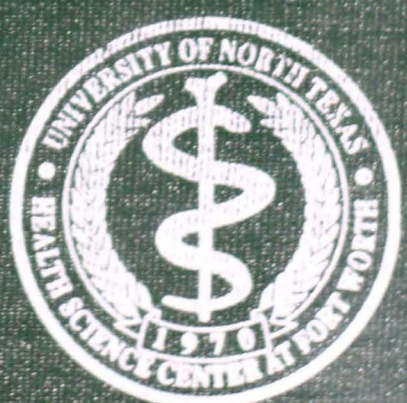
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The objective of the study was to define approaches to commercialize technology by biotech companies affiliated with academic institutions, determining the most effective ones. The hypothesis was approaches biotech companies use to commercialize technology influence their success and a specific combination of approaches would be most successful. A survey provided data from 85 biotech companies on technology origins, patenting, licensing, funding, and product focus. Multiple regression analyses suggested significant relationships between variables and success. Companies with marketed products acquired technology from non-academic sources ($p=0.0495$), particularly inhouse research/discovery ($p=0.0028$) rather than other sources. With one academic-sponsored technology, younger companies ($\leq$10 yrs) have a greater probability (74%) of success than older companies (57%). Younger companies with technology transfer offices and companies patenting before publishing are more likely to have marketed products than companies who don't. Chances of success increase with age and revenues. Results suggest approaches used by biotech companies influence their success.

DEFINING EFFECTIVE APPROACHES OF
BIOTECH COMPANIES TO
COMMERCIALIZE
TECHNOLOGY

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DEFINING EFFECTIVE APPROACHES OF BIOTECH COMPANIES TO COMMERCIALIZE TECHNOLOGY

Thesis

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CHAPTER I

INTRODUCTION

The Study and its Purpose

This study defines approaches used by biotech companies to commercialize technology into new products. The objective of the study was to define approaches that are used by biotech companies affiliated with academic institutions and to determine which are the most effective approaches.

Relationships were observed between approaches used and the number of technologies commercialized by each company. "Approaches" includes steps and methods used for the commercialization process. Technologies "commercialized" in this thesis refer to products marketed or with high potential to reach the market, such as: 1) pharmaceutical compounds or medical devices undergoing phase II clinical trials or higher; and 2) biomedical technology not subject to FDA approval that is at the stage just prior to manufacturing (all required documentation for manufacturing has been prepared). While definitions of success may vary depending on each companies' own strategy, for purposes of this thesis, having a product on the market was the measure used of a company's success. Approaches used by both companies with and without marketed products were reviewed.

Background

Preliminary research was conducted to identify approaches biotech companies are using to commercialize technology. This also can be termed the technology transfer process or the process of taking an invention from a laboratory to the marketplace. This preliminary research led to the development of the hypothesis and the types of questions included in the questionnaire used in the survey. This section summarizes this preliminary research and also subsequent research that was ongoing throughout the study. The sources of information are described later in this chapter.

From this background research, it was observed that many different approaches and combinations of approaches were used by biotech companies to commercialize technology. Narrowing the scope, I found that most of the approaches fell into the five general categories described below. I then included detailed questions in the questionnaire so that companies would have options from which to identify the approaches they used within these categories. In other words, I narrowed the universe of information down to five broad areas and then used a highly detailed questionnaire to determine how the companies surveyed would fall into those areas. This section will review background information related to these approaches and will also provide steps for starting a company, keys to success, and pitfalls based on the information. There is overlap between the categories, such as between funding and patenting.

The following table describes the five categories of approaches identified from the preliminary research.

Category	Approach
1	Origins of Technology
2	Protection of Technology
3	Granting Rights to Technology
4	Sources of Funding
5	New Product Focus

Table 1. Categories of approaches.

Category 1. Origins of Technology

Approaches for a company to obtain technology include in-house research and discovery, or acquiring it from other sources such as academic laboratories or other companies. A means for an academic institution to commercialize its technology is to license it out directly to a company who will then be responsible for developing the technology and taking it to the market as a product. The academic laboratory can receive licensing fees, royalties, up-front money or other incentives (Bookbinder, 1997; Lavrich, 1997).

Another approach is to start up a company with the specific purpose of commercializing the academic laboratory's technology. In this case, it is likely the laboratory will be involved to a greater extent with the company, possibly receiving an equity share in the company and having faculty on the board or management team. It may also occur that a faculty member involved in the invention of the technology may actually be the founder of the new company. The President/CEO of Lexicon Genetics, Arthur T.

Sands, M.D., Ph.D., was the founding scientist (Lexicon Genetics, Inc., 1997). Introgen's Chief Medical and Scientific Advisor, Jack A. Roth, M.D., was the primary inventor of the company's technologies (Introgen Therapeutics, Inc., 1997).

If the approach selected is to start up a new company, then the steps that follow are typically those that are used. These steps will be discussed next since they provide background on the subsequent approaches companies use.

Starting a company

The first step in starting a company is to have the technology appraised for its commercial value. An independent consultant can be hired to do this. Obtaining seed money is the next step. This can then be used to finance the expenses of patenting the technology. All intellectual property related to the invention should be covered in the application(s). Establishing a strong proprietary position as soon as possible when starting the company adds value to the company and helps attract investors (Fielding, 1996).

There appeared to be some controversy about when to patent, at the early stage or at a later stage when an agreement with a licensing partner has been secured. Trade secrets and copyrights are also options that can provide a limited level of protection (Leiseca, 1997; Paul, 1996). Caution is advised in publishing before patent applications have been filed in order to not risk loosing a proprietary position (Armitage, 1997). This will be further discussed later in this chapter.

A business plan must be written that includes the following elements: the executive summary, the opportunity, company strategy, development of a marketing plan,

the product, operations plan, major milestones, and financial statements. Also included are risks and contingency plans (competition, marketing, development, financial) and the company offering (funding requirement, company ownership, use of proceeds). The business plan must allow for flexibility and be updated as the company grows and matures (Fielding, 1996).

Raising Initial Capital

To secure initial funding, a private placement memorandum must be issued. A securities law firm can be hired to develop this. Although the amount to be obtained varies, about $75,000 can be expected for a big firm and about $18,000 for a small firm. If good communicators, the founders can go out on their own and raise funds. Types of investors include: private investors, investment bankers (may take 70-80% in equity in the company), venture capital, and merchant bankers. It is highly advisable to maintain more than 50% of the company to not loose control (Fielding, 1996).

Initial funding should be for purposes that are highly focused and clear to the investors (Fielding, 1996). Near-term profitability is expected although in the biotech industry today it appears that investors are becoming more patient in the cases where high long-term growth potential and ROI (return on investment) is foreseen.

Keys to success and Pitfalls

Many factors are involved for a start-up company to be successful. The most important of these are sound science, good management, and sufficient funding. These three were stressed frequently in this background research. In fact, good management is

as important as the science (Fielding, 1996). A significant element is the person running the company. The President/CEO must have a background in the industry, management, science and technology, and expertise in fund raising and business development. One of the pitfalls is that the founder may not have the appropriate background to manage the company but is reluctant to give up control of the company and does not allow good management to be brought in (Kierman, 1997).

A realistic approach is required to understand the actual market needs and where the company's technology fits into the market. This requires extensive market research and an understanding of the competition. The science may be good but it must produce a product that will have a place in the market. Focus groups can be used to observe customers' initial response to the proposed new product. A realistic estimate of time to market is also necessary in order to project costs of development. Investors want to know what the costs to market will be and when and how large a return on investment can be expected. Unrealistic estimates and projections can lead to disappointment by investors and reduced future funding. It's important to keep investors aware of milestones achieved and any delays expected (Fielding, 1996; To, 1997).

