

# Opt-Out Options in New Product Co-Development Partnerships

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We study three contractual arrangements - co-development, licensing and co-development with opt-out options - for the joint development of new products between a small and financially constrained innovator firm and a large technology company, as in the case of a biotech innovator and a major pharma company. We formulate our arguments in the context of a two-stage model, characterized by technical risk and stochastically changing cost and revenue projections. The model captures the main disadvantages of the traditional co-development and licensing arrangements: In co-development the small firm runs a risk of running out of capital as future costs rise, whilst licensing for milestone and royalty payments, which eliminates the latter risk, introduces inefficiency as profitable projects might be abandoned. Counter to intuition we show that the biotech's payoff in a licensing contract is not monotonically increasing in the milestone/royalty terms. We also show that an option's clause in a co-development contract that gives the small firm the right but not the obligation to opt out of co-development and into a pre-agreed licensing arrangement avoids the problems associated with fully committed co-development and immediate licensing: The probability that the small firms runs out of capital is greatly reduced or completely eliminated and profitable projects are never abandoned.

*Key words:* New product development, pharmaceutical R&D, contracts, real options

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## 1. Introduction

In many industries, most notably in the high-tech sector, R&D alliances and partnerships are valuable complements to the wholly owned industrial R&D labs (Hagedoorn 2002, Aggarwal and Hsu 2009). The pharmaceutical industry is a case in point. The growth in biomedical knowledge has largely occurred in relatively small biotechnology companies (Danzon et al. 2005). These firms raise finance on the back of promising scientific and technological developments and the hope that these can be turned into products of value. As they lack the vast resources necessary to develop a drug to market they seek to partner with major pharma corporations in order to access further funding and capabilities, such as full-scale clinical development, marketing and sales. A second example is the impact of nanotechnology on materials and electronics. Much of these advances come directly

from universities and associated spin-off companies, rather than the labs of major electronics firms (Libaers et al. 2006). As in the case of the bio-pharmaceutical industry, commercialization of innovation often involves partnering with large corporations, which provide funds and capabilities in industrial manufacturing and distribution.

This paper focuses on how such relatively small and financially constrained innovator firms can strike effective collaboration agreements with more established industry majors within a context that is dominated by high levels of technical as well as commercial risk. To study this we build a stylized model that captures two key elements of such early stage R&D: staging and uncertainty. In its simplest form, R&D has two phases: an exploratory phase to establish proof-of-principle, followed by a confirmatory phase with the aim of producing a working prototype, establishing manufacturing viability or, as in the case of pharmaceutical R&D, gaining regulatory approval (DiMasi et al. 2003, Girotra et al. 2007). While the cost of exploration is typically relatively low, prototyping and scaling up for manufacturing can be very expensive and may well stretch the financial muscle of the small partner. In addition, costs and revenues of R&D projects are notoriously uncertain; commercial prospects can and often do change unpredictably, as and when new technical or commercial information becomes available. Therefore, after an initial exploratory phase, and in light of its results and the commercial potential of the new product candidate, a decision needs to be made whether or not to invest in further development and ultimate industrial manufacturing. This staged commitment gives R&D projects an options-like characteristic, with implications for their economic valuation (Trigeorgis 1996, Huchzermeier and Loch 2001, Santiago and Vakili 2005).

We investigate here the implications of staged commitment within the context of collaborative efforts between a small innovator firm and a large industry major. An emerging blockbuster drug may be excellent news for the pharma company as it is fully aligned with its business model, but at the same time the increased cost of bringing a blockbuster to market may overwhelm the biotech company's resources. It is therefore imperative that we understand how staging, and in particular how changes in the economic value of the project, affect the partners' ability and willingness to fund such projects. Naturally, we expect this to be a function of the chosen contractual agreement.

We examine three contractual modes of collaboration: pure co-development, licensing, and a hybrid of the two, co-development with the option for the small firm to opt out from co-development to pre-agreed licensing terms after the first stage. In pure co-development the two firms share both the costs and, if successful, the revenues at a fixed and pre-agreed proportion. All decisions are taken jointly. In a licensing contract the small innovator firm transfers the rights to its larger partner who assumes responsibility for completing the R&D. If the project is successful the licensor

pays a pre-agreed royalty rate as well as fixed milestone payments to the innovator firm. In co-development with a licensing option both firms share the costs of the first stage of development at a pre-agreed split. Before the second stage commences, and provided the first stage is technically successful, the innovator firm makes a decision whether or not to continue with co-development. If it decides to continue with co-development, it will pay its share of the future costs and, if successful, will receive its share of the revenues. If it exercises its licensing option the partner assumes liability for all future costs and if the project is successful the innovator firm receives milestone payments and royalties on sales at a pre-agreed rate.

While much of the contracting literature is dominated by a focus on incentives and inefficiencies due to unobservable actions or private information (Scotchmer 2004), our focus is different. We will view collaborative development activities as partnership-embedded licensing agreements (Hagedoorn et al. 2009). Such partnerships are longer-term collaborations which, in addition to rights-transfers, may also involve collaboration on other parts of the value chain, such as other joint R&D projects, production, marketing or distribution of products. Partnership-embedded licensing agreements are frequently encountered in technologically sophisticated industries, partly because secrecy is an important component of appropriability and partly because the licensors are smaller and more financially constrained than the licensees (Hagedoorn et al. 2009). Within the context of such long-term partnerships inefficiencies arising from moral hazard or asymmetric information are less prevalent as the two firms will invest in information sharing activities and governance structures that ameliorate such frictions. Nevertheless, developing effective R&D agreements remains challenge in our setting due to a volatile commercial environment.

An example in case is the partnership between the UK-based biotech Cambridge Antibody Technology (CAT) and AstraZeneca, signed in 2004. This long-term alliance covered specific therapeutic areas and stipulated that any promising molecule discovered by CAT over the following five years would be developed jointly by both firms, with a 50/50 share of costs and revenues. The agreement won the Business Development Deal of the Year award at the Pharmaceutical Achievement Awards conference in 2005 for its innovative use of co-development with opt-out options to better align the incentives and resources of the two companies. These clauses gave the partners the right to exit a joint project at specified stages of the R&D process and revert to pre-agreed licensing terms. This paper is partially the result of the authors' involvement in structuring the original co-development contract. We will argue that contracts with opt-out clauses to standard licensing terms can be valuable generic templates for partnership-embedded licensing agreements.

To facilitate the exposition, we will refer to a biotech-pharma partnership throughout the paper. The results and insights, however, apply more generally to new product development alliances that share the following characteristics:

- the partnership is between a relatively small and financially constrained innovator and an established industry major;
- projects under the agreement are staged and are subject to significant uncertainty over market value which is resolved progressively as the project advances through the development stages.

We note a number of interesting findings. In the case of a pure co-development project, the firms take the continuation decision jointly. Since they share costs and revenues, they have every incentive to make optimal continuation decisions, i.e. they proceed with the development of every project whose expected revenue exceeds the costs and abandon projects which are deemed too expensive to develop further. As such, the two firms share the benefits of the natural option value inherent in such R&D projects according to their pre-agreed share. However, for co-development to work well for both firms, the biotech needs to have sufficient financial resources to be able to participate in the project. Within the context of our model there is a positive probability that a biotech with finite financial resources will find itself unable to participate in the further co-development of expensive blockbuster projects. This probability is non-decreasing in the share the biotech retains, but perhaps more surprisingly we find that when the biotech is not highly constrained it is also increasing in the volatility of the projected cash flows.

Licensing has one substantial advantage for the biotech over pure co-development: the pharma assumes full responsibility for the project and incurs all future costs and therefore the possibility that the biotech will run out of capital in the process is eliminated. However, this advantage comes at a cost. The late stage payments from the pharma to the biotech distort the continuation decision of the pharma after the end of the first stage. Therefore the pharma finds it optimal to abandon projects that are technically viable and economically profitable as stand-alone projects but, after deduction of expected milestone/royalty payments, do not deliver sufficient revenue to allow the pharma to recoup the remaining R&D costs. In the words of a senior executive from one of the top ten European pharmaceutical companies: *“The in-licensed project would need a relatively higher than expected pay-off than self-originated compounds, as the expected profits from the in-licensed compound would usually need to generate royalties for the biotech company in addition to the profit for the pharmaceutical company.”* (Lou and Rond 2006).

Standard licensing contracts are therefore inefficient in the sense that they can potentially hamper the swift development of projects that have commercial value in a single-party development. We show that the expected value lost due to these inefficient abandonments is increasing in the royalty and milestone payments and, perhaps more surprisingly, we find that the biotech’s economic value from licensing is non-monotonic in royalty and milestone. Initially as these payments increase the value appropriated by the biotech increases, but so does the value that is destroyed

through inefficient abandonments. Eventually the second effect dominates: high royalty/milestone terms destroy so much value that the biotech is also worse off.

Turning to co-development with opt-out options we show that, if properly designed, it allows the firms to efficiently develop every economically profitable project while at the same time significantly reduce or even completely eliminate the possibility that the biotech runs out of capital. Unlike licensing, economically profitable projects are not inefficiently abandoned as the rational biotech chooses not to exercise the opt-out option on the projects that are profitable to co-development but become uneconomical if the pharma had to develop alone. Unlike pure co-development, the biotech can choose to opt out of the co-development of projects that require more capital than it can afford to dedicate to the project and therefore circumvent financial constraints. As long as the contract is carefully designed so that the biotech does not run out of capital for those marginal projects that need to be co-developed, this contract restores efficiency. Furthermore, one can argue that this contract allows the coordination of option exercise with the firms' core competencies. It can be designed so that the biotech company opts out of blockbuster drugs for very favorable M&R terms. The commercialization of such drugs is at the core of the big pharma business model.

