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 traditional co-development and licensing arrangements: In co-development the small firm runs a risk of running out of capital as future costs rise, while licensing for milestone and royalty (M&R) 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 M&R terms. We also show that an option 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 or licensing: the probability that the small firm will run 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

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. Many 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. 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 initial phase which aims to validate 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 the initial stage is typically relatively low, the cost of the second stage, which involves prototyping and scaling up for manufacturing, can be very expensive and may well stretch the financial muscle of the smaller 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 the initial 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 option-like characteristic, with implications for their economic valuation (Trigeorgis 1996, Huchzermeier and Loch 2001, Santiago and Vakili 2005).

In this paper we investigate 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 of co-development and into pre-agreed licensing terms after the first stage. In pure co-development the two firms share both the costs and, if successful, the revenues in 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 M&R payments 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). We assume that 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, governance structures, and incentives mechanisms that reduce such frictions. Therefore, we chose not to model moral hazard or informational asymmetry problems explicitly. Nevertheless, developing effective R&D agreements remains a challenge in our setting due to the 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. Perhaps more surprisingly, however, we find that when the biotech is not highly constrained this probability 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 the possibility that the biotech will run out of capital in the process is therefore 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 M&R 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 payoff 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 positive commercial value. We show that the expected value lost due to these inefficient abandonments is increasing in the M&R payments and, perhaps more surprisingly, we find that the biotech's economic value from licensing is non-monotonic in the M&R terms. 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 M&R 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, this contractual agreement allows the firms to develop every economically profitable project, while at the same time significantly reduce or even completely eliminate the possibility that the biotech will run 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 under co-development but would 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. The contract 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 exercise the opt-out option optimally.

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). While much of the research effort has focused on collaboration within the firm and the challenge of coordinating conflicting the goals of divisions or teams (Anderson and Joglekar 2005, Mihm 2010, Chao and

Kavadias 2008, Hutchison-Krupat and Kavadias 2009), research has begun more recently 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 preliminary stages and has created intellectual property that has the potential to generate commercial value. 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 and 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 M&R 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 M&R 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). Under 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.

The dynamics of R&D alliances have been examined in two-period principal–agent settings where one (Crama et al. 2012) or both (Xiao and Xu Forthcoming, Edlin and Hermalin 2000, Bhattacharya et al. 2012) partners need to exert costly and unverifiable effort and where the parties are asymmetrically informed. We add to the literature on the dynamics of R&D partnerships in two ways. First, the extant literature assumes that revenues and costs associated with a successfully developed project do not change during the R&D process. In contrast, we explicitly model the dynamic evolution of the project value and how the firms respond to such changes. 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 explicitly model moral hazard or asymmetric information in this work. Second, we draw attention to a specific type of contract that is particularly appropriate for managing risks in the context of volatile project values: a co-development contract with the additional option for the biotech to switch to pre-agreed licensing terms at a future time. This complements extant work which examines pure licensing contracts (Crama et al. 2012), royalty based contacts with the possibility of renegotiation (Xiao and Xu Forthcoming), milestone-based option contracts (Bhattacharya et al. 2012), or buy-out option contracts (Edlin and Hermalin 2000).

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 be less than 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, and 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 initial investigative phase 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 (and/or regulators) 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 are not verifiable and are 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 not only 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 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 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. for any $t \leq s \leq t_2$

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

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 the probability distribution $f(x)$. However, for some parts 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 the first stage cost and stage durations is much lower than uncertainty in revenues and technical performance and therefore treat first stage 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 initial 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 (i.e. $C_1(0) > 0$), as well as manufacturing and marketing expenditure. This expenditure 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 can be sold under monopoly protection. Naturally, both 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 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 $\lim_{x\to\infty} C_1'(x) = 0$. 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 characteristic 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. In other words, we assume that the partnership has put governance structures such as joint steering committees and incentive structures such as late stage payments in place to minimize inefficiencies associated with asymmetric information or non-verifiable effort. 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 an 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

$$V_2\left(X(t_2)\right) = X(t_2).$$

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

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

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 a random variable 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 net present value (NPV) of the project 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*