Steps for starting a company include the following (Fielding, 1996):

- Appraisal of technology
- Private placement memorandum
- Obtain seed money
- Patent intellectual property
- Can publish after patenting
- Write business plan

Category 2. Protection of Technology

"The company should assure that it adequately protects its intellectual assets and secures the right to benefit financially from them. This includes implementation of confidentiality and non-competition agreements and policies, thoughtful licensing and co-development agreements, patent identification and application, and enforcement of patent and other intellectual property rights. The company should seek to protect both the right to use the intellectual property exclusively and the right to market it without infringement on the intellectual property rights of others" (Kimball, 1997).

Patents have played a major role in the pharmaceutical industry for years. However, the industry has changed phenomenally over the past several decades. Patents now seem to take longer to issue. The effort required in patenting has become increasingly formidable, as have the costs. "The latency between the inception of a drug development program and the profitable sales of a pharmaceutical entity - if it is ever achieved - is an order of magnitude longer today compared to the 1950's. Existing, successful pharmaceutical products provide a much higher hurdle for prospective new entrants to surmount" (Kimball, 1997).

In the case of biotech companies, they are often consumers of cash, not producers. Patents today have a different function and purpose than previously. It is the patent that serves to generate cash. How the company chooses to develop its patent portfolio can make a significant difference in the company's ability to transform itself from a consumer

to a producer of cash (Armitage, 1997). Information that would normally be published is sometimes withheld to be included in patent applications. Patents have become the currency of technology and the foundation of new companies.

The first step to protect the company's IP (intellectual property) is to select legal counsel. Usually, small companies do not have in-house legal counsel and an IP attorney must be found. Often, biotech patents may take years to issue so inconsistencies can appear. It could be possible that more recent information would allow broader claims to be made or that limitations in the patent could make enforcement difficult. Review for exclusivity is recommended. In cases where a competitor has filed a patent for the same invention, an option is to license their technology, ending any potential conflict. When licensing out proprietary technology, a solid patent can provide leverage (Armitage, 1997).

A patent is an economic vehicle providing a monopoly to the holder by excluding others from making, using, or selling the invention for the life of the patent. Patents are granted by the government as an incentive to invest resources and effort to bring new products to the market (Paul, 1996). Expenditures related to filing patents can range from $10,000-$20,000 for a US filing to more than $100,000 for an international entry as well as annual maintenance fees for the life of patent. Patent filings should be focused only on key markets. It is not necessary to patent in every country worldwide, such as third-world countries (Paul, 1997) where the market for the product may be limited.

The process of due diligence attempts to weigh both the exclusivity value and adverse risks arising from patents. Using patents to obtain funding provokes two questions: 1) what does the company know (conflicts identified, status of their patents filed, what is the scope of their claims), and 2) what are the risks that could block marketing the technology or decrease the value of patents issued or pending. Since patent applications filed are published in most countries and now, in 1998, in the US, potentially infringed or infringing patents can be identified (Armitage, 1997).

"Since the time sensitive process of raising money in the public markets can be wholly frustrated by a surprise patent problem, the only tolerable course of action is one that is calculated not to produce any surprise" (Armitage, 1997). Demonstrate ownership, establish lack of conflicts, and verify the absence of adverse patents. Where issues or problems exist, develop opinions of counsel that can both guide the organization's business strategy and resolve the issues of disclosure needed to proceed with a public offering. "Just as you cannot sell shares in a gold mine without a full disclosure of anticipated gold production, selling shares in a biotechnology company necessarily depends on a parallel assessment of the biotechnology 'patent gold' " (Armitage, 1997).

Category 3. Granting Rights to Technology

While companies may acquire technology or start up due to technology acquired from academic laboratories or other sources, at some point in the development of the technology, the company may choose to license it out to another company to complete the commercialization process. This occurs for numerous reasons. The company may select a

partner with an established marketing presence or with the expertise and resources to complete the commercialization process including obtaining registration approval. The goal when the technology was licensed in may have been to develop it to the prototype stage and then license it out. Strategic alliances can be beneficial for product development, registration, and marketing. Again, according to this research, it is important to patent early to protect the company's proprietary position prior to entering into partnerships with other companies (Headon, 1996).

Partnering allows large pharmaceutical companies access to new technology in research and development by smaller biotech companies, while allowing the biotech companies access to funding needed to carry on or extend its research. A current trend in the industry is "to carry out R&D with a small R and a large D" (Headon, 1996). This allows the large companies to focus on the development aspects of commercialization and the smaller biotech companies to focus on research and discovery.

Normally, partnering agreement terms provide up-front fees, milestone/ benchmark royalties, and earned royalties paid to the licensor by the licensing company. The value of the technology increases the farther along the technology is in the development cycle. "At the early stage, royalties are lower (3-8%) and require negotiation, while at a later stage royalties can be 8-30% with little negotiation necessary" (Lavrich, 1997). A current trend is that the "total value of preclinical stage biotechnology has fallen while that of clinical stage has increased" (Headon, 1996). Agreements may also provide the company's partner exclusive rights to specific markets and therapeutic

applications, while the company may retain other rights to therapeutic applications or geographic regions.

Academic Laboratories and Third-Party Licensing

Terms related to sub-licensing or third-party licensing need to be clear to protect the interests of the academic laboratories while at the same time not unrealistically restricting the company. The university usually does not have a say in who the licensing company can sub-license to but all parties must abide by the terms of the agreement. The company needs to show they added value to the technology to justify a high sub-license price (Case, 1997). An example of this is a company that licensed in technology from a university laboratory for $10,000 and then sub-licensed it out to another company for $10 million (Key, 1996). Normally, the university does not receive royalties or other fees when the technology is sub-licensed to a third party.

The time between the original license and the sub-license is important. In the event that a company does not carry forward the commercialization of the technology, the university should get their rights to the technology back. This is the case at Texas A&M. All rights to the technology are returned back to them in the event their technology is not commercialized by the licensing company (Key, 1996).

Category 4. Sources of Funding

Approaches used to obtain funding include those discussed above as well as government grants, pharmaceutical companies, and even personal credit cards. Different

types of funding are used at different stages of the company's development or the development of the product.

Based on a venture capital brokerage firm's perspective, investors want a 40% return on their investment and about five times their investment in five years. An average business does not have that type of growth. Venture capitalists want 5-10 times their investment and look at 500-1000 companies before selecting one to invest in. Certain venture capitalists ask for 40% interest. Credit cards, in this case, are less expensive at 18% (Gerhart, 1997). Fast growing companies must have sufficient capital for growth.

Sources of investor funding include: 1) friends, family, credit cards; 2) venture capital firms can normally provide up to $5M; 3) banking firms - more than $5M. Private investors can provide up to $2-3 M. Investors will want to know if the company can generate returns and the experience of the entrepreneur leading the effort (Gerhart, 1997).

When a company has reached the stage of its development where it can choose to go public, then funding from an initial public offering (IPO) and subsequent offerings can present a source of funding. A registration statement must be filed with the Securities and Exchange Commission (SEC) in compliance with the Securities Act of 1933 (Kimball, 1997). Adequate disclosure is required to allow investors to make informed decisions related to investments. Advantages of going public include unrestricted use of the proceeds of the public offering; an increase in the company's net worth allowing better terms of borrowed capital; securities can be used to make acquisitions instead of using

cash; employee hiring and retention; prestige, and liquidity (market value of stock can easily be determined) (Kimball, 1997).

