The Evolution of Alliance Structure in the Biopharmaceutical Industry (1978-2008)

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Using a unique dataset containing 398 technology commercialization agreements signed between 1978 & 2008 that involve the transfer of U.S. marketing rights to 866 identifiable products, this paper analyzes how the structure of technology commercialization agreements between biotech and pharmaceutical firms has evolved since the pioneering Genentech/Lilly alliance was signed in 1978. Many empirical researchers have used biotech alliances to test theories in economics, and strategic management. However, that literature largely ignores how alliance structure may have changed as industry norms have evolved over time. We present evidence that while traditionally the biotech firm licensed all the rights to perform the commercialization activities (i.e., clinical development, marketing, and distribution) to the pharmaceutical firm in exchange for financial payments, over time biotech firms have become increasingly more integrated into the commercialization activities of the alliance product through Co-Development and Co-Promotion arrangements. At the same time, the pharmaceutical firm has become less likely to retain an Equity stake or enter an equity-based Joint Venture. We argue that this trend is related to the demand from public financial markets, and particularly a preference for full integrated, product-based firms over 'platform' or licensing-based firms, which we attribute to the informational problems that public equity investors face in evaluating technology. This paper adds to the existing literature on contracting by demonstrating the importance of the underlying industry trends for understanding alliance structure.

1. Introduction

The structure of the contractual agreement affects both the size and share of the returns that the two parties will capture from an alliance arrangement (Adegbesan & Ricart, 2005; Adegbesan & Higgins, 2009). The structure of financial payments prescribes how the value generated through the alliance will be divided between the parties. Meanwhile, the allocation of control rights over the alliance activities dictates the extent to which each party can direct the alliance activities to its benefit and thereby capture a larger share of the expected returns.

The structure of the contractual agreement is of particular concern in the biopharmaceutical industry where an alliance between a technology-based biotech firm and a product-based pharmaceutical firm is the predominant mode through which innovations are commercialized. However, the structure of these arrangements has changed significantly since the pioneering Genentech/Lilly alliance in 1978. This paper analyzes how the structure of these arrangements has changed over the life of the industry. Traditionally the biotech firm licensed all the rights to perform the commercialization activities (i.e., clinical development, marketing, and distribution) to the pharmaceutical firm in exchange for financial payments. However, over time biotech firms have become increasingly more integrated into the commercialization activities of the alliance product through co-promotion arrangements. Meanwhile, the pharmaceutical firm has become less likely to retain an equity stake or enter an equity-based joint venture. We argue that this trend is related to the demand from public financial markets, and particularly a preference for fully integrated, product-based firms over 'platform' or licensing-based firms, which we suggest is the result of informational problems that public equity investors face in evaluating technology.

Despite an abundance of papers on alliances in general, and on biotech alliances in particular, very few papers have paid much attention to alliance structure or in particular how alliance structure responds to the underlying conditions in the external environment. Moreover, to the extent that papers have analyzed alliance structure, they have tended to abstract from the actual terms which firms explicitly negotiate to

broadly construed variables, such as whether the alliance contains an equity investment (Pisano, 1989) or the allocation of a bundle of control rights (Lerner & Merges, 1998; Ciccotello & Hornyak, 2000; Elfenbein & Lerner, 2003; Higgins, 2007; Elfenbein & Lerner, 2009). More recent work (Lerner & Malmendier, 2005) has sharpened the focus on the specific terms of these alliances that firms seriously negotiate. However, this work still takes a one-shot view of alliance structure, implicitly presuming that the default structure has remained constant over time. Hence this paper adds to the existing literature by highlighting a trend in alliance structure that is of great importance to industry executives but has been largely ignored in the literature. Secondly it relates this trend to changes in the underlying conditions in the biotech firm's external environment, particularly the ability to raise capital on the public financial markets.

The next section reviews the literature on alliance structure in more depth. Section 3 describes the major trends in alliance structure over the life span of the biopharmaceutical industry. Section 4 discusses and interprets the results.

2. Literature review

A. Theoretical literature on alliance structure

The literature in organizational economics, stemming from Coase (1937) and Williamson (1975; 1985), provides a range of theoretical frameworks that have been (or might be) applied to explain the structure of alliance contracts. These frameworks were developed primarily to address the choice between arms-length contracting (or market-based arrangements) and vertical integration (or internal organization). However, arguably it is a simple extension to apply these frameworks to analyze variations in alliance structure. The first part of this section describes the frameworks themselves, and then the next part reviews the empirical literature that applies these alternative frameworks to analyze alliance structure.

Coase (1937) made the insight that organizing activities inside a firm provides a way to economize on the costs of transacting in the market, and Williamson (1975; 1985) developed this into a stream of research known as transaction cost economics

(TCE). The main prediction of the TCE literature is that parties choose more hierarchical organizational forms for governing their relationship when there are greater risks of opportunistic behavior. He then extended this concept to incorporate different types of contract forms by introducing the notion of hybrid arrangements, which are governance intermediate forms lying between arms-length contracts and firms on the spectrum between markets and hierarchies (Williamson, 1991). They include joint ventures, equity-based alliances, and other more integrated forms of contracting.

Meanwhile, Grossman& Hart (1986) and Hart & Moore (1990) developed and formalized the same insight that parties use vertical integration to solve contracting problems in an alternative stream known as the 'property rights theory' (PRT). In contrast to Williamson (1975; 1985), Grossman, Hart & Moore focused on how the inability to contract on the outcome affects the parties' ex ante incentives to invest in the joint product (as opposed to the firm's incentives to act opportunistically after the contract is signed). The main prediction from this literature is that the parties will allocate property rights (or control) over the outcome to the party whose effort has a greater marginal impact on the outcome.

Aghion & Tirole (1994) reconsidered the PRT framework for a context in which a financially constrained inventor seeks to develop an invention in combination with a partner. They showed that, even when it would be optimal to allocate the ownership to the inventing firms (in the sense that that would generate optimal incentives to maximize the joint outcomes), this allocation may not occur because the inventing firm cannot compensate its partner for giving up control. The implication for alliance structure is that, all else being equal, the parties will allocate control rights over the commercialization process to the party whose effort is likely to have the greatest impact on the joint outcome (Haeussler & Higgins, 2009).

B. Empirical literature on alliance structure

Despite the importance of the contract structure for a firm's ability to capture value from an alliance, the empirical research on the structure of alliances is relatively sparse. In large part this is due to the opacity of contractual terms, and the fact that

detailed data on contractual terms are not easily available in prepared datasets. Nevertheless, there are two lines of research that have attempted to explain the structure of contracts generally, and biotech alliances in particular, using the theoretical frameworks described above.

