

OUTSOURCING OF RESEARCH AND DEVELOPMENT ACTIVITIES: EVIDENCE FROM U.S. BIOPHARMACEUTICAL FIRMS

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ABSTRACT

This paper examines changes in outsourcing in biopharmaceutical firms over the past ten years using a survey of 86 firms. The data suggest that in spite of the rising expenses in research and development (R&D) and the trend toward external sourcing, a large segment of the firms still prefer to conduct discovery and research in-house. Despite a growing literature on the importance of R&D outsourcing in the biopharmaceutical industry, the data suggest that most firms have recently been reducing their dependence on external R&D partners. The results indicate that the biopharmaceutical firms are using a combination of domestic and foreign firms to outsource their R&D activities and there is no correlation between outsourcing and R&D intensity. The paper concludes with a brief discussion of the implications of the survey findings and the role outsourcing play for R&D activities in the biopharmaceutical industry.

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INTRODUCTION

The biopharmaceutical industry is experiencing an extremely challenging period primarily with respect to constant changes in traditional drug development strategies. While sufficient evidence and empirical analyses of innovation and research and development (R&D) activities exist among large biopharmaceutical firms, it is surprising to note that very little academic research has focused on the small and medium-sized (SMEs) firms. The underlying importance of this paper is to examine R&D strategies and whether outsourcing of R&D as part of a firm's strategy is a growing practice and is likely to continue as more companies become dependent on the external biotechnology know-how that they have corporated internally. According to Achilladelis and Antonakis (2001), the biopharmaceutical industry as compared to other high technology industries is highly competitive and innovative research and development (R&D) is the key to success in the market. This industry has been dominated by a few multinational companies, which are involved in research and development, manufacturing, and marketing of drugs both domestically and globally (Lane and Probert, 2007, Tapon and Thong, 1999). Although, such a focus is logical in light of sheer dominance of large firms in this industry, small and medium-sized enterprises (SMEs) ought not to be overlooked. Just like their larger counterparts, however, SMEs in the biopharmaceutical industry regularly outsource and exploit external sources of knowledge and expertise.

My interest in the SME segment of the biopharmaceutical industry is based on two key factors. First, the extent of utilizing external sources is much greater with SMEs as compared to its larger counterparts (Seget, 2002). Second, R&D productivity has been steadily declining in the biopharmaceutical sector during the past three decades (Buxton and Easton, 2003).

Much of the recent literature has shown that small firms tend to augment their internal competencies by engaging networks of external innovation support (Hall and Bagchi-Sen 2001; Howells, 2006). Extensive literature exists on R&D collaboration and the effect of alliances and joint ventures on large and small firms. However, there is a paucity of research that examines the value and extent of outsourcing within biopharmaceutical firms. While studies have been conducted that identify the advantages and disadvantages of outsourcing and critical success factors in other industries, this paper explores the extent and impact of outsourcing of R&D and other services within the biopharmaceutical industry.

Set against this backdrop I address three primary questions on outsourcing in the empirical section. More specifically the objectives of this section of my research were to determine:

- What is the role of outsourcing as it relates to the product development process?
- What are the key factors in outsourcing R&D and other services for effective implementation?
- What is the impact of outsourcing and the impact on biopharmaceutical R&D?

A major factor for outsourcing has been made on the basis of comparative cost. However, it has also been determined that outsourcing has other strategic benefits such as flexibility and product quality. The R&D process of the biopharmaceutical industry is comprised of two primary phases: drug discovery which focuses at discovering a new compound, and the development phase which evaluates the efficiency of the new compound. One major form of accessing external sources during the clinical and preclinical phase of R&D is through outsourcing. The basic idea behind core competencies and strategic outsourcing is to leverage a firm's core internal skills and available resources while outsourcing non-core activities for which the firm does not have in-house expertise. According to Tesse et.al (1997), a competence is created when firm-specific assets are assembled into integrated clusters between different individuals and groups thereby allowing distinctive activities to be performed.

This paper is organized as follows. The next section provides a research context for the study and gives an overview of current theoretical perspectives with regard to outsourcing. Next I describe the survey methodology and the main characteristics of the sample. I then examine the outsourcing of research and development activities of the survey firms. The paper concludes with a brief discussion of the implications of the survey results for R&D strategies of innovation function.