On the other hand, going public can have several disadvantages such as public disclosure of information the company may consider confidential, loss of flexibility, pressure to focus on short-term goals, significant IPO-related expenses, loss of company control as it is transferred to investors, and liabilities related primarily to public disclosures (Kimball, 1997).

Although not required, the first step in going public usually is to select an underwriter. Investment banks are usually the underwriters for IPOs and are knowledgeable of the market and have the ability to appropriately price the securities. Sales price and the number of shares to be offered are negotiated with the underwriter. The underwriter can make a firm commitment to purchase the shares from the company and sell them to the public, or it may agree to use its "best efforts" to sell the shares but not agree to purchase the shares that aren't sold. The most advantageous method for the company is the firm commitment. The underwriter's commission is the largest cost of going public and ranges from 6-10% of the gross proceeds of the offering (Kimball, 1997).

Offering Expenses (not including underwriter's compensation):

- Legal fees - $100,000 - $200,000
- Accounting fees - $100,000 and up

- Printing expenses - $75,000 - $150,000
- Filing fee - 1/33 of 1% of maximum aggregate offering price of the securities

Private Placements

Traditional placements with venture capitalists are offerings of securities that do not have to be registered with the SEC. Public capital may not be an option for companies at the early development stage and it must look for other sources such as seed capital investors or venture capital investors. Private placements must be in compliance with federal laws. Normally, they must also comply with state laws but federal laws take precedence over any inconsistent state laws (Kimball, 1997).

An underwriter of the IPO uses the following to advise companies to go public and to value the stock: management, sales and earnings, present and projected cask flow positions, relative competitive position, and growth potential. Normally, the technology should be not more than three years away from launch, the lead product should be in late phase development, and the company should present itself as a credible business model. The IPO can then be marketed through presentations to potential investors by the company's research and management team (To, 1997).

Investment Banks

Investment banks look for companies that would be viewed positively by public markets. They look at the technology (sound science), management, projected results and

milestones (at least phase III), peer review, well planned trials that build on each other, competition, and a good business plan (Kierman, 1997).

Government-Funded Programs

While there has been a general decline in government expenditures for R&D, there are funds available through government agencies to support biomedical research and development. The National Institutes of Health's mission is to "manage a portfolio of investments to improve health through science. Small business grants catalyze the transfer of technology from academia to companies by supporting innovative, embryonic research that feeds potential products into the R&D pipeline" (Kreitman, 1997). The Small Business Innovation Research Program (SBIR) and the Small Business Technology Transfer Research Program (STTR) grants make it possible for the government to partner with small companies and provide up to $850,000 for innovative projects that will benefit the public health. The intellectual property of the company belongs to it alone and not to the funding agency. The grants promote and foster partnerships with academic laboratories (Kreitman, 1997).

An STTR program can provide an academic laboratory long-term financial and scientific benefits, possibly generating licensing revenue and industrial partnerships. These programs also help large pharmaceutical companies who are looking at the smaller biotech companies as sources of new, innovative research. While the small company may

focus only on the initial embryonic research, the pharmaceutical company may acquire it for further development and commercialization. Therefore, the NIH can help bridge the gaps between the small company in need of funding for research and promoting partnerships with larger companies leading to a product on the market that will benefit the consumer (Kreitman, 1997).

Small Business Innovation Research Program (SBIR)

There are three phases of this program with the first two providing funding for up a potential total of $850,000. Only phase I winners are eligible for phase II award. Phase II requires a two-page report answering key questions: 1) what will the first product be? 2) Who will the customers be? 3) What is the size of market? 4) Who are the competitors and what is the advantage? The criteria used to evaluate eligibility for an SBIR grant include: 1) soundness and technical merit, 2) potential for commercial (government or private sector) applications, 3) adequacy of the proposed effort to fulfill the research topic, and 4) qualifications of the PI (principal investigator), not only the ability to do the work, but also the ability to commercialize the results.

The following table describes the amount of SBIR grants available for the three phases of development defined below (Jacobs, 1997; Brand, 1997):

Type of SBIR Grant		Length	Grant Amount
Phase I	Technical feasibility study	6 month-1 yr.	$100,000 limit
Phase II	Principal R&D effort	2-5 yrs	$750,000 limit
Phase III	Transition to commercial applications		Private funding - no SBIR funds

Table 2. Sources of funding, SBIR grants, funding phases, and amounts.

Small Business Technology Transfer Research (STTR) Program

The STTR program provides an opportunity for cooperative R&D between small business and a university, FFRDC (Federally-Funded R&D Center) or non-profit research institution. A small business can now exploit research with commercial promise from universities, federally-funded research and development centers, and non-profit research institutions. The objective is to bring researchers and commercializers together to facilitate tech transfer. It is expected that the small business will conduct at least 40% of the research and the institution will conduct at least 30%. Participating agencies include: DOD, NSF, NASA, DOE, HHS.

A three phase program for STTR grants similar to the SBIR above is described below (Jacobs, 1997; Brand, 1997):

Type of STTR Grant		Length	Grant Amount
Phase I	Technical feasibility study	1-yr. awards	$100K
Phase II	Principal R&D effort	2-yr. awards	$500K
Phase III	Transition to commercial applications		Private and/or non-STTR funding

Table 3. Sources of funding, STTR grants, funding phases, and amounts.

Other types of programs include: Technology Reinvestment Project (TRP), Advance Technology Program (ATP), Cooperative Research and Development (CRADAs), and Defense Advanced Research Projects Agency (DARPA) (Jacobs, 1997).

Federal Laboratory Consortium (FLC) for Technology Transfer

The FLC was formed in 1974 and it was further strengthened by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and

Advancement Act of 1995 (Brand, 1997). More than 700 labs and 16 federal agencies are participants of the FLC. The function of the FLC is to promote rapid movement of technology, coordinate tech transfer support needs, provide professional development to tech transfer personnel. The FLC is the nationwide network of federal laboratories that provides the forum to develop strategies and opportunities for linking technology with the laboratory's mission and the marketplace. The NIH participates in this consortium (Brand, 1997).

The keys to successful tech transfer as defined by the FLC Chair are (Brand, 1997):

- Establish a tech transfer investment strategy
- Identify technologies with commercial potential
- Promote resources to target audience
- Determine optimal tech transfer strategy
- Accomplish tech transfer
- Implement effective post-transfer administration process

Category 5. Company New Product Focus

There were many approaches for a company's new product focus but nearly all were related to innovation. Identify a problem or an unmet need and then develop a product as a solution to the problem. Identify a potential market and develop an innovative product. Target your market and determine the uniqueness of your product compared to competitor products. The product must be very different from available

products. It can be a replacement of older products. Consider the changing needs of the industry and applicability to other industries, such as a veterinary product with potential application for humans. The new product must offer a significant advantage over other products and at a lower cost. The following are examples of types of products attractive to investors:

- Breakthrough enabling technologies (Bookbinder, 1997; Ulrich, 1996).
- As many discrete uses of a technology as possible within reason (Lavrich, 1997).
- A single application with blockbuster potential (large market) (Ulrich, 1996).
- Core technology with potential for broad applications (Headon, 1996; Ulrich, 1996).
- "Unfair" advantage (Ulrich, 1996).

The goal of many biotech companies is to be first to the market. Advantages to being first include exclusive rights to intellectual property. If the technology is successful, the company will have an advantage in hiring and retaining employees, obtaining funding, and collaborations. However, certain disadvantages exist. The technology can be rejected by the market or replaced by an improved second-generation product, making it obsolete. As one technology reaches the market, a new improved product can already be approaching launch. Of all the entrepreneurial strategies, being first is the greatest

gamble. The challenge is to continue innovative efforts. The entrepreneur who succeeds in being first "has to make his product or his process obsolete before a competitor can do it" (Drucker, 1993). Work on the next generation product has to begin immediately and with the same level of effort and investment that led to the initial success.

