

# Commercialization Strategies of Biotechnology Companies

by

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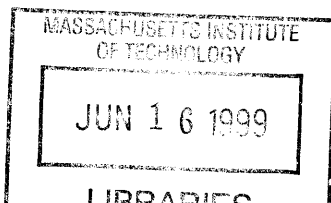
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Submitted to the Sloan School of Management  
on May 6, 1999 in Partial Fulfillment of the  
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## **ABSTRACT**

In the biotechnology industry today, there are many business models for project commercialization. These models range from independent vertical integration to certain forms of collaboration with pharmaceutical companies to complete acquisitions of projects by the big pharmaceutical companies. In this thesis, we wanted to study commercialization strategies of several biotechnology companies. We wanted to investigate the rationale for commercialization decisions and the consequence of these decisions on biotechnology firms'. Thus, we conducted interviews with either founders or senior managers of business development of nine biotechnology firms to address these issues.

Our results demonstrate that biotechnology firms reluctantly enter partnership agreements with pharmaceutical companies. In addition, there are delays in the negotiation process before agreements are reached, which can have negative impact on biotechnology firms. Furthermore, concentration on core competencies and the presence of champions at the pharmaceutical partners are two essential elements of successful commercialization for biotechnology firms.

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## INTRODUCTION

When running a biotechnology company, the founders of these companies discuss at length the business model around which to build their companies. The dominant model in the past was the fully integrated pharmaceutical company in which a biotech firm attempted to duplicate the model of established pharmaceutical companies. More recently, a new model emerged in which biotechnology firms rely more on corporate partnerships with larger pharmaceutical companies. The goal of this thesis is to understand the process by which small biotechnology firms decide on commercialization strategies for their projects and the consequence of these decisions. Thus, we asked founders and senior managers of business operations of several biotech firms questions addressing our goal. Four areas were covered in our questionnaires. First, project commercialization history including the type of project and the time in the project's life cycle in which commercialization was decided upon. Second, commercialization decision making including people who made the decision and the main motive for that decision. Third, interactions with partners, if any, including the length of negotiation and the main terms of agreements. Finally, consequence of the commercialization decision making including the effect of the decision on biotech firm's culture and function.

Our results show several findings. First, biotech firm's founders are reluctantly seeking partnerships with larger pharmaceutical companies. Second, there are long delays in negotiation on the part of the pharmaceutical companies when dealing with biotech firms, which could negatively impact the competitiveness of these firms. Third, biotechnology firms concentrating on their core competencies have a better rate of success. Finally, the presence of both a scientific and a business champion in the

pharmaceutical company who work to support the agreements formed with the biotechnology firm is an essential element for successful partnerships.

#### **A. The Biotechnology Industry:**

Perhaps unique among industries, biotechnology is not defined by its products but by the technologies used to make those products. Biotechnology refers to a set of enabling technologies used by a broad array of companies in their research, development and manufacturing activities. To date, these technologies have been used primarily by the pharmaceutical industry.

Although biotechnology includes any application that uses living organisms to modify human health or the human environment, the key to modern biotechnology is the manipulation of DNA. Until James Watson and Francis Crick's 1953 discovery of the DNA structure, most genetic tinkering involved whole organisms (for example, hit-or-miss breeding of plants or livestock). Understanding the cell protein production process was a major advancement. The discovery of the recombinant DNA process led to the use of clone cells to attack viruses, methods for reading DNA sequencing, and, eventually, the placement of a gene in a mouse.

The applications of biotechnology to the pharmaceutical sector include:

- Drugs using recombinant DNA technology.
- Drug targeting.
- Applications to conventional drug production.
- New diagnostic technologies.

In the roughly 30 years since the establishment of the biotechnology industry, more than 2,000 firms have been founded in the United States alone. (1). Approximately 30 new products have reached the medical market and several hundred more are in human clinical trials. The market for such product is expected to grow dramatically from \$8.0 billions in 1997 to \$24 billions in 2006 (1).

Ernst & Young 's 1996 report on the biotechnology industry identifies 1,308 companies in the United States that were founded primarily to commercialize biotechnology (1). The Institute for Biotechnology Information (IBI) estimates employment in the biotechnology firms at 111,600. IBI sets the mean number of employees per company at more than 104.

The peak year for new company formation occurred between 1981 and 1987 and the average biotechnology company is now 10 years old. IBI reports that 30 percent of the biotech companies are publicly traded, 54 percent are privately owned, while 16 percent are divisions, subsidiaries, or joint ventures. The subsidiaries and divisions may be either public or private.

By far the largest concentration of biotechnology companies is in California, followed by Massachusetts and New Jersey (1). Table 1 shows the leading biotechnology states in the U.S.



*Table 1. Leading Biotechnology States*

Rank	State	Number of Companies
1	California	267
2	Massachusetts	130
3	New Jersey	80
4	North Carolina	71
5	Maryland	70
6	Pennsylvania	58
7	Wisconsin	56
8	New York	55
9	Texas	50
10	Washington	40

According to Consulting Resources Corporation (Lexington, Massachusetts), global sales from U.S. biotechnology products in 1996 reached \$10 billion (2).

The biggest market area for biotechnology companies is therapeutics. However, many biotech companies pursue more than one market area. Table 2 lists the areas of focus of United States biotechnology firms.

*Table 2. Biotechnology Market Area*

Market Area	Number of Companies	% of All Companies
Therapeutics	448	41.8
Diagnosis	346	32.3
Reagents	224	20.9
Specialty Chemicals	159	14.8
Immunological products	146	13.6
Cell Culture products	133	12.4
Fermentation/Production	116	10.8
Plant Agriculture	106	9.9
Vaccines	105	9.8
Drug Delivery Systems	94	8.8
Environmental treatment	93	8.7

**B. Commercialization challenges:**

The biotechnology industry is the most research-intensive industry in civilian manufacturing. According to a 1995 survey by Business Week, five of the top 10 firms in terms of research expenditure per employee were biotechnology companies (3). Estimates on total research and development spending by this industry range from \$7.9 billion to \$10 billion (4). R&D alone accounts for 36 percent of all costs incurred by public biotech companies. The average firm spent \$69,000 per employee on research in 1995, about eight times the United States corporate average of \$7,651. In addition, the new biotechnology research is technically more complex and require large investments in

research facilities and plants (5). And only one in about 5,000 biological compounds reach an end-user form the R & D phase. Of these, only 30% achieve the commercial success level in the market (6). A study released in the early 1990s estimated that \$359 million and approximately 10 years were required to move a drug from the test tube to the end user (6).

For biotechnology companies in the field of human drug research, access to large amounts of capital over an extended period of time is necessary to finance the expensive clinical trials and meet the complicated regulation process. Furthermore, most biotechnology companies lack the distribution system to successfully launch a new drug to the market (7). These biotechnology companies are not in the position to engage in extensive promotion or marketing of new drugs involving sizable sales force. And, many of these drugs are likely to be prescribed by specialists rather than the general practitioner because of the focus of biotechnology companies on niche areas of medicine. Thus, with financial pressures, scarce resources and inexperience, small biotechnology companies have found that alliances and partnerships with large pharmaceutical companies have become a viable option. Because, alliances offer managers of biotechnology firms the ability to share risks and capabilities, thereby minimizing the time and resources necessary to develop a new technology.

### **C. Alliances:**

Alliances or strategic partnerships are venture between two companies where these two companies remain competitors outside the relationship (7). Alliances are based on pooling resources, exchange or integrate specified business resources for mutual gain.

All alliances entail some degree of inter-corporate integration among partners. The integration seen in an alliance is less than that seen with a merger but more than a simple buy/sell relationship. On one end of the alliance spectrum are partnerships, such as cross-distribution agreements or licensing pacts. At the other end of the alliance spectrum are partnerships such as joint venture. In the biotechnology industry, most alliances are in the form of partnerships in which R&D, distribution, or marketing agreement are formed between small biotechnology firms and their large pharmaceutical counterparts.

For biotechnology firms alliances provide many advantages including:

- Build wide market capabilities that they lack.
- Cope with escalating technology and R&D costs.
- Pre-emptive threat by another newly established biotechnology firm.
- Speed innovation and product introduction by having enough capital to continuously pursue research.
- Build higher and wider technical capabilities.
- Establish credibility by associating the biotechnology company with an established and respected pharmaceutical company.
- Risk sharing. Because many biotechnology firms can no longer afford the risks of betting all their investment opportunities.
- Market segment access. Many of the biotechnology firms lack customer links in terms of relationships and infrastructure.

In 1994-1995 period, there were 5,539 alliances in the U.S.; biotechnology and medical alliances made 1,037 out of the total alliances for that year (8). In 1997, the twenty-five companies most active in alliances in the U.S. achieved a 17.2% return on

equity, which is 40% more than the average of the fortune 500 (9). The twenty-five companies least active in alliances lagged the fortune 500, with an average return on equity of only 10.1%.

#### **D. The Pharmaceutical Industry:**

The pharmaceutical market today is one of the fastest growing markets with an annual growth rate of 8.4% from 1991-1996. The total market for the pharmaceuticals industry in 1996 was US\$ 300 billions (10). The U.S. market is the largest in the world with a share of 35% of the total value followed by Western Europe (29%) and Japan (22%) (11).

Historically, the US pharmaceutical industry has been made up of many medium-sized companies that were fully integrated from R&D and clinical trials to production, sales and marketing. And ever since the late 1800s and up to the 1970s, pharmaceutical companies have been producing drugs the slow old-fashioned way, by mixing organic compound to produce drugs that may or may not work in the human body (10). Thus, it was common for each pharmaceutical company to launch only one or two drugs per year.

