude, we measure the impact of each factor relative to a benchmark, and based on these results, we will fix each factor's amplitude. As a benchmark, we use two well-known pharmaceutical indexes: i) the S&P 500 Pharmaceutical Index and the ii) NYSE ARCA Pharmaceutical Index. Both data series run from July 1992 to April 2016. Table 2 provides the results.

Table 2: S&P 500 and NYSE Pharmaceutical Index factor analysis. This table presents the linear relations between the benchmark indexes and the economic factors (p-values in parentheses). Note that the economic factors are scaled to fit the index boundaries.

	S5PHAR Index	DRG Index
GDP cyclical component	0.4907 (<0.001)	0.5011 (<0.001)
VIX cyclical component	0.0932 (0.195)	0.0913 (0.192)
VIX long-term component	0.3440 (<0.001)	0.3151 (<0.001)
R^2	0.1275	0.1350

In both cases, we observe that the VIX cyclical component, that is, the factor composed of two periods of 1.4 and 3.8 years, is not statistically significant. In contrast, both the GDP cyclical and the VIX long-term components have

significant relationships with the pharmaceutical return indexes. Recall that the objective here is not to find all possible external factors. The use of pharmaceutical indexes aggregates different projects and might hinder the impact of some interesting external factors. Our objective is to show that our model can accommodate the impact of any type of external force as part of the valuation. Hence, for the stress test analysis, we only consider these two factors, and we fix the amplitude parameter according to these results and the initial cash flow:

$$f(t) = 100\left\{0.4959\cos\left(1.1753\cdot t+\phi_1\right)+0.3296\cos\left(0.4742\cdot t+\phi_2\right)\right\} \qquad (19)$$

where each ϕ_i; $i = 1, 2$ defines the phase factor.

Note that the amplitude itself might be a parameter to be modeled and simulated to perform the stress test. Finally, for the sake of simplicity, we will use a constant risk-free rate of 1.5%, although the current value is much lower. Our model can be easily extended to include finer assumptions about the underlying parameters.

4.3. Implementation

Having defined and calibrated all the input parameters, we can compute the value of this project using the following steps. We assume that the underlying process C_t defines the monthly net cash flow stream. Then, we simulate 100,000 paths considering a monthly time increment of $\Delta t = 1/12$. The discrete cash flow at any time t is given by equation [11]. Once the marketing of the product is approved, the marketing and production costs are included in the net cash flow process. Therefore, discounting all the discrete cash flows up to market launch and summing them could yield a negative aggregate value. For that reason, an abandon option is considered at market launch, although there is no further investment in developing the drug. Recall that the probability of a negative aggregate cash flow at market launch is the consequence of considering an arithmetic Brownian motion process and the impact of the Fourier component

on that process; therefore, such a probability tends to decrease as the economic state improves. Accordingly, at market launch, the abandon option is given by

$$V\left(t_{ML}, C_t, I_t; \Phi^{(j)}\right) = \max\left\{\sum_{t=t_{ML}}^{T} C_t \cdot e^{-r(t-t_{ML})}\ , 0\right\} \tag{20}$$

where t_{ML} and T represent the market launch and patent expiration date, respectively.

The exercise time for the subsequent abandon options is defined on a yearly basis, and the option is evaluated conditional on not having been previously abandoned; therefore, the time increment during the development phase is given by $\Delta t^* = 1$. The backward procedure consists of discounting[2] the project value to the exercise time and evaluating the optimal abandon option, that is,

$$V\left(t, C_t, I_t; \Phi^{(j)}\right) = \max\left\{V\left(t + \Delta t^*, C_{t+\Delta t^*}, I_{t+\Delta t^*}; \Phi^{(j)}\right) \cdot e^{-(r+\lambda)\Delta t^*} - I_t\ , 0\right\} \tag{21}$$

The procedure continues rolling back to the present time for those paths that are not optimally abandoned in previous interactions.

4.4. Business cycle stress test

In this section, we perform a sensitivity analysis of the project valuation with regard to the business cycle factor only. In other words, we analyze the impact of launching the project at different phases. We study the project's evolution when launching i) at the peak of the cycle and then entering a recession, that is, $\phi_1 = 0$; ii) at the trough of the cycle and then entering the recovery phase, that is, $\phi_1 = \pi$; and iii) at an intermediate phase, that is, $\phi_1 = \pi/2$. In this case, we use the following Fourier expansion:

$$f(t) = 100\left\{0.4959\cos\left(1.1753 \cdot t + \phi_1\right)\right\} \tag{22}$$

[2]Note that during the development phase, the discount factor is given by $e^{-r_d t} = e^{-(r+\lambda)t}$, where λ represents the annual rate of failure and can be considered a technical or technological risk premium.

When considering, 100,000 path simulations and following the above procedure, the expected patent value conditional on each phase in the business cycle is given as in Table 3.

Table 3: Conditional expected patent value. Business cycle. This table presents the patent value conditional on the phase parameter in the business cycle.