An example of new product focus can be seen with the company, Diagnostic and Biologic Technologies (DBT), that addressed an unmet need in human and veterinary medical fields with diagnostic DNA testing using Polymerase Chain Reaction (PCR) technology. They in-licensed proprietary technology and perform testing in their labs (Burk, 1997). Another company, Austin Innovations, did this with their electroluminescent (EL) technology used by the military and taken to the consumer as a unique lighting source (Marischen, 1997).

Cell Genesys, Inc., focuses its R&D efforts on human disease therapies based on innovative gene modification technologies. Their business areas are based on "broadly enabling technology which could lead to multiple opportunities" (Cell Genesys, Inc., 1995). "There remains a significant unmet medical need for the treatment of many advanced cancers including cancer of the colon and rectum" (Sherwin, 1997). Their technology can potentially be applied to many different types of cancer.

Another example of a company focusing on developing products for an unmet need is Genzyme, Inc. The company's mission is "creating solutions for unmet medical needs worldwide". Their vision is "a complete global infrastructure supporting a diversity

of innovative programs" (Genzyme Corporation, Inc., 1997). Using this strategy, the company has developed a broad range of cutting-edge technologies and therapies.

Definition Of Terms

The following definitions were used in this thesis:

Academic Institutions: Medical schools, research-oriented hospitals, health science centers and other non-industrial institutions conducting research.

Approach includes the different steps, methods, and strategies involved in commercializing a new research discovery.

Biotechnology refers to new compounds, devices, procedures, methods, uses, instrumentation, equipment, or other technology with application for the pharmaceutical or medical industries that are proprietary discoveries or inventions. This includes new compounds or technologies with pharmaceutical or medical applications that resulted from identifying and characterizing novel intracellular targets through the use of biological tools. These products would normally be subject to FDA approval. Biomedical technology will also be included with biotechnology for purposes of this thesis. Biomedical is defined as the application of natural sciences (biology, biochemistry, biophysics, etc.) to the study of medicine (Dorland, 1988). High technology products such as computers, imaging, photographic, or other equipment with biomedical applications will be placed in this category. These products normally would not be subject to FDA approval.

Commercialization: The process or taking research technology from the laboratory to the

market. Commercialization applies to products marketed or potential products with a high potential to reach the market. A pharmaceutical compound or medical device that is undergoing at least phase II clinical trials or higher is considered to have a high potential to be commercialized. This then includes phases II, III, awaiting FDA approval, launched, and marketed products. For biomedical technology products not subject to FDA approval, marketed or the pre-manufacturing stage is considered effective. This is the stage when all required manufacturing documentation has been prepared.

Cutting Edge Product: A product that is the first of its class to be marketed or provides treatment for a previously untreatable disease.

Effectiveness. The approach used to commercialize a pharmaceutical compound, medical device, or a biomedical technology product as described above is considered effective.

Enabling Technology: A device, drug delivery system or other technology that provides the means for another technology to have a therapeutic benefit (i.e. transdermal patches, liposomal systems, medical implants).

Success: In this thesis, in order to have a quantifiable measure of success, a company having a product on the marketed was used.

Technology Transfer (T^2): The process by which technology, knowledge, and information developed in one organization, area, or for one purpose, is applied or used in another area, or for another purpose (Brand, 1997).

Sources of Data

Survey

A survey of biotech companies was conducted by mail using a questionnaire to obtain data to determine effective approaches used by a sampling of biotech companies to commercialize their research discoveries. The questionnaire was sent to a key, high-level individual, such as the CEO, President, or a Vice President, at each company, who was likely to know or have access to the data requested.

Case Study

A meeting with a biotech company was held to obtain data on approaches used by a single company. The President/CEO of the company was interviewed and provided the information required for a case study of this company.

Background Information Sources

Background information was obtained from a variety of sources for the study. The information facilitated development of the hypothesis that was tested, preparation of the questionnaire, and identification of biotech companies included in the survey. Sources include articles in journals and publications such as Science, Nature, Nature Medicine, Worth, Business Review, Research Technology Management, Pharmaceutical Executive, Genetic Engineering News, The Scientist, MedAd News, BioPharm, Chemical and Engineering News, Pharmaceutical Industry Guide (Biotech), the Thomas

Register, Biomedical Strategies, and other relevant news sources. More than 30 books were reviewed on business and entrepreneurism, as well biostatistics and study design. Conferences, meetings, and coursework related to the pharmaceutical and biotechnology industries, commercialization and technology transfer processes were attended. Information was gathered on a continuing basis throughout the study.

A University of North Texas Health Science Center course, "Introduction to Industry Practice", was attended during the Fall semester 1996. Instructors were from the pharmaceutical industry from both large and small companies and the course covered the various stages of commercialization of a drug, from discovery to the market. The annual conference of the Texas Technology Transfer Association was attended in 1996, in Houston, and again in 1997. Individuals from Texas biotech companies, academia, and government made presentations that covered starting and running a new company, protecting and licensing technology, funding for all stages, state and federal government's role and participation, interactions with large pharmaceutical companies, relationships between academia and industry, problems encountered, and successes.

Various aspects of commercialization such as views of venture capitalists, negotiating licensing agreements, pitfalls and failures were observed at the Texas Venture Capital Conference in Austin, Texas, May 1, 1997, and the BIO '97 International Biotechnology Meeting and Exhibition in Houston, Texas, June 8-12, 1997. Workshops in Fort Worth attended include the Small Business Innovation Research

(SBIR)/ Small Business Technology Transfer (STTR) Workshop, and the Legal Aspects of International Trade Seminar (Baker-MacKenzie).

I also participated in the Fort Worth Strategy 2000 biomedical development initiative group meetings and activities. This group is responsible for creating a biomedical district including an incubator in Fort Worth. Speakers were from industry, academia, venture capitalist groups, an incubator, and government. Government speakers were from the city's Economic Development Agency, US Department of Commerce, state and US elected officials.

The following table summarizes meetings and courses attended for purposes of gathering information related to approaches used for commercialization of technology by biotech companies.

DATE	**CONFERENCE/SEMINAR/COURSE**	**LOCATION**
Oct. 2-4, 1996	Texas Technology Transfer Association Annual Conference	Houston, Texas
Oct-Dec, 1996	Introduction to Industry Practice course - UNTHSC	Fort Worth, Texas
Jan '96 - present	Strategy 2000 (monthly meetings) - city initiative to develop a biomedical district and incubator	Fort Worth, Texas
March 24, 1997	Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) Workshop	Fort Worth, Texas
May 1,1997	Texas Venture Capital Conference	Austin, Texas
May 22, 1997	Legal Aspects Of International Trade Seminar (Baker-MacKenzie),	Fort Worth, Texas
June 8-12, 1997	BIO '97 International Conference on	Houston, Texas

	Biotechnology	
September 9-11, 1997	Texas Technology Transfer Association Annual Conference	Houston, Texas

Table 4. Conferences/seminars/courses attended.

Significance of the Study

Observation of the various approaches falling into each of the five categories used by biotech companies led to the hypothesis to be tested that approaches used by biotech companies for commercialization of technology significantly influence the success of these companies, and that a specific combination, described in Chapter 2, Methods, of these approaches would be the most indicative of success.