In summary, our paper makes the following contributions:

1. We present and analyze a new model of R&D partnerships which explicitly captures the staged nature of R&D, as well as the technical and market risk inherent in such projects. It also incorporates the asymmetric nature of the two partners by introducing finite funding capacity on behalf of the innovator firm.
2. We use our model to analyze two conventional contracts - pure co-development and licensing - and a novel contract which we have seen implemented in a biotech/pharma collaboration that combines co-development with the option to opt out to licensing. Our model sheds light on the drawbacks of the two conventional contracts: in co-development the innovator firm runs a significant risk of running out of capital, while in licensing profitable projects are being inefficiently abandoned. Our model also helps to explain the economic benefits behind the option-based contract which avoids both the risk of running out of capital and inefficient abandonments.
3. Finally, with appropriate calibration our model has the potential to provide prescriptive advice on how to structure such contracts to achieve efficiency and when to optimally exercise the opt-out option.

## 2. Literature review

Recent research in new product development has acknowledged the collaborative, cross-functional and often complex nature of innovation (Hauser 1998, Mihm et al. 2003). Whilst much of the research effort has focussed on collaboration within the firm and the challenge of coordinating conflicting goals of divisions or teams (Anderson and Joglekar 2005, Mihm 2010, Chao and Kavadias

2008, Hutchison-Krupat and Kavadias 2009), more recent research has begun to study collaborative efforts between firms and the effectiveness of corresponding contractual agreements. We contribute to this line of research. Most R&D efforts can naturally be thought of as staged investments in information with the goal of creating valuable intellectual property. Appropriate collaboration structures depend crucially on the stage at which collaboration is sought. At the one end of the timing spectrum, Bhaskaran and Krishnan (2009) consider two firms that wish to combine complementary resources to develop a new technology from its inception. They explain the phenomenon that simple revenue sharing mechanisms will distort the firms' incentives for future effort and suggest better agreements, depending on the type of project uncertainty and type of project revenue. Erat and Kavadias (2006) and Erat et al. (Forthcoming) study the other end of the timing spectrum, where an NPD supplier has finished the R&D project and wishes to license the technology to competing downstream OEMs. Their focus is on the competitive aspects of the market for new technology. Our work addresses a midpoint on the staging scale. We assume that a firm has already carried a research project through its initial phase and achieved proof-of-principle and created intellectual property related to the project. It is now contemplating partnering with a firm with an appropriate skill set for the next phase of development, after which it hopes to launch a fully developed product. We will assume that this development phase is fairly lengthy, relative to a fast moving marketplace. Therefore, not only is the technical success of the development phase uncertain but so is the commercial potential of a successfully developed product. While Bhaskaran and Krishnan (2009) started from the inappropriateness of simple revenue-sharing mechanisms when effort is non-contractible, we will explain why both pure co-development as well as the ubiquitous royalty-based licensing arrangements are equally undesirable in our context, and demonstrate that an alternative partnering arrangement - co-development with an opt-out option - is preferable.

Licensing for milestone and royalty payments has been discussed in the economics literature. Early research in this field, surveyed by Kamien (1992), argues that upfront sale, with the price determined by auction, should be the preferred technology transfer mechanism for the innovator. Later stage milestone and royalty payments are deemed inefficient because they distort downstream effort and production decisions. However, late stage fees and/or royalties become a desirable technology transfer mechanism in a static (i.e. one period) principal-agent model with asymmetric information (Gallini and Wright 1990, Beggs 1992, Sen 2005, Savva and Taneri 2011) or moral hazard (Macho-Stadler et al. 1996, Choi 2001, Crama et al. 2008). In these circumstances, the contingent nature of royalties turns them into either an information extraction mechanism, via signaling or screening, or a motivational device which better aligns the interests and efforts of both parties involved.

Licensing has also been studied in dynamic (i.e. multi-period) principal-agent settings where one (Crama et al. 2012) or both (Xiao and Xu 2010, Edlin and Hermalin 2000, Bhattacharya et al. 2012) partners need to exert costly and unverifiable effort, sequentially. We add to the literature in two respects. First, in contrast to extant literature where the value of the completed project does not change during the R&D process, in our work we explicitly model the dynamic evolution of the value and how the firms react to it. Partly to focus on dynamic evolution of value, and partly in view of the longer-term collaborative nature of licensing-embedded partnerships which makes it more difficult to keep information and actions private, we do not model moral hazard or asymmetric information in this work. Our second contribution comes from the types of contracts we examine. While extant work has examined pure licensing contracts (Crama et al. 2012), milestone-based option contracts (Bhattacharya et al. 2012) or buy-out option contracts (Edlin and Hermalin 2000), to the best of our knowledge this is the first paper to discuss a hybrid of co-development and licensing contract, where the biotech retains the option to switch from one to the other.

### 3. Model development

We consider two firms that engage in an R&D partnership. The partnership is motivated by the biotech's limited financial resources, which could potentially exceed the required R&D expenditure. This leads the biotech to seek a partnership with a large pharma firm which, for the purposes of our model, is assumed to have unlimited financial resources. Besides capital constraints, the partnership is also motivated and even necessitated by other factors which are outside our model. These could include technological complementarities and synergies, operational complementarities such as reduction of lead times, costs and uncertainty, as well as better market access and enhanced search opportunities (see review by Hagedoorn (1993)). In fact, we assume that the reasons for collaboration are so strong that they preclude a direct sale of the project from the biotech to the pharma.

To gain insight into the economics of different collaboration agreements we develop a model based on a number of simplifying assumptions. First, we model the staging of R&D investments in the simplest possible way, via two phases: an exploration and a confirmation phase. In the pharmaceutical context, this translates into exploratory clinical trials and confirmatory clinical trials (Girotra et al. 2007). Exploratory trials are smaller scale clinical trials, carried out on healthy volunteers and a small panel of patients with the aim being to establish safety, determine dosage and demonstrate clinical proof of concept. Confirmatory trials include large-scale clinical trials aiming to establish statistical efficacy as well as investments in manufacturing and possibly distribution and marketing in anticipation of the successful completion of the project. Exploratory trials are performed during the time interval  $(t_0, t_1]$  and confirmatory trials during  $(t_1, t_2]$ .



Second, we distinguish between two types of uncertainty, technical and commercial. Technical uncertainty is modeled as a binary random variable. After each phase, evidence is collected and analyzed and scientists form an opinion as to whether or not the project has, on scientific metrics, passed the hurdles set out in the phase description. If not, the project is then abandoned on technical grounds (technical failure). The chance of abandonment on technical grounds after Phase 1 is estimated as  $p_1$  and the chance of abandonment after Phase 2, given technical success in Phase 1, is estimated as  $p_2$ . In a partnership situation, the success probabilities are estimated jointly by both partners but they are not verifiable in court and therefore non-contractible.

The market value of the project, conditional on technical success, is also uncertain and, critically for our model, can change during the R&D process. In the case of a drug candidate, market uncertainty can be driven by factors such as epidemics, changing disease demographics, macroeconomic variables such as GDP growth in developing countries, and changes in the competitive landscape, such as entries or failures of competing drug candidates, but also as a consequence of the revealed safety and efficacy characteristics of the drug. In our model, we assume that the expected market value of the project is estimated by a joint team of business developers and that this projection is regularly updated as the drug is developed. This market value forecast is common knowledge during the R&D phase but is unverifiable by a third party and therefore cannot be included in the contract. However, after the drug is launched, the revenue becomes verifiable and so royalties can be implemented. To formalize the above statements, let the market value projection over time to be represented by a non-negative random process  $X(t)$ . The value  $X(t_2)$  is the market value of the fully approved drug. At any time  $t < t_2$ ,  $X(t)$  is a forecast of this market value. The forecast  $X(t)$  is updated as new information arrives. We assume that the forecasting process is unbiased, i.e.  $X(t) = \mathbf{E}[X(t_2)|X(t)]$ . This makes the forecast  $X(t)$  a martingale by construction, i.e.

$$\mathbf{E}[X(s)|X(t)] = \mathbf{E}[\mathbf{E}[X(t_2)|X(s)]|X(t)] = \mathbf{E}[X(t_2)|X(t)] = X(t),$$

for  $t \leq s \leq t_2$ . The second equality holds due to the law of iterated expectations because the information at time  $s$  subsumes the information at the earlier time  $t$ . We denote the probability density function of  $X(t_1)$  at time  $t_0$  by  $f(x)$ . For most of our results we will not make any specific assumptions about this probability distribution  $f(x)$ . However, for some of our analysis, which we make explicit, we will make the additional assumption that  $X(t)$  follows a driftless Geometric Brownian Motion (GBM) and therefore  $f(x)$  is the log-normal probability density function. This assumption is similar to revenue models argued by practitioners to be applicable to the biotech/pharma industry (Villiger and Bogdan 2005).

Third, we assume that any uncertainty in costs and durations is much lower than uncertainty in revenues and technical performance and therefore we treat costs and durations as deterministic.