In the latter half of the 1970s the established pharmaceutical companies found themselves confronted with the rapid development of biotechnology companies. These biotechnology firms started developing successful products through research and development in the latest scientific innovation.

Today, one of the keys to success in the pharmaceutical industry is to have several strong-selling drugs coming out of the pipeline at all times. The need for more drugs on the market, the development of new biotech companies and the escalating pressure on

pricing led the big pharma to consolidation. In 1996 alone there were 27 mergers valued at \$9.4 billion in the US and 16 US-international company mergers valued at \$1.9 billion.

These merged companies quickly realized, however, that whereas consolidation can generate savings in other areas of the value chain, research and development is one essential activity in the pharmaceutical industry that is not scale economic. Thus, big pharmaceutical companies started looking for new alternatives to increase the number of their drug portfolio, and alliances with biotechnology companies turned out to be a very attractive alternative. Because, these alliances allowed the big pharma to access particular technologies at biotechnology firms without all the excess baggage that a merger or acquisition might bring. Today, pharmaceutical companies are teaming up with biotechnology firms on research for new products and on disease and health-management programs.

With these strategic moves and with the financial, clinical, manufacturing, and marketing infrastructure on their side, the pharmaceutical companies were successfully able to overcome the challenges presented to them by the emerging biotechnology firms. And in contrast to such industries as computers and automobiles, companies founded in the 1940s and 1950s still dominate the pharmaceutical industry today (12). This dominance is taking place despite earlier predictions that the emergence of the new biotechnology industry will make the big pharmaceutical companies obsolete.

Thus, in today's harsh environments, where small, nimble companies often do better than their larger rivals, the pharmaceutical industries are demonstrating that such rules do not always apply. Large American biotechnology and pharmaceutical companies are enjoying a good surge on Wall Street. Whereas small biotechnology firms

worth less than \$200 million have fallen in value by 12% according to Hambrecht and Quist, an investment bank in the last year (13). Rich biotechnology and pharmaceutical companies seem to be getting richer today mainly because they offer results that investors can understand: products on the market and profits right now.

Many biotechnology executives are not very enthusiastic of partnership deals with pharmaceutical companies and are entering these agreements for the lack of better alternatives. There are two reasons that executives cite for their dislike of partnerships. First, if the science fails, the extra income that the biotechnology firm got will be very short term and will cause big problems to the company. Second, if the science turns to be a big success, the contract usually assures the big company of most of the upside, with very little remaining for the small company.

These founders would prefer going it alone by raising capital through venture capitalist or in the stock market because that will enable them to retain more control over the business, get most of the potential future profit and keep their entrepreneurial culture intact. However, investors today no longer lavish rewards for slow progress that goes into building a biotechnology company, such as promising results from early clinical trials. Also, investors have learned about the risks of making new drugs. These investors understand that very few molecules will stand up to the rigorous of early experiments. Only one in ten of these survivors will then make it through clinical trials and scrutiny by government regulators. The main problem for the biotech firms wanting to go public is that most of them have little more to offer than the bright ideas and the early positive R&D results. Also, European investment funds moved more of their focus toward home markets. Matters for the biotechnology industry desiring to go public are not helped by

the recent consolidation among investment banks. According to KPMG consultancy firm, the number of biotech analysts researching small companies in biotechnology has fallen by half since 1997 (13).

#### **E. Implementation of Commercialization Strategies:**

Ordinarily, the process of implementing a strategic decision in an organization involves senior executives in the organization (14). In small biotechnology firms, the decision making process is concentrated mostly with the founder of the company with very few individuals exerting additional influence.

Analyzing the motives behind commercialization decisions and who makes the decisions in these biotechnology firms is essential. Because, some times, the motives of the founder of a biotech company might not be aligned with that of the long-term success of the company. For example, as discussed earlier, founders of biotech firms might be looking to expand their companies by raising money through public funding only. However, more efficient way for these companies might be to partner with pharmaceutical firms and use their resources and experiences to grow. It is accepted today, that for biotechnology company to survive, only 10% of the several hundred million in capital required over its first decade come from venture sources, and 40% comes from public equity markets. This leaves Big Pharma to providing 50% of the capital that biotech firms like to have tapped into over their first decade of operations (15).

For a small biotech firm, the speed to reach a decision on commercialization is essential. Because, some times the small biotech company is desperate for capital to



continue its R&D and the speedy delivery of this needed capital would be critical for the company's continued success. The size of the organization plays an important role in the time required for decision-making. Large pharmaceutical companies, for example, have greater number of committees and slower process of decision-making (16). On the other hand, biotechnology firms which tend to be controlled either by individual or corporate owners have fewer impediments to decision making (16).

In this thesis is we wanted to understand the process by which commercialization strategies are chosen and implemented in the biotechnology industry. Specific attention is focused on whether commercialization is achieved through partnering and/or the exchange of intellectual property (hereafter referred to as a cooperation strategy) or through internal development and marketing (hereafter referred to as a competition strategy). We also wanted to identify the time it takes for a commercialization decision making to be reached between biotech firms and large pharmaceutical companies.

## **METHODS**

A list of twenty-five biotechnology companies was generated for potential inclusion in the study. Nine out of the twenty-five companies were eventually included. The senior management of the remaining sixteen companies refused to be interviewed mainly for confidentiality reasons. Interviews were conducted with high level management of the remaining nine biotechnology firms. A survey questionnaire was first mailed to the participant to familiarize them with the topic being studied. Subsequently, either a telephone or a personal interview was conducted with the participants. Four areas were emphasized upon in these interviews: A; commercialization history, B; commercialization decision-making, C; interactions with partners and D; consequence of the decision. Table 3, which is shown below lists the four areas that were studied in the survey. A complete copy of the survey questionnaire that was sent to the various participants prior to the interview is included in the appendix.

*Table 3. The Four Areas Covered in the Survey*

<b>A: Commercialization History:</b>	<b>B: Commercialization Decision Making:</b>	<b>C: Interactions with partners:</b>	<b>D: Consequence of the Decision:</b>
<ul style="list-style-type: none"> <li>• Who was the partner for the commercialized project?</li> </ul>	<ul style="list-style-type: none"> <li>• Who made the decision on commercialization?</li> </ul>	<ul style="list-style-type: none"> <li>• What was the length of negotiation before a formal agreement was signed?</li> </ul>	<ul style="list-style-type: none"> <li>• What was the effect of commercialization On R&amp;D?</li> </ul>
<ul style="list-style-type: none"> <li>• What project was being commercialized with the partner?</li> </ul>	<ul style="list-style-type: none"> <li>• What was the motive for commercialization?</li> </ul>	<ul style="list-style-type: none"> <li>• What were the terms of agreement?</li> </ul>	<ul style="list-style-type: none"> <li>• What was the effect of commercialization On the organization as a whole?</li> </ul>
<ul style="list-style-type: none"> <li>• At what stage of the project life cycle was the decision to commercialize made?</li> </ul>	<ul style="list-style-type: none"> <li>• What type of data was used to reach the decision on commercialization?</li> </ul>	<ul style="list-style-type: none"> <li>• What were the sticking points in the negotiation process?</li> </ul>	<ul style="list-style-type: none"> <li>• What was the effect of commercialization On the culture of the firm?</li> </ul>

The questions in part A (commercialization history) on who to partner with and what to commercialize required straightforward and simple answers regarding the presence or absence of partners for a project. The critical question here was the time framework in which the firm decided to pursue partnerships. We wanted to know whether firms were seeking to commercialize their projects at early stages of R&D, at a later stages when more positive R&D data show a promise for commercialization, or when marketing expertise were needed to sell their product.

The first question in part B (commercialization decision making) was to identify the main individuals in the firm who made the decision on whether or not to form

partnerships. We also wanted to determine the main motive for the decision (profit, market share, competitive pressure, cost, culture clash, etc.). It is frequently suggested that the main reason for commercialization is to increase profit. However, we wanted to uncover, the presence of potentially more fundamental reasons for such a critical decision.

In terms of part C (interactions with partners) we wanted to know the length of the negotiations before signing an agreement and whether the delay in time duration have an effect on the firms functional abilities. Nevertheless, due to confidentiality agreements between partners and due to competitive issues among biotechnology firms, we were unable to study in-depth the terms of agreements and the sticking points in the negotiations.

In part D (consequence of the decision), we wanted to explore the impact that partnering had on firm's culture and morale. This is important because partnerships can have a profound impact on firm's entrepreneurial drive, innovation and learning.

## RESULTS

A summary of the companies that were included in the interviews is listed below (Table 4). All companies were less than 20 years old, and all except for Chiron employed less than 200 people in their organization.