The results of this study were expected to show that, of the companies sampled, there was a significant relationship between approaches used by companies and their success as measured by having a product on the market. It was expected that a specific approach, outcome A, for all categories used by biotech companies for commercialization of technology significantly would have influenced the success of these companies. Therefore, it was hypothesized that companies with a marketed product:

1. Acquired their technologies from academic institutions, rather than from other sources such as pharmaceutical companies or through their own in-house research and discovery.

2. Patented their technologies before entering into licensing-out agreements with other companies rather than after entering into such agreements.
3. Granted rights, such as through licensing agreements, to other companies rather than retaining rights for research and development and/or marketing.
4. Obtained the largest overall percentage of their funding from sources other than private placements, such as public offerings.
5. Focused on innovative products rather than "me-too" products.

CHAPTER 2

METHODS

Procedures

Survey

From the preliminary research, 354 publicly and privately-held biotech companies were identified from published information to participate in the survey. All were reported to be companies focused on medical biotechnology or related activities. Large pharmaceutical houses were not included with a small exception of their affiliates if they were focused on biotechnology. Companies were selected without preference as to ownership (public or private), geographic location, age, or revenues.

Questionnaire

A questionnaire was designed as the instrument for obtaining data. Its design was based on the Dillman (1978) method. Four types of questions were used: 1) close-ended questions with ordered response choices, 2) close-ended questions with unordered response choices, 3) partially close-ended questions, and 4) open-ended questions. Questions relating to dollar ranges of R&D budget, expenditures, product sales, and sources of funding are examples of ordered, close-ended questions. Origins of

company, types of products, and product focus are examples of unordered, close-ended questions. Partially close-ended questions were also used in some cases where an "other" category of response is needed. Open-ended questions requiring a qualitative response were used infrequently when necessary to obtain certain data. This allowed the respondent to volunteer advice and opinions, such as the final question on the questionnaire, "Do you have any comments or suggestions for someone interested in commercializing their technology".

Questions and answers were placed in a vertical flow format on the page. This made it more difficult to skip questions or to answer in the wrong space. Dillman (1978) suggests that this format has the psychological effect of giving the respondent a sense of accomplishment as he moves down the page. Brief transition statements were used for each new line of inquiry ("Next, we would like to ask you how your technology reaches the market."). This was done to serve as a signal for a new topic and to break the monotony of a long series of questions on a single topic. Answer categories were numbered which was a form of precoding. Numbers were placed to the left of the questions throughout the questionnaire for consistency. In yes/no answers, no was always number "1" and yes was always number "2".

The questionnaire was designed to take 30 minutes to complete. It was 14 pages in length including the cover sheet and contained 38 questions with 182 responses possible, but with about 120 likely to be answered. This was modeled on Dillman's (1978) recommendations on the optimal length of a survey. Response rates

decline when longer than this. The design made the questionnaire appear interesting, without requiring too much time or effort to complete.

The questionnaire was divided into seven sections. Five of these, C-G, corresponded with the categories in the hypothesis. Two sections, A and B, were for background information on the companies. Each section was divided into subsections with 4 to 12 major questions. Each question had from 2 to 15 possible responses. Certain responses allowed the participant to skip questions, such as question D1a (page 6 in the questionnaire), where a "no" response allows 42 possible responses to be skipped. Other questions, if not appropriate, did not require a response.

To test the appropriateness of the types of data obtained and to obtain additional information useful for the questionnaire, nine individuals were contacted who were either involved in start-up companies or in the pharmaceutical industry. The questionnaire was then finalized and approved by the UNTHSC IRB prior to starting the survey.

Database

All possible responses to questions correspond to data points in a database that was set up prior to initiating the study. The data, when received, were entered and stored in the database. The following summarizes the number of questions and possible responses for each section in the questionnaire.

Section	Topic	Number of Questions	Number of All Possible Responses
A	Origins of the Company	4	14
B	Number of Technologies	3	30
C	Origins of Technologies	7	23
D	Rights to Proprietary Technology	12	51
E	Sources of Funding	6	38

F	Protection of Technology	4	16
G	New Product Focus	2	7
Total		38	182

Table 5. Organization of the questionnaire and number of possible responses

Correspondence and Mailings

A cover letter was attached to the questionnaire indicating the purpose of the survey was to obtain data on methods and steps involved in the commercialization of technology used by biotech companies. Proprietary information was not requested. The letter was written in normal business style using the University of North Texas Health Science Center letterhead stationery. A date for responding to the survey was indicated in the cover letter, which was about two weeks after the date of the letter. Additionally, a letter of endorsement was written by the Chair of the Department of Pharmacology, University of North Texas Health Science Center, Fort Worth. This letter served to introduce me, and to explain the objective and importance of the study. It pointed out that while the questionnaire seemed detailed, it was designed to take only 30 minutes for completion.

For companies not responding to the first mailing, a follow-up letter was sent as a reminder two weeks following the date the questionnaire was mailed. A second follow-up was made four weeks after the first mailing. It contained a reminder letter and a second copy of the questionnaire. This letter restated the appeals in the first letter indicating the importance of their response.

The questionnaire was confidential and provided anonymity for participants. This was to allow participants to respond as openly as possible. The participants were

informed in the cover letter that the questionnaire had an identification number but this was for mailing and follow-up purposes only. The number was not used to link the company name with the questionnaire. This facilitated follow up and saved costs. The first questionnaire mailed had a four-digit number starting with one and the number of the second questionnaire mailed started with two in order to prevent duplication when questionnaires were returned.

As an incentive, participants were offered the opportunity of receiving a copy of the results by contacting me separately. In addition, the participants were told of the social benefits of the study and that their response was important. According to Dillman (1978), giving the participant the feeling he is making a worthwhile contribution to a study that will benefit others is a reward that serves as an incentive to complete the questionnaire. The following table describes the three mailings of the questionnaire.

Mailings	Date	Contents
1	May 5, 1997	Letter of endorsement. Survey cover letter. Questionnaire (numbered with "1" prefix). Return envelope (postage paid if returned).
2	May 20	Reminder letter.
3	June 6	Survey cover letter (similar to first mailing). Questionnaire (numbered with "2" prefix). Return envelope (postage paid if returned).

Table 6. Survey - mailings, dates, contents.

Analytical Methods

Data obtained from the survey were entered into the database described in table five, using Microsoft Excel and converted to SAS-readable form for the analyses. Data were entered for all possible responses. Since each questionnaire contained 182 possible responses and 85 completed questionnaires were received, the total data points were then 15,470. This includes negative responses such as when a response was "no technologies". Codes x, y, z were used in data to indicate no data was provided (x), no response (y) (responded yes to a question but did not give numbers of technologies), and not applicable (z) . Data used for SAS analyses were summarized in the database using calculations defined in the study design described in table 8, and the aggregated data were tested for significance related to the hypothesis. The individual variables from each section were then tested. The structure of the database corresponds to the questionnaire format. The questionnaire and database were organized into sections A-G as described in table five.

Approaches used by all companies responding to the survey were observed. The success of companies was measured by having a product on the market. Companies with and without a marketed product were statistically analyzed to determine relationships between approaches used and having a product on the market.

Company Data

In section A of the survey questionnaire, the participants were asked to contribute information on how their company was started. An academic institution was defined in the questionnaire as any college, research institute, or university, either for profit or non-profit. There were four parts to this section: origin (A1, how the company was founded), company age (A2), ownership (A3, public or private), and overall revenues (A4, dollars in millions). All companies responded to each of these sections. A1 is described below.