LITERATURE REVIEW

The pharmaceutical industry has experienced major changes in the research and development activities with the increase of research-based biotechnology and biopharmaceutical firms that have been established during the past three decades (Howells, Gagliardi, and Malik, 2008). The biopharmaceutical industry is unlike other high-tech industries. From its establishment, the biopharmaceutical industry has become one of the most research-intensive and innovative sectors of manufacturing (Achilladelis and Antonakis, 2001).

Academic literature that links external knowledge sourcing with successful innovation at the firm level spans several decades, (for early examples, see Carter and Williams, 1957). For small firms operating in technology-intensive fields, the decision to engage networks of external partners is rarely a simple make-or-buy decision (MacPherson, 1997). Instead, the decision is typically powered by sheer necessity because in-house resources are fully stretched. Moreover, technology-based SMEs often need to combine multiple strands of expertise for any given product development initiative (Freel, 2006) – rendering the need for external resources quite critical. A common denominator across recent studies is that SMEs *must* develop external partnerships or collaborative arrangements in order to bring new products to the marketplace.

The fortune of a biopharmaceutical firm is its ability to produce a “blockbuster” drug. A blockbuster drug is typically a drug to treat a common disease, which provides a substantial perceived health benefit and is marketed in several countries with sales exceeding \$1 billion. The discovery and development of a new drug is a lengthy and complex process. In order to develop a drug, the biopharmaceutical companies are involved in extensive R&D that extends an average of 10-15 years of research, and the results of this research are then submitted to the FDA with an application for approval. For every 5,000-10,000 compounds tested, only one will receive FDA approval.

The development process is long and complex and it represents the heart of the development process in the biopharmaceutical industry. With the rapid increase in R&D expenditures, clinical trials have become more complex and expensive. With a lack of new drugs in their development pipeline, the large biopharmaceutical companies are reorganizing their in-house R&D by outsourcing all but their core competencies. They have sought external partners for innovation and entered into strategic alliances with small and medium-sized biotech companies, which control more than two-thirds of the industry's total product pipeline. Lim et al., 2006 mention in their study that even though R&D activity showed a high level of outsourcing activity because of shortening the time period for drug introduction, but more particularly for the lack of in-house skills in process technology. Process technology is less proprietary and thus seen as a less risky option as compared to outsourcing of R&D activities which has a much higher level of risk and uncertainty because of disclosure of information and knowledge which is a core competency of the firm.

Outsourcing has evolved into a strategic alternative for biopharmaceutical firms for a variety of reasons, such as cost and time savings, and lack of in-house resources required for new product development (Stephen, 2006). R&D plays an important role in the entire product development process within the biopharmaceutical industry and in order to focus on the core activities outsourcing is a critical element to the activities of the R&D process. Although cost savings is a major factor for outsourcing R&D activities, many of the biopharmaceutical firms have been outsourcing in order to improve their profitability, increase market share, and the ability to improve the speed of the product to market (Lacey, 2005).

The reason for such strategic alliances between biotech and biopharmaceutical companies is because each contributes a different set of competencies that is necessary for successful new drug development. While the small and medium-sized biotech companies provide the technology for drug innovation, the large drug companies contribute the capital required to take the product through FDA approval, marketing, and distribution. Many outsourcing SMEs have evolved that specialize in preclinical and clinical trials and excel in new drug development. Although there are a number of generic issues and strategies that firms need to be aware of in relation to outsourcing R&D activities, there are certain peculiarities with outsourcing associated with R&D and innovative activity of a firm. There is a high level of risk and ambiguity in relation to the result of the research that is being outsourced, risk of transforming information to the outsourced firm, quality of the work performed by the outsourced firm, and the significance of the research and technology which is a core competency of the firm and by having the R&D outsourced and receiving poor quality work will have a major impact on the credibility and profitability of the firm (Howells, Gagliardi, & Malik, 2008).

The constant pressure to develop drugs faster and at lower cost is the reason for outsourcing, collaboration and strategic alliances between biotech firms and the large drug companies. This, at least, is what the mainstream literature suggests (e.g., Lane and Probert, 2007). The strategic response of biopharmaceutical firms has been to develop multiple competencies and to collaborate with multinational enterprises (MNEs) and small and medium-sized enterprises (SMEs) located in the emerging countries such as India and China (Rao, 2008).