Pisano (1989), in one of the first papers to study the organization of the biopharmaceutical industry, made the distinction between equity-based alliances and pure contractual arrangements in order to test the prediction (derived from TCE) that firms choose more hierarchical arrangements when there are greater potential transacting problems associated with the alliance relationship. He showed that firms are more likely to choose equity-based alliances when the alliance involves a research component, and argued that this was because there is more likely to be problems involving transaction-specific knowledge, uncertainty, and small-numbers bargaining conditions. Much of the subsequent work on alliance structure in the biopharmaceutical industry and elsewhere has followed this equity-vs-non-equity characterization.[1] For instance, Hansen (2003) showed that firms are more likely to adopt equity-based alliance arrangements when there is greater technological uncertainty. Aggarwal & Hsu (2009) use the distinction between equity and non-equity alliances to describe the firm's 'modes of commercialization'.

A benefit of this categorization of alliances is that equity-based alliances fit neatly between 'markets' (or arms-length contracting) and 'hierarchies' (or vertically integrated firms) on Williamson's (1991) spectrum of discrete organizational forms, which makes it possible to test arguments that depend on the level of hierarchy.

However, this framework implicitly assumes that equity ownership necessarily gives the holder more control over alliance governance than under a non-equity alliance, a claim that is not supported by evidence. An in-depth analysis of the governance

[1] Much of this work relies on Deloitte ReCap LLC's Alliances database, and particularly Recap's coding "Equity" in the alliance description whenever the "Client" firm (which in most cases is the pharmaceutical firm) makes a minority investment in the "R&D firm".

terms of a large set of biopharmaceutical alliances revealed that the pharmaceutical firm's equity stake is usually small (around 10%) and only occasionally does it take a board seat or any other equity-related form of substantive control.[2] In order to achieve greater control over alliance activities, pharmaceutical firms typically rely on control over the alliance management committee, specific control rights, or (in extreme cases) the threat of termination (Lerner & Malmendier, 2005) to manipulate the biotech firm's behavior. Hence the existence of an equity investment does not usually imply a stronger governance mechanism, and the parties do not use equity-based arrangements as a way of achieving greater control. Moreover, in biotech commercialization alliances it is almost always the pharmaceutical firm that makes the equity investment (in the biotech firm), never the other way around, so even if it were the case that the firms used equity investment to increase control, it would only be a relevant when the issues involved the pharmaceutical firm taking greater control.

Lerner & Merges (1998) used a different approach in their analysis of the Aghion & Tirole framework. They created a taxonomy of the alliance structure based on how many of the 5 "key" and 25 "important" control rights in the alliance were allocated to a pharmaceutical firm. While they did not find evidence for the principal PRT prediction that the allocation of rights varies with the likely impact on the outcome, they did find evidence consistent with Aghion & Tirole's caveat on the PRT that the allocation of rights will depend on the biotech firm's financial position. Subsequent papers have used the same or a similar framework to highlight the importance of financial cycles on the alliance structure that the biotech firm can negotiate (Lerner, Shane, & Tsai, 2003) and to contrast the effect of the biotech firm's financial position against the pharmaceutical firm's product position (Higgins, 2007).

[2] An analysis of 50 alliances in which the pharmaceutical firm partner made an equity investment in the biotech firm revealed that the mean amount invested was approximately 10% with a standard deviation of 7%. A separate analysis of 44 alliances in which the pharmaceutical firm made an equity investment revealed that only in half (22) of the alliances was it entitled to a board seat.

The strength of this approach is that the control rights included in Lerner & Merges' aggregate variable were selected through interviews with industry practitioners as ones which are consequential to the parties negotiating the alliance. Therefore this approach comes closer than the equity-based framework to reflecting the focus of alliance negotiations. Nevertheless, a limitation of this approach is that, by aggregating all the control rights into one variable, it implicitly assumes that all rights are weighted equally and factors which the influence the allocation of control impact the set of rights monotonically.

However, the importance of each control right depends on the context. For instance, the allocation of ownership over the alliance technology is usually only relevant (and contentious) when the parties engage in joint R&D. Moreover, different factors will affect the allocation of each control right. While the biotech firm's financial position may have a large effect on whether it can retain downstream rights, it may not be very relevant to determining the allocation of ownership over the alliance technology. Hence, while the aggregate of control rights may provide a rough proxy for the general balance of power in negotiations, it will not be a good variable for capturing the allocation of control of specific alliance activities.

Arguably, a more precise approach is to focus on the specific alliance terms that are both contentious in negotiations and are relevant to the phenomenon being analyzed. Lerner & Malmendier (2005) take this approach in seeking to analyze how the pharmaceutical firm's ability to control the use of its financial investment affects the structure of alliances. They focus on the allocation of termination rights, an indirect but effective mechanism by which the pharmaceutical firm can control the biotech firm's behavior and hence one that is vigorously fought over in the alliance negotiations. They find that the pharmaceutical firm is more likely to negotiate termination rights when there is a greater risk that its financial investment will be diverted to another project.

Nevertheless, this analysis (together with all the research described above) takes a one-shot view of alliance structure, implicitly presuming that the underlying context, in which the parties negotiate their alliance, remains constant across time. One

example of work that takes a longitudinal approach is Hagedoorn (2002), which uses the MERIT-CATI cross-industry dataset of R&D partnerships to examine trends for the period 1960-1998. In particular, Hagedoorn shows a decline in the number of joint ventures relative to pure contractual forms of alliances over this period. However, this work does not attempt to explain what factors are driving these changes across time. This paper provides a more analytical approach to the longitudinal variation in alliance structure, and focusing particularly on the allocation of marketing rights in alliances between biotech and pharmaceutical firms.

3. Empirical analysis

A. Empirical Context

The biotech industry – more accurately called the "biopharmaceutical" industry – applies biological discoveries to the development of pharmaceutical products.[3] The industry has its origins in the advances in biological science in the second half of the twentieth century, most notably the discovery of the structure of DNA by Watson & Crick in 1953. However, it was the development of recombinant DNA techniques by Herbert Boyer at UCSF and Stanley Cohen at Stanford in 1972, and the foundation of Genentech in 1976 to exploit these techniques, which heralded the new industry.

Genentech's first major project was its participation in a race with the University of California at San Francisco and Harvard University to clone human insulin, the key protein that diabetics need to normalize their metabolism (Edwards & Hamilton, 1998). Eli Lilly, the leading supplier of insulin, was purifying the material from pig glands, but internal projections showed that demand would exceed supply by around 1992. Hence, to remedy the shortfall, Lilly launched a race to clone the protein, which Genentech won. The prize was an alliance with Lilly to commercialize the discovery (named "Humulin") as a pharmaceutical product.