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

where $f(x)$ denotes the density of $X(t_1)$ at time t_0. The value of the project for the biotech is given by $B_0(s) = sV_0$ while for the pharma 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 GBM (i.e. $dX(t) = X(t)\sigma dz$) with volatility σ (i.e. at t_0 the t_1 revenue projection follows a log-normal distribution) then V_0 is non-decreasing in σ.*

In the case of the driftless GBM described in Corollary 1, the uncertainty in the revenue projection is captured entirely by the volatility parameter σ. 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 projects that are more uncertain 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. $X(t_1) \geq x_c$), it will be required to invest a further

$sC_1(X(t_1))$ 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*

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

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 GBM $dX(t) = X(t)\sigma dz$ with $X(0) = x_0$, this probability is increasing (decreasing) in σ 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 GBM) 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 σ, 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 σ. 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 will run 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.

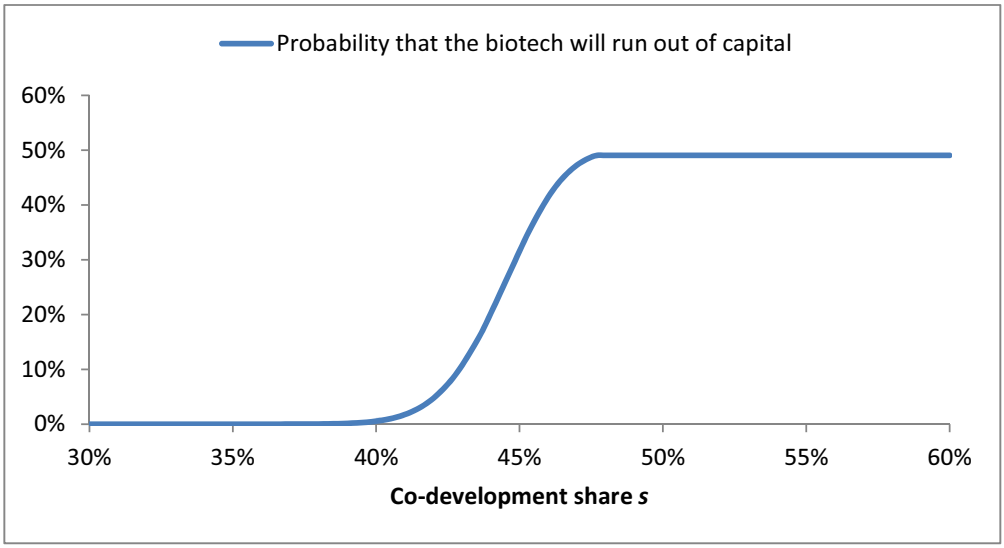

Figure 1 **The probability the biotech will run out of capital is increasing in the co-development share s it retains in the joint project.**

One may argue that raising more capital could resolve this problem and in perfectly efficient markets this should be the case. However, the same reasons that necessitated the partnership in the first place 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.

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 M&R 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 project at time t_2 as a royalty payment. Consistent with our assumption that the partnership seeks to eliminate moral hazard problems, which we do not model explicitly, by providing appropriate incentive structures, we assume that the bulk of the transfer from the pharma to the biotech will take place in the form of late stage payments such as the second stage milestone, M_2, and royalties. This ensures that the biotech is adequately incentivized to remain engaged 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 $P_1^l(X(t_1)) = p_2\mathbf{E}\left[P_2^l(X(t_2))|X(t_1)\right] - C_1(X(t_1)) = p_2((1-k)\,X\,(t_1) - M_2) - C_1(X(t_1))$. 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 $p_2\left((1-k)X(t_1) - M_2\right) \geq C_1(X(t_1))$. 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 $p_2\mathbf{E}\left[B_2^l(X(t_2))|X(t_1)\right] = p_2(kX(t_1) + M_2)$. 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 abandoned when $X(t_1) \leq x_l(k, M_2)$. The threshold is the positive root of the equation*

$$C_1(x) = p_2((1-k)x - M_2), \tag{3}$$

and is strictly increasing in k and M_2. The values 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

$$P_0^l(k, M_2) = p_1p_2\int_{x_l(k,M_2)}^{\infty}\left((1-k)x - M_2 - C_1(x)/p_2\right)f(x)dx - C_0, \tag{4}$$
$$B_0^l(k, M_2) = p_1p_2\int_{x_l(k,M_2)}^{\infty}\left(kx + M_2\right)f(x)dx, \tag{5}$$