SURVEY METHODOLOGY

In a preliminary effort to explore the business characteristics of firms in this industry, self-administered questionnaires were mailed to the Chief Executive Officers (CEOs) or R&D Directors of 390 companies. The sampling frame for the project was developed from the database of the North American Biotechnology Directory (May 2006). The database included dedicated biotechnology companies, biopharmaceutical biotech divisions, and other biotech companies. SMEs were defined as firms with less than 500 employees (small firms were defined as having 1-100 employees, whereas medium-sized firms were allocated to the 101-500 employee class).

From a total sampling base of 862 U.S. based companies, a random sub-sample of 390 companies (45 percent) was selected for the study and questionnaires were then mailed. A cover letter and 4-page survey instrument was then distributed to the 390 R&D Directors or CEOs. A return postage-paid envelope was included in the survey package. Follow-up telephone calls and faxes were made to the companies and 60 usable responses were received (yielding an initial response rate of 15.4 percent). Second requests were mailed to the companies who had not responded. Follow-up telephone calls and faxes were made and 26 additional completed surveys were received giving a final response rate of 22.0 percent.

RESULTS-OUTSOURCING

Because of the increased complexities of the R&D process, drug discovery has become a process that involves cooperation and collaboration with many sectors, both public and private. Major biopharmaceutical companies are now evolving into the primary source for R&D funding both for in-house research and for research licensed from other sectors. Small to medium-sized companies are now driving this innovative process from drug discovery, preclinical and clinical trials (Audretsch and Feldman, 2003). All stages of the innovation process (from drug discovery to marketing/distribution) are being performed through various forms of networking arrangements. Firms have entered into these networking arrangements because of access to new markets, speed of entering a new market, complementary assets, and shared risk (Audretsch and Feldman, 2003).

A current crisis exists in the biopharmaceutical industry as in-house R&D fails to generate a significant number of high-value products to drive company growth and replace revenue generated by products approaching the end of their life cycle that are facing patent expiry and generic competition. The industry shift is now to utilize licensing and other outsourced R&D strategies that will replace this lackluster in-house performance.

From the outset, however, it should be emphasized that outsourcing is not the same as external collaboration. Outsourcing is a form of vertical disintegration, where specific production or service activities are subcontracted to external suppliers. The goal is usually to reduce unit costs by engaging outside vendors that enjoy higher levels of efficiency than in-house alternatives. From this perspective, outsourcing reflects the transactions cost explanation for external linkage development. In contrast to these cost-containment goals, external collaboration is more typically spurred by the need to access specialized expertise that is not internally available. This strategy corresponds with the resource-based explanation for external linkage formation, where the goal is to innovate with the help of outside partners. Both strategies have become common in the U.S. biopharmaceutical industry. In some cases, however, there is a degree of overlap between the two strategies.

Tapon et al. (1999) suggests that an effective outsourcing strategy can enable a biopharmaceutical company to develop new drugs in a more cost effective way, obtain new knowledge and capabilities from its outsourcing partners, improve its core competencies by encouraging in-house research departments to become more competitive than the external research institution, achieve greater speed in the drug development process, and cut risk in the drug development process.

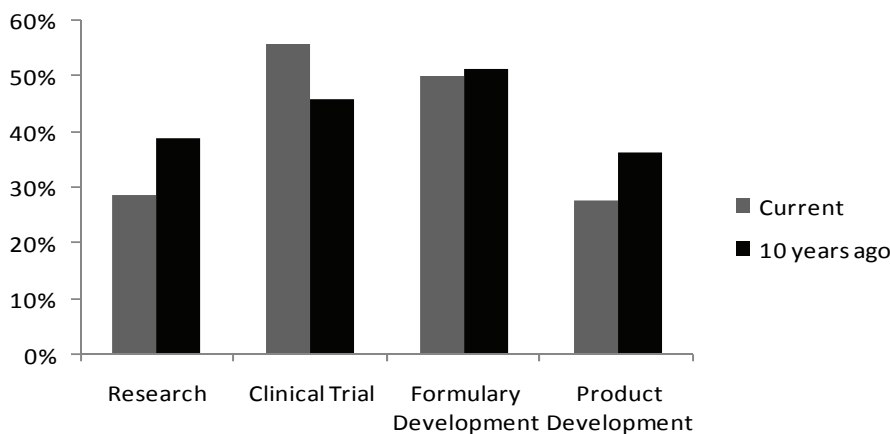
However, research conducted by Piachaud (2002) identifies certain disadvantages with outsourcing primarily related to effective management of the outsourcing partner in terms of lack of control, underestimating the cost and time for new drug development, and creating a competitor. Thus, a firm should clearly understand the nature of its R&D activities and realize outsourcing should be considered a complement to the firm's research activities and non-core competencies rather than a substitute strategy. Strategic outsourcing is not a panacea for whatever ails the company. Rather, it is a sophisticated approach to the strategic use of non-core business functions. This outsourcing encompasses several challenges to high tech firms, and biopharmaceutical firms must understand the entire process before

implementing this strategy for drug development. Outsourcing represents an extension of a biopharmaceutical firms research and development capabilities and has become a critical part of the drug manufacturing process.