This is close to reality in the pharmaceutical industry, where the minimal requirements for the eligibility and success of development phases are mandated by regulatory bodies such as the US Food and Drug Administration (FDA). At the decision point  $t_0$  the project requires known cash injections  $C_0$  to complete the exploratory trials. At the decision point  $t_1$  the project requires a cash injection  $C_1(x) \geq 0$  to complete development and be ready for launch. This cost  $C_1(x)$  includes any fixed costs associated with exploratory trials that need to be incurred irrespective of the project market value, as well as manufacturing and marketing expenditure. This expenditures needs to be made concurrently with the confirmatory trials to be ready to launch and scale-up the sales of the new product as soon as FDA approval is granted. This is necessary in order to maximize the window in which the product is sold under monopoly protection. Naturally, both the manufacturing and marketing expenditure would be substantially greater for a potential blockbuster than they would be for a small scale drug (i.e.  $C_1(x)$  is increasing in  $x$ ). Furthermore we assume that the production and the marketing investments are both subject to economies of scale (i.e.  $C_1(x)$  is continuous and strictly concave). We will also make a further mild technical assumption for the costs, namely that  $\lim_{x \rightarrow \infty} C_1'(x) = 0$ . This assumption allows us to establish existence and uniqueness of solutions in some of our propositions. For simplicity we will assume that all costs and revenues used in the model are appropriately discounted to time  $t_0$ .

Fourth, we assume that the biotech has a limited amount of capital  $K$  which can be invested in the project. This assumption reflects the fact that small entrepreneurial firms find it hard to raise capital, even if they have promising projects. This “funding gap” has been well documented in finance literature and a number of market imperfection hypotheses have been proposed to explain its prevalence (Himmelberg and Petersen 1994, Hall and Lerner 2010).

Fifth, we will assume that R&D is investment in information only, i.e. that the two firms cannot influence the technical or market uncertainties themselves. The chance of technical success is assumed to be an inherent but unknown characteristics of the biological or chemical compound under clinical trial. Any potential effort to improve the value of a technically successful product is assumed to be already incorporated in the market value projections. This is clearly a simplification, however we believe this assumption to be consistent with the philosophy behind licensing embedded partnerships (Hagedoorn et al. 2009).

Finally, we assume that both firms are risk neutral. While risk neutrality is a sensible assumption for a well-diversified pharmaceutical company (Schwartz 2004, Crama et al. 2008) the assumption is more questionable for a biotech firm. Finance orthodoxy would suggest that a biotech’s shareholders are diversified and do not want their company to be unduly risk-averse (Schall 1972). We make the risk-neutrality assumption for modeling convenience but we keep track of the major risk a small firm faces, namely that of finding itself with insufficient financial resources to complete a project.

## 4. Analysis of three contractual agreements

Having defined our model we proceed with the analysis of three contractual modes of collaboration: pure co-development, licensing, and co-development with opt-out option.

### 4.1. Pure co-development

In a pure co-development agreement the two companies share all future costs and revenues on pre-agreed terms. We assume the biotech company holds a share  $s$  in the project and the pharma company the residual share  $1 - s$ , where  $0 \leq s \leq 1$ . All information is held and assessed by a joint business development team and all investment decisions are taken jointly. To calculate the value of the project we work backwards in time starting at time  $t_2$ . Conditional on the technical success of Phase 1 and Phase 2, the value at time  $t_2$  is by definition

$$V_2(X(t_2)) = X(t_2).$$

Using the martingale property of the market value projection we can express the value of the project at time  $t_1$ , conditional on technical success in Phase 1 as

$$V_1(X(t_1)) = \mathbf{E}[p_2 V_2(X(t_2)) | X(t_1)] - C_1(X(t_1)) = p_2 X(t_1) - C_1(X(t_1)).$$

Note that in our model the Phase 2 development cost  $C_1$  depends on the revenue projection  $X(t_1)$  at time  $t_1$  and is therefore unknown at time  $t_0$  but known at time  $t_1$ . An important implication of the uncertainty in the revenue projection is that conditional on all the information revealed about the project at time  $t_1$ , the projected revenue of the project (given by  $p_2 X(t_1)$ ) might be less than the costs of continuing with the development of the project (given by  $C_1(X(t_1))$ ). Therefore, consistent with rationality, the owner of the decision rights for the project will only proceed to Phase 2 if the value of the drug at time  $t_1$  is positive. Ignoring any biotech capital constraints for the moment we summarize this continuation decision along with the value of the project in the following proposition.

**PROPOSITION 1.** *There exists a threshold  $x_c$  such that at time  $t_1$  the project is optimally abandoned when  $X(t_1) < x_c$ . The threshold is the unique positive root of the equation  $C_1(x) = p_2 x$ . The total value of the project at time  $t_0$  is given by*

$$V_0(X(t_0)) = p_1 p_2 \int_{x_c}^{\infty} (x - C_1(x)/p_2) f(x) dx - C_0, \quad (1)$$

where  $f(x)$  denotes the density of  $X(t_1)$  at time  $t_0$ . The biotech payoff is given by  $B_0(s) = sV_0$  while the pharma payoff by  $P_0(s) = (1 - s)V_0$ .

All proofs are presented in the Appendix. As the two companies engage in real co-development, without any informational or moral hazard frictions, they generate the maximum possible value  $V_0$ , which they share in proportion to their shares  $(s, 1 - s)$  in the project. It is worth noting that the value of the project  $V_0$ , and thus the share for each of the two companies, is naturally decreasing in the costs of development  $C_0$  and  $C_1(x)$ , but what is less obvious is that this value is increasing as the revenue projections become “more uncertain”. We make this comment more precise with the following corollary.

**COROLLARY 1.** *When the revenue projection  $X(t)$  follows a driftless Geometric Brownian Motion  $dX(t) = X(t)\sigma dz$  with volatility  $\sigma$  (i.e. the  $t_1$  revenue projection follows a log-normal distribution at time  $t_0$ ) then  $V_0$  is non-decreasing in  $\sigma$ .*

In the case of the driftless Geometric Brownian Motion described in Corollary 1, the uncertainty in the revenue projection is captured entirely by the volatility parameter  $\sigma^2$ . More volatile cashflows suggest that there is a higher probability of extreme scenarios; both high revenue and low revenue extremes become more likely. However, the owner of the project has an asymmetric exposure to these extremes. She can choose to abandon any project whose projected revenues drop below the costs of development, therefore limiting the downside without affecting the upside. This possibility to abandon such ex-post unprofitable projects, often referred to as a Real Option (see Trigeorgis 1996, Huchzermeier and Loch 2001), has substantial value. It allows the firm to limit its downside exposure to the revenue uncertainty as unprofitable projects are terminated, while fully capturing the upside potential from projects that turn out to be blockbusters. For this reason, the value of the project is increasing in the volatility of the revenue projections, implying that more uncertain projects are more valuable.

Turning to the biotech’s share of the value, as shown in Proposition 1, this is increasing in  $s$ , implying that if the biotech wants to retain a larger share of the value then it needs to retain a higher share of the project  $s$ . In order to retain a share  $s$ , the biotech is required to invest  $sC_0$  at time  $t_0$  and, provided the project has been technically successful in the first stage and it was not abandoned on commercial grounds (i.e.  $X(t_1) > x_c$ ), it will be required to invest a further  $s(C_1(X(t_1)))$  at time  $t_1$ . This capital requirement is a random variable at time  $t_0$ . More specifically, at time  $t_0$  there is a probability that the co-development investment  $C_B(s) = s(C_0 + C_1(X(t_1)))$  required by the biotech that retains a share  $s$  exceeds its available capital  $K$ . We summarize this probability and its comparative statics in the following proposition.

**PROPOSITION 2.** *The time  $t_0$  probability the investment required by the biotech  $C_B(s)$  that retains a share  $s$  in the co-development exceeds the available capital  $K$  is given by*

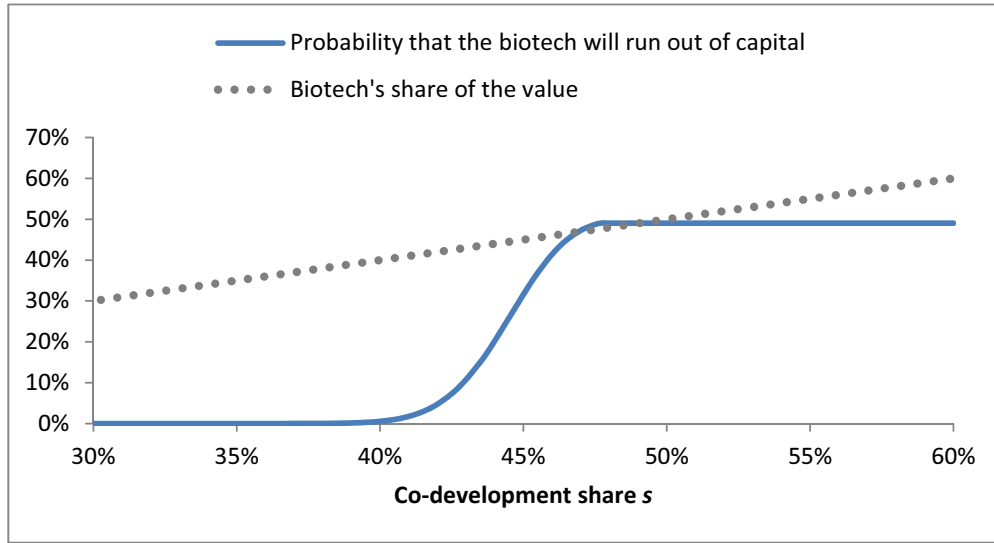
$$Pr(C_B(s) > K) = p_1 \int_{\max\{x_c, x_B(s, K)\}}^{\infty} f(x) dx, \quad (2)$$

where  $x_B(s, K) = C_1^{-1}(K/s - C_0)$ . This probability is non-decreasing in  $s$  and non-increasing in  $K$ . When the revenue projection  $X(t)$  follows a driftless Geometric Brownian Motion  $dX(t) = X(t)\sigma dz$  with  $X(0) = x_0$ , this probability is increasing (decreasing) in  $\sigma$  if  $Pr(C_B(s) > K) < \frac{p_1}{2}$  ( $Pr(C_B(s) > K) > \frac{p_1}{2}$ ).