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 M&R 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

project 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 inefficiently abandoned. This problem of inefficient abandonment harms both firms as it destroys value, i.e. licensing in the contexts of staged projects would be Pareto-dominated by co-development if the biotech's financial constraints were not an issue. Furthermore, these inefficient abandonments 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. 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* $\Delta V = p_1 p_2 \int_{x_c}^{x_l(k,M_2)} (x - C_1(x)/p_2)\, f(x)dx$ *and 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 (M&R), suggesting that the problem of inefficient abandonment 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 NPVs that were 10% higher than their R&D costs.

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 M&R payment. This happens because although increasing the M&R terms 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 M&R payments increase, the second effect begins to dominate.

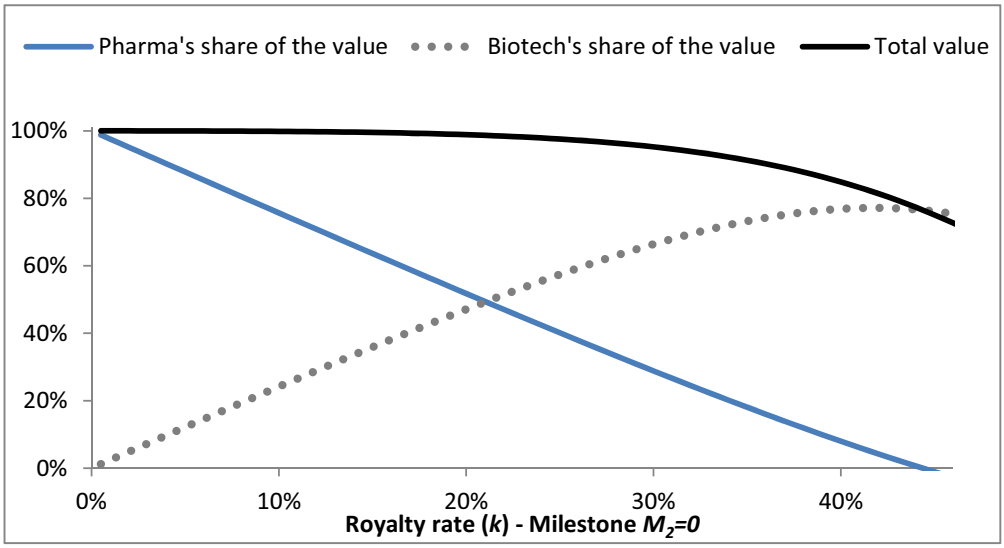

Figure 2 **While the value appropriated by the pharma is decreasing in the royalty rate k so does the total value to both firms due to inefficient abandonments. The value appropriated by the biotech is initially increasing in the royalty rate k but eventually, as the value destroyed by the inefficient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

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 M&R 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 – on the contrary, 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 turn leads to projects that would have been economically viable in a co-development contract being abandoned in a M&R contract.

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 GBM 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 σ and then decreasing. For high royalty rates this probability is decreasing in σ. 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 ($x_l(k, M_2) < X_0$).