Keeping the literature in mind, I looked at the current outsourcing activities and compared it to ten years ago. Within the biopharmaceutical firms the data indicate that in spite of the rising R&D expenses and the trend toward external sourcing, almost half (56.9 percent) of the firms still prefer to conduct discovery and research in-house. From Table 1 and figure 1, I can see that the percentage of the total budget used for outsourcing of research has decreased to 28.4 percent as compared to 38.7 percent ten years ago. Despite a growing literature on the importance of R&D outsourcing in the biopharmaceutical industry, the results shown in Table 1 suggest that most firms have recently been cutting their dependence on external R&D partners. This is evident for all three size-classes of firms, though the most dramatic drop has been for small firms (i.e., from 48.1 percent 10 years ago to 35.4 percent today).

The discovery phase of R&D identifies lead compounds and eliminates any problem compounds before progressing into the pre-clinical and clinical trials. The study data show a decline in the outsourcing of the research phase because discovery, the first phase of the drug development process, is considered as a core competency and firms are reluctant to outsource this phase (see Table 1). Such competencies lead a company to new products and/or new markets. Also, attractive and reliable discovery partners are not always available. Outsourcing of discovery is a strategic commitment involving difficult and risky management decisions, as revealed later when I discuss the results of personal interviews with 20 respondents. The data as revealed in Table 1 also indicate a variation by firm size in outsourcing the research component of the drug development process. The medium-sized firms reported using only 9 percent of their total budget in outsourcing research as compared to 35 percent by small firms and 25 percent by the large firms. Interestingly, medium-sized firms exhibit the lowest levels of outsourcing across all the categories listed in Table 1. For example, the sample as a whole currently outsources around 56 percent of clinical trial work -- but the proportion for medium-sized firms is only 31 percent.

Figure 1: Percentage of Total Budget Used for Outsourcing - Current and 10 Years Ago



This figure shows the percentage of total budget used for outsourcing

Table 1: Percentage of Total Budget Used for Outsourcing and Firm Size (Number of Employees)

	Sample Mean %	Firm Size			ANOVA
		Small %	Medium %	Large %	
Research: Current	28.4	35.4	9.3	25.4	.112
10 years ago	38.7	48.1	13.4	31.7	.147
Clinical Trial: Current	55.9	63.0	31.3	56.0	.128
10 years ago	45.8	50.5	29.3	56.0	.458
Formulary Development: Current	49.9	61.8	17.6	55.0	.132
10 years ago	51.4	75.6	6.5	44.0	.033
Product Development: Current	27.5	30.6	14.6	33.8	.345
10 years ago	36.2	47.6	8.8	37.0	.100

This table shows current outsourcing activities and compares it to ten years ago. The data suggest that most firms have recently been reducing their dependence on external partners. This is evident for all three size-classes of firms, though the most dramatic drop has been for small firms. The large and small firms tend to outsource more in all the categories as compared to the medium-sized firms. Total budget used for outsourcing of research has decreased ten percentage points from ten years ago. Medium-sized firms exhibit the lowest levels of outsourcing across all the categories. The ANOVA statistics show that most of the outsourcing categories are inter-correlated at $p = 0.05$ or less.

A step that is critical in bringing new drugs into the market is clinical trials. Table 1 shows an increase in outsourcing of clinical trials from 45.8 percent ten years ago to 55.9 percent in 2006. The success of a company relies on strategic decisions between utilizing in-house capabilities and taking advantage of external sources. The spiraling cost of drug development and the high failure rate makes the drug development process highly risk-intensive. The value of a firm's compounds increases with the completion of each phase of the clinical trials (phases I to III). Furthermore, the clinical trial process is the most expensive phase of the entire drug development process representing about 40 percent of R&D expenditure (UBS Warburg, 2001). Because of the pressure to get the drugs through the clinical trial process and the amount of expense involved during this phase, biopharmaceutical and biotech companies consider the outsourcing of clinical trials to be a viable option. Outsourcing of all three phases of the clinical trial process is predicted to increase given the pressure to produce new drugs and the overall time and cost involved bringing a new drug to market. However, the results indicate that the small firms outsource almost two-thirds of their clinical trials and the large firms outsource over half of their clinical trial while the medium-sized firm outsource about a third of their clinical trials budget (see Table 1).