*Table 4. Summary of companies*

Company	Founded	Number of Employees	Specialty	Sales (Millions)	Net Income (Millions)	Partner of Discussed Project
Chiron	1981	6,482	Therapeutics	736.7	524.1	Bayer
Infectech	1988	<20	Microbiology Diagnostics	_____	_____	None
Aphios	1988	20	Medical Therapeutics	_____	_____	Eli Lilly
BioTransplant	1991	63	Anti Rejection drugs	8.0	9.2	Novartis
Hybridon	1993	78	Molecular Diagnostics	3.9	69.5	Hoffman-LaRoche
Interneuron	1988	92	Cardiovascular Disease	6.5		AHP
Avant	1998	36	Autoimmune Disorders	2.2	51.8	Novartis
Inhale	1995	147	Drug Delivery System	21.8	18.4	Pfizer/Hoechst

A summary of the results of these interviews is shown below in table 5. This table lists the four areas that were covered in these interviews. First, the commercialization history of the project being discussed including potential partners for the project, the product being commercialized and the timing rational behind commercialization. Second, the commercialization decision making including who made the decision to commercialize, what was the main motive for the decision and what kind of data was used to evaluate the decision. Third, in terms of interaction with partners, the length of the negotiation before a decision was reached, the terms of agreements and potential sticking points in the process of negotiating the deal. Finally, the consequences of the commercialization decision in terms or its effect on R&D, On the organization as a whole and on firm's culture.

*Table 5. Summary of company interviews*

<b>Company</b>	<b>A: Commercialization History:</b>	<b>B: Commercialization Decision Making:</b>	<b>C: Interactions with partners:</b>	<b>D: Consequence of the Decision:</b>
<b>Chiron</b>	<p><b>Partner:</b> Bayer</p> <p><b>What:</b> diagnostics division</p> <p><b>When:</b> at the peak of the consolidation period in the diagnostic industry</p>	<p><b>Who:</b> CEO and board of directors</p> <p><b>Motive:</b> concentrate on core competency</p> <p><b>Collection of Data:</b> cost and return on investment were evaluated by outside consultants</p>	<p><b>Length of negotiation:</b> 15 months</p> <p><b>Terms of agreement:</b> sell diagnostic unit for \$1.1 billion + licensing and royalty fees</p> <p><b>Sticking points:</b> time of payments, facilities and personnel division</p>	<p><b>On R&amp;D:</b> positive due to infusion of capital</p> <p><b>On organization:</b> positive because it is now smaller and more nimble</p> <p><b>On culture:</b> positive because of the return to entrepreneurial style</p>
<b>Infectech</b>	<p><b>Partner:</b> unable to find a partner</p> <p><b>What:</b> diagnostics kits</p> <p><b>When:</b> the research on kits proved successful</p>	<p><b>Who:</b> CEO and CSO with consultation from the board of directors</p> <p><b>Motive:</b> ability to develop and market the product</p> <p><b>Collection of Data:</b> cost and output were evaluated by CEO and CSO</p>	<p><b>Length of negotiation:</b> few months, but still negative outcome</p> <p><b>Terms of agreement:</b> none</p> <p><b>Sticking points:</b> ability to develop the product</p>	<p><b>On R&amp;D:</b> negative because of the inability to develop the project</p> <p><b>On organization:</b> it led the company to look for IPO possibilities</p> <p><b>On culture:</b> negative because of loss of confidence</p>
<b>Aphios</b>	<p><b>Past Partner:</b> Bristol-Myers</p> <p><b>What:</b> anti cancer extraction process</p> <p><b>When:</b> preliminary research data showed promise</p>	<p><b>Who:</b> CEO</p> <p><b>Motive:</b> ability to develop and market the product</p> <p><b>Collection of Data:</b> cost and output were evaluated by CEO</p>	<p><b>Length of negotiation:</b> 12 months</p> <p><b>Terms of agreement:</b> milestone payments at each step. However, agreement collapsed by the departure of an Aphios champion at Bristol-Myers</p> <p><b>Sticking points:</b> ability to develop the product</p>	<p><b>On R&amp;D:</b> the collapse of the agreement was negative because it halted the development of the project</p> <p><b>On organization:</b> Negative, it led to negative cash flow</p> <p><b>On culture:</b> negative because of loss of confidence</p>

Company	A: Commercialization History:	B: Commercialization Decision Making:	C: Interactions with partners:	D: Consequence of the Decision:
<b>BioTransplant</b>	<p><b>Partner:</b> Novartis</p> <p><b>What:</b> anti rejection immune drug</p> <p><b>When:</b> research data showed positive results</p>	<p><b>Who:</b> CEO with consultation from the board of directors</p> <p><b>Motive:</b> ability to develop and market the product</p> <p><b>Collection of Data:</b> cost and output were evaluated by CEO</p>	<p><b>Length of negotiation:</b> 12 months</p> <p><b>Terms of agreement:</b> Novartis has the license to the technology in exchange for payments totaling \$36million</p> <p><b>Sticking points:</b> within BioTransplant, the board of directors wanted a better deal for the company</p>	<p><b>On R&amp;D:</b> positive due to infusion of capital</p> <p><b>On organization:</b> positive because the presence of extra capital allowed the company to remain independent and more nimble</p> <p><b>On culture:</b> positive because of the vote of confidence from Novartis</p>
<b>Hybridon</b>	<p><b>Past Partner:</b> Hoffman-LaRoche</p> <p><b>What:</b> drug for AIDS treatment</p> <p><b>When:</b> R&amp;D data showed very positive results</p>	<p><b>Who:</b> CEO and the board of directors</p> <p><b>Motive:</b> ability to conduct clinical trials</p> <p><b>Collection of Data:</b> cost of clinical trails evaluated by CEO</p>	<p><b>Length of negotiation:</b> 12 months</p> <p><b>Terms of agreement:</b> Novartis had the license to the drug but terminated the agreement after the failure of clinical trials</p> <p><b>Sticking points:</b> none</p>	<p><b>On R&amp;D:</b> no effect because the agreement was for clinical trials</p> <p><b>On organization:</b> the termination of the agreement was very negative because the market lost confidence and so did many people in the organization</p> <p><b>On culture:</b> the termination of the agreement had a profound change on culture, the company shifted its approach to drug development</p>
<b>Interneuron</b>	<p><b>Partner:</b> AHP</p> <p><b>What:</b> Redux, anti obesity drug</p> <p><b>When:</b> while looking for a marketer after licensing the drug from its French developer</p>	<p><b>Who:</b> CEO and SVP for business operation</p> <p><b>Motive:</b> ability to market the drug to the largest number of customers</p> <p><b>Collection of Data:</b> CEO was looking for the best marketing company that would agree for co-promotion</p>	<p><b>Length of negotiation:</b> 12 months</p> <p><b>Terms of agreement:</b> Interneuron had an undisclosed licensing and royalty revenue generated through marketing agreements and product sales</p> <p><b>Sticking points:</b> none</p>	<p><b>On R&amp;D:</b> no effect because the agreement was for marketing plans</p> <p><b>On organization:</b> the agreement was a very positive influence until the drug was banned due to side effects</p> <p><b>On culture:</b> No effect</p>



Company	A: Commercialization History:	B: Commercialization Decision Making:	C: Interactions with partners:	D: Consequence of the Decision:
Avant	<p><b>Partner:</b> Novartis</p> <p><b>What:</b> drug to improve lung function</p> <p><b>When:</b> R&amp;D data showed very positive results</p>	<p><b>Who:</b> CEO with consultation from board of directors</p> <p><b>Motive:</b> ability to launch clinical trials and market the drug to the largest number of customers</p> <p><b>Collection of Data:</b> CEO was looking for the best company in that particular field</p>	<p><b>Length of negotiation:</b> 15 months</p> <p><b>Terms of agreement:</b> Avant gets equity investment, licensing fees, milestone payments totaling \$20 million</p> <p><b>Sticking points:</b> none</p>	<p><b>On R&amp;D:</b> very positive to see the effects of research being carried forward</p> <p><b>On organization:</b> Very positive to give the people validation that the organization is on the right track</p> <p><b>On culture:</b> positive for reinforcing the success of entrepreneurial culture</p>
Inhale	<p><b>Partner:</b> Pfizer</p> <p><b>What:</b> insulin delivery through the lung rather than by injection</p> <p><b>When:</b> R&amp;D data showed very positive results</p>	<p><b>Who:</b> CEO, VP of research with consultation from board of directors</p> <p><b>Motive:</b> ability to launch clinical trials and market the drug to the largest number of customers</p> <p><b>Collection of Data:</b> CEO was looking for the best marketing company, external consultant was hired by Inhale</p>	<p><b>Length of negotiation:</b> 15 months</p> <p><b>Terms of agreement:</b> Inhale gets equity investment, and royalty from sales</p> <p><b>Sticking points:</b> none</p>	<p><b>On R&amp;D:</b> very positive to see the effects of research being carried forward</p> <p><b>On organization:</b> Very positive to learn from a great company like Pfizer</p> <p><b>On culture:</b> positive for reinforcing the success of entrepreneurial culture</p>
Circe	<p><b>Partner:</b> none</p> <p><b>What:</b> device for liver failure</p> <p><b>When:</b> the company was spun-off from G.R. Grace</p>	<p><b>Who:</b> CEO, and board of directors at R. G. Grace</p> <p><b>Motive:</b> the spun-off was to provide Circe with the ability to solely concentrate on developing the device</p> <p><b>Collection of Data:</b> no information available</p>	<p><b>Length of negotiation:</b> NA</p> <p><b>Terms of agreement:</b> Circe now has a deal with a group of VC to develop the device</p> <p><b>Sticking points:</b> none</p>	<p><b>On R&amp;D:</b> the spinning-off was good to focus the team on the task at hand</p> <p><b>On organization:</b> positive because it is a small nimble organization rather than a section in a diversified giant</p> <p><b>On culture:</b> too soon to judge</p>

A detailed description of the results of Infectech, Hybridon and Interneuron are discussed below. These companies were chosen because they highlight different outcome of commercialization. Infectech demonstrates the inability of some companies to find partners to commercialize their products. Hybridon shows a partially successful partnership that failed to reach its final goal of marketing a product. Interneuron on the other hand, illustrates a successful commercialization strategy that earned the company large amount of profit. The detailed results of the remaining six companies are found in the appendix at the end of this manuscript.