[3] The biopharmaceutical or medical "biotech" industry is distinct from the agricultural and industrial "biotech" industries.

The Genentech/Lilly alliance set the standard for how the new biotechnologies would be commercialized. The biotech firm would remain involved through the pre-clinical stages of development, but then would pass responsibility onto the pharmaceutical firm to do the clinical development, marketing, and sales throughout the world. For instance, in its alliance with Lilly to commercialize Humulin, Genentech granted Lilly exclusive rights to do all commercialization activities. It was not uncommon in the early alliances for the biotech firm to retain rights to some territories (especially its home country) or, in a few cases, rights to specific indications. For instance, at the same time as Genentech entered the Lilly alliance, it also signed a deal with Kabi Pharmaceutical, a Swedish firm, to commercialize human growth hormone in which it retained the rights to commercialize the product in the United States. At the same time, Amgen (one of the other industry pioneers) retained rights to sell to kidney dialysis patients in its alliance with Ortho Biotech to commercialize EPO.[4] Nevertheless, in these cases, the firms kept their own commercialization activities separate from those of their pharmaceutical firm.

Over time, while industry has grown to include over 4,000 start-ups and generate over $63B in revenues (Ernst & Young, 2006), the structure of these commercialization arrangements has evolved significantly. Initially, biotech firms sought to participate in the clinical development stages of the alliance, both by being involved in management of the clinical trials and by sharing in the costs (and thereby also the profit or loss) from clinical development. This arrangement, known as "co-development", implied a substantial shift downstream in the biotech firm's alliance

[4] In cases like the two just mentioned, the biotech firm would attempt to commercialize the product alone in the retained territories or indications. However, in other cases it would license these retained rights to another pharmaceutical firm at a later stage in the process. A popular practice was to license the product rights for Japan to a Japanese pharmaceutical firm at an early stage in the commercialization process, then license the remaining rights to a multi-national pharmaceutical firm at a later stage. The rationale was that the funds gained from the first, partial grant of rights enabled the firm to develop the technology through to a later stage at which it could expect to capture a larger share of the rents.

activities. More recently biotech firms taken a step even further downstream, retaining rights to participate in the marketing and distribution of the alliance product, and arrangement called "co-promotion".

B. Data sources

In order to describe and analyze the evolution in alliance structure over time, we compiled a dataset of 398 unique alliance contracts signed between biotech and pharmaceutical firms between 1978 & 2008, which relate to 864 identifiable product-indications in the RecapRx dataset to which biotech firms held the U.S. marketing rights at the time of the license. [5]

The data comes from RecapRx, a proprietary database compiled by Deloitte Recap ("Recap"). RecapRx contains clinical trials and other product development data by each indication for all biopharmaceutical products that have been under development over the life of the industry. RecapRx also provides links to the related alliance agreements. Following the links on the alliances, we merged the product data in RecapRx with the more detailed data on the alliances contained in Recap's Alliances database (called "RDNA"). We then used this data, to trace the ownership of the U.S. product marketing rights over time and to identify those alliances that involved the transfer of U.S. marketing rights.

What is unique about this dataset – and what distinguishes it from the datasets used in previous research on alliances, many of which were based on the RDNA database – is that this dataset includes only alliances that involve the transfer of U.S. marketing rights to identifiable biopharmaceutical products. Therefore the dataset excludes pure technology-based alliance agreements (i.e., those that do not involve the rights to any specific biotech products) as well as product licensing agreements that do not relate specifically to the U.S. product rights. This makes the contracts much more homogeneous – all contracts involve the transfer of U.S. marketing rights

[5] A biopharmaceutical product may be implicated for more than one therapeutic indication, and the own may license the different indications either separately or together.

of an identifiable biopharmaceutical product firm – and hence we can be much more confident that trends we see relate to the hypothesized effects rather than spurious changes in the make-up of the dataset or the underlying phenomena.

We further supplemented the information available from RecapRx and RDNA with details on the biotech firm's valuation at the time of the alliance. We used the CRSP database to obtain the market capitalization for those biotech firms that were publicly listed. At the same time, we used Recap's Financing database (also contained within RDNA) to obtain information about the private financing events, where available.

Table 1 provides summary statistics of the terms of the alliance contracts that are included in the dataset. Figure 1 shows the number of product commercialization alliances across time between 1978 & 2008. The first contract in the dataset is the Genentech/Lilly alliance in 1978, but the bulk of the alliances were signed since 1990. Approximately a quarter of the alliances involve the biotech firm participating in Co-Development or Co-Promotion, while around a third of the alliances involve the pharmaceutical firm taking an Equity stake in the biotech firm. Only 5% of the alliances involve a Joint Venture.

Only limited data is available on the financial payments provided for in the alliance contract, but where the information is available it shows the contracted payments varying over a wide range of payment, with up to milestone and equity payments up to $1B (in 2008 US dollar terms). The data on license grants is similarly limited, but where it is available the data shows that the grant is almost always exclusive, half the time it includes all fields of use, and just over two thirds of the time it is worldwide.[6]

The biotech firms involved in these alliances vary widely in experience and valuation, from no prior alliances and negative valuation to worth over $66B. About 12 percent have the right to market an approved product in the same therapeutic area at the

[6] The license grant for all contracts in the dataset by definition includes the U.S. territory.

time they sign the alliance (which suggests they also have the complementary assets necessary to commercialize the innovation alone).

C. Empirical approach

Our empirical approach focuses on identifying the effects of the time trend on the various alliance terms. We represent the time trend alternatively with a continuous variable and with dummies to represent various time periods. The basic equation we estimate is:

$$\Pr(Y=1|T, X) = f(T,X;\beta)$$

where Y is an indicator of whether a contract is of a particular type, T is the time trend (either a continuous time variable or a vector of dummy variables that represent different time periods), and X is a vector of covariates.

We focus on five alliance "types", which represent different (but not necessarily mutually exclusive) ways in which the parties may structure their arrangements. The default agreement 'type' – and the counterfactual in the regressions – is a straight licensing agreement in which the biotech firm licenses all rights to perform the commercialization activities (i.e., both clinical development and marketing & distribution) to the pharmaceutical firm in exchange for a financial payment. Under the default type, the biotech firm may continue to be involved in the (pre-clinical) research stages, but the contract does not provide for it to participate in the commercialization of the alliance product. At the same time, under the default agreement type the pharmaceutical firm does not take an equity stake in the pharmaceutical firm, nor is the agreement structured as a joint venture.