Business Cycle Phase	Panel	
	A	B
$V(t, C_t, I_t; \phi_1 = 0)$	908.7 (3.2)	604.1 (4.3)
$V(t, C_t, I_t; \phi_1 = \pi)$	2553.7 (4.2)	2522.3 (4.4)
$V(t, C_t, I_t; \phi_1 = \pi/2)$	1584.4 (3.9)	1486.2 (4.4)

Panel A: With abandon option

Panel B: Without abandon option

We can clearly see that the timing of the launch has a dramatic impact on project value. Launching the project at the peak of the business cycle and then entering a recession yields a much lower expected value, roughly 66% lower than when launching at the trough phase and 43% lower than when launching at an intermediate phase. This evidence shows that our model is able to capture the impact of market conditions or other external forces on the project's cash flow generation. This finding has strong managerial implications, as a flexible model can accommodate any type of situation, evaluate the impact of external factors and determine the resilience of the project to endogenous risks and external economic forces. The timing of project kick-off affects not only the overall project value but also the value of the embedded abandon option. Table 3 Panel B shows the project value when the abandon option is not considered: the abandon option has a higher value when the project is launched at the peak of the phase. Table 4 disaggregates by state and period the number of paths optimally abandoned, that is, the number of abandon options exercised. We have already stated that the first exercise date is at market launch. Since the net cash flow stream takes into consideration not only the sales revenues but also

the production and marketing costs, this variable can, and indeed does, become negative for some paths. Hence, the abandon option may be optimally exercised despite there being no further investment in developing the drug at market launch. As expected, the number of optimally abandoned paths is significantly higher when the phase factor is $\phi_1 = 0$, making the abandon option considerably more valuable when the project is launched at the beginning of a recession state.

Table 4: Abandon rate. Business cycle. This table presents the number of optimally abandoned projects of 100,000 path simulations. In light gray, we have the number of paths optimally abandoned disaggregated by state and period. In gray, we have the number of paths optimally abandoned aggregated by period.

Development stage	Preclinical testing		Clinical phase I		Clinical phase II		Clinical phase III			Regulatory review	Market launch
Period	0	1	2	3	4	5	6	7	8	9	10
Investment	60	60	82	82	196	196	174	174	174	11	0
$\phi_1 = 0$	1625	1225	1323	1026	1850	1451	1031	806	599	27	22272
	33235	31610	30385	29062	28036	26186	24735	23704	22898	22299	22272
$\phi_1 = \pi$	342	237	202	177	299	205	130	109	72	1	1543
	3317	2975	2738	2536	2359	2060	1855	1725	1616	1544	1543
$\phi_1 = \pi/2$	947	729	735	573	1043	815	528	399	290	18	8092
	14169	13222	12493	11758	11185	10142	9327	8799	8400	8110	8092

4.5. Market volatility stress test

In this section, we study the effect of market volatility on an R&D project. In the previous section, we use the VIX as a proxy for market volatility and find that two short- to medium-term cycles of 1.4 and 3.8 years and a long-term cycle of 13.25 years. We also analyzed the effects of these factors on two pharmaceutical indexes and found that only the long-term component outcome is significant.

As with the business cycle, we study the project evolution when launching i) at the peak of the volatility cycle, that is, $\phi_2 = 0$; ii) at the trough of the cycle, that is ,$\phi_2 = \pi$; and iii) at an intermediate phase, that is, $\phi_2 = \pi/2$. For

this study, we use the following Fourier expansion:

$$f(t) = 100\left\{0.3296\cos\left(0.4742\cdot t+\phi_2\right)\right\} \tag{23}$$

Considering 100,000 path simulations, the expected patent value conditional on each phase in the volatility cycle is given as in Table 5

Table 5: Conditional expected patent value. Volatility cycle. This table presents the patent value conditional on the phase parameter in the volatility cycle.

Volatility Cycle Phase	Panel	
	A	B
$V\left(t, C_t, I_t; \phi_2 = 0\right)$	1132.2 (3.5)	914.93 (4.4)
$V\left(t, C_t, I_t; \phi_2 = \pi\right)$	2248.8 (4.2)	2215.5 (4.4)
$V\left(t, C_t, I_t; \phi_2 = \pi/2\right)$	1677.5 (3.9)	1588.5 (4.4)

Panel A: With abandon option

Panel B: Without abandon option

We observe similar behavior as in the business cycle analysis: launching the project at the peak of the volatility cycle yields a lower patent value, roughly 50% lower than launching at the trough phase and 32% lower than launching at an intermediate phase. Table 6 disaggregates by state and period the number of paths optimally abandoned conditional on each phase value. We observe a higher abandon rate when the project is launched at the peak of the cycle.

Table 6: Abandon rate. Volatility cycle. This table presents the number of optimally abandoned projects of 100,000 path simulations. In light gray, we have the number of paths optimally abandoned the disaggregated by state and period. In gray, we have the number of paths optimally abandoned aggregated by period.