In the area of commercialization history, Seven out of nine firms decided to look for partners when the R&D on their projects demonstrated positive results. Only Interneuron was looking for a partner to market its product rather than to further the R&D efforts. Because Interneuron had purchased an already completed R&D product from a French biotechnology company, and therefore, there was no need to find a partner to further expand on R&D. Looking for partners at the early stage of drug development, before any proven clinical effectiveness, reduces the negotiation power of these biotech firms when dealing with larger pharmaceutical companies. This was evident in this study in which most of the bargaining power was in the hand of the big pharmaceutical companies.

In the area of commercialization decision making, the founders or the CEOs were the key decision-makers in all nine firms surveyed. Only Inhale Corporation hired an outside consultant to assist in evaluating the strength and weaknesses of the various partners.

In terms of interaction with partners the duration of time which was needed to finalize an agreement was very similar in all firms. There was a period of 12-15 months of negotiations and reviews before a final agreement was signed. All firms agreed that they were able to reach a decision within few weeks, and that the big pharmaceutical companies caused the delay. In regards to all companies, we were unable to obtain a comprehensive data on the term of agreements. Confidentiality agreements between partners and the reluctance of biotechnology companies to reveal their financial agreements to other biotech competitors were the two main reasons for our inability to obtain a broad set of data on agreement terms.

The consequence of the commercialization decision on firms R&D and culture varied depending on the success or failure of commercialization. The consequence of the decision on companies like Aphios and Infected, which had a failed partnerships, was very negative because it halted further R&D development and had a negative impact on their personnel's confidence. On the other hand, the impact was very positive on companies like Avant and Inhale, which had successful commercialization partnerships.

## **A. INFECTECH**

### **Commercialization History:**

Infected, Inc. is a biotechnology company founded in 1988 for the development of diagnostic kits for infectious disease. Dr. Felder, founder and CEO, says that the reason for founding the company is that when he was a medical resident at New York Medical College, he had a patient dying of some bacteria. That bacteria turned out to be Mycobacterium Avium Intracellulare (MAI), the No. 1 bacterial infection of AIDS

patients in the entire developed world. In the 1980s, however, little was known about it, Dr Felder wondered if there weren't a better way of identifying and killing bacteria, like the one that was killing his patient. In time, Ollar, a microbiologist, and Felder, now a neurologist, formed Infectech, and developed a microscopic slide technology and gene amplification method that could revolutionize the identification and treatment of dozens of life-threatening bacteria.

Recently, Infectech was granted patents in the United States, Australia and England for the world's first use of gene amplification in identifying certain bacteria. The Company has several projects spanning from chemical waste treatment to cancer research. Infectech plans to market the identification kits for microbiology before its other projects because the identification kits are at the most advanced stage of development among the company's portfolio of items under development. Potential markets for the IDENTIKITS include hospitals, clinical laboratories, medical research institutions, medical schools, pharmaceutical companies and physician's offices. The Company has estimated the U.S. market for the nongenetic microbiology IDENTIKITS at five million units annually with a total world market, including the United States, of twenty million units annually. The Company has estimated the market for gene amplification IDENTIKITS in the U.S. at approximately 500 thousand units annually with a total world market of two million annually.

#### **Commercialization Decision making:**

Both Dr. Felder, M.D., CEO and Dr. Ollar, Ph.D., CSO, tried unsuccessfully to pursue a large pharmaceutical or diagnostic partner to market their products. They

wanted to cooperate with a larger, more established firm rather than pursue their projects independently due to the lack of capital and infrastructure to pursue it independently. The failure to cooperate with a larger company led the firm to concentrate its efforts on its original plan which was to go public, which they have plans to do by the year 2000. The CEO and the CSO made these decisions after consultation with the board of directors. All members were in agreements about the needs for a partner and alternatively the plan to go public. For the most part, the CEO and the CSO used their different educational background to analyze their options and to negotiate with others. Dr. Felder concentrated on finding potential markets for the company's products in hospitals and medical school, whereas Dr. Ollar concentrated on his strong knowledge of microbiology to make contacts with diagnostics organizations about the merits of the identification kits. There was no outside expert used to evaluate the various alternatives for commercialization. The basis for the decision to attempt to find a partner and consequently the decision to go public was made in an attempt to reach the market as soon as possible.

**Consequence of the Decision:**

The long-term impact of the decision to go public would not be known at this stage. However, the inability to cooperate with a partner had a negative impact on the company. Because, it delayed the commercialization of the product, let potential competitors catch up, and showed a lack of confidence in the company which negatively impacted other commercialization opportunities that the company is pursuing.

## **B. Hybridon**

1997 Sales (mil.): \$3.9

1-Yr. Sales Growth: (1.5%)

1997 Net Inc. (mil.): (\$69.5)

1997 Employees: 78

1-Yr. Employee Growth: (62.1%)

### **Commercialization History:**

Dr. Paul C. Zamecnik, a scientist-physician whose work on protein biosynthesis revolutionized the field of biochemistry, founded Hybridon in 1989. The company discovers, develops, and licenses genetic medicines that have the potential to treat diseases such as AIDS and cancer. The company's drug development is based on antisense technology, which involves the use of synthetic segments of DNA, called oligonucleotides, that are designed to interfere with the body's protein production at the genetic level. Unlike conventional drugs, which target molecules that a disease has already produced, antisense drugs target the genes that create these molecules in the first place, increasing efficacy and decreasing side effects and costs. Antisense drugs in the clinical stages of development include treatments for AIDS and HIV, cancer and a form of herpes.

Hybridon was in phase II clinical trials testing its drug GEM91 for AIDS treatment when in the summer of 1997 the company announced that it has elected to stop further development of the drug. Because, based on data from the field, three of the nine participants in the study who were tested experienced decreases in platelet counts that required dose interruption. In addition, a review of the data showed inconsistent

responses to the treatment and failed to confirm the decrease in cellular viremia observed in an earlier trial.

Hybridon had expanded very quickly with new offices in Cambridge, MA and in Paris, France. The failure of the clinical trial for the AIDS drug was near fatal to the company. Its main collaborator, Hoffmann-La Roche announced that it had decided not to pursue further its antisense collaboration with Hybridon, and was terminating the collaboration effective February 28, 1998.

#### **Commercialization Decision Making:**

The main financial strategy of the company was to try to get research and development costs covered and to have royalty stake in the outcome. The research and development collaboration with Hoffmann-La Roche began in 1992 for which the company made milestone payments to Hybridon. Roche has later indicated that all licenses granted to it under the agreement will be returned to Hybridon.

Following these major set backs, and in the process of restructuring, the company decided to close the Paris site and announced the relocation of its corporate headquarters to the more affordable Milford, MA.

The company now has collaboration with Searle pharmaceutical division of Monsanto to support more modest goal of antisense research at Hybridon through January 2000.

The chairman and the board of directors were involved in the decision making process. After all the setbacks, the company's only alternative option was to utilize its knowledge of antisense technology research to collaborate with various companies on the

basis of providing antisense research services in return for predetermined fees.

Generally, The head of business development is in charge of looking for deals with bigger pharmaceutical companies. Usually, The process to reach a decision regarding collaboration is very short (within 2 weeks). However, it takes large pharmaceutical companies much longer (approximately a year) to finalize a deal. According to Hybridon, one essential point that acts against small biotechnology companies in their collaboration with big pharmaceuticals is the turnover in champions at the collaborator's site. The negotiated terms of agreements could be altered or completely terminated if the sponsors at the larger company moved from their positions.

#### **Consequence of the Decision:**

The termination of the agreement with Hoffman Laroch was inevitable due to the failed clinical trials. The company was quick in responding to this devastating result by shifting its focus to more modest goals. The effect of the termination of the agreements with Hoffman LaRoche and the subsequent agreement with Monsanto-Searle shifted the focus of the R&D division from a blockbuster approach of achieving success to more incremental one, and made the company focus on servicing a large number of pharmaceutical companies. The new cooperation with various companies has been essential for survival. The effects on the firm's R&D, culture and organization have been substantial. The company's new approach to provide value-added service to as many companies as possible has shifted the organizational structure and culture from a traditional pharmaceutical like company that attempts to perform most of the tasks internally to a one that focuses on one part of the value chain only.



### **C. Interneuron Pharmaceuticals**

1998 Sales (mil.): \$6.5

1-Yr. Sales Growth: (90.4%)

1998 Net Inc. (mil.): (\$70.0)

1998 Employees: 92

1-Yr. Employee Growth: (46.2%)

#### **Commercialization History:**

Massachusetts Institute of Technology (MIT) scientist Richard Wurtman, whose obesity research was largely regarded as innovative and influential, formed Interneuron in 1988 to commercialize certain MIT drug discoveries. Interneuron Pharmaceuticals now is developing and commercializing a diversified portfolio of products primarily for neurological, behavioral and metabolic disorders. The company's lead products target stroke, congestive heart failure, panic/anxiety, and liver disease. Interneuron is also funding the development of technologies and products through its majority-owned subsidiary company, Intercardia, Inc., focused primarily on cardiovascular disease.