A1. Origins of the Company

The company was asked if it was founded as a result of any of the following approaches and to explain any other approaches. More than one response was acceptable.

Question A1:

a. Research discovery that originated at an academic institution

b. Initiative with an academic institution

c. Partnership of an established company and an academic institution

d. Divestiture from a larger company

e. Merger of two or more companies

f. Joint venture with another company

g. Newly-created subsidiary or spin-off from another company

h. Industrial cluster or incubator of companies

i. Academic consortium

j. Initiative of patent holder(s)

k. Other (please explain)

Companies indicating origins in at least one of the academia-related categories above (response a, b, c, or i) or appropriate comments in "other" (k) were considered to have originated from academia. Companies who did not respond to one of these categories were considered to have non-academia related origins. Responses to the other questions on age, ownership, and revenues were calculated from the data provided in parts A2, A3, and A4 of this section.

Categories of Approaches and Possible Outcomes

Company outcomes, either A or B, for each of the five categories of approaches in the table below were determined based on the specified response criteria. The number of technologies for each outcome was calculated from the response data listed in "response criteria". For responses to categories of approaches 1, 2, and 3, the actual numbers of technologies were entered into the database. Responses for categories 3 and 4 were entered as yes (1) or no (0). Companies with marketed products were entered as yes (1) and those with no marketed products were entered as no (0).

Categories of Approaches	Approaches - Outcome A	Approaches - Outcome B
Category 1. Origins of technology	Technologies acquired from academic institutions	Technologies not acquired from academic institutions
Category 2. Protection of technology	Patent applications were filed prior to licensing agreements	Patent applications were filed after licensing agreements

Category 3. Granting rights to proprietary technology	Rights acquired by another company	Rights not acquired by another company
Category 4. Sources of funding	The company's largest overall (%) source of funding was from sources other than private placements (i.e. industry, government, IPO's, etc.)	The company's largest overall (%) source of funding was from private placements
Category 5. New product focus	Innovative products	Non-innovative products ("me-too")

Table 7. Categories and outcomes of approaches.

Company identification numbers and not names were used in the survey. In the thesis, a set of numbers separate from the company identification numbers was used when it was necessary to attribute facts, such as comments, to specific companies. This provided an extra measure of confidentiality for the participants in the study.

Calculations of the data to determine outcomes A and B for each category are explained in this section and described in table 8 showing the experimental design. Following analyses of the aggregated data as described, each individual variable in categories 1-5 was tested independently to determine relationships with companies having a product on the market.

Category 1. Origins of Technology

In this section, the companies were asked questions regarding the origins of their proprietary technologies including products marketed and under development. Participants were given five options related to where they acquired their technologies and asked to provide the number of technologies involved and phase (marketed, late phase

development, early stages) for each question. Two additional questions were on agreements with academic institutions and technology transfer offices. The topics of the questions are described below:

- Did any of the company's technologies originate from the following:
    1. The company's in-house research or discovery departments
    2. Collaborative research efforts with another company for joint development of a product(s)
    3. Acquired from an academic institution
    4. Licensed from a pharmaceutical company
    5. Other sources (explanation requested)
- Does the company have a standing agreement with an academic institution allowing options to all their new technology
- Does the company have an office dedicated to technology transfer and commercialization.

Outcome A (technologies acquired from academic institutions) was calculated using the number of technologies in question C3b-d of the questionnaire. Questions C5 (other) and C5b-d can be included if the response refers to academia. Question C6 regarding a standing agreement with academia is a yes/no response and does not contain numbers of technologies but rather the number of academic institutions. Outcome B (technologies not acquired from academic institutions) was calculated from the numbers

of technologies in questions C1 (in-house research/discovery), C2 (collaborative efforts with another company for joint development), and C4 (licensed from a pharmaceutical company). C5 could be included if it referred to non-academic sources.

Category 2. Protection of Technology

In this section, the companies were asked their views on protecting proprietary technology. Four questions were asked related to the topics described below. The participants were requested to provide the number of technologies involved and phase (marketed, late phase development, early stages) for each question. The topics are as follow:

1. Were patent applications filed by their company prior to entering into agreements to out-license their proprietary technology to other companies.
2. Were patent applications filed by their company after entering into agreements to out-license their proprietary technologies to other companies.
3. Were patent applications filed by the originator of technologies if licensed in from outside.
4. Were data Published on their company's technologies before patent applications were filed.

Outcome A was calculated using the number of technologies in question F1 (patent applications filed prior to agreements to license out their technology) in the questionnaire. Outcome B was based on responses in question F2 (patent applications filed after agreements to license out their technology).

Category 3. Granting Rights To Proprietary Technology

This section concerns rights to the companies' technologies acquired by another company for purposes such as research, development, and/or marketing. Companies were asked questions related to the topics below and requested to provide the number of technologies involved and stage (marketed, late phase development, early stages). The objective was to determine if granting out rights to other companies to technologies for commercialization is an indicator of success, and to gather additional data related to this topic. The topics are as follow:

- How rights were acquired by the other company:
    1. Licensed out.
    2. Joint venture with the other company.
    3. The other company is/was their parent company.
    4. Rights acquired by the other company through some other means.
- If technologies were out-licensed, was funding received in exchange for rights and by what means:
    1. Milestone payments.
    2. Royalties.
    3. Up-front payments.
- Does the company have agreements with other companies to share profits for their technologies.

- If technologies were out-licensed, were any rights to the technologies retained by the company and what kind:
    1. Co-marketing
    2. Geographic areas
    3. Therapeutic indications
    4. Other rights
- Does the company have technologies under in-house development.

Outcome A (rights acquired by another company) was calculated using the number of technologies in question D1b-d (rights acquired by another company) and D11b-d (shared profits). Responses to questions D2 - D5 describe the type of arrangements made with the company acquiring rights, such as licensing or a joint-venture. Questions D6-9 apply to types of funding in exchange for rights. Outcome B (rights not acquired by another company) was calculated from responses to D12b-d which show the number of technologies under in-house development.

Category 4. Sources of Funding

In this section, the companies were asked to provide information on their sources of funding and each of four questions provided nine options for sources of funding for taking the company from the start-up stage through manufacturing of their products. The participants were asked to indicate all appropriate sources for each stage and provide a breakdown by percentage. In addition, they were asked to identify their initial and second sources of funding and were provided five options. The topics are as follow:

1. Starting the company
2. Research costs
3. Development costs
4. Manufacturing costs

Options of Sources for topics 1-4 above:

1. Pharmaceutical industry
2. Government (grants, loan, etc.)
3. Private placements (venture capital, private investors, friends, associates, etc.)
4. Public offerings
5. Equity investments
6. Revenues from marketed products
7. Revenues from licensing agreements
8. Contract research
9. Other sources (explanation requested)

Additional topics include:

1. Company's initial source of funding
2. Company's second source of funding

Options of funding for 1-2 above

1. Pharmaceutical industry
2. Government (grants, loans, etc.)

3. Private placements (venture capital, private investors, friends, associates, etc.)
4. Public offerings
5. Other (explanation requested)

This section provided the participant with nine options for each of four stages of development: starting the company, research, development, and manufacturing costs. Answers to Outcome A or B are yes/no. Outcome A (company's largest source of funding from sources other than private placements) was calculated from the combined total of responses to E1, E2, E3, E4, excluding item 3 for each of these. Outcome B (company's largest source of funding was from private placements) was calculated from the combined total of responses to questions E1-3, E2-3, E3-3, E4-3.