Proposition 2 shows that for any value of the initial capital  $K$  and any share of value  $s$ , the biotech has a non-zero probability of running out of capital. Naturally, this probability is non-decreasing in the share the biotech retains in co-development  $s$  and is non-increasing in the initial capital endowment  $K$ . What is less obvious is how uncertainty in the cashflow projections (at least in the case of the driftless Geometric Brownian Motion) affects the probability that the biotech will run out of capital. If the probability of running out of capital is below  $p_1/2$  (i.e.  $\max\{x_c, x_B(s, K)\} < x_0$ ), then this probability is increasing in cashflow volatility  $\sigma$ , while if it is above  $p_1/2$  (i.e.  $\max\{x_c, x_B(s, K)\} > x_0$ ) it is decreasing in cashflow volatility  $\sigma$ . This is interesting because it suggests that as the uncertainty of future cashflows (and thus development costs) increases, it is more difficult for a conservative biotech (i.e. one that wants to have a probability of running out of capital that is less than  $p_1/2$ ) to ensure that it does not run out of capital.

It is important to note that while the value the biotech is able to retain in the joint venture is increasing in the share  $s$  it retains, the probability the biotech runs out of capital  $Pr(C_B(s) > K)$  is a non-increasing function of the share  $s$  it has in the joint venture (while it is a non-decreasing function of its initial capital position  $K$ ). We demonstrate this result with a specific example presented Figure 1. The parameters used for the numerical example are presented in the Appendix and are chosen to represent a project which at time  $t_0$  is projected to become a blockbuster drug (peak revenues in excess of \$1 billion p.a.) if technically successful. In this example the total value of the project is \$251M and  $x_c = \$711M$ . As proven in Propositions 1 and 2, and illustrated in Figure 1, co-development makes it difficult for a financially constrained firm (low  $K$ ) to appropriate a large share of the value of the project (large  $s$ ) without incurring a substantial risk of running out of capital. When the  $t_1$  revenue projections are log-normally distributed at time  $t_0$ , this effect is exacerbated by an increase in revenue uncertainty (provided the probability of running out of capital is less than  $p_1/2$ ).

One may argue that raising more capital could resolve this problem. In perfectly efficient markets this should be the case. However, the same reasons that necessitated the partnership make it more difficult for third parties to appraise the project and be able to frictionlessly supply the additional capital without demanding a substantial premium from the biotech (Hall and Lerner 2010). Therefore, even if running out of capital does not necessarily suggest that the project and the partnership will be terminated it does suggest that the biotech will have to give up a substantial part of the generated value.



**Figure 1** The value appropriated by the biotech is increasing in the co-development share  $s$  it retains in the joint project, as is the probability that it will run out of capital.

#### 4.2. Standard licensing

Given the capital restrictions faced by the small firm, would it not be preferable for the biotech to out-license the project to the pharma in return for milestone and royalty payments? In such a contract the pharma company that in-licenses the project from the biotech company at time  $t_0$  will incur all future development costs. The biotech company obtains an upfront payment  $M_0$ , two milestones  $M_1$  and  $M_2$  payable upon technical success in Phases 1 and 2, respectively, and a share  $k$  of the value of the drug at time  $t_2$  as a royalty payment. Consistent with our assumption of a licensing embedded partnership, we assume that the bulk of the transfer from the pharma to the biotech needs to take place in the form of late stage payments such as the second stage milestone,  $M_2$ , and royalties in order for the biotech to be incentivized to further engage with the project and exchange technological expertise and know-how with the pharma. In the interest of parsimony we therefore disregard early stage milestones and assume  $M_1 = M_0 = 0$ .

As in the case of the co-development contract, we work backwards to find the value of the M&R contract for each party. At time  $t_2$ , assuming technical success, the pharma value  $P_2^l$  and the biotech value  $B_2^l$  are

$$P_2^l(X(t_2)) = (1 - k)X(t_2) - M_2$$

$$B_2^l(X(t_2)) = kX(t_2) + M_2.$$

Backtracking to time  $t_1$  and assuming technical success, the pharma's expected value if it was to continue with the project is given by  $P_1^l(X(t_1)) = p_2 \mathbf{E}[P_2^l(X(t_2)) | X(t_1)] - C_1(X(t_1)) =$

$p_2((1-k)X(t_1) - M_2) - C_1(X(t_1))$ . Naturally, the pharma company, as the new owner of the project, will only continue with the development if this expected value is positive, i.e. if  $p_2((1-k)X(t_1) - M_2) \geq C_1(X(t_1))$ . The biotech company however is a passive observer whose payoff from the contract is influenced by the decisions of the pharma company. If the pharma chooses to continue with the project, the biotech's expected payoff at  $t_1$  will be given by  $p_2 \mathbf{E}[B_2^l(X(t_2))|X(t_1)] = p_2(kX(t_1) + M_2)$ . If the project is abandoned, the biotech will receive neither the second stage milestone payment nor any royalty payments.

We summarize the threshold for abandonment as well as the value of the project for the licensee (pharma) and the licensor (biotech) with the following proposition.

PROPOSITION 3. *There exists a threshold  $x_l(k, M_2) \geq x_c$  such that at time  $t_1$  the project is optimally abandoned when  $X(t_1) \leq x_l(k, M_2)$ . The threshold is the positive root of the equation*

$$C_1(x) = p_2((1-k)x - M_2), \quad (3)$$

*and is strictly increasing in  $k$  and  $M_2$ . The value of the project at time  $t_0$  for the pharma ( $P_0^l(k, M_2)$ ) and the biotech ( $B_0^l(k, M_2)$ ) are given by*

$$P_0^l(k, M_2) = p_1 p_2 \int_{x_l(k, M_2)}^{\infty} ((1-k)x - M_2 - C_1(x)/p_2) f(x) dx - C_0, \quad (4)$$

$$B_0^l(k, M_2) = p_1 p_2 \int_{x_l(k, M_2)}^{\infty} (kx + M_2) f(x) dx, \quad (5)$$

where  $f(x)$  denotes the density of  $X(t_1)$  at time  $t_0$ .

It is interesting to note that for any strictly positive royalty  $k$  or milestone payment  $M_2$  the abandonment threshold under licensing  $x_l(k, M_2)$  is strictly greater than the threshold under co-development  $x_c$ . This illustrates the problem of licensing in the context of staged projects with an uncertain value that changes over the duration of a stage. The late stage royalty and milestone payments raise the threshold which the  $t_1$  revenue projection of the licensed project needs to exceed in order to continue with the development of the project. This happens because in order for the drug to be economically viable and therefore worth taking to second stage development, not only do the expected revenues need to exceed the development costs  $C_1(x)$  but also the projected royalty ( $kX(t_1)$ ) and milestone ( $M_2$ ) payments to the biotech. From the pharma's perspective these payments are no different to development costs. Therefore projects with positive NPV, i.e. whose expected revenue exceeds the cost of development, are uneconomical for the pharma to develop because of the licensing payments, and are therefore abandoned. We investigate the value lost by these *inefficient* abandonments with the following corollary.

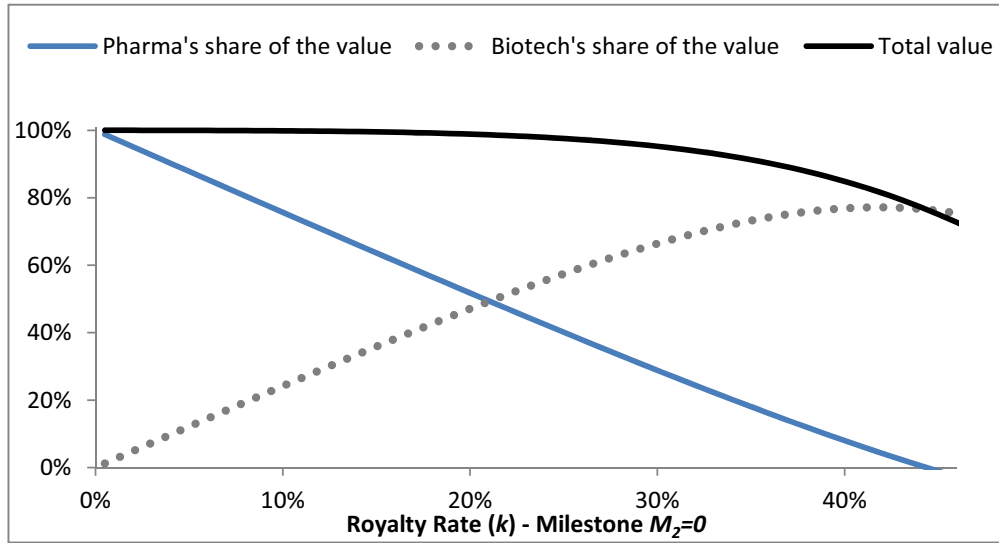
COROLLARY 2. *The total value lost by licensing compared to co-development is given by  $\Delta V = p_1 p_2 \int_{x_c}^{x_1(k, M_2)} (x - C_1(x)/p_2) f(x) dx$  and it is non-decreasing in the royalty rate  $k$  and milestone payment  $M_2$ . Furthermore, the value to the biotech  $B_1^l(k, M_2)$  is non-monotone in the royalty  $k$  and milestone  $M_2$  parameters.*