The company licensed Redux, an anti obesity drug from its developer, French firm Les Laboratoires Servier, and then licensed the drug to AHP division Wyeth-Ayerst. In April 1996 Redux became the first new diet drug to win FDA approval in 20 years. By the end of 1996, a million prescriptions had been written for Redux and a related drug, Pondimin (also sold by AHP). However, critics were already questioning the drug's safety, and after a negative Mayo Clinic study, Interneuron withdrew Redux from the

market in 1997 after the drug was linked to potentially fatal heart and lung conditions.

The company insisted that a different (but related) drug, fen-phen, was causing the reported medical problems.

### **Commercialization Decision Making:**

Key elements in Interneuron's business strategy with regards to the drug Redox was acquiring the late pre-clinical stage compound which had a potential broad applications and large unsatisfied markets from the French firm Les Laboratoires Servier. Because Interneuron was a new company with underdeveloped marketing arm, the firm was looking for a marketing partner that will help ensure the penetration of targeted markets as rapidly as possible. Interneuron was able to negotiate a deal for marketing and development of the drug with American Home Product (AHP), division Wyeth-Ayerst. The agreement with AHP stated that Interneuron sales force would sell the product to niche markets, such as endocrinologists and weight experts, while AHP will market and sell the product to the rest of the market including the general practitioners.

The key people involved in the decision making were the CEO and the executive vice president with an initial approval from the board of directors. The main motive for the decision to cooperate with AHP was the ability to co-promote the drug. Other potential partner was Pfizer, however, the direct marketing by Pfizer would not have given Interneuron the ability to co-promote the drug. The decision to co-promote with AHP was a strategic decision because the company wanted to establish a brand name for itself. Another factor for choosing AHP was the speed in which AHP was able to deliver their initial approval for the deal. The process by which the decision was made started

with a scientific review of the product by AHP. A business review to evaluate the potential marketing and sales arrangements was then conducted by AHP business development and licensing groups with the negotiation lasting for about a year. Another important point in the firm's dealing with AHP was the presence of an Interneuron champion at AHP. Having a business and scientific individuals at the big pharmaceutical company was essential to securing a good and fair deal.

Interneuron had undisclosed licensing and royalty revenue generated through corporate marketing agreements and product sales.

**Consequence of the Decision:**

The decision to cooperate with AHP did not have an impact on the company's culture. Overall, the interaction with AHP was very positive for Interneuron. Within 14 months of having the product on the market, the company generated \$240 million dollars in revenue. Everybody at the firm agrees that the decision to deal with AHP was a very positive one.

## DISCUSSION & CONCLUSIONS

The goal of this thesis was to draw useful insights from founders and senior managers of biotechnology firms about strategic decisions in commercialization. We wanted to examine the reasons that these managers have when deciding to either compete or cooperate with larger pharmaceutical companies. We also wanted to explore the consequence of these critical decisions on biotechnology firm's culture and function. The results of this thesis indicate that biotechnology firms founders are seeking partnerships with pharmaceutical companies due to their inability to raise capital independently. In addition, this study demonstrates that biotechnology firms endure a very slow negotiation process which pharmaceutical companies conduct before they reach an agreement with biotechnology firms. Successful biotech firms were able to cultivate support from champions who worked in pharmaceutical companies and supported the firms' objectives. Furthermore, these successful companies were able to concentrate on their core competencies and avoid distractions.

### **A. The Need for Cooperation:**

Collaboration is a critical strength of the biotech industry and a continuing challenge. Because of the extensive research efforts and testing necessary to bring new medical products to market, biotech companies have substantial continuing needs for capital that cannot yet be met through product revenue. And as technology development becomes more costly, complex and interdisciplinary, it is increasingly difficult for a single firm to assume the cost and risk of developing new technologies.

In the early 1990s, the industry secured large amounts of funding through public offerings. For example, in 1991 the industry acquired a record \$3.27 billion from public offerings. However, recently these sources became less productive. Thus, in the past few years the industry has undergone changes, both in managing the rate at which it consumes capital and in finding new ways to secure capital.

The first biotechnology companies to reach public capital markets often sought to follow in the footsteps of the larger pharmaceutical companies. They sought money from public markets to develop and market their own integrated product lines. This model held the promise of significant returns on successful products but also carried a large number of risks, which made this approach less popular. For example, all executives of the companies that were interviewed cite that the reason for them to seek partners to develop their product is the inability to raise capital in the financial market.

Public markets have become increasingly cautious about investing in biotech companies for several reasons. The costs and time commitment required to bring a new pharmaceutical product through the regulatory process to market were substantial and were increasing during the early 1990s. It was not unusual for a company to spend several million of dollars shepherding a product through phase III clinical trials. Equally important, the costs and efforts forced most companies to focus on one or two products and to thus place themselves at risk in the event of delays or unfavorable developments. Finally, the burn rate for these companies increased dramatically, with one study suggesting a tripling of annual costs from \$6 millions in 1992 to \$18.8 millions in 1994 (17). Biotechnology companies in this survey, reacted by finding new ways to manage their risks and maintain financial support. Increasingly, they began to spread the risks of

their operations through partnerships with other companies. These partnerships brought both funding and expertise to the table, leveraging the resources of the participating companies.

Thus, alliances and partnerships have become in vogue today between the pharmaceutical and biotechnology industry. The insufficiency of public funding and the need to run a successful biotechnology organization has led biotechnology executive to seek partnerships with large pharmaceutical companies. For example, partnership with AHP provided Interneuron a vehicle for faster, less costly, and more permanent skill borrowing and internalization than any other potential alternative that might have been available to the firm. On the other hand, the established pharmaceutical firms increasingly need access to new technology developed by smaller firms. These companies need innovative products to exploit and extract the most benefit for their shareholders. Only with these new technologies can the big pharma leverage the market access capabilities they built over the years.

Therefore, the new model developing in the biotechnology industry is to have more reliance on alliances and less on equity investment and venture capital in the early stages of a biotechnology firm's life. This new model is taking place even when there is strong patent protection in favor of the biotechnology companies. These biotech firms are unable to exclude big pharma from potentially large economic returns, despite their strong patent protection. Because, these firms are in desperate need for early seed money for research and development that only the big pharma are willing to provide today.

This new model which is driving biotechnology firms to form collaborative agreements with big pharmaceutical companies is in contrast to many of the

biotechnology firms founders desire to pursue strategies of independent forward integration. Staying independent would allow the biotech firms to reap more of the financial rewards associated with potentially successful commercialization.

The founders of biotech firms believe that the ability to raise money independently will allow them the chance to stay independent, keep their entrepreneurial drives, invest the money in vertical integration or establish new line of products. Also, it is believed that by staying independent, competition in this area would flourish which is a positive element to the industry (18) and that alliances are stifling competition.

This conflict raises the question: What model is better for the long-term value of the firm? Strategic alliances, particularly those that coordinate the research interests of corporate partners, helped companies maintain financial stability over the long term. Increasingly, venture capitalists are encouraging start-up firms to enter into agreements with larger companies. Consequently, biotech companies have improved their asset management, and were learning through creative partnerships with other companies, to produce new products more efficiently. Also, there are many uncertainties associated with staying independent including, If a biotechnology company bet everything on its lead product, there is only 50% chance that it will reach the market. Even when a product works, it might later develop clinical side effects or new negative regulation might be established. In addition, the capital market fluctuate, so even if founders can secure money today, it is uncertain what will happen in few years when they need urgent capital for new projects.

Thus, partnering with big pharmaceuticals can still provide the biotechnology industry with many benefits without the financial predicaments and risks associated with

staying independent. Partnering provides the biotech firms with capital and expertise in drug development, marketing and sales. In addition, collaboration with the big pharma still allows biotechnology firms to compete among themselves. These firms are now racing to develop new technologies that would give them better negotiating deals with the big pharmaceuticals.

However, planning for alliances can be a complex process. In striking a deal between a biotechnology and a pharmaceutical company there are always issues that are not clearly addressed. In interviewing the various companies in this project, there were two common themes that occurred about the financial structure being negotiated. First, the actual financial deal between two companies is not published clearly. Because, the biotechnology companies are fearful of revealing to their competitors and to other pharmaceutical companies the terms of the agreements. Second, the announcement of these financial agreements, also called BioBucks, serve a specific purpose for both the big pharmaceutical company and the smaller biotechnology firm. For the biotech, BioBucks say that the deal was a great one; so that it will attract interest and capital. For the pharma, BioBucks say that this is a pharma who really cares and ought to be every biotech's first choice alliance partner. However, the bad thing about BioBucks is that you can't spend them anywhere but in the deal press release, because the payments they describe are hardly ever paid. In addition, there is a healthy dose of investor skepticism that most alliance press releases are heavily padded in BioBucks and thus, the news releases don't carry the desired significance intended.

Thus, although collaboration has become an important alternative for biotech and pharma companies, both parties have to exercise prudence when approaching these deals.



For a pharmaceutical company, one key issue that must be addressed is the degree to which it should rely on alliances. Some companies warn that too much reliance on ventures and on partner's know how can endanger the company's long term ability to develop state of the art technologies. There is a risk that some companies will become so dependent on outside sources to acquire technology, products or market know-how that their competitive edge will be reduced to their negotiating skills.

For biotechnology companies the lack the experience of managing a successful cooperation is a large issue. For example, several of the small start-up firms in this survey lacked the experience needed for successful cooperation. Many companies do not treat collaboration as a personal commitment. They fail to build a social contact with collaborators from the opposite company, which is very essential in a successful collaboration. Also collaboration can fail if a large pharma partner changes its strategic outlook, or if there is a change in corporate leadership. Aphios for example, was faced with new executives at Eli Lilly who had different approach to pursuing their drug development, which led to the termination of the collaboration deal.