Category 5. New Product Focus

In this section, the companies were asked to provide information on their company's focus for selecting new technology for product development and overall new product focus. They were also asked to contribute advice for someone interested in commercializing their technology. This section of the questionnaire contained two primary questions. The first one provided six options on new product selection focus. Participants were asked to indicate all that applied. The second concerned overall new product focus and participants were asked to select one of four options provided. The topics are:

- New Product Focus:
    1. Developing technology for the treatment of previously untreatable diseases.
    2. Developing a new therapeutic class of drug.
    3. Developing products similar to those currently marketed but with an advantage such as efficacy, safety, or cost.
    4. Developing "me-too" products.
    5. Developing enabling technology (drug delivery systems, etc.).
    6. Other (explanation requested).
- Overall Focus for new products:
    1. Developing a single core technology with potential multiple indications.
    2. Developing a technology that has a single therapeutic application but with blockbuster potential.
    3. Providing a service function (contract research, etc.).
    4. Other (explanation requested).

Data for the analysis of innovative and non-innovative product focus were compiled from the responses provided in the first set of questions described above. Responses 1, 2, 3, 5, and possibly 6 were considered innovative while four and possibly six were non-innovative. Outcomes to this category were either yes (innovative products) or no (non-innovative products). Outcome A was calculated from responses on the

questionnaire to questions G1a,b,c,e, and possibly f (other). Outcome B was calculated from question G1d and possibly G1f (other).

Summary Table for Categories 1-5

The following table illustrates the procedures described above used for each category to calculate aggregated data for the analyses.

Experimental Design

Specific Aims	Experimental Procedure			
Determine outcomes for approaches used:	Outcome A	Response Criteria	Outcome B	Response Criteria
Category 1. Origins of technology	Technologies acquired from academic institutions	C3a, C3b-d, possibly C5	Technologies not acquired from academic institutions	C1a, C1b-d, C2a, C2b-d, C4a, C4b-d possibly C5
Category 2. Protection of technology	Patent applications were filed prior to licensing agreements	F1a, F1b-d	Patent applications were filed after licensing agreements	F2a, F2b-d
Category 3. Granting rights to proprietary technology	Rights acquired by another company	D1 (yes), D1b-d, D11	Rights not acquired by another company	D1 (no), D12
Category 4. Sources of funding	The company's largest overall (%) source of funding was from sources other than private placements (industry, government, IPO's, etc.)	Combined totals of E1, E2, E3, and E4 (other than -3 for each)	The company's largest overall source (%) of funding was from private placements	Combined totals of E1-3, E2-3, E3-3, and E4-3
Category 5. New product focus	Innovative products	At least one: G1a, b, c, e, and possibly G1f	Non-innovative products ("me-too")	At least one: G1d and possibly G1f

Table 8. Experimental design for calculating outcomes using aggregated data.

Statistical Analysis of Data

Data from the questionnaire were statistically analyzed to test the hypothesis that

approaches used by biotech companies for commercialization of technology significantly influence the success of these companies and that a combination of the approaches, described in table 8, were used by these companies. In the analyses, the "X" variables were rights, origins, protection, funding, and focus. The "Y" variables indicated success: companies with marketed products (yes) or companies without marketed products (no). Multiple regression analyses were selected for use since they test relationships or associations between two or more variables, according to Zar (1984) and the University of North Texas Health Science Center at Fort Worth Biostatistics course handbook (Beitinger, 1994). Logistic regression was used since it tests relationships.

Logistic multiple regression was used to construct a mathematical model for the probability of having marketed products. The method of "maximum likelihood" was used to estimate parameters in the logistic model. The backward elimination procedure systematically removed independent variables one at a time to find the best possible model. Parameters were retained in the model if they were significant at alpha = 0.05.

The Fisher's Two-Tailed Exact Test and the Mantel-Haenszel Chi-Square tests were conducted to explain the relationships between each variable (X) independently with success (Y), products marketed. These provided reliable findings when data was missing from data sets.

All hypotheses tests were conducted with a 5% chance of a type I error (alpha=0.05).

The following table describes the procedures involved in the statistical analyses used in this thesis.

Experimental Design

Specific Aims	Analytical Procedure
A. Determine from data which approaches significantly influence the success of companies. B. Determine which combinations of approaches significantly influence the success of companies.	1. Conduct multiple regression analyses to test interactions of variables (X, Y). 2. Conduct analyses such as Fisher's 2-tail Exact Test to test variables independently. 3. Show significance (a=0.05%).

Table 9. Statistical analyses, experimental design.

Acquisition of Additional Data

In addition to obtaining data from the survey, a successful biotech company was identified for a case study. The objective was to determine if the company's approaches to commercialize technology accepted or rejected the hypothesis. An interview in person was conducted with the CEO/President to obtain information regarding the company's origins, current status, and approaches they used to commercialize technology.

In addition to the data related directly to the hypothesis, the interview sought to answer the following additional questions:

1. R&D Budget allocations.
2. Costs and time for development of products.
3. In partnerships, what are the divisions of responsibilities?
4. Location selection - did the company relocate, when and why?

5. Product selection - who is involved in the decision-making and what type of criteria is used?
6. Company organization - what are the backgrounds of the employees and how many are there? What is management's mix of business and scientific backgrounds?
7. What is the company's long-term product focus?

CHAPTER 3

RESULTS

The purpose of this chapter is to describe the findings when the hypothesis described in Chapter 1, Introduction, was tested. Data provided by the participating companies in the questionnaires are reviewed and findings presented in this chapter. Comments from the companies regarding approaches they used and their advice are also included. The first part of this chapter addresses the section of the questionnaire concerning origins, age, and revenues of the participating companies. This chapter also reviews findings from the case study of ILEX Oncology, survey demographics, and sample representation.

Origins of the Company (Section A Data)

Of the total sample of 85 companies, 54 companies originated from academic institutions representing 64% of the total. Thirty-one companies did not have academic origins, 36% of the total.

Company Origins	Number of Companies
Academic Institutions	54 (64%)
Non-Academic Institutions	31 (36%)
Total	85

Table 10. Company origins.

The data showed that a total of 104 approaches were used by the 85 responding companies when starting their companies. Sixty-five (63%) of these approaches were related to academic institutions. This includes five in the "other" category, which were determined to be academic in nature based on the companies' comments. Thirty-nine approaches were not related to academia. This includes 14 in the "other" category.

Company Origins	Number of Types of Origins
Academic Institutions	65 (63%)
Non-Academic Institutions	39 (37%)
Total	104

Table 11. Number of types of origins.

The following table illustrates companies originating from academia.

Code	*Origins*	*Number*
A1a	Academic research	45
A1b	Academic initiative	11
A1c	Academic partnership	4
A1i	Academic consortium	0
A1k	Other (as appropriate)	5
	Total	65

Table 12. Companies with academic origins.

Ten companies used combinations of origins. All ten of these companies indicated their origins were from academia. Eight of them listed non-academic origins in addition to academic. These were patent holders' initiative (four companies), divestiture (one company), joint venture (one company), merger (one company), and other (three

companies). Codes used in the tables correspond to question numbers in the questionnaire.

Origins (Academic companies)	Approaches Used
Academic approaches	65
Non-Academic approaches used by companies with academic origins	8
Total	73

Table 13. Academic companies and number of approaches used.

Companies with Academic Origins Using Combined Approaches

Of the 54 companies with academic origins, ten companies used a combination of methods when starting their companies. The remaining 44 companies used a single method falling into only one of the four academic categories. As can be seen from table 14 below, from two to four approaches were used by each of these companies. Nine of the ten companies indicated they originated from an academic discovery, while academic initiatives (6) and academic partnerships (3) followed. Four companies cited a patent holder initiative in addition to academic origins. Three companies each indicated they originated from a combination of an academic discovery and a divestiture, joint venture, or a merger. Three companies indicated "other" in addition to an academic discovery and explanations are provided below.