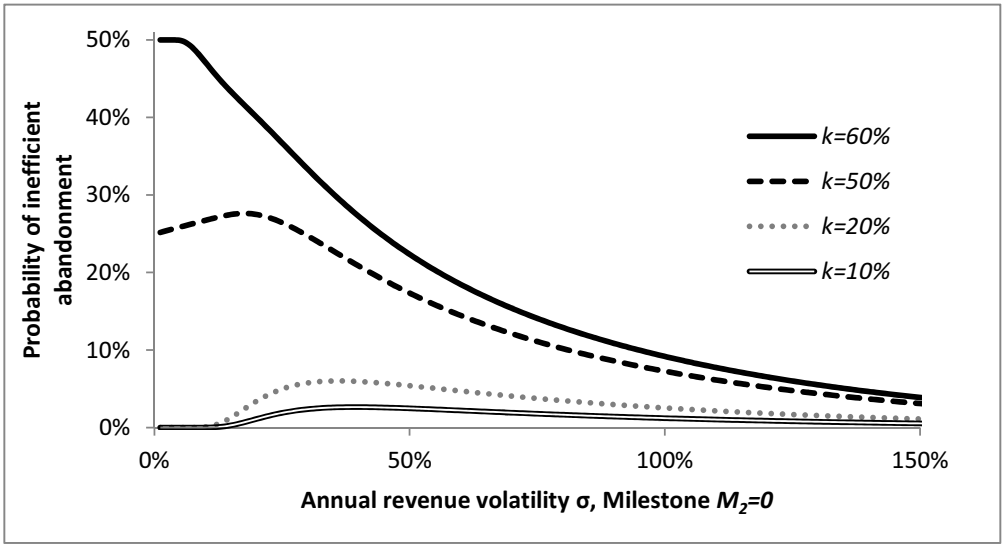

Figure 3 **For a sufficiently low royalty rate k the probability of inefficient abandonments is first increasing and then decreasing in revenue volatility σ. For high royalty rates the probability of inefficient abandonments is decreasing in σ.**

Other, more complicated models that explicitly allow for ex-post renegotiation may restore efficiency in this context. After all, if the project is going to be abandoned because the M&R payments are too high, one would expect both the biotech and the pharma to be willing to renegotiate the contract terms. Such renegotiation could potentially improve the outcome for both firms. However, relaying for renegotiation to restore efficiency comes at a costs of adding complexity.[1] 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 contract structure which allows the biotech company to manage the risk that it

[1] For example, renegotiation is time-consuming and 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 patent protection and where margins reduce drastically when patents expire.

will run out of capital 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 M&R payments. 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 naturally be 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 initial 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. $C_1(X(t_1)) - C_0 \leq K/s$) and we assume for simplicity that 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:*

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

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

$$B_0^{opt}(s,k,M_2) = p_1 s \int_{x_c}^{\min\{z_1,z_3\}} (p_2 x - C_1(x))\, f(x)\, dx + p_1 p_2 \int_{z_1}^{z_2} (kx + M_2)\, f(x) dx$$

$$+\ p_1 s \int_{\min\{z_2,z_3\}}^{z_3} ((p_2 x - C_1(x))\, f(x) dx + p_1 p_2 \int_{\max\{z_2,z_3\}}^{\infty} (kx + M_2)\, f(x) dx - sC_0,$$

$$P_0^{opt}(s,k,M_2) = p_1(1-s) \int_{x_c}^{\min\{z_1,z_3\}} (p_2 x - C_1(x))\, f(x)\, dx + p_1 \int_{z_1}^{z_2} (p_2((1-k)x - M_2) - C_1(x))\, f(x) dx$$

$$+\ p_1(1-s) \int_{\min\{z_2,z_3\}}^{z_3} ((p_2 x - C_1(x))\, f(x) dx + p_1 \int_{\max\{z_2,z_3\}}^{\infty} (p_2((1-k)x - M_2) - C_1(x))\, f(x)\, dx - (1-s)C_0.$$

We first note that the threshold x_c, below which any project is abandoned, is identical to that of the pure co-development contract, suggesting that unprofitable projects are optimally abandoned. It is 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 M&R 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 M&R 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 a project. 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 co-development is more profitable than opting out, it is simply too expensive 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 M&R-based payments.