### **B. Venture Capital and Public Funding:**

Between 1995 to 1997, U.S. venture capital money invested in various industries was highest in software, followed by communication then biotechnology (Table 6) (19).

*Table 6. US Venture Capital Investment 1995/1997 in Billions of Dollars*

Industry	1995	1996	1997	% change
Software	0.75	1.6	2.6	+65%
Communication	1.06	1.6	2.4	+49%
HealthCare	0.54	1.1	1.1	+1.7%
Biotech	0.42	0.95	0.65	+45.8%
Electronics	0.48	0.73	0.87	+0.84%
Med. Devices	0.63	0.71	0.75	+5.4%
Other	2.8	3.7	3.51	-5%
Totals	6.7	10.1	12.2	+20%

In general, bases for venture capital and investors interest are: large market potential, short time to high value exit, occupying a spot in a hot spot and the needs for significant dollars. In considering the recent biotech industry trend, it is clear that biotechnology companies are not meeting several of the bases for investor's interest. Today, biotechnology companies have been struggling to attract investors from both venture capital companies (20), and from new initial public offerings (IPO) (21). Earlier in the evaluation of the industry, public markets offered high prices for companies, whose products were in early stages of development, allowing them to go public at high multiples. The spotlight on new Internet offerings has become so intense that it threatens to leave most other deals lost in Internet hype. This attention put on upstart Internet stocks has left little room for other sectors, such as biotech, to flourish. Statistics today show that there are two-tiered system place within the IPO market. Internet stocks in

1999 have seen average first day bounces of 142%, compared with 16% gains for non-internet stocks (21). Only in the last 12 months, 14 IPO were either postponed or withdrawn entirely. Furthermore, new Internet stocks seem to gain steam in the after market. The 17 online sector stocks that have debuted in 1999 have climbed an average of 226% since opening. Non-internet deals have risen an average of 18%. Infected inability to go public so far can be attributed in part to this phenomenon. Also, the desire for short time to high value exit is not available to investors trying to invest in early biotech start-ups where it takes several years before bringing a product to the market.

Thus, today, other companies are willing to support early science, while investors and the public markets are focusing on companies with advanced products. Circe Biomedical followed this pattern. In early stage development, the company was part of R.G. Grace, a large diversified conglomerate that provided it with the needed capital for early development. At that early stage of development, the company was unable to raise capital in the financial market due to the high risk and the long time commitment required. However, when the company reached later stage of development and the time required reaching the market shortened it spun-off from the parent company and was able to attract venture capitalist to support its product.

### **C. The Need For Speed and Flexibility in Pharmaceutical Partners:**

Large pharmaceutical companies seem to be very slow in making decision of engagements with small biotechnology companies. As pharmaceutical companies get successful, they also grow in size. Size usually becomes an inhibitor of agility and flexibility, which are essential criteria for success in today's new pharmaceutical science

and are prerequisites for remaining competitive. Thus, these pharmaceutical companies should be more agile about their strategic decision making with partners.

One consistent observation that was unanimous among all the biotech companies was the lack of speed in which big pharma conducted business with these smaller firms. All the biotech companies wanted to carry out negotiations with flexibility and speed. One of their goals was to negotiate a deal and reach an agreement on mutually beneficial terms in the least possible time while spending the least possible resources. According to all the biotech companies interviewed, collateral legal issues relating to the term of the agreement sometimes delayed the negotiation of agreements. They all agreed that the delay in negotiations on the part of the big pharma was costly in legal, administrative, managerial and technical resources. Faced with these delays and frustrations, biotechnology firm's management should attempt to get faster actions on the big pharmaceutical companies by carefully establishing high informal interactions with the decision makers of these organizations. By forming these interactions, biotech executives would be able to identify some of the stumbling blocks leading to the delays and could subsequently provide assistance to lessen the lag period before an agreement is reached.

Big pharma also have a lot to lose when there is delays in these collaborative deals. A delay in negotiation by a big pharmaceutical company would send a message to biotechnology firms that this particular company is a difficult partner. Subsequently, the large pharmaceutical company could lose out to more aggressive companies who will be able to sign deals with biotech firms.

#### **D. Core Competency:**

Core competence is a set of differentiated skills, complementary assets and routines that provide the basis for a firm's competitive capacities and sustainable advantage in a particular business (22). To build core competencies, senior executives should first establish an ambitious strategic goal for the organization and be very focus on reaching that goal. In this study, Infected founder for example, had several goals that he tried to achieve that were very broad and diverse. The founder's goal was to develop and market five of his early projects that were in different segments of biotechnology. This led the company not to have a clearly articulated strategic goal that it desperately needed. If the company had a clear goal, then the people in the organization, from R&D to top executives would have had a total focus to reaching their objectives. Looking at Aphios, a similar pattern emerges. Aphios portfolio includes R&D to produce vaccines against HIV, cancer, and techniques to extract natural substances and methods to deliver drugs to the body in more efficient ways. Again, no concise, clear vision to achieve its goal. Hybridon biotechnology concentrated on its core technologies, however, the company didn't focus on building a core competency that would have included a clear and focused vision. Thus, the company built extravagant branches in Paris and Cambridge rather than uses the extra capital that it possessed to advance R&D in their core businesses.

Once a solid strategy is developed, then a comprehensive plan should be drawn to achieve that goal. Interneuron for example, decided that they wanted to be in the obesity market. After analyzing their competitors and the technologies available, the senior executives at the firm decided that the best way to achieving their goal was to acquire the technology from a French company which was developing such a drug. In their strategic

plan, they wanted to have a partnership with a large pharmaceutical company that would be able to co-promote their drug. The executives at the firm were able to execute their vision and plan because of their clear goal that they initially established. Therefore, core competencies do not represent only technical capabilities, they also mean understanding the market and the competitive environment, and leveraging the company's strength and weaknesses. These dimensions have to be present for a company to become and sustain success. Also, the ability to focus on the firm's core competency and the aptness to remain focus on the firm's strength is essential ingredients for sustainable long-term success.

Chiron for example, eventually realized that its core competencies were not in the diagnostics area of biotechnology. Thus, it sold the diagnostics business to concentrate on its core capabilities, which is more in molecular biology. Avant Immunotherapeutics and Interneuron both have been able to focus on their competencies and concentrate on combining good science with sound business decision. On the other hand, companies like Aphios have been struggling to find a partner or hold on to one due to their inability to focus their effort on one area of research where they can build strong core competency that would attract partners or investors to their projects.

#### **E. The Need for champion:**

All firms interviewed emphasized the need for a champion or a sponsor in the bigger pharmaceutical company to ensure that the collaboration continues uninterrupted and gets the support needed at times of doubts. Champion is defined here as a company advocate who would be willing and able to promote the project in the smaller company.

Such a person will prevent a particular project from being snuffed out by other members of the bigger organization. The CEO of Avant for example, suggested that it is very advantageous to have more than one champion in the pharmaceutical company. She suggested that it is important to have both a scientific and business champions. An Interneuron executive suggested that it is important to be able to sustain the relationship with the champions by constantly providing updates, fueling discussions, keeping them informed and building a personal relationship with these individuals. Everybody suggested that the company could not get complacent about its relationship with their champions. Because, there are always great ideas and great products ready to be utilized in the market. Therefore, with limited amount of capital available in the industry, biotechnology firms should be aggressive in forming relationships with bigger pharmaceutical companies to insure that their ideas and projects are the one to be picked rather than their competitors. Thus, these small biotechnology firms have to keep a high profile with continuous networking. In all the cases in which the collaboration with the bigger pharmaceutical companies collapsed, one of the main reasons for the collapse was the lose of champions. In the case of Aphios for example, the scientific champion that the firm had at Eli Lilly left the company and Aphios was unable to convince the new person at Eli Lilly of the importance of the project. The consensus of the biotechnology executives was that it is very important to cultivate relationships with more than one person at the big firms and to keep high profile at these companies.

Taken together, the results presented in this study demonstrate that there are several items that would increase the chances for long-term successful commercialization of projects in the biotechnology industry. First, the importance of identifying and

collaborating with large pharmaceutical/biotech partners which can provide financial, technical and business support and expertise to the smaller biotech firms. Second, the need of small biotech firms to help design a method to accelerate the process in which big pharma negotiates agreements with the smaller biotech firms. Because the average 12-15 months required today finalizing a deal between the big pharma and the small biotech firms can have a very negative impact on firms' competitiveness. Third, the need to concentrate on core competencies is an essential element of success in the biotechnology industry. Because, with limited capital and expertise, it is very difficult for biotech firms to be able to perform many projects with the same level of excellence and focus. Finally, the need to cultivate close relationships with members of the business and scientific divisions at the larger pharmaceutical firms. All of the biotech firms agreed that the presence of business and scientific champions at the larger company was the most important element for successful partnerships.

More studies should follow our preliminary work on elements of successful commercialization in the biotechnology industry. It is essential that more studies be conducted, with larger sample size, that look solely and more in-depth, on the impact of each of the following items; core competencies, presence of champions, speed in negotiation and comparing partnership to other form of commercialization strategies. Such studies would shed more light on the significance of these various elements, and biotechnology firms would then understand their strength and weaknesses and develop better strategies for a successful marketplace commercialization.