The other two specific areas of the R&D process that showed an overall decline in outsourcing were formulary development and product development. This relates to the previous discussion of utilizing in-house discovery to build and maintain competitive advantage in this rapidly changing environment. Overall, about half of the total budget in formulary development is used for outsourcing primarily by the small and medium-sized firms. Medium-sized firms spend only 18 percent of the budget for formulary development in outsourcing as compared to 62 percent by the small firms and 55 percent by the large firms. The trend is also similar with product development where again medium-sized firms are spending less for outsourcing. Medium-sized firms utilized 14.6 percent of the product development budget for outsourcing as compared to 30.6 percent by small firms and 33.8 percent by large firms. I also computed a one-way ANOVA comparing the variance of the different R&D categories of outsourcing by firm size and the results show that most of the outsourcing categories are inter-correlated at $p = 0.05$ or less (see Table 1). Results from further analysis shows for example, R&D outsourcing correlates positively with the outsourcing of formulary development ($r=0.527$; $p=0.020$).

When looking at outsourcing by firm size (small, medium, and large), the small and large firms tend to outsource more in all the categories as compared to the medium-sized firms (see Table 1). Of the total cost necessary to develop a drug, 68 percent of the cost occurs during the clinical development stage (phases I, II, and III). This is one reason why most outsourcing occurs at the clinical stages of the drug-development process. The small companies that are generally cash poor tend to outsource this phase of drug development in order to preserve their cash reserves. The large firms outsource to access the technology and expertise in conducting clinical trials. Their primary objective is to expand their product

portfolios by controlling and developing new drugs outside their own organization. The medium-sized firms have the financial resources and the expertise in-house and conduct their own clinical trials rather than outsourcing. In some instances, it is less cost effective to outsource because in-house R&D offers more control and better quality during this critical stage of the drug development process. Small and large firms outsource more of the product development than do their medium-size firm counterparts. The medium-sized firms outsource about 15 percent of the product development, which is half of the small and large firms (see Table 1).

The primary reasons for outsourcing R&D activities by all sizes of firms are because of the expertise of the external source, and lack of in-house skills and knowledge (see Table 2). The small and large firms also outsource their R&D activities because they lack in-house resources. If a firm lacks the resources, outsourcing can help whether it is a small firm with limited resources or a large firm that must utilize its existing resources more effectively. Through outsourcing, a firm can get the required expertise that it can't expect a small group of people to have in-house. The opportunity to save expenses is also a big reason for small firms to outsource their R&D activities. Through outsourcing, the small firms can rely on some other firm's infrastructure and resources rather than providing the capital itself. Small firms have limited financial resources and have to utilize such resources more cost effectively. The medium-sized firms outsource their R&D activities if they lack the external expertise required. However, the data suggest that they outsource the least as compared to their small and large firm counterparts.

But, despite the benefits achieved through outsourcing, the firms are concerned about the risks involved in outsourcing R&D. Biotech and biopharmaceutical firms are concerned that the lack of control and relying on external partners could cause them to risk losing their competitive edge. The cost savings may fail to develop any profitable products. The survey participants identified a number of risks when considering outsourcing (see Table 3). These include lack of control, quality of work, project delay, product failure, cost, and confidentiality problems. Looking by size of firms, the major risk factor encountered by the small firms is lack of control. Slightly over a third (36 percent) of the small firms indicated that 'lack of control' is the major risk factor in outsourcing R&D activities. The major concern expressed by 36 percent of the medium-size firms is 'project delay', which could result in big losses. The large firms are more concerned about the 'quality of work' as stated by 42 percent of the respondents (see Table 3).

When developing a new drug, poor quality, mistakes, and delay in the development of the drug can result in big losses and delays in the FDA approval process. A SVP of business and commercial development at one of the biopharmaceutical firms surveyed says: "The cost savings do not justify the risks." This is why many of these firms are keeping the research in-house to avoid costly mistakes and liabilities. The drug industry must also comply with rigorous regulations and project delays, and mistakes can result in problems with compliance issues and more costly process. Finally, confidentiality and protection of intellectual property of patent information is subject to great risks at some of the offshore countries.