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 M&R-based licensing contract. Bearing in mind the biotech's capital constraint, these projects will only be co-developed, and therefore inefficient abandonment can be avoided if the biotech company has sufficient capital K to pay for its share s of the co-development costs. 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*

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

where z_1 and z_3 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 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 an 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 $[z_2, z_3]$ may not 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 M&R payments. We believe this specific contractual agreement, with a single co-development region which is focused 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 $z_1 < z_3$, 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 of 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. 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.

Figure 4 illustrates the somewhat surprising fact that, taking opt-out option into account, the biotech's expected share of the project value may be lower than its share s of a fully co-developed project. To see why this may occur, note that the expected value is the probability-weighted average of the value it receives if it co-develops – which is equal to a share s of the total co-development value – and the value it receives if it opts out. The latter value can be realized in two ways: If the t_1 revenue projections are between z_1 and z_2, then the biotech chooses to opt out because licensing is more valuable than co-development. In this case it receives more than the share s of the total co-development value. However, the biotech also opts out when the t_1 revenue projections are greater than z_3, not because it is more profitable to do so but because it would have run out of capital had it decided to continue with co-development. In this case the value it receives may well be less than the share s of the total co-development value. Decreasing royalties k will reduce the biotech's appropriated value when it opts out due to capital constraints, which, as illustrated in Figure 4, can affect its expected share of the project value to fall below s.

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 NPV valuation technique used 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

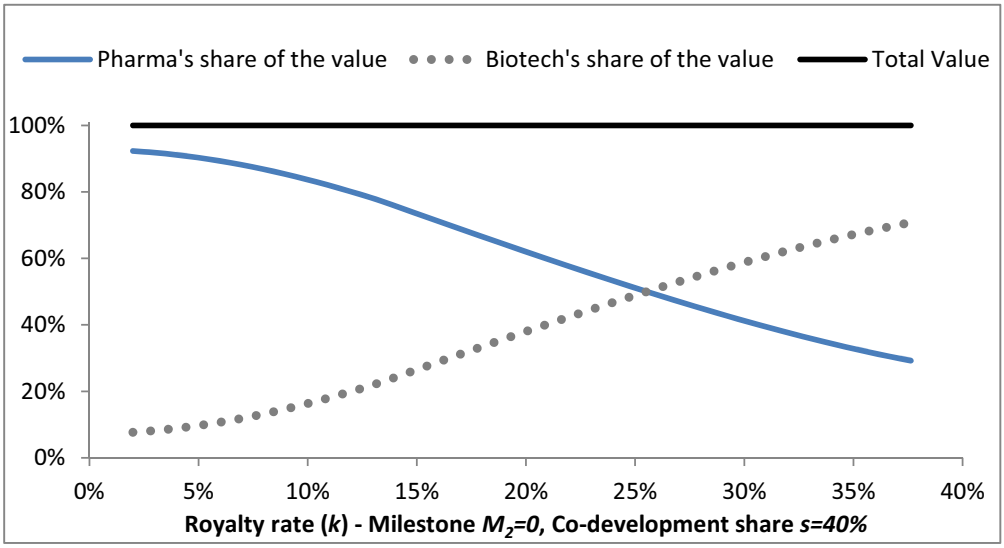

Figure 4 **The value appropriated by the biotech is increasing in the opt-out royalties. This contract allocates 100% of the value to the two firms.**

licensing-out in return for royalty and late stage milestone payments completely eliminates this risk, it 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 also reduce the probability of creating commercially 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 M&R 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 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. The model can be used to offer advice on how to structure such contracts to achieve efficiency and reduce the risk of the smaller firm running out of financial resources. Furthermore, it can also provide advice on the optimal exercise of the opt-out option by identifying the cash-flow 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. Indeed, as mentioned in the introduction, the model in this paper is a stylized version of the valuation models that we used to advise the biotech firm Cambridge Antibody Technology in its negotiations with the pharma major AztraZeneca of a significant co-development partnership. The final, prize-winning contract included opt-out clauses at various points of development for both companies. Models akin to the one presented in this paper helped to rationalize the design of these options and evaluate their consequences in terms of opt-out incentives and associated values for both parties.