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## **APPENDIX**

### **A. Copy of the Questionnaire:**

#### **A. Commercialization History**

In this section the questions asked were about the commercialization history of the project, including:

- The origin of the initial idea
- The key experiments or technical breakthroughs which initiated discussions of commercialization prospects
- The decision of how, when, and what exactly to commercialize
- History of working with partners or exchanging intellectual property associated with this technology/entity
- The subsequent history of the technology/entity in the marketplace (ideally including revenue numbers, market share, assessment of success, etc.)

#### **B. Commercialization Decision-making**

Here, I asked about the critical decision-making process that led the company to either remain independent (compete) or cooperate with other biotechnology firms in regards to the company as a whole or on a particular project/technology

- Who were the key personnel involved and what was their authority level?
- What was the main motive for the decision (profit, market share, competitive pressure, cost, culture clash, etc.)?

- What was the process by which the decision was made?
- Was the decision made in the context of established procedures, an ad-hoc group, at the board of director's level, etc.?
- Were there any points of contention between people at the firm about the viability and benefits of alternatives? What were these key debates and who was involved?
- How much influence did each have in the decision making process?
- What analytical tools or expertise was used in making this strategic choice?
- Was hard data used and who gathered it? Was an outside expert or consultant used to facilitate the strategy process?
- On what basis was the decision made? For example, was it hard criteria like costs, output, quality, return on investment, etc., or soft criteria like reputation, attitude, morale, image, etc.?
- What was the atmosphere in the discussion? Did people in the organization respect each other's opinion?
- How important were organizational politics and how?

**C. In terms of interactions with partners:**

- What were the terms of the main agreements?
- Were there any sticking points in the negotiations? How were they resolved?
- How long did negotiation go on for?
- How much external influence was exerted?

#### **D. Consequence of the decision:**

The question asked here was about looking back and evaluating the long-term impact of the decision on the firm?

- In terms of the R&D function
- In terms of other functional areas of the firm
- In terms of the firm culture
- Was this commercialization strategy a success? Why or why not?
- Do you think that different stakeholders would agree or disagree with your assessment? Who might disagree and why?

#### **B. The Detailed Results of the Remaining Six Companies:**

##### **1. CHIRON**

1998 Sales (mil.): \$736.7

1-Yr. Sales Growth: (36.6%)

1998 Net Inc. (mil.): \$524.1

1-Yr. Net Inc. Growth: 636.1%

1997 Employees: 6,482

1-Yr. Employee Growth: (12.8%)

Founded: 1981

##### **Commercialization History:**

Chiron is a leading biotechnology company that participates in three global healthcare markets: therapeutics, blood testing and vaccines. Chiron also conducts

research and development in the fields of recombinant technology, gene therapy, vaccines, small molecule discovery, and genomics.

Chiron Blood Testing's for hepatitis and HIV is sold through a joint business with Ortho Diagnostic Systems, Inc. Chiron Blood Testing also has a partnership with GenProbe Inc. to develop, manufacture and market nucleic acid probe assay systems for blood screening.

On November 30, 1998 Bayer acquired Chiron's *in vitro* diagnostics Business for \$1.1 billion in cash, plus licensing and royalty fees. The company will also collect royalties from Bayer on diagnostic applications related to hepatitis C and HIV. Included in the agreement were Chiron's immunodiagnostic, critical care diagnostic, nucleic acid diagnostic and clinical chemistry businesses. Consequently, Bayer's Business Group Diagnostics, has become one of the largest diagnostics businesses in the world. The company now serves customers in 100 countries with an offering that includes diagnostics systems in three key segments: Laboratory Testing, Point of Care Testing and Self-Testing. Bayer Diagnostics is a member of the worldwide Bayer Group, a \$32 billion chemical and pharmaceutical company.

Before being acquired by Bayer, Chiron diagnostics had several areas of strength in technologies including the measurements of blood gases, blood electrolytes and various immunoassay measurements. Bayer diagnostics was weak in all these technologies and it saw in Chiron a company that can complement its diagnostics portfolios.

Chiron Corporation intends to use the proceeds from the \$1.1 billion sale of its diagnostics business to purchase promising late stage drugs for cancer and cardiovascular drugs that Chiron can bring to market within 18 months.

Chiron has a long history of working with partners. By 1988, the company had signed 14 joint venture agreements with various pharmaceutical and biotechnology companies such as GenProbe, ortho diagnostics and J&J. In the early 1990's, the

#### **Commercialization Decision Making:**

In this industry, companies discuss among themselves about the potential deals in the market and future market activities. Initially, Chiron wanted to form a joint venture with Bayer. However, there was a major disagreement about who would control the board and who would have the final decision making in strategic issues. This led to the collapse of the joint venture negotiation. Subsequently, Chiron decided that it had to either buy another company or sell its diagnostic division to a larger company in order to be effective in the quickly consolidating diagnostic market. The decision was finally made to sell the diagnostic division and use the revenue from that sale to strengthen other areas of the company.

Chiron cited that the most frequent reasons for consolidation in the biotechnology industry are as follows: 1) "Market CapCreep", whereby institutional investors with more funds under management are now requiring much higher thresholds in market capitalization and/or liquidity; 2) poor returns on recent biotech IPOs; and 3) lower

analyst coverage and financing interest due to the consolidation among investment banks specializing in biotechnology.

The key personnel involved in the decision making that led to the divestment of the diagnostics division were the board of directors and the CEO. They reached the decision based on the competitive pressure facing them in the market and the consolidation of the industry. The decision to sell involved many players ranging from attorneys, consultants and outside financial advisors. The main point of contention between people at the firm about the viability of the deal was whether to buy a competitor or to sell to a competitor. The negotiation to reach the final agreements took about 15 months to conclude. During the negotiations, the main sticking points were about the amount of money to be paid to Chiron, the time of payment, facilities to be included in the deal and the number of personnel that had to join Bayer.

**Consequence of the Decision:**

The long-term impact of this choice on Chiron is difficult to assess due to the short period of time since the consummation of the deal. In terms of R&D function, the extra capital that Chiron got from this deal should strengthen its R&D capabilities. In terms of other functional areas of the firm, it will make the new company more nimble and able to concentrate on its core capabilities. In terms of the firm's culture, Chiron diagnostics was part of Ciba-Corning before Chiron acquired it in 1994. Thus, the old culture of Chiron diagnostics matches that of the new owner in terms of being large multinational European conglomerate. Consequently, the divestment of the diagnostics division should give



Chiron back its West Coast innovative and entrepreneurial culture that it had before acquiring the diagnostic division in 1994.

Commercially, It is difficult to evaluate the consequence of the sales at this time. But, it appears that both companies will benefit from the deal. Bayer Diagnostics became a larger and more integrated player in the market. Also, it appears that none of the major personnel in the diagnostic division left the company after it became part of Bayer. And the company did not lose any market share to competitors. Chiron also should benefit from the deal due to the large infusion of capital, which can be used now to strengthen its position in the therapeutic market. Overall, Chiron was able to make a substantial amount of profit from the sale of the division relative to the amount of money paid in 1994 to Ciba-Corning when it acquired the division.

Pressure on health care budgets started to have a negative impact on hospitals, the primary customers of diagnostics tool companies. Health care budget constraints led to wide activities of mergers and consolidation in the diagnostics industry to try to cope with shrinking hospital budgets

## **2. APHIOS**

### **Commercialization History:**

Aphios Corp. is involved in many projects including: 1) R&D aimed at selective disruption of microbial cells for the recovery of recombinant proteins and the inactivation of viruses in therapeutic efficacy, 2) The encapsulation of difficult to formulate anticancer and designer drugs for improved drug delivery, 3) Marine microorganism discovery and saline fermentation development program for novel therapeutics, fine

chemicals and industrial enzymes, 4) Taxol extraction from the precursor taxoid molecules from the needles or leaves of the American ornamental yew tree. The company also investigates HIV vaccines that elicit immune responses from the introduction of recombinant proteins as well as through other methods.

The origin of the initial idea was born due to humanitarian reasons (The tragic impact of HIV and cancer). The decision to pursue the commercialization of Taxol extraction, an anti cancer drug, was due to the fact that Taxol was in the most advanced stage of development among the many projects in research stage. Aphios partnered with Eli Lilly, which was the first experience in working with partners or exchanging intellectual property for the company.

#### **Commercialization Decision making:**

The partnering with Eli Lilly lasted for three years and was subsequently terminated. The critical decision-making process that led the company to remain independent following the termination of the contract with Eli Lilly was the lack of a sponsor from a bigger pharmaceutical or biotechnology company. From the start, Eli Lilly was willing to provide some research money but they did not attempt to pursue full partnering efforts. The key personnel involved in the decision making process was the CEO, who is also the founder of the company with a consultation from the CSO. The main motive for the decision to attempt to find a partner was the desire to reach to market before competition. Everybody agreed upon the decision in the organization. The basis for the decision was the impact of cost on the project, which could not be handled independently, and the delayed output of the product without partnering.

In terms of interactions with Eli Lilly, the most difficult part was finding a stable and reliable sponsor in the company. The sponsor at Eli Lilly was a senior scientific advisor, however, that individual left the company during the term of the agreement. Consequently, the arrangements between Eli Lilly and Aphios fell apart. The negotiation to provide Aphios with R&D money lasted one year due to the large size of Eli Lilly and its bureaucratic way of reaching a decision.

### **Consequence of the Decision:**

The long-term impact of dealing with Eli Lilly was very positive. It provided the company with needed capital and gave it a vote of confidence and legitimacy in the market. However, the inability to complete the partnership and the fact that the deal collapsed with the departure of the main sponsor had a negative impact on the company. Aphios has to look for a new sponsor, delay its commercialization and lose key people in the process.