Proposition 3 states that the threshold which the  $t_1$  projection needs to exceed in order for the project to be continued is increasing in late stage fees (royalties or milestones), suggesting that the problem of inefficient abandonments is exacerbated as the licensor tries to extract more value by increasing the fees. Interestingly, the projects that are *inefficiently* abandoned are those whose revenue projection is only marginally above the costs of development, i.e.  $x_c \leq X(t_1) \leq x_l(k, M_2)$ . Therefore, the inefficiency becomes more problematic in settings where there is a significant probability that the project's revenues will turn out to be close to its costs. Arguably, this is the case in pharmaceutical R&D; for example, DiMasi and Grabowski (2012) (see Figure 2.14 p.39) report that less than 20% of the pharmaceutical projects introduced between 1990 and 1994 delivered ex-post after-tax Net Present Values that were 10% higher than their R&D costs. This problem of inefficient abandonment harms both firms as it destroys value, i.e. it would be Pareto-dominated by co-development if the biotech's financial constraints were not an issue. Furthermore, the inefficient abandonments induced by licensing are problematic from a consumer/patient welfare perspective as they halt the development of new products that are perfectly viable on medical grounds but are only marginal on commercial grounds.

A final interesting observation is that contrary to what one might expect, the biotech is not always better off by negotiating a higher royalty rate  $k$  or milestone payment  $M_2$ . On the contrary, Corollary 2 shows that the value the biotech extracts from licensing is not always increasing in the royalty/milestone payment. This happens because although increasing the royalty/milestone rate gives a higher proportion of the value of the finished product to the biotech, it also reduces the probability that a finished product will materialize in the first place. As royalty/milestone payments increase, the second effect begins to dominate.

We demonstrate the relationship between the royalty rate  $k$  and the value appropriated by each of the two firms with our example in Figure 2. Clearly, licensing for late stage milestones and royalties is not without drawbacks, especially for a biotech that wants to retain a larger share of the value it creates. Unlike in the case of co-development, the drawbacks have nothing to do with capital constraints - indeed licensing reduces the probability that the bioech will run out of capital to zero. The drawback of licensing is that it increases the effective development costs for the pharma, which in turns leads to projects that would have been economically viable in a co-dvelopment contract to be abandoned in a royalty/milestone contract.

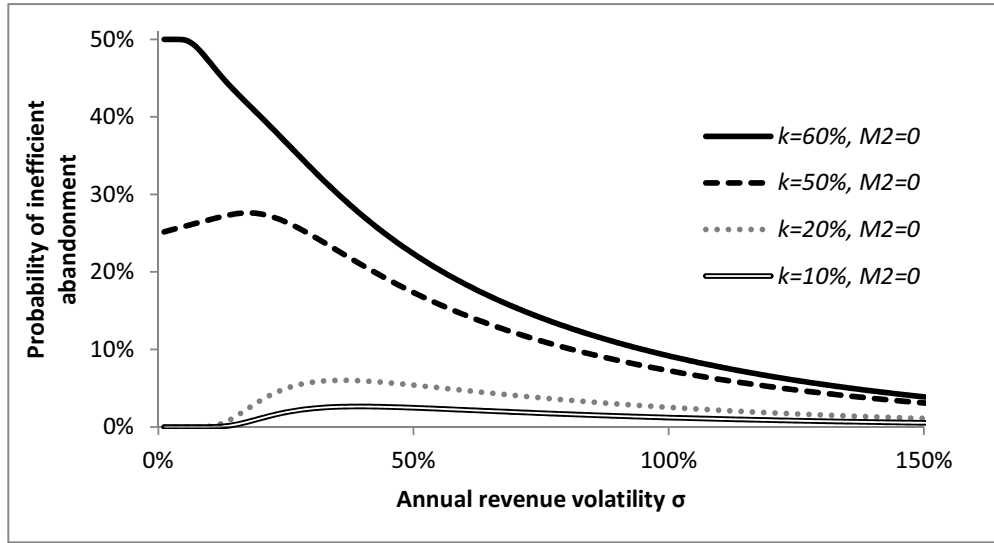




**Figure 2** While the value appropriated by the pharma is decreasing in the royalty rate  $k$  so does the total value to both firms due to inefficient abandonments. The value appropriated by the biotech is initially increasing in the royalty rate  $k$  but eventually, as the value destroyed by the inefficient abandonments becomes significant, it is decreasing in the royalty rate  $k$ .

While it would have been interesting to investigate analytically the impact of revenue volatility on the probability of inefficient abandonments, a simple or useful characterization is not possible even under the Geometric Brownian Motion assumption. We therefore revert to a numerical investigation in the context of our example, which we present in Figure 3. As can be seen, for sufficiently low royalty rates (such that  $x_l(k, M_2) < X_0$ , i.e. for the project to be inefficiently abandoned the revenues need to be revised downwards after the end of the first stage) the probability of inefficiency abandonment is initially increasing in volatility  $\sigma$  and then decreasing. For high royalty rates this probability is decreasing in  $\sigma$ . Therefore, one can argue that an increase in volatility is more problematic when revenue projections are not exceedingly volatile and for licensing contracts where the royalty terms are such that the project will not be inefficiently abandoned on the base case scenario ( $x_l(k, M_2) < X_0$ ).

One may argue that renegotiation is a way to restore efficiency in this context. Afterall, if the project is going to be abandoned because the milestone/royalty payments are too high, one would expect both the biotech and the pharma to be willing to renegotiate the contract. Such renegotiation could potentially improve the outcome for both firms. However, renegotiation is time-consuming which could delay the launch of the finished product. This is problematic in any industry, for example Hendricks and Singhal (1997) find that markets penalize delays of new product introductions by an average of 5.25%, and even more so in industries with short lived



**Figure 3** For sufficiently low royalty rate  $k$  the probability of inefficient abandonments is first increasing and then decreasing in revenue volatility  $\sigma$ . For high royalty rates the probability of inefficient abandonments is decreasing in  $\sigma$ .

patent protection and where margins reduce drastically when patents expire. Opt-out options, which we analyze next, are an alternative to explicit renegotiation.

#### 4.3. Co-development with opt-out options

We have so far established that co-development with a fixed sharing arrangement  $(s, 1 - s)$  entails a significant risk for the biotech as there is a non-trivial probability that its limited financial resources will not be sufficient to cover its share of the R&D cost. We have also shown that licensing-out in return for royalty  $k$  and late stage milestone payment  $M_2$  induces inefficient abandonments which destroy value for both firms, as well as reduce the probability of creating medically and commercially viable drugs. Furthermore, both the probability of running out of capital in co-development and the value destroyed by inefficient abandonments in licensing increase as the biotech tries to appropriate a larger share of the value generated. In this section we investigate a more innovative contractual structure which allows the biotech company to manage this risk while at the same time overcoming the suboptimal abandonment decisions associated with licensing.

We consider the case of co-development with an opt-out option that gives the biotech company the right to opt out of co-development at the end of the first phase. If the option is exercised, ownership of the project is transferred to the pharma company, which will then have to cover all of the remaining development costs and take the continuation decision unilaterally. If the project is successful in Phase 2 the biotech will receive a milestone  $M_2$  and a royalty percentage  $k$  at time  $t_2$ . To avoid trivial situations where the option is always or never exercised, we assume that  $M_2 \geq 0$ ,

$0 \leq k \leq s \leq 1$ . Note that this option contract is quite different from co-development during Phase 1, followed by a *pre-agreed* exit to milestones and royalties. In fact, the latter contract is equivalent to a standard licensing contract with an upfront payment from the biotech to the pharma equal to  $sC_0$ . Notice that the inefficiency region of the contract depends on the milestone  $M_2$ , paid at project completion and the royalty  $k$  so the forced exit contract inherits the inefficiency of the M&R contract.

The co-development with opt-out contract can be naturally analyzed via backwards induction. To understand when the option will be exercised we need to consider the projected payoffs to each of the two parties under co-development and under opt-out at time  $t_1$ . On the one hand, if the biotech was to exercise the option after the successful completion of the exploratory clinical trials, the projected payoff at time  $t_1$  would be given by  $p_2(kX(t_1) + M_2)$  *provided* the pharma company chose to continue with the development of the project and zero otherwise. In turn, the pharma company would only choose to continue with the development if its  $t_1$ -projected payoff after the biotech opted out is non-negative, i.e.  $p_2(1 - k)X(t_1) - M_2 - C_1(X(t_1)) \geq 0$ . On the other hand, if the biotech was to continue with the co-development, its  $t_1$ -projected payoff would be given by  $s(p_2X(t_1) - C(X(t_1)))$  *provided* it has sufficient capital to exercise the option (i.e.  $C_1(X(t_1)) - C_0 \geq K/s$ ) and we assume for simplicity it is zero otherwise. Comparing the payoffs under different revenue projections at time  $t_1$  yields the optimal exercise policy for the biotech, which is summarized in the proposition below.