Alternatively, the parties may agree that the biotech firm has the rights to participate in the clinical development (known as "Co-Development") or the marketing & distribution ("Co-Promotion") of the alliance product. Co-Development involves both parties cooperating to design and conduct the clinical trials, and typically involves the parties sharing the profits (as well as the costs) of the product. Co-Promotion

involves the parties cooperating in the development of a marketing strategy and employment of a sales force to 'detail' the product.[7]

Meanwhile, in contrast to the 'arms length' arrangement that occurs under a straight licensing agreement, the pharmaceutical firm may take an equity stake in the biotech firm ("Equity") or the two firms may form a joint venture ("Joint Venture"). Under an Equity arrangement, the biotech still licenses the product rights to the pharmaceutical firm in exchange for pay upfront, milestone, and royalty payments, but the pharmaceutical firm also takes an equity stake (although often only around 10%) in the biotech firm. By contrast, under a Joint Venture, the product rights are licensed to a new entity in which both parties take an equity stake.

D. Results

As a first step we estimated the likelihood of negotiating each of the four alternative agreement types with alternatively a time trend and a set of dummies representing the 5-year periods from 1975 to 2010. The results, presented in Table 2, show that the likelihood of the firms negotiating Co-Development and Co-Promotion arrangements has risen consistently over time, although only the increase in the time trend is significant (at the 1% level) only for Co-Promotion. The 5-year-period dummies show that the likelihood of Co-Promotion has increased monotonically over time, while the likelihood of Co-Development has risen and fallen a couple of times, albeit with a generally increasing trend. By contrast, the likelihood of Equity and Joint Venture arrangements has fallen over time. Both peaked in the early 1990s and have fallen consistently since then.

Nevertheless, as Lerner et al. (2003) showed, the allocation of rights depends on the equity financing cycles. In periods where the financial markets are more favorable, a

[7] Note that Co-Development and Co-Promotion are significantly different from an arrangement in which the parties agree to develop or promote the product in different territories or for different indications. In the dataset such a 'split territory' or 'split indication' arrangement is treated as a straight licensing arrangement, albeit it one where limited territories or indications are licensed.

biotech firm has stronger outside options and therefore is more likely to obtain better terms in the alliance contracts. This is particularly pertinent for Co-Development and Co-Promotion where the biotech firm is essentially retaining rights to participate in the clinical development and marketing & distribution (respectively). Its ability to negotiate such in an agreement depends on having considerable bargaining power, which in turn depends on having outside options.

To allow for the fluctuation in financing conditions, we limited the analysis to periods where the financing conditions were more favorable – specifically, the periods when (by our estimation) the 'IPO window is open'. To determine the periods of favorable financing conditions, we estimated the hazard of making an IPO in a particular month. Using data from the RDNA Financing database we estimated an OLS regression of a privately held firm making an IPO in a given month. Figure 2 shows the estimated hazard of IPO from 1980-2007, as well as the yearly moving average trend. The points show the point estimates and the line traces the yearly-average hazard of IPO.

We defined an IPO window as periods longer than a month where the 13-month moving-average hazard of IPO rose above the mean. The seven IPO windows we identified were:

- Apr 1979 To Aug 1982
- Dec 1982 To Jun 1984
- Dec 1985 To Dec 1987
- Dec 1990 To Nov 1994
- Apr 1995 To Sep 1998
- Jun 1999 To Jun 2001
- May 2003 To Aug 2006

Table 3 shows the results of the basic regressions with the time variable substituted by the IPO window and the 5-year time periods substituted by the IPO windows. These regressions show the same trends as in Table 2. In particular, the likelihood of Co-Promotion arrangement occurring has risen increasingly over time, while the likelihood of the parties negotiating an Equity or a Joint Venture arrangement has

decreased (at least since 1990, when there have been sufficient observations to calculate).

We know from other research that the biotech firm's financial position (Lerner & Merges, 1998), the firms' relative bargaining position (Higgins, 2007), and the biotech's strategic objectives (Wakeman, 2009) influence the allocation of rights. We include variables for the biotech firm's valuation and the hazard of IPO at the time the alliance was signed to account for the biotech firm's financial position and the financing conditions at the time the alliance was signed, variables that capture the stage of development of the alliance product (preclinical, clinical, and approved) and a count of the biotech firm's prior alliances to proxy for the firms' relative bargaining position, and an indicator whether the firm has rights to an approved product to reflect the strategic objectives of the firm.

Table 4 shows that the upward trend in Co-Promotion arrangements and the downward trend in Equity arrangements persists, even after accounting for all these factors. Meanwhile, there appears to be a positive relationship between a more advanced stage of development and entering a Co-Promotion arrangement, and a negative relationship with entering an Equity arrangement. Not surprisingly, biotech firms in a better financial position are less likely to grant the pharmaceutical partner an equity stake. Finally biotech firms that have the marketing rights to an approved product (suggesting that they also have the complementary assets to develop and market a product) are less likely to enter into a Co-Development or Co-Promotion arrangement. On its face this seems counterintuitive since these firms have stronger outside options and therefore are likely to be in a stronger bargaining position. However, because these firms are more likely to be in the position to commercialize the product themselves, when they do outlicense a product they likely have different reasons (such as the product is in an area where they do not wish to develop expertise) that may drive different arrangements.

4. Discussion

The results show that over time biotech firms have retained more control over the alliance product by becoming increasingly more integrated into the

commercialization activities of the alliance product through a Co-Promotion arrangement. Meanwhile, the pharmaceutical firm has obtained less control by becoming less likely to retain an Equity stake or enter an equity-based Joint Venture. Section 2 presents a number of explanations that traditionally have been used to explain variation in vertical integration (or more specifically alliance structure). However, these do not appear to be sufficient to explain this trend.

The most serious contractual hazard a biotech firm is likely to encounter in an alliance with a pharmaceutical firm is the risk that its partner will "shelve" the alliance product at a later stage in the commercialization process. This is a real concern for biotech firms and a reason why they may wish to retain some control over the commercialization of an alliance product. However, there is no evidence that the likelihood of this occurring has risen over time. Pharmaceutical firms have been managing portfolios of biotech products since the inception of the industry, and Moreover, the greater weaknesses in pharmaceutical firm product portfolios in more recent years suggest that if anything the risk of a pharmaceutical firm shelving a biotech firm's product has decreased. Furthermore, greater experience on the side of biotech firms in writing contractual protections against shelving mean that, to the extent that the risk of shelving still exists, biotech firms are now in a better position to mitigate contractually than they were previously. Therefore the risk of shelving – or of contractual hazards more generally – does not appear to explain the increase in popularity of co-promotion arrangements.