Table 14 shows combinations of approaches used by companies with academic origins. The numbers in the top row are company identification numbers. These are different from the identification numbers used in the survey.

	Company Survey Identification Numbers										
	10	*15*	*31*	*33*	*37*	*44*	*62*	*64*	*69*	*82*	*Total*
Origins											
Academic discovery	x		x	x	x	x	x	x	x	x	9
Academic initiative	x	x		x		x	x	x			6
Academic partnership				x	x		x				3
Academic consortium											0
Patent holder initiative	x	x		x		x		x			5
Divestiture			x								1
Joint venture						x					1
Other								x (1)	x (2)	x (3)	3
Merger									x		1
Number of methods used by each company	3	2	2	4	2	4	3	4	3	2	29

Table 14. Companies with academic origins, by ID number, and their combined approaches used.

(1) Founders left previous employers to start a company and arranged ties to university collaborators.

(2) Founded from an academic discovery in 1986 and then acquired two companies in 1995.

(3) Licensed technology.

Companies with Academic Origins Using a Single Approach

Forty-four companies indicated they were founded from a single academic institution-related origin shown in table 15 below. Thirty-six companies (67% of the total 54 companies originating from academia) indicated a research discovery that originated at an academic institution (A1a) as their origin. Five companies originated from an academic initiative, and one from an academic partnership. No companies originated from an academic consortium. "Other" methods related to academia were used by two companies.

Table 15 shows companies with academic origins using a single approach to start the company. The numbers in the top row represent the number of responding companies using each type of origin.

	Number of Companies				
	0	*1*	*2*	*5*	*36*
Origins					
Academic Discovery					x
Academic Initiative				x	
Academic Partnership		x			
Academic Consortium	x				
Other			x		
Total Companies	44				

Table 15. Companies with academic origins using a single approach.

"Other" methods used:

1. Combination of academic institutions, company investments, and venture investments. (Company ID 58.)
2. Eight academics formed for-profit company - principle research discovery. (Company ID 66.)

Companies with Non-Academic Origins

While 54 (64%) companies originating from academia indicated 73 approaches were used to start their companies, 31 (36%) companies originated from sources other than academia. All of the companies from non-academic origins reported only one approach was used to start the company. There were no combinations of approaches. Ten companies were started as a result of a newly-created subsidiary or spin-off from another

company (A1g). Seven companies were founded as the result of an initiative by patent holder(s) (A1j) . Fourteen companies were founded as a result of "other" (A1k) reasons which are described in table 16. All company comments reflect some form of an entrepreneurial initiative was taken to start their company.

Origins	Number
Total number of approaches used by companies with academic origins	73 (70%)
Total number of approaches used by companies with non-academic origins	31 (30%)
Total Approaches Used	104

Table 16. Number of approaches used by academic and non-academic companies to start their company.

The following table shows approaches used by companies that are not of academic origin.

Code	*Origin*	*Number*
A1d	Divestiture	0
A1e	Merger	0
A1f	Joint venture	0
A1g	Subsidiary	10
A1h	Incubator	0
A1j	Patent holder	7
A1k	Other	14
	Total	31

Table 17. Companies with Non-Academic Origins.

Table 18 describes methods used by companies with non-academic origins as indicated in "other" in this question.

	Company ID #	*Origin*
1.	6	New venture.
2.	16	Ex-Syntex employee began recognizing need for sustained delivery system.
3.	19	Selling, repackaging non-proprietary products.
4.	28	Carried out independent research, filed patent, and then formed company.
5.	41	Newly-created company that performed basic discovery research.
6.	45	Business concept.
7.	46	Private scientists taking discovery research to clinic by founding new company.
8.	49	Strategic initiative of a venture capital group (Warburg Pincus).
9.	50	Entrepreneurs and investors had an idea to in-license small market compounds.
10.	57	Venture company.
11.	74	Business/technical concept of founders based on their industrial experiences.
12.	75	Two individuals with an idea.
13.	76	New corporate entity - IPO.
14.	78	Initiative of individual scientists.

Table 18. "Other" methods used by companies with non-academic origins.

The following table 19 summarizes academic and non-academic origins of the companies in the sample responding to the survey. The 85-company sample used 104 approaches to start their companies. A total of 54 academic-based companies used

73 approaches. Ten of these companies combined approaches. The 31 non-academic-based companies used a single approach to start the company.

Code	*Origin*	*Academic*	*Non-Academic*	*Total*
A1a	Academic discovery	45	0	45
A1b	Academic initiative	11	0	11
A1c	Academic partnership	4	0	4
A1d	Divestiture	1	0	1
A1e	Merger	1	0	1
A1f	Joint venture	1	0	1
A1g	Subsidiary	0	10	10
A1h	Incubator	0	0	0
A1i	Academic consortium	0	0	0
A1j	Patent Holder	5	7	12
A1k	Other	5	14	19
	Total	73	31	104

Table 19. Summary of origins - academic and non-academic.

Statistical Analyses

A1. Origins of Companies - Academic and Non-academic

According to the data, there was not a significant relationship between companies originating from academic institutions and companies having products on the market

(Logistic regression, Fisher's Exact Test, two-tail, p=0.355). Of the 85 companies tested, 54 companies responded they had academic origins, and 31 companies did not have academic origins. Forty-two percent of the non-academic based companies had products on the market while 31% of the academic-based companies had products on the market. Fifty-eight percent of the non-academic-based companies did not have products on the market, while 69% of the academic-based companies did not have products on the market. These findings were not significant. They are described in the table below.

	Academic Origins	Non-academic Origins	Total
Companies without products	37 (69%)	18 (58%)	55
Companies with products	17 (31%)	13 (42%)	30
Total	54	31	85

Table 20. Academic origins and companies having marketed products. (Percents are by row.)

Furthermore, when academic origins of companies and company age were tested, there was not a significant relationship between companies with academic origins and company age (Logistic regression, Chi Square p=0.1096).

A2. Age of Companies

The average age of the 85 participating companies was 10 years. The minimum age was three years and the maximum was 35 years. Fifty-eight (68%) companies were ten years old or under, while 27 (32%) companies were from 11-35 years old. The table below shows frequencies of companies for years three through 35 in age. As can be seen

from the data, the number of companies participating in this survey decreases with age. The top row is age in years and the second row is the number of companies falling into that age category.

Age in Years

Age	3	4	5	6	7	8	9	10	11	12	13	14	15	16	27	29	35	Number of Companies
Number of Companies	2	10	8	7	6	9	6	10	6	4	2	2	6	4	1	1	1	85

Table 21. Company age in years.

Age and Having a Product on the Market

The data showed there was a significant relationship between company age and having a product on the market. Of the younger companies in this study, 24% (14 companies) had marketed products while 58% (15 companies) of the older companies had marketed products. Seventy-five percent (44 companies) of the younger companies did not have products while 42% (11 companies) of the older companies did not have products. (Chi Square p=0.003.)

Range of Company Age:

- Minimum Age = 3 yrs Average Age = 10 yrs Maximum Age = 35 yrs
- Number of companies 10 years old and younger 58 (68%)
- Number of companies over 10 yrs 27 (32%)

Table 22. Company age.

A3. Company Ownership

Of the 85 companies participating, 63 (74%) were public and 22 (26%) were privately owned, as shown in table 23 below.

Origin	Private		Public		Total	
Total	22	26%