Development stage	Preclinical testing		Clinical phase I		Clinical phase II		Clinical phase III			Regulatory review	Market launch
Period	0	1	2	3	4	5	6	7	8	9	10
Investment	60	60	82	82	196	196	174	174	174	11	0
$\phi_2 = 0$	1357	1029	1110	802	1613	1216	880	718	480	29	16047
	25281	23924	22895	21785	20983	19370	18154	17274	16556	16076	16047
$\phi_2 = \pi$	470	349	382	251	450	337	229	167	144	9	2751
	5539	5069	4720	4338	4087	3637	3300	3071	2904	2760	2751
$\phi_2 = \pi/2$	926	644	682	499	913	717	456	375	260	14	7060
	12546	11620	10976	10294	9795	8882	8165	7709	7334	7074	7060

The stress test reveals that for both cycles (the business cycle of 5.35 years and long-term volatility cycle of 13.25 years), the optimal strategy is to launch the project at the trough of each cycle. By launching at this point, we achieve the highest expected patent value and the lowest abandon rate. However, synchronizing both cycles might not be possible, and we still have to determine the optimal launching time conditional on certain economic conditions.

4.6. Business cycle and market volatility stress test

In this analysis, we jointly consider the economic forces to understand their joint effect on the project value, time to launch and abandon option. The Fourier expansion is given as follows:

$$f(t) = 100\left\{0.4959\cos\left(1.1753\cdot t+\phi_1\right)+0.3296\cos\left(0.4742\cdot t+\phi_2\right)\right\} \qquad (24)$$

Fig. 5 presents all possible combinations of phases and corresponding patent values. As previously stated, the best possible combination is launching the project when the business and the volatility cycle phase parameters are both equal to π, that is, at the trough of both cycles.

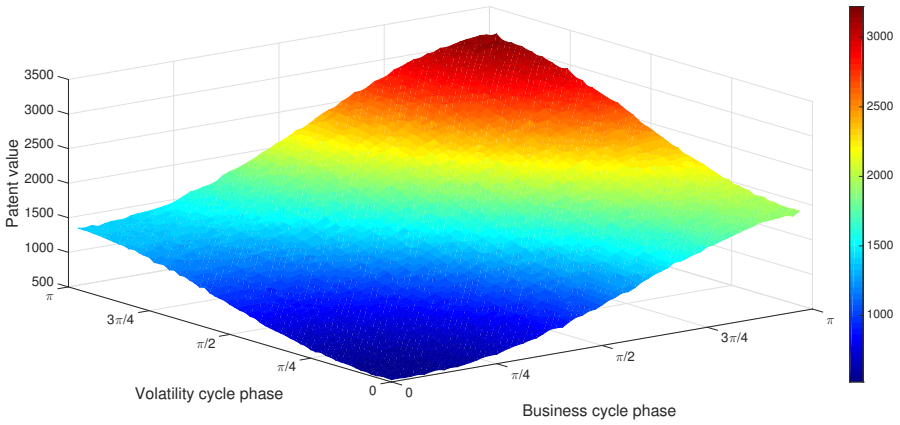

Figure 5: This figure presents the conditional patent value sensitivity considering different combinations of the business and volatility cycle parameters.

Fig. 5 provides the patent value surface at any phase combination. It constitutes a powerful analytical tool to understand the impact of external forces on the project value. It provides managers with important information for timing the introduction of an R&D product to the market.

5. Concluding remarks

Given the social and economic benefits of R&D and the amount at stake (R&D expenditures amounted to $ 1,143,005 million in 2015 for OECD countries), any restrictions on public spending should require priority in selecting projects and a proper evaluation of their risks and value.

Traditionally, R&D projects have been evaluated following the real options approach, which relies on one diffusion process to model the idiosyncratic source of risk and the possibility to abandon the project. The models used in the literature also allow for the incorporation of the impact of technical risk and a stochastic cost of completion. In this paper, we developed a novel valuation model that accounts for, beyond idiosyncratic and technical risk, the interaction

of market and economic external forces. The approach allows us to evaluate the effects of these risk factors on the project value, on the option to abandon and on the option to delay the project.

For illustrative purposes, we posit business and volatility cycles as potential economic risk factors driving the stock return process and the risk premium, and we consider i) the business cycle as the cyclical movement of GDP around its long-term trend and ii) the VIX index, which is considered the barometer of investor sentiment and market volatility.

To capture these risk factors and account for economic conditions, we introduce a Fourier series into the cash flow generation. This representation enables us to capture the potential interactions among different market and economic forces. In this sense, the Fourier series allows us to properly embed an economic scenario within the project's cash flow generation. Our model is flexible and can accommodate various scenarios by modeling different economic state scenarios, for instance, by increasing the number of forces affecting the project's value.

In Section 4, we illustrate the application of this model and methodology using a simple numerical example applied to a pharmaceutical project. We also perform a stress test analysis to determine the effects of certain economic forces on the overall project value and to determine the optimal time to launch a project based on the interactions among these forces.

The model and methodology presented in this paper constitute a powerful yet simple valuation instrument with strong practical applications for managers and policy makers. As stated above, research-intensive industries are extremely complex and competitive. This context requires careful selection of projects. When ranking projects, several forces, both economic and technical, driving the drug development process that should be taken into account. In this regard, our proposed model addresses forces playing significant roles in the project valuation process in a very simple manner and provides a comprehensive tool for the decision-making process. The model and methodology proposed here can be easily extrapolated to any other industry or corporate project.

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