According to the property rights theory (Grossman & Hart, 1986; Hart & Moore, 1990), higher downstream integration is due to an increase in the biotech firm's contribution to the alliance and accordingly the need to incentivize greater effort by the biotech firm. Under this argument, granting the biotech firm more control over the commercialization process will give them a greater incentive to invest effort.[8] However, Guedj & Scharfstein (2004) demonstrate that start-up biotech firms

[8] Under this framework, the allocation of control is a concession its partner makes for the benefit of the overall alliance.

actually are more likely to advance equivalent products through clinical trials than more established firms. This suggests that biotech firms are sufficiently – if not overly – incentivized to commercialize their technology by the expectation of milestone and royalty payments if and when the product gets to market. Moreover, there is no evidence that such a need has increased over time.

Aghion & Tirole (1994) suggest that vertical integration might have increased, even if the need for governance and incentives has remained constant across time, if the financial constraints on biotech firms have been relaxed over time. If biotech firms collectively were financially constrained in earlier periods, so that they did not have sufficient bargaining power to negotiate the optimal allocation of rights, the earlier division of responsibilities might not have been an efficient equilibrium. Hence, according to this argument, as their relative financial strength increased they have integrated downstream in order to remedy this inefficiency. However, the data presented in Figure 2 suggest that the hazard of IPO – and by proxy the financing conditions – have in fact increased over time. Therefore, this does not appear to provide an explanation why biotech firms have become more integrated.

Anecdotal evidence obtained from interviews with biotech executives suggests that a large driver for biotech firms to retain co-promotion rights is that they believe the public investors will reward them for it (Wakeman, 2007). Many echoed the refrain that "Wall Street values 'decision rights' over 'revenue rights'".[9]

However, this begs the question: "Why would public investors prefer to invest in firms that retain co-promotion rights?" On the face of it, such a preference appears illogical. From a financial investors' perspective, the revenue profile of a co-promotion arrangement is much less favorable than that of a straight-licensing agreement. Since the biotech firm participates in the marketing and distribution of the product under a co-promotion arrangement, typically it receives a larger proportion of

[9] This statement was made by Stephen R. Davis, Executive Vice President and Chief Operating Officer, Neurogen, in his presentation at the *Allicense* conference in San Francisco on May 25, 2005.

its compensation as a share of the profits than as milestone or royalty payments. Moreover, because the biotech firm's participation detracts from both the pharmaceutical firm's control over and share of the profits from the commercialization process, typically the biotech firm must forego some financial payments (particularly, upfront payments) to entice the pharmaceutical firm into the deal, all else being equal. Hence, compared to a straight licensing deal, the biotech firm's payoff from a co-promotion deal is back-loaded. Since such payments are paid further into the future, they are inherently more uncertain. Moreover, since this arrangement relies on the biotech firm diversifying (or integrating) downstream into a set of activities in which it has less expertise, the revenues would appear to have a smaller expected value and be less reliable. These factors should make co-promotion arrangements less appealing to public investors, not more so.

One reason that public equity investors may prefer co-promotion arrangements to straight licensing arrangements is because the former alleviate the informational problems they have with the commercialization of biotechnology. Public equity investors and market analysts are at substantial informational disadvantage relative to pharmaceutical firms or venture capital firms in evaluating the potential of a biotech firm's technology. Typically they have neither the same technological expertise nor the same access to information about the underlying technology that a pharmaceutical firm has in negotiating an alliance (Majewski, 1998; Pisano, 2006).

Integrating into the commercialization activities may alleviate these problems in any (or all) of three ways. Firstly, even if a co-promotion arrangement does not enable the biotech to capture more value relative to a straight licensing agreement, it can provide a credible signal of the technology's value to the public markets. Spence (1973) demonstrated that an action can provide a credible signal of a firm's 'type' if the cost of taking the action varies for firms of different types *and* it is only worthwhile for the higher type of individual to perform the action. Since retaining co-promotion rights requires the biotech firm to forego upfront payments and to receive compensation through a (less predictable) profit split, it imposes a short-term cost on the biotech firm, relative to a straight licensing arrangement. However, firms with better technology will be able to recover that money later and hence are more likely

to be willing to take that risk. Hence, if a biotech firm has greater confidence in its technology, it can signal this to investors by retaining co-promotion rights rather than negotiating upfront payments or higher royalties. Moreover, since agreeing to a co-promotion arrangement also means that the pharmaceutical firm will capture a smaller share of the rents from commercialization, its agreement indicates that it places a higher value on the technology. Hence, the financial markets are likely to interpret the fact that the biotech firm was able to co-promotion rights as a positive signal about the technology.

Secondly, despite the greater risks and delayed payoff, public equity investors may be more comfortable with the back-loaded, product-based revenue profile that comes out of a co-promotion arrangement than the series of upfront, milestone, and royalty payments likely to come out of a straight licensing arrangement. Public market analysts have extensive experience forecasting and interpreting pharmaceutical product revenues, so it is relatively straight forward for them to put an expected value on such a revenue profile. By contrast, since milestone payments depend on the likelihood that a product will get to a particular stage in the commercialization process, predicting the stream of revenues requires a detailed knowledge of the technology's strengths and weaknesses and its path to commercialization. Hence, public market analysts without detailed knowledge of the technology may discount these payments. Evaluating royalties based on net sales would not seem to be too different from evaluating product revenues. However, since the public investors are not party to the alliance, and do not exercise any direct control over the firm's behavior (by taking a board seat or the like), they cannot influence how the returns are distributed. Hence, they may put greater weight on the product-based revenues that come out of a co-promotion arrangement because the biotech firm has some control over that commercialization process.

Finally, unable to evaluate each firm's idiosyncratic business plan individually, public investors may prefer firms that enter more integrated arrangements because they believe that these firms are more likely to be successful in building a product-based business model. As the interviews revealed, industry executives believe that by retaining co-promotion rights and participating in the commercialization process

alongside a pharmaceutical firm the biotech firm can acquire the capabilities necessary to build a product-based business model. Hence they perceive retaining co-promotion arrangement as a substantial step towards becoming a fully integrated pharmaceutical firm.