### **3. BioTransplant Incorporated**

1998 Sales (mil.): \$8.0

1-Yr. Sales Growth: (34.4%)

1998 Net Inc. (mil.): (\$9.2)

1997 Employees: 63

1-Yr. Employee Growth: 10.5%

### **Commercialization History:**

BioTransplant's proprietary ImmunoCognance technology is designed to enable long-term acceptance of specific transplanted tissue by re-educating the patient's immune system. The ImmunoCognance approach is based on mixing elements of the donor's immune system with that of the recipient to establish recognition of the donor organ as "self." This technology has the potential to reduce or eliminate the need for lifelong anti-rejection or immunosuppressive drug therapy and to significantly improve a patient's long-term clinical outcome. Its Xenomune System would create genetically mixed bone marrow (from mini swine and humans) to enable a human to take an incompatible organ. BioTransplant has teamed with a number of partners to develop its systems, including Novartis, MedImmune and Stem Cell Sciences. Investment firm HealthCare Ventures owns about one-third of the company.

### **Commercialization Decision Making:**

The critical decision making process that led the company to cooperate with Novartis on the technology is the difficulties in raising money through venture capitalists or investors. Because, investors lost money dealing with biotechnology companies in 1998. Thus, for venture capitalists, there is a very large risk involved in investing in biotechnology. An alternative way to acquire capital is to cooperate with a large, established pharmaceutical company. Therefore, unlike Genzyme and Amgen which were established in the early 1980s when investors poured millions of dollars in financing to achieve a fully integrated companies, Biotransplant Inc. was established at a time in which it was not able to raise the money independently.

The decision to cooperate was made by the CEO with consultation from the board of directors. It took the company only two weeks to reach a decision, however, the final agreement was reached after several months due to the inertia and bureaucracy associated with a big pharmaceutical company like Novartis. The board of directors felt, as it always does, that the CEO could have done better in negotiating a deal with Novartis. The ability to continue R&D was a major reason for the decision to cooperate with Novartis and the deal was essential for the survival of the project.

BioTransplant Inc and Novartis Pharma AG (Basel, Switzerland) agreed to expand their present collaboration in xenotransplantation technology to include BioTransplant's proprietary mixed bone marrow chimerism approach for creating specific transplant tolerance. Novartis now has a worldwide license to the technology in exchange for payments, research funding and milestone payments totaling as much as \$36 million.

### **Consequence of the Decision:**

The long-term impact of the choice to cooperate is positive. Because, the alternative would have been delays and consequently failures to continue. The deal generated enthusiasm in the company about the potential successful commercialization. In addition, the deal kept the entrepreneurial culture of the company intact by not requiring the company to be acquired by a large established pharmaceutical company. This view is shared by everybody in the firm who were involved in the decision making process.

#### **4. AVANT Immunotherapeutics**

1998 Sales (mil.): \$2.2

1-Yr. Sales Growth: 83.3%

1998 Net Inc. (mil.): (\$51.8)

1997 Employees: 36

1-Yr. Employee Growth: (16.3%)

#### **Commercialization History:**

AVANT Immunotherapeutics, formerly T Cell Sciences, develops treatments for cardiovascular, pulmonary, and autoimmune disorders caused by misregulation of the body's natural defense systems. It also makes vaccine delivery technology. Its leading therapeutic compound, TP10 – developed to reduce injury and improve lung function after lung transplant surgery and to inhibit adult respiratory distress syndrome is undergoing clinical trials. The company is also developing T cell activation regulators to prevent organ transplant rejection. Also under development is a cholesterol-lowering vaccine against atherosclerosis. The company was formed from the merger of T Cell Sciences and Virus Research Institute in 1998.

#### **Commercialization Decision Making:**

The critical decision making process that led the company to cooperate with Novartis to develop TP 10 drug, which is in phase II clinical trial, was the inability of the company to independently bear the cost of developing the drug and conducting clinical trials. The company decided on cooperation rather than raising money in the financial market because of the huge amount of money required for the project which would have

been impossible to raise. The CEO made the decision to cooperate with consultation from the board of directors. The negotiations and the signing of the agreement lasted for about 15 months.

In the collaborative agreement announced in October 1997, AVANT granted Novartis a two-year option to license TP10 with exclusive worldwide marketing rights (except Japan) in the fields of allo- and xenotransplantation. In addition to the agreed option payments, Novartis is responsible for providing AVANT with supplies of TP10 for clinical trials. Upon exercise of its option to license TP10 for continued development, Novartis will pay AVANT an equity investment, licensing fees, milestone payments based on development goals valued in total at \$20 million. AVANT will also receive royalty payments on sales of commercialized products. More recently Immunotherapeutics received a further option payment from Novartis relating to the ongoing collaboration between the two companies. .

### **Consequence of the Decision:**

The decision to cooperate was essential for the survival of the project in terms of R&D. In terms of the functional area of the firm and its culture, the deal was very positive in giving everybody in the company the assurance and the validation of the work being done. Everybody in the firm agrees with the decision that was made strategically with Novartis because the excellent track record of the company in this particular area of pharmaceuticals.

## **5. Inhale Therapeutics**

1998 Sales (mil.): \$21.8

1-Yr. Sales Growth: 34.6%

1998 Net Inc. (mil.): (\$18.4)

1997 Employees: 147

1-Yr. Employee Growth: 59.8%

### **Commercialization History:**

Inhale Therapeutic Systems hopes to help patients breathe a little easier by offering them an alternative to medication injections. The firm is developing a deep-lung drug delivery system for existing macromolecule drugs, which are currently delivered by injection. Inhale is developing inhalants to treat diabetes, osteoporosis, Paget's disease, asthma, emphysema, infertility, hepatitis, multiple sclerosis, and other illnesses. Several of the drugs are in clinical trial. Regarding the diabetes drug, Inhale has collaborative agreements with Hoechst Marion Roussel, and Pfizer.

### **Commercialization Decision Making:**

The critical decision making process that led the company to cooperate with both Hoechst and Pfizer was the need for a company that excels in producing insulin and Hoechst fulfilled that role and the need for excellent marketing capabilities which Pfizer possesses.

The key personnel involved in the deal were the CEO, VP of research with consultation from the board of directors. The negotiation and the signing of the deal



lasted for 15 months. The company hired an outside consultant to evaluate the deal (the former president of Smith Kline).

Recently, Pfizer announced worldwide agreements with Hoechst Marion Roussel to co-develop and co-promote the inhalable insulin product based on Inhale's pulmonary delivery system. Inhale will use recombinant insulin supplied by Hoechst Marion Roussel for producing the dry powder insulin for Phase III trials. In 11/98 Hoechst Marion Roussel signed an agreement with Pfizer to construct a plant in Frankfurt, Germany, that would make bulk insulin and help Inhale Therapeutic Systems develop as well as promote an inhaled form of insulin. The plant is estimated to cost \$500-800 million. There are 4.1 million diabetics and that possible sales of the product in the US are \$3.3 billion annually. The CEO suggested that Hoechst and Pfizer could generate global sales of \$300 mil of the drug by 2001. He figures Inhale could earn \$3 per share or pretax \$45 mil. Inhale will continue to have responsibility for manufacturing powders and supplying devices and will receive a royalty on inhaled insulin products marketed jointly by Pfizer and Hoechst. Thus, this collaboration will build upon Inhale's therapeutics collaboration with Pfizer, and adds the insulin expertise and resources of Hoechst Marion Roussel. The two companies working together will provide an extraordinarily strong development and marketing team for bringing the benefits of pulmonary insulin to a broader population of diabetics.

**Consequence of The Decision:**

The long-term impact of this deal is very positive. It allowed the company to pursue R&D and go into clinical trials which it would not have been able to do without

its collaboration. In terms of the functional area of the firm and its culture, the deal has been a great learning experience with its partners. The company has been able to develop many skills due to this experience. The collaboration boosted the company's moral and added to it an invaluable amount of legitimacy.

## **6. Circe Biomedical**

G. R. Grace Figures:

1998 Sales (mil.): \$1,511.9

1-Yr. Sales Growth: 2.2%

1998 Net Inc. (mil.): (\$183.6)

1997 Employees: 6,300

1-Yr. Employee Growth: (63.8%)

### **Commercialization History:**

Just last month, February 1999, Circe Biomedical was spun-off from G. R. Grace & Co, a huge diversified conglomerate that was under pressure to simplify. Grace & CO. reduced its operation from more than 30 businesses to three. After reducing its operations to three, the company is focused on catalysts, construction materials, and coatings sealant. Circe Biomedical is in phase II clinical trials for a device that acts as a temporary bioartificial liver in acute liver failure patients. The company has gone through a venture capitalist group to raise money. Due to the spin-off from W.R. Grace, the company is in a healthy financial and organizational state. Negotiation was fast, beneficial and the company is in a sound financial position

### **Commercialization Decision Making:**

The decision that led the parent company to spin off Circe biomedical was the financial pressure facing the company. The market was sending the message to the company that it had to divest its vast portfolio of heterogeneous companies. The CEO and the board of directors made the decision regarding Circe biomedical with an outside help from consulting company. The decision was made to establish Circe as an independent entity to give it a sharp focus on the goal that it was pursuing without the distraction of the parent company.

In terms of long term impact and the consequence of the decision is unknown. Circe became an independent entity only at the beginning of 1999.