**PROPOSITION 4.** *There exists a threshold value  $x_c$  such that at time  $t_1$  the project is optimally abandoned when the revenue projects  $X(t_1) < x_c$ . There also exist threshold values,  $z_1$ ,  $z_2$  and  $z_3$  such that the optimal  $t_1$  exercise policy for the opt-out option is to opt-out when  $z_1 \leq X(t_1) \leq z_2$  or  $X(t_1) \geq z_3$ . The thresholds are the unique positive roots of the following equations:*

$$C_1(x_c) = p_2x_c, \quad z_1 = \frac{C_1(z_1) + M_2}{p_2(1 - k)}, \quad z_2 = \frac{C_1(z_2) + M_2}{p_2(s - k)}, \quad C_1(z_3) = \frac{K}{s} - C_0.$$

The value of the project at time  $t_0$  for the biotech and the pharma are given by

$$\begin{aligned} B_0^{opt}(s, k, M_2) &= p_1 s \int_{x_c}^{\min\{z_1, z_3\}} (p_2x - C_1(x)) f(x) dx + p_1 p_2 \int_{z_1}^{z_2} (kx + M_2) f(x) dx \\ &+ p_1 s \int_{\min\{z_2, z_3\}}^{z_3} ((p_2x - C_1(x)) f(x) dx + p_1 p_2 \int_{\max\{z_2, z_3\}}^{\infty} (kx + M_2) f(x) dx - sC_0, \\ P_0^{opt}(s, k, M_2) &= p_1(1 - s) \int_{x_c}^{\min\{z_1, z_3\}} (p_2x - C_1(x)) f(x) dx + p_1 \int_{z_1}^{z_2} (p_2((1 - k)x - M_2) - C_1(x)) f(x) dx \\ &+ p_1(1 - s) \int_{\min\{z_2, z_3\}}^{z_3} ((p_2x - C_1(x)) f(x) dx + p_1 \int_{\max\{z_2, z_3\}}^{\infty} (p_2((1 - k)x - M_2) - C_1(x)) f(x) dx - (1 - s)C_0. \end{aligned}$$

We first note that the threshold  $x_c$ , below which every project is abandoned, is identical to that of the pure co-development contract, suggesting that unprofitable projects are optimally abandoned. Its worth examining the intuition behind the thresholds of the opt-out option. Ignoring capital constraints, for projects whose  $t_1$  projected value is less than  $z_2$  the biotech's payoff if it chooses to opt-out of co-development to royalty and milestone payments is greater than the projected payoff if it chooses to continue with co-development. Naturally, based on its own payoff alone the biotech will want to opt-out in all scenarios where the project's value is less than  $z_2$ . However, in order for the biotech to realize this payoff upon opt-out, the pharma's residual projected payoff (after the milestone/royalty payment) needs to exceed the costs of development, otherwise the pharma would simply abandon the project. The projected revenues are sufficiently large when  $X(t_1) \geq z_1$ . For revenue projections less than  $z_1$  the biotech does not opt-out in order to prevent the project from being inefficiently abandoned by the pharma. Clearly, since  $k \leq s \leq 1$  and  $M_2 \geq 0$  then  $z_2 \geq z_1$ , suggesting that ignoring capital constraints, the opt-out region is non-empty. For revenue projections that exceed  $z_2$  the project is so profitable that the biotech would naturally want to co-develop. The only problem is that the project may become so costly to develop that the biotech runs out of capital. This happens if the project's value exceeds the threshold  $z_3$ . Therefore the biotech will opt out of these projects.

It is worth emphasizing that there are two distinct reasons for opting out of projects. The first, occurring in the interval  $[z_1, z_2]$  of the  $t_1$  projected revenue, is due to the fact that the option is "in the money", i.e. the payoff of exercising the option exceeds the payoff of continuing with co-development and the project is sufficiently valuable for the pharma to develop alone. The second reason, occurring in the interval  $[z_3, \infty)$ , is due to capital constraints. While the option might still be "in the money", the effective "strike" price of the option is simply too high for a capital-constrained biotech. It therefore decides to opt out of the capital- and resource-intensive co-development, in favor of the more benign royalties/milestone-based licensing.

However, this second reason for opting out may give rise to an inefficiency. Projects whose projected revenue at time  $t_1$  falls in the interval  $[x_c, z_1)$  can only be co-developed; the pharma would find them too costly to develop alone in a milestone/royalty based licensing contract. Bearing in mind the biotech's capital constraint, these projects will only co-developed, and therefore inefficient abandonment avoided, if the biotech company has a sufficiently low co-development share  $s$ . We summarize the probability that the biotech will not have sufficient capital in a co-development with opt-out option contract with the following corollary.

COROLLARY 3. *The time  $t_0$  probability that the investment required by the biotech in a co-development with opt-out option contract with parameters  $(s, k, M_2)$  will exceed the available capital  $K$  is given by*

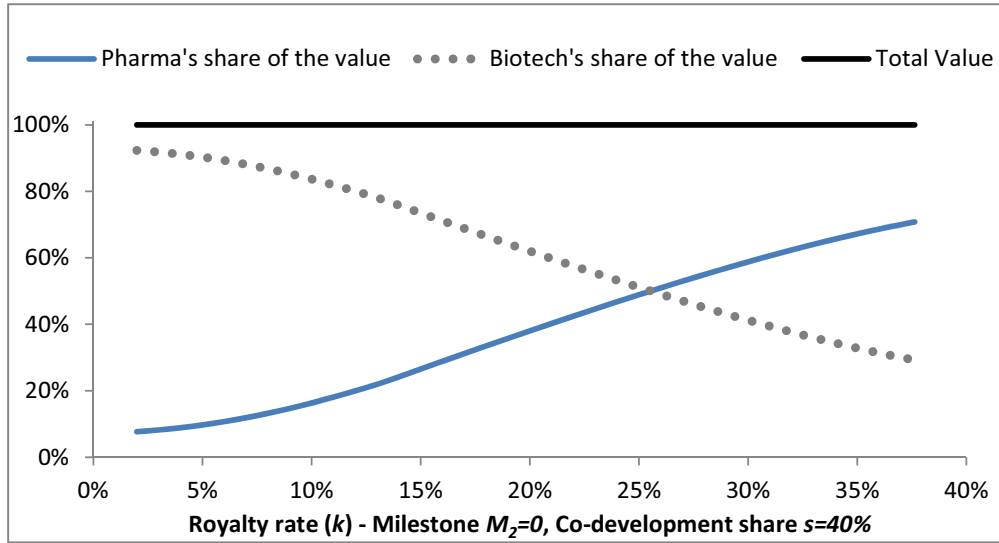
$$Pr(C_B > K) = p_1 \int_{\min\{z_1(k, M_2), z_3(s, K)\}}^{z_1(k, M_2)} f(x) dx,$$

where  $z_1(k, M_2)$  and  $z_3(s, K)$  are given in Proposition 4. This probability is zero when  $z_1 \leq z_3$  and is non-decreasing in  $s$  and non-increasing in  $K$ . For any  $K$  and  $s$ , the probability that the biotech will not have sufficient capital in a co-development with opt-out option agreement is not larger than the probability that it will not have sufficient capital in a pure co-development agreement.

As shown in Corollary 3, the possibility that the biotech will run out of capital is entirely avoidable provided it takes a small enough share  $s$  in the project or has enough capital  $K$  such that  $z_1 \leq z_3$ . This is in sharp contrast with the pure co-development contract where this possibility was unavoidable. Furthermore, compared with the pure co-development, for any level of  $s$  and  $K$ , the biotech has a lower probability of running out of capital. This illustrates the main advantage of the partnership based on co-development with opt-out option. With modest capital the biotech can retain a larger share of the value with a smaller risk (or no risk at all in many cases) of running out of capital.

Finally, we note that the second co-development region, which occurs for the relatively high  $t_1$  revenue projections of the interval  $[z_2, z_3]$  does not have to exist. In fact, the contract can be designed so that this region disappears altogether. This happens when the thresholds  $z_2$  and  $z_3$  are designed so that  $z_3 \leq z_2$ . In this case the optimal strategy for the partnership is to co-develop projects to the completion of the first stage (i.e. time  $t_1$ ) and then (optimally) abandon any project whose  $t_1$  projected revenue falls below  $x_c$ , to co-develop to completion any project with  $t_1$  projected revenue in the interval  $[x_c, z_1]$ , and for the pharma to develop alone any project with a value greater than  $z_1$  with the biotech receiving generous royalty/milestone terms. We believe this specific contractual agreement, with a single co-development region which is focussed on relatively small, low revenue projects, to be of practical interest as it is better aligned with the business models of the two firms. This contract allows the biotech company to co-develop small and niche products which are not too capital- or resource-intensive and to opt out of blockbuster drugs for very favorable M&R terms. The commercialization of such drugs is at the core of the big pharma business model.

We demonstrate our results with a specific example in Figure 4. In this example  $z_1 < z_3 < z_2$ , therefore the biotech never runs out of capital, even if it appropriates most of the value. This is in sharp contrast to the pure co-development contract of Figure 1 where the biotech had to accept a substantial risk of running out capital in order to appropriate more than 40% of the value. Furthermore, there are no inefficient abandonments and no value is ever destroyed in this contract.