Investors' preference for the product-based model appears to stem from a belief, based on historical experience, that such firms are more likely to produce sustainable revenues over the longer term. The outstanding success of Amgen and (to a lesser extent) Genentech[10] in integrating downstream into the development and commercialization of pharmaceutical products, has inspired a lot of confidence in the product-based business model (Fisken & Rutherford, 2002; Pisano, 2006). Meanwhile, the paucity of firms that have made a long-term success out of pure technology- or licensing-based model means that public investors are wary of firms that merely license their technology to pharmaceutical firms. Finally, although both Amgen and Genentech built their product portfolios by retaining exclusive rights to their products in specific territories or for specific indications, the high costs of commercializing alone, and start-up biotech firms' lack of expertise relative to established pharmaceutical firms, mean investors appear to believe that firms which build a product-based model by participating in the commercialization alongside a pharmaceutical firm are likely to be more successful than firms that go it alone.

This interpretation accords with recent literature which has argued that the vertically integrated product-based model is superior to the technology- or licensing-based model. Pisano (2006) has argued that the biopharmaceutical industry would be better off with greater vertical integration between R&D and commercialization, as well as fewer, closer, longer-term collaborations between firms, and fewer independent biotech firms. He claims that this "anatomy" would better enable the firms to deal with the inherent uncertainty associated with commercializing biotechnology and to capture the benefits of cumulative learning. Meanwhile

[10] Although Genentech is today regarded as an outstanding success story, it had to be rescued by Roche in 1990 (Chandler, 2005).

Cockburn (2005) argues that high levels of uncertainty and high transactions costs imply that there are serious problems with the licensing-based model. Moreover, the lack of competition in specific areas of technology and lack of clear price signals from end-users mean that the industry does not benefit from the informational advantages of market-based organization. Furthermore, he argues that the strong patents in this industry may induce excess entry by biotech firms, exacerbating contracting problems and striking the wrong balance between incentives for pioneers and subsequent innovators.

This paper does not present any direct evidence about the long-term performance of those firms that have retained co-promotion rights. This is largely because at this stage there is not sufficient data on firms that have successfully commercialized an innovation under a co-promotion arrangement to conduct a meaningful analysis of performance in terms of long-term profitability or survival. Although retaining co-promotion rights has become a popular strategy in recent years, the very long commercialization process and the high failure rate of products during that process mean that only a few biotech firms have actually got to the point of exercising their co-promotion rights.[11]

Recent anecdotal evidence suggests that those biotech firms getting to the point of exercising co-promotion rights are discovering that they are not the panacea that they may have been held out to be. Business development executives of several major pharmaceutical firms report that the complexity and costs of putting the marketing infrastructure in place appear to be causing some unanticipated problems

[11] The best example of this happening is IDEC Pharmaceuticals, which did a co-promotion deal with Genentech in early 1995 to commercialize Rituxan, a drug for Non-Hodgkin's lymphoma which had recently completed Phase II trials. Rituxan was approved and launched in late 1997, with IDEC co-promoting in the US and Canada. IDEC subsequently commercialized Zevalin, a second-in-line drug for Non-Hodgkin's lymphoma launched in early 2002, retaining the rights to market alone in the US. IDEC then merged with Biogen to form Biogen IDEC a year later.

for biotech firms during the launch phase.[12] Meanwhile, Amgen's purchase of Abgenix suggests that their partners are not always eager to market jointly with a smaller firm.[13] Nevertheless, if the biotech firms have increased their chances of raising money on the financial markets by retaining co-promotion rights then the strategy would appear to have paid off, at least in the short term.

Hence, in conclusion, this paper presents evidence that the structure of alliances has evolved over time from straight licensing to co-promotion arrangements, and suggests that this trend is related to the demand from public financial markets. It attributes this relationship to the informational problems that public equity investors face in evaluating alliances, and particularly to a recent preference for full integrated, product-based firms over 'platform' or licensing-based firms.

[12] Panel discussion on "Alliance Strategy & Management", *Allicense* conference, Fairmont Hotel, San Francisco, April 11, 2007, involving Barbara Kozacs (Head of Life Sciences Practice, Cooley Godward), Graham Brazier (VP, Business Development, Bristol Myers Squibb), Michael McCully (Senior Analyst, Recombinant Capital), Joseph McCracken (VP, Business & Commercial Development, Genentech), Thomas Picone (VP, Strategic Alliances, Schering-Plough), and Robert Willis (VP, Alliance Management, Johnson & Johnson).

[13] In July 2000 Abgenix entered a deal with Immunex to co-promote the Abgenix's product panitumumab, a drug for late-stage colorectal cancer therapies that was then in Phase I trials. However, after Amgen acquired Immunex and the product passed through Phase III trials, Amgen decided to purchase Abgenix outright to avoid having to share the marketing rights with a smaller firm.

Table 1: Descriptive statistics of product licensing agreements in dataset

Variable	Obs	Mean	Std. Dev.	Min	Max
Year of alliance	398	2000.64	5.25	1978	2008
Date of alliance	398	Feb-01	23833	Aug-78	Dec-08
type_Co_Development	398	0.27	0.45	0	1
type_Co_Promotion	398	0.28	0.45	0	1
type_Equity	398	0.33	0.47	0	1
type_Joint_Venture	398	0.05	0.21	0	1
Upfront payments ($2008)	96	19.10	62.20	0	456.00
Equity payments ($2008)	57	41.68	156.67	0	1188.50
Milestone payments ($2008)	101	37.46	98.32	0	943.26
License grant is exclusive (d)	274	0.95	0.23	0	1
License grant includes all fields of use (d)	227	0.49	0.50	0	1
License grant worldwide (d)	285	0.69	0.46	0	1
Number of prior alliances	398	32.06	44.77	0	309
Valuation at start of alliance month ($M)	266	2019.06	7870.42	-172.711	66199.91
Hazard of IPO in month (d)	360	0.03	0.02	0	0.12
Biotech firm has rights to market an approved product in therapeutic area (d)	398	0.12	0.32	0	1

Figure 1: Alliances between start-up biotech and established pharmaceutical firms (1978-2008)