Table 2: Top 3 Reasons for Outsourcing R&D Activities by Firm Size

	Total Sample %	Firm Size		
		Small %	Medium %	Large %
Do not have the skill/external expertise	61.9	65.8	61.5	50.0
Lack of in-house resources	25.4	26.3	7.7	41.7
Cost effectiveness	23.8	23.7	7.7	8.3

This table shows the primary reasons for outsourcing R&D activities by all sizes of firms. The three key reasons are the expertise of the external source, lack of in-house skills and knowledge, and the opportunity to save expenses. The small and large firms also outsource their R&D activities because they lack in-house resources. The opportunity to save expenses is also a big reason for small firms to outsource their R&D activities. The medium-sized firms outsource their R&D activities if they lack the external expertise required.

Table 3: Top 6 Risk Factors for Outsourcing R&D Activities by Firm Size

	Total Sample %	Firm Size		
		Small %	Medium %	Large %
Lack of control	32.2	36.1	18.2	33.3
Quality of work	30.5	30.5	18.2	41.7
Project delay	28.8	27.8	36.4	25.0
Product failure	11.9	11.1	9.1	16.7
Cost	10.2	11.1	9.1	8.3
Confidentiality	6.8	8.3	-	8.3

This table shows the risks involved in outsourcing R&D. A number of risk factors were identified when considering outsourcing. These include lack of control, quality of work, project delay, product failure, cost and confidentiality problems. The major risk factor encountered by the small firms is lack of control while the major concern for medium-sized firms is project delay. The large firms are more concerned about the quality of work.

Research Limitations

Caution should be taken in generalizing the results of this study because this study is subject to several limitations. The two major limitations are: 1) sample size and 2) low response rate.

The first limitation concerns the small sample size used in this study. I collected data utilizing a sub-sample instead of the total population because of my limited budget. I could not afford to survey more than 45 percent of the population. A second weakness of this study is the low response rate of 22 percent. Usually a 20 percent or lower response rate in survey research with business establishments is quite common, but nevertheless my response rate of 22 percent is insufficient to provide conclusive findings, and thus the results should be treated as suggestive only.

SUMMARY AND CONCLUSIONS

Over the past decade, strategic outsourcing has become a critical decision within the biopharmaceutical industry. Increased pressure for new products in the pipeline, rising R&D expenses, the pressure to reduce costs, and the need to bring new products to the market have led to the outsourcing of not only the traditional non-core functions, which include clinical trials and drug manufacturing, but also the technically demanding areas of drug discovery and development. However, a decline in the outsourcing of these areas (core competencies) and an increase in the outsourcing of non-core functions have also been observed. In this study I have attempted to understand how biopharmaceutical companies have employed outsourcing in an effort to conduct declining product pipelines and patented product portfolios. From previous studies it has been established that networks of collaboration and outsourcing dedicated to the creation of innovation during the past decade seem to be the expected formula for new product development among biopharmaceutical firms. However, from this study I can conclude that there is some evidence that for the large firms, outsourcing and product development activity were strongly correlated 10 years ago.

Furthermore, R&D outsourcing has declined significantly over the past 10 years. Across all three size-classes of firms, R&D appears to be gaining ground as an internalized activity. Medium-sized firms currently conduct over 90 percent of their R&D in-house, compared to 75 percent among large firms and 65 percent among small firms. The trend toward declining levels of R&D outsourcing is not what we would expect in light of the recent literature (e.g., Chiesa et al., 2004). The budget used by these firms for outsourcing research has decreased from 10 years ago. Outsourcing of the discovery process is a strategic commitment and involves a lot of risks, as mentioned by 20 respondents during follow-up interviews. The respondents were asked to explain why their research budget for outsourcing had decreased from 10 years ago. The firms have developed more in-house research expertise and are conducting more research in-house. Some of the main reasons included the poor quality of research being conducted, delays in

meeting deadlines by the external firm, and the difficulty of maintaining control of the research activity due to distance and insufficient in-house manpower to control it. These factors led to more ineffective research and ultimately ended up being more costly. This study has offered an exploratory review of a topic that has attracted significant attention in the recent academic literature on innovation and outsourcing within the U.S. biopharmaceutical sector. The task remains to conduct specific case studies to more fully understand the relationships between innovation and outsourcing.

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BIOGRAPHY

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