Beyond the pharmaceutical industry context that motivated our study, we believe tour research has implications for other sectors where innovation is a collaborative endeavor, such as the commercialization of university-based research in nanotechnology (Savva and Taneri (2011)). It could be possible that contracts with option-like features could also be attractive in such collaborations (Agrawal and Oraiopoulos (2012)).

Before transferring any insights of the present study directly to other contexts it is important to check that its main assumptions are valid. In our attempt to explain the fundamental link between staged commitments and uncertain project values within partnership arrangements, we have chosen to present our arguments under the simplifying assumption that there is neither asymmetric information nor unobservable future effort. While we believe this to be a reasonably realistic assumption in the context of long-term pharmaceutical R&D alliances that involve joint project teams and span whole therapeutic areas, such as the CAT-AZ collaboration mentioned above, it is clearly an over-simplification in many other contexts. If an innovator firm is ex ante better informed about the value of its project than its potential partners, then adverse selection may occur. If both firms need to exert costly effort after signing the contract for the project to be technically and commercially successful, and if these efforts are not verifiable, then any contingent payment, such as the ones discussed in this paper, may lead to effort distortion. Research to date has only addressed how such opportunistic behavior can be tackled contractually in the multi-staged context of R&D under the assumption that revenue projections do not change over time (see Xiao and Xu (Forthcoming), Crama et al. (2012)). Our research allows valuations to fluctuate but has assumed that there is no opportunistic behavior. It would be interesting to combine these two lines of work in

a comprehensive multi-stage model with volatile revenue projections, informational frictions, and moral hazard. Such a model could be used to investigate whether appropriate option clauses allow the partners to signal their private information to each other, and whether appropriately designed opt-out clauses reduce the moral hazard problem associated with royalty-based licensing. We leave these questions for further research.

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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, $p_2 x - C_1(x) \geq 0$. Therefore x_c is given by the positive root of $C_1(x) = p_2 x$. Given the assumption placed on $C_1(x)$, namely continuous, $C_1(0) > 0$, increasing, strictly concave, and $\lim_{x\to\infty} C_1'(x) = 0$, the root x_c exists and is unique. The projected value of the project at time t_0 is given by

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

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

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 σ. 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 σ. Consider a random variable Y which also follows the log-normal distribution with volatility τ. 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. □

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 ($X(t_1) \geq x_c$) 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 $x_B(s,K) = C_1^{-1}(K/s - C_0)$, which given the properties of $C_1(x)$ exists and is unique. Turning to the comparative statics,

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

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

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 σ on the probability of $Pr(C_B(s) > K)$ in the case of the driftless GBM 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 $Pr(C_B(s) < K) = p_1 \int_{y_0}^{\infty} \phi(\frac{y - \frac{1}{2}\sigma^2 t}{\sigma\sqrt{t}}) dy > \frac{p_1}{2}$. □

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, given the assumptions placed on $C_1(x)$ exists, is unique and increases in k and M_s. Furthermore, comparing x_l with x_c, which is the solution of $p_2 x = C_1(x)$, 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

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

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. □

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

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

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 at least once in the interval $k \in (0,1)$. □

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 had to pay M&R to the biotech would 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. Given the assumptions placed on $C(x)$, all thresholds exist and are unique.

Finally, by noting that any project whose t_1 revenue projections fall in the interval $[0, x_c]$ is abandoned, $[x_c, \min\{z_1, z_3\}] \bigcup [\min\{z_2, z_3\}, z_3]$ is co-developed (i.e. the opt-out option *is not* exercised), and $[z_1, z_2] \bigcup [\max\{z_2, z_3\}, \infty)$ 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. □

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 that 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 of because it is not sufficiently profitable for the pharma to develop alone. At time t_0 the probability of this happening is given by

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

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

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

$$\frac{\partial z_3}{\partial K} = \frac{1}{s}\left(\frac{d}{dz_3}C_1(z_3)\right)^{-1} > 0,$$

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 pair (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 that in a co-development without an option. □

Parameters for the illustrative numerical example

Parameter	Value	Unit
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 σ	20%	p.a.
Biotech capital K	300	\$M