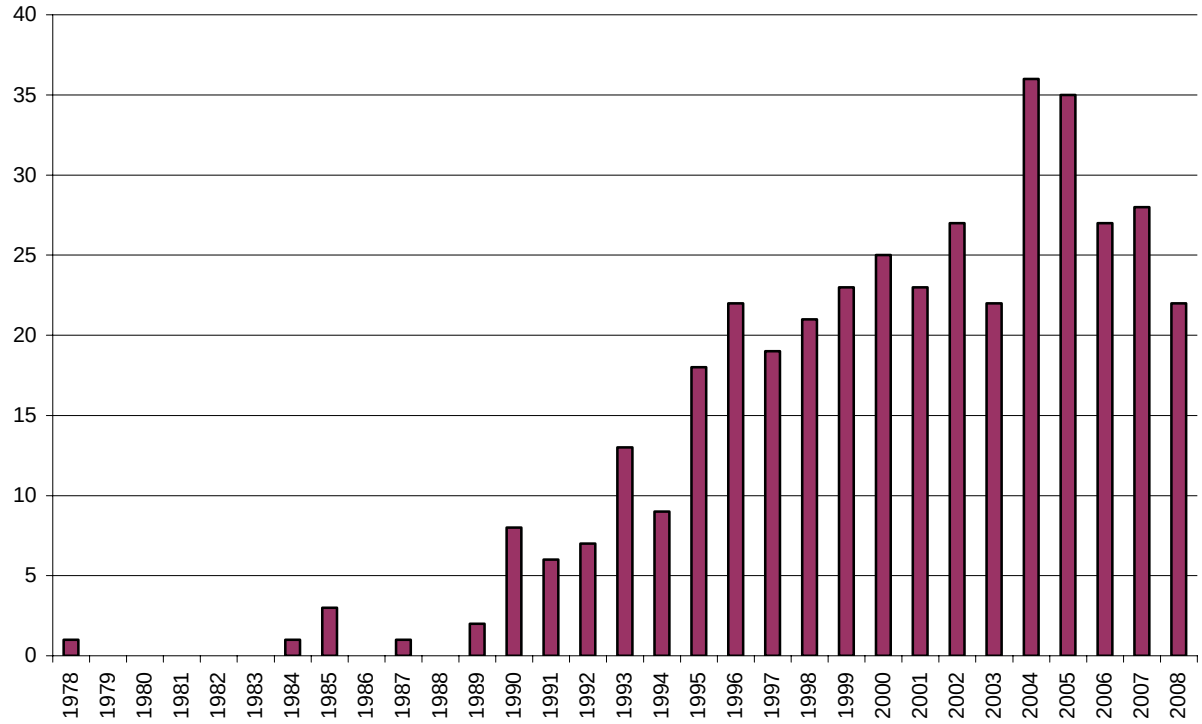

Table 2: OLS regressions on contract types (with 5-year time periods)

	(1)	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*	*(7)*	**(8)**
VARIABLES	type_Co_Development		type_Co_Promotion		type_Equity		type_Joint_Venture	
Period	-0.0000671		0.000807**		-0.00201***		-0.000515***	
	(0.00036)		(0.00036)		(0.00036)		(0.00016)	
Year = 1975 to 1979 (d)		0		0		0		0
		(0.45)		(0.45)		(0.45)		(0.21)
Year = 1980 to 1984 (d)		0		1**		0		0
		(0.45)		(0.45)		(0.45)		(0.21)
Year = 1985 to 1989 (d)		0.333*		0		0.333*		0
		(0.18)		(0.18)		(0.18)		(0.084)
Year = 1990 to 1994 (d)		0.326***		0.209***		0.674***		0.116***
		(0.068)		(0.068)		(0.069)		(0.031)
Year = 1995 to 1999 (d)		0.265***		0.265***		0.422***		0.0882***
		(0.044)		(0.044)		(0.045)		(0.020)
Year = 2000 to 2004 (d)		0.256***		0.278***		0.286***		0.0226
		(0.039)		(0.039)		(0.039)		(0.018)
Year = 2005 to 2009 (d)		0.277***		0.339***		0.188***		0.00893
		(0.042)		(0.042)		(0.043)		(0.019)
IPO window number								
Constant	0.297**		-0.0213		1.086***		0.238***	
	(0.14)		(0.14)		(0.14)		(0.062)	
Adjusted R^2	-0.00243	0.261	0.0103	0.284	0.0693	0.389	0.0218	0.0642
Number of alliances	398	398	398	398	398	398	398	398
Number of firm-product-indications								
Standard errors in parentheses								
***** p<0.01, ** p<0.05, * p<0.1**								

Figure 2: Hazard of IPO (1975-2007)