**Figure 4** The value appropriated by the biotech is increasing in the opt-out royalties. This contract allocates 100% of the value to the two firms.

This is again in sharp contrast to the pure licensing contract where it was impossible for the biotech to appropriate more than 60% of the value without destroying a significant amount of the total value of the project. Finally, in this example when  $k \geq 14\%$  we have  $z_3 < z_2$ , therefore there exists a single co-development region in the interval  $[x_c, z_1]$ . The biotech opts out of all projects with value above  $z_1$ .

## 5. Discussion and conclusions

In this paper, we have analyzed the economic effects of three contractual agreements: co-development, licensing, and co-development with an opt-out option for the joint development of a new product, such as a pharmaceutical drug between a small and financially constrained innovator firm (biotech) and a large technology company (pharma). To this end, we built a simple model which is close to the prevalent risk-adjusted net present value valuation technique in the bio-pharmaceutical industry, but adds commercial risk and abandonment decisions. We show that co-development, which entails sharing costs and revenues at a pre-agreed fixed proportion, imposes a significant risk on the small firm as there is a non-trivial probability of running out of R&D capital. While licensing-out in return for royalty and late stage milestone payments completely eliminates this risk it also creates a different problem: it raises the hurdle the projected revenues of the project need to exceed in order to continue with development after the completion of the first stage, thus leading to inefficient abandonments. Such abandonments not only destroy value for both firms, but reduce the probability of creating technically (and medically) viable products. Furthermore, both the probability of running out of capital in co-development and the value destroyed

by inefficient abandonments in licensing increase as the small firm tries to appropriate a larger share of the value generated. We show that the co-development contract which gives the small firm the option to opt out of co-development to licensing after the end of the first stage at pre-agreed terms largely avoids these problems. This contract incentivizes the small firm to continue with co-development after the (successful) completion of the first stage when the projected revenues are above costs but *not* above costs plus projected milestone/royalty payments, thus avoiding inefficient abandonments. Such projects are typically small enough to be well suited to the specialized sales force that small firms such as the biotech should be able to develop. This contract also incentivizes the small company to opt out of projects with a large market value, e.g. pharmaceutical blockbusters, which are geared toward the large technology company's sales power.

Our work shows that uncertainty does not need to be regarded as an inhibitor to alliance formation. However, effective partnership arrangements need to recognize that flexibility is a core value driver for R&D projects in high-risk environments. Alliances should anticipate the problems caused by uncertainty and be based on creative contract designs that are enforceable and provide the necessary flexibility for dealing with the evolving value of R&D projects. Our model, besides allowing us to identify and investigate the structural properties of the inefficiencies associated with pure co-development and licensing has, with appropriate calibration, the potential to provide prescriptive advice to firms negotiating such joint new product development alliances. Our model can help advise on how to structure such contracts to achieve efficiency and reduce the risk of the small firm running out of financial resources. Furthermore, it can also provide advice on the optimal exercise of the opt-out option by identifying the cashflow projections for which the owner of the option, in this case the biotech, would be better off opting out of co-development in favor of licensing.

The pharmaceutical industry is not the only sector where innovation is increasingly a collaborative effort. University-based research, e.g. in nanotechnology, is another example of innovation commercialized in partnership, in fact often with more than two stakeholders (Dechenaux et al. 2009). However, this industry displays different characteristics to those of pharmaceuticals, which will have a bearing on the transferability of our findings. For example, the symmetric information assumption, which is motivated by the scientific spirit underlying the partners in biotechnology/pharma R&D alliances, is not necessarily valid in other industries. Further research is necessary to identify sensible contracts and property right agreements to foster collaborative innovation (see e.g. Aghion and Tirole (1994)) and to develop the most effective models for the commercialization of emerging technologies (Cassiman and Ueda 2006).



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## 6. Appendix

**Proof of Proposition 1** The project proceeds at time  $t_1$  only if the projected revenue exceeds the costs of development,  $p_2x - C_1(x) \geq 0$ . Therefore  $x_c$  is given by the positive root of  $C_1(x) = p_2x$ . Given the assumption placed on  $C_1(x)$ , namely continuous, positive, increasing, strictly concave and  $\lim_{x \rightarrow \infty} C_1'(x) = 0$ , the root  $x_c$  exists and is unique. The projected value of the project at time  $t_0$  is given by

$$\begin{aligned} V_0(X(t_0)) &= p_1 \mathbf{E} \left[ (V_1(X(t_1)))^+ | X(t_0) \right] - C_0 \\ &= p_1 \mathbf{E} \left[ (p_2 X(t_1) - C_1(X(t_1)))^+ | X(t_0) \right] - C_0 \\ &= p_1 p_2 \int_{x_c}^{\infty} (x - C_1(x)/p_2) f(x) dx - C_0, \end{aligned}$$

where we have used the notation  $x^+ = \max(x, 0)$ . Finally, the two firms share the value according to the pre-agreed ratios  $(s, 1 - s)$ .  $\square$

**Proof of Corollary 1:** Ignoring the constant  $C_0$ , the value  $V_0$  of the project is given by

$$V_0 = \int_{x_c}^{\infty} g(x) f(x; \sigma) dx,$$

where  $g(x) = p_1 p_2 x - p_1 C_1(x)$  is an increasing strictly convex function in  $[x_c, \infty)$  with  $g(x_c) = 0$  and  $f(x; \sigma)$  is the density function of the log-normal distribution with drift zero and volatility  $\sigma$ . Define  $u(x) = g(x)$  if  $x \geq x_c$  and  $u(x) = 0$  otherwise. Clearly  $u(x)$  is a (weakly) increasing convex function, and  $V_0$  can be written as  $V_0 = \int_0^\infty u(x) f(x; \sigma) dx = \mathbf{E}(u(X))$ , where  $X$  is a random variable following the log-normal distribution with volatility  $\sigma$ . Consider a random variable  $Y$  which also follows the log-normal distribution with volatility  $\tau$ . Following Müller and Stoyan (2002), p. 63,  $X$  is less than  $Y$  in increasing convex order for  $\tau \geq \sigma$ . By the definition of the increasing convex order (see Müller and Stoyan (2002), p. 16),  $\mathbf{E}(u(X)) \leq \mathbf{E}(u(Y))$  for any increasing convex function  $u$ . Therefore the value  $V_0$  is non-decreasing in the volatility. This result generalizes the standard Black-Scholes pricing result from non-decreasing piecewise linear payoff functions to more general convex functions.  $\square$

**Proof of Proposition 2:** The investment required by the biotech at time  $t_1$  is  $s(C_1(X(t_1)))$  provided the project was technically successful in the first stage and that it has not been abandoned on commercial grounds ( $X(t_1) > x_c$ ) and zero otherwise. At time  $t_1$  the biotech runs out of capital if  $s(C_1(X(t_1))) > K - sC_0$  or  $X(t_1) > C_1^{-1}(K/s - C_0)$  and  $X(t_1) > x_c$ . At time  $t_0$  the probability of this happening is given by

$$Pr(C_B(s) > K) = p_1 \int_{\max\{x_c, x_B(s, K)\}}^{\infty} f(x) dx,$$

where  $x_B(s, K) = C_1^{-1}(K/s - C_0)$ . Turning to the comparative statics,

$$\begin{aligned} \frac{\partial}{\partial s} Pr(C_B(s) > K) &= \begin{cases} 0 & \text{if } x_c > x_B(s, K) \\ p_1 \frac{K}{s^2} \frac{f(x_B(s, K))}{C_1'(x_B(s, K))} > 0 & \text{if } x_c \leq x_B(s, K), \end{cases} \\ \frac{\partial}{\partial K} Pr(C_B(s) > K) &= \begin{cases} 0 & \text{if } x_c > x_B(s, K) \\ -p_1 \frac{1}{s} \frac{f(x_B(s, K))}{C_1'(x_B(s, K))} < 0 & \text{if } x_c \leq x_B(s, K), \end{cases} \end{aligned}$$

where we have used the fact that  $C_1(x)$  is an increasing function. Finally, to understand the impact of an increase in the volatility  $\sigma$  on the probability of  $Pr(C_B(s) > K)$  in the case of the driftless Geometric Brownian Motion consider the variable  $y = \ln \frac{x}{x_0}$  where  $x$  is the  $t_0$  projection of cashflows at  $t_1$  and  $X(t_0) = x_0$ . Then  $y \sim N(-\frac{1}{2}\sigma^2 t, \sigma^2 t)$  and the probability of running out of capital can be written as

$$Pr(C_B(s) > K) = p_1 \int_{y_0}^{\infty} \phi\left(\frac{y - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}\right) dy,$$

where  $\phi(x)$  is the standard Normal distribution probability density function and  $y_0 = \ln \frac{\max\{x_c, x_B(s, K)\}}{x_0}$ . Then

$$\begin{aligned} \frac{\partial}{\partial \sigma} Pr(C_B(s) > K) &= p_1 \frac{\partial}{\partial \sigma} \int_{y_0}^{\infty} \phi\left(\frac{y - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}\right) dy \\ &= p_1 \frac{\partial}{\partial \sigma} \left(1 - \Phi\left(\frac{y_0 - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}\right)\right) \\ &= p_1 \frac{y_0 + \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}} \phi\left(\frac{y_0 - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}\right). \end{aligned}$$