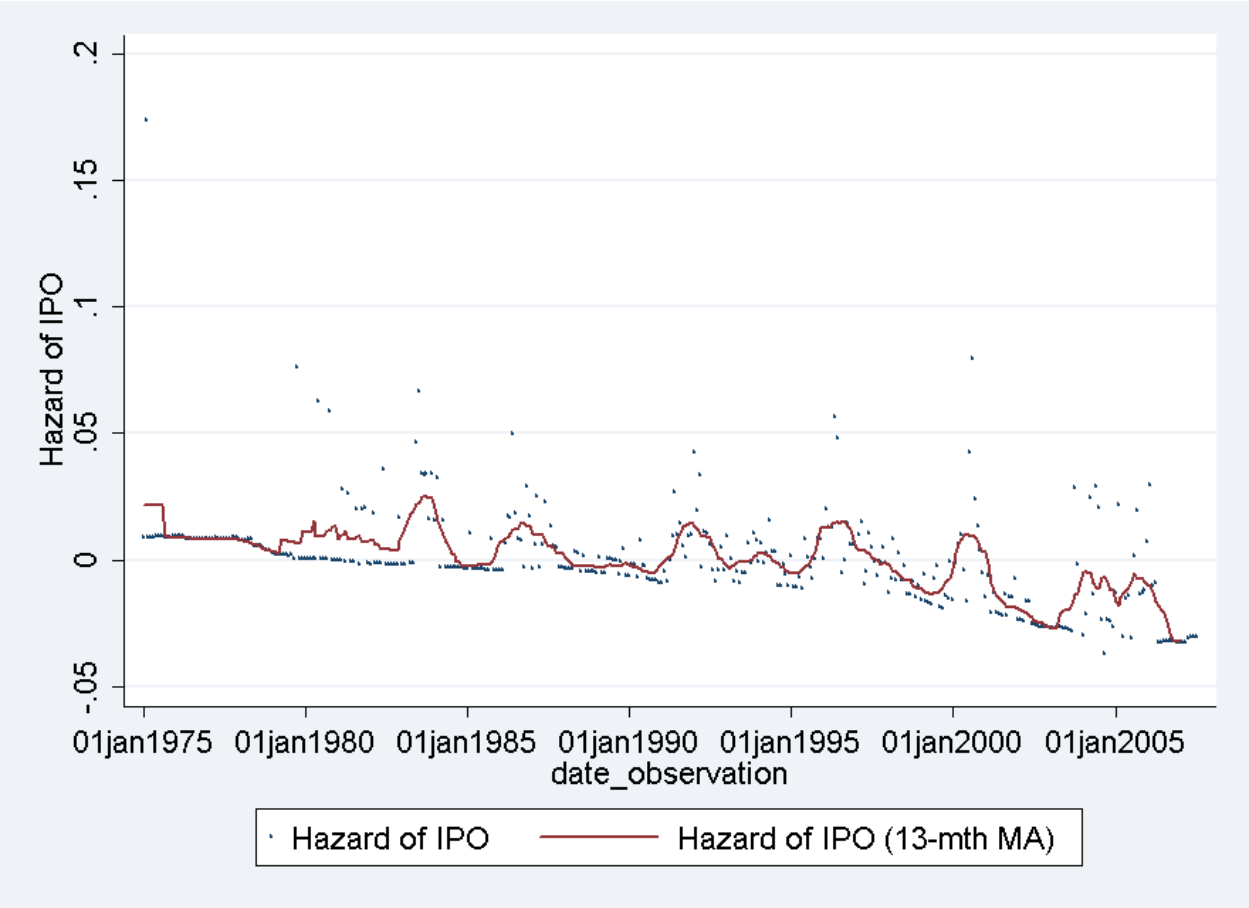

Table 3: OLS regressions on contract types (with IPO windows)

	(1)	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*	*(7)*	**(8)**
VARIABLES	type_Co_Development		type_Co_Promotion		type_Equity		type_Joint_Venture	
IPO window number	-0.0334		0.0404*		-0.125***		-0.0308**	
	(0.025)		(0.024)		(0.025)		(0.013)	
IPO window = Apr 1979 To Aug 1982 (d)		0		0		0		0
		(0)		(0)		(0)		(0)
IPO window = Dec 1982 To Jun 1984 (d)		0		0		0		0
		(0)		(0)		(0)		(0)
IPO window = Dec 1985 To Dec 1987 (d)		0		0		0		0
		(0.44)		(0.44)		(0.45)		(0.23)
IPO window = Dec 1990 To Nov 1994 (d)		0.361***		0.222***		0.639***		0.111***
		(0.074)		(0.073)		(0.075)		(0.038)
IPO window = Apr 1995 To Sep 1998 (d)		0.275***		0.203***		0.406***		0.0870***
		(0.053)		(0.053)		(0.054)		(0.027)
IPO window = Jun 1999 To Jun 2001 (d)		0.255***		0.234***		0.277***		0.0426
		(0.065)		(0.064)		(0.066)		(0.033)
IPO window = May 2003 To Aug 2006 (d)		0.229***		0.314***		0.200***		0.0190
		(0.043)		(0.043)		(0.044)		(0.022)
Constant	0.459***		0.0194		1.061***		0.234***	
	(0.15)		(0.14)		(0.15)		(0.075)	
Adjusted R2	0.00327	0.257	0.00681	0.252	0.0845	0.386	0.0192	0.0596
Number of alliances	258	258	258	258	258	258	258	258
Number of firm-product-indications								
Standard errors in parentheses								
***** p<0.01, ** p<0.05, * p<0.1**								

Table 4: OLS regressions on contract types (with 5-year time periods) with covariates

	(1)	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*	*(7)*	**(8)**
VARIABLES	type_Co_Development		type_Co_Promotion		type_Equity		type_Joint_Venture	
Period	-0.0000697		0.00146***		-0.00134*		-0.000272	
	(0.00059)		(0.00051)		(0.00069)		(0.00018)	
Year = 1975 to 1979 (d)		0.275		-0.795***		-0.0965		-0.0754
		(0.18)		(0.14)		(0.16)		(0.052)
Year = 1980 to 1984 (d)		0		0		0		0
		(0)		(0)		(0)		(0)
Year = 1985 to 1989 (d)		0.440*		-1.018***		0.419		-0.0282
		(0.25)		(0.088)		(0.26)		(0.019)
Year = 1990 to 1994 (d)		0.435***		-0.762***		0.673***		0.0595
		(0.17)		(0.12)		(0.13)		(0.044)
Year = 1995 to 1999 (d)		0.365**		-0.736***		0.459***		0.0347
		(0.16)		(0.10)		(0.12)		(0.024)
Year = 2000 to 2004 (d)		0.478***		-0.628***		0.443***		-0.0152
		(0.15)		(0.11)		(0.12)		(0.019)
Year = 2005 to 2009 (d)		0.399**		-0.580***		0.255**		-0.0129
		(0.17)		(0.11)		(0.12)		(0.026)
Stage Of Development = Clinical (d)	-0.00776	0.00338	0.105*	0.115**	-0.102*	-0.0745	-0.0203	-0.0201
	(0.054)	(0.054)	(0.057)	(0.057)	(0.057)	(0.056)	(0.014)	(0.014)
Stage Of Development = Approved (d)	-0.189*	-0.192*	-0.00136	-0.00878	-0.210*	-0.179*	-0.0276	-0.0231
	(0.10)	(0.10)	(0.11)	(0.12)	(0.11)	(0.11)	(0.020)	(0.021)
Count of biotech firm's prior alliances	0.0209	0.0192	-0.00106	-0.000663	0.0136	0.0148	-0.00220	-0.00193
	(0.031)	(0.031)	(0.030)	(0.029)	(0.031)	(0.032)	(0.013)	(0.013)
Biotech firm valuation at start of alliance month ($M, log)	0.0355	0.0284	0.0104	0.00947	-0.0437*	-0.0492**	-0.00796	-0.00608
	(0.023)	(0.024)	(0.021)	(0.021)	(0.022)	(0.022)	(0.0077)	(0.0076)
Hazard of IPO in month	-0.926	-0.376	0.694	0.409	0.328	0.382	0.222	0.0655
	(1.69)	(1.64)	(1.70)	(1.70)	(1.81)	(1.73)	(0.34)	(0.30)
Biotech firm has marketing rights to an	-0.231**	-0.217**	-0.216*	-0.203*	-0.0345	-0.0289	0.00942	0.00404

approved product in therapeutic area (d)	(0.10)	(0.10)	(0.12)	(0.12)	(0.12)	(0.11)	(0.022)	(0.023)
Therapeutic area fixed effects	Y	Y	Y	Y	Y	Y	Y	Y
Constant	-0.199		-0.613***		0.772***		0.503*	
	(0.22)		(0.19)		(0.24)		(0.28)	
Adjusted R^2	0.0863	0.386	0.0898	0.414	0.0949	0.473	0.0233	0.0641
Number of alliances	398	398	398	398	398	398	398	398
Number of firm-product-indications	863	863	863	863	863	863	863	863
Standard errors in parentheses								
***** p<0.01, ** p<0.05, * p<0.1**								

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