Clearly, this is positive for  $y_0 > -\frac{1}{2}\sigma^2 t$ . Note that  $-\frac{1}{2}\sigma^2 t$  is the mean of the Normally distributed random variable  $y$  and we know from the properties of the Normal distribution that when  $y_0 > -\frac{1}{2}\sigma^2 t$  then  $\int_{y_0}^{\infty} \phi(\frac{y - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}) dy < 50\%$ , which implies  $Pr(C_B(s) > K) < \frac{p_1}{2}$ . Conversely, the derivative is negative for  $y_0 < -\frac{1}{2}\sigma^2 t$  which in turn implies  $Pr(C_B(s) < K) = p_1 \int_{y_0}^{\infty} \phi(\frac{y - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}) dy > \frac{p_1}{2}$ .  $\square$

**Proof of Proposition 3** The pharma proceeds with the project at time  $t_1$  only if the projected revenue exceeds the costs of development,  $p_2((1-k)X(t_1) - M_2) \geq C_1(X(t_1))$ . Therefore  $x_l$  is given by the positive root of  $p_2((1-k)x - M_2) = C_1(x)$  which exists, is unique, and increases in  $k$  and  $M_s$  (given the assumptions on  $C_1(x)$ , namely that  $C_1(x)$  is a positive, increasing and strictly concave function with  $\lim_{x \rightarrow \infty} C_1'(x) = 0$ ). Furthermore, comparing  $x_l$  with  $x_c$ , which is the solution of  $p_2x = C_1(x)$ , we can conclude that for  $k, M_2 > 0$  then  $x_l > x_c$ . Using the law of iterated expectations, the projected value of the project at time  $t_0$  is given by

$$\begin{aligned} P_0^l(k, M_2) &= p_1 \mathbf{E} \left[ (P_1^l(X(t_1)))^+ | X(t_0) \right] - C_0 \\ &= p_1 p_2 \int_{x_l(k, M_2)}^{\infty} ((1-k)x - M_2 - C_1(x)/p_2) f(x) dx - C_0, \\ B_0^l(k, M_2) &= p_1 \mathbf{E} \left[ (B_1^l(X(t_1)) I_{P_1^l(X(t_1)) \geq 0}) | X(t_0) \right] \\ &= p_1 p_2 \int_{x_l(k, M_2)}^{\infty} (kx + M_2) f(x) dx, \end{aligned}$$

where  $I_{P_1^l(X(t_1)) \geq 0}$  is the indicator function that takes the value of 1 when  $P_1^l(X(t_1)) \geq 0$  (i.e. when the pharma continues with the project's development) and 0 otherwise.  $\square$

**Proof of Corollary 2:** Comparing the abandonment thresholds from Proportions 1 and 3 we can observe that any project whose  $t_1$  projection falls between  $x_c \leq X(t_1) < x_l(k, M_2)$  would be developed under co-development but not under licensing. The (total) value of these inefficiently abandoned projects is given by

$$\Delta V = p_1 p_2 \int_{x_c}^{x_l(k, M_2)} (x - C_1(x)/p_2) f(x) dx - C_0$$

and since the upper limit of the integral  $x_l(k, M_2)$  is non-decreasing in  $k$  and  $M_2$ , the value lost is non-decreasing in  $k$  and  $M_2$ . Turning to the biotech's payoff  $B_0^l(k, M_2)$  it suffices to show that it is non-monotone in royalties  $k$  when  $M_2 = 0$ . To do so, observe that  $B_0^l(0, 0) = B_0^l(1, 0) = 0$  and that

$$\frac{\partial}{\partial k} B_0^l(k, 0) = p_1 p_2 \int_{x_l(k, 0)}^{\infty} (x) f(x) dx - p_1 p_2 x_l^2(k, 0) \frac{f(x_l(k, 0))}{1 - k - 1/p_2 \frac{\partial}{\partial x} C_1(x_l(k, 0))},$$

which implies that  $\frac{\partial}{\partial k} B_0^l(0, 0) > 0$ . By continuity of  $B_0^l(k, 0)$ , we conclude that the derivative of  $B_0^l(k, 0)$  changes sign in the interval  $k \in (0, 1)$ .  $\square$

**Proof of Proposition 4:** If at time  $t_1$  the costs of the development of the project exceed the revenues generated by the project, i.e. when  $p_2x - C_1(x) < 0$ , the project will naturally be

abandoned as it is not sufficiently profitable for either partner in a co-development and if the biotech was to opt out of co-developement, the pharma that has to pay royalties and milestones to the biotech will certainly find it unprofitable to develop alone, i.e for any  $k \geq 0$  or  $M_2 \geq 0$ ,  $p_2x - C_1(x) < 0$  implies  $p_2(1 - k)x - M_2 - C_1(x) < 0$ . The condition  $p_2x - C_1(x) = 0$  gives the threshold  $x_c$ .

For the opt-out option to be exercised the biotech's projected payoff under licensing needs to be (weakly) greater than that under co-development. Therefore  $p_2(kX(t_1) + M_2) \geq s(p_2X(t_1) - C(X(t_1)))$ , which suggests that  $x \leq \frac{C_1(x)+M_2}{p_2(s-k)}$ . This inequality gives the threshold  $z_2$  of Proposition 4. Furthermore the pharma's residual projected payoff if the biotech opts-out needs to be non-negative. Therefore  $p_2(1 - k)X(t_1) - M_2 - C_1(X(t_1)) \geq 0$ , which suggests that  $x \geq \frac{C_1(x)+M_2}{p_2(1-k)}$ . This inequality gives the threshold  $z_1$  of Proposition 4. Finally, the biotech's share of the cost of co-development needs to be no greater than the available capital  $K$ , which suggests that  $C_1(X(t_1)) + C_0 \leq K/s$  or  $C_1(x) \leq \frac{K}{s} - C_0$ . This inequality gives the threshold  $z_3$  of Proposition 4. All thresholds exists and are unique as  $C(x)$  is a continuous, positive, increasing and strictly concave function and  $\lim_{x \rightarrow \infty} C'_1(x) = 0$ . A project whose projected revenue at time  $t_1$  falls between  $x_c$  and  $z_1$  can only be co-developed as the pharma would find it too costly to develop alone in a licensing contract. It is therefore necessary for the biotech to have sufficient capital to co-develop such a project. For this to be the case  $z_3$ , which is the threshold above which the biotech cannot afford to co-develop such a project, must satisfy  $z_3 > z_1$ .

Finally, by noting that any project whose  $t_1$  revenue projections fall in the interval  $[0, x_c]$  is abandoned,  $[x_c, \min\{z_1, z_3\}] \cup [\min\{z_2, z_3\}, z_3]$  is co-developed (i.e. the opt-out option *is not* exercised), and  $[z_1, z_2] \cup [\max\{z_2, z_3\}, \infty)$  is licensed to the pharma (i.e. the opt-out option *is* exercised), and rolling back to time  $t_0$  we derive the value to the biotech and the pharma given in Proposition 4.  $\square$

### Proof of Corollary 3:

From Proposition 4 we know that any project with time  $t_1$  revenue projections greater than  $z_3$  will require more capital to co-develop than the biotech has available. Furthermore, we also know that the pharma will find it unprofitable to develop alone any project with  $t_1$  projected revenues less than  $z_1$ . Therefore, any project with  $t_1$  valuation between  $z_1$  and  $z_3$  (if such a project exists, i.e.  $z_1 < z_3$ ) requires more capital to co-develop than the biotech has available and cannot be opted out because it is not sufficiently profitable for the pharma to develop alone. At time  $t_0$  the probability of this happening is given by

$$Pr(C_B > K) = p_1 \int_{\min\{z_1(k, M_2), z_3(s, K)\}}^{z_1(k, M_2)} f(x) dx,$$

where  $z_1(k, M_2)$  and  $z_3(s, K)$  are given in Proposition 4. Turning to comparative statics, note that  $z_1$  does not depend on either  $K$  or  $s$  and that

$$\begin{aligned}\frac{\partial z_3}{\partial s} &= -\frac{K}{s^2} \left( \frac{d}{dz_3} C_1(z_3) \right)^{-1} < 0, \\ \frac{\partial z_3}{\partial K} &= \frac{1}{s} \left( \frac{d}{dz_3} C_1(z_3) \right)^{-1} > 0,\end{aligned}$$

where we have used the fact that  $C_1(x)$  is increasing. Therefore the probability  $Pr(C_B > K)$  is non-increasing in  $s$  and non-decreasing in  $K$ . Compared with the probability of running out of capital in a pure co-development given by Proposition 2, we note that  $z_3(s, K) = x_b(s, K)$  and therefore for any given  $s, K$  and a finite  $z_1$ , the probability of running out of capital in a co-development with an opt-out option is less than in a co-development without an option.  $\square$

#### Parameters for the illustrative numerical example

Parameter	Value	Units
Technical success probability of first stage $p_1$	50%	
Technical success probability of second stage $p_2$	80%	
First stage costs $C_0$	60	\$M
Second stage costs $C_1(x)$	$462.4 + 4\sqrt{x}$	\$M
Duration of first stage $t_1 - t_0$	3	years
Duration of second stage $t_2 - t_1$	4	years
Initial revenue projection $X(t_0)$	1550	\$M
Time $t_0$ distribution of $t_1$ cashflow projects $f(x)$	LogNormal(0, $\sigma$ )	
Annual revenue volatility $\sigma$	20%	p.a.
Biotech capital $K$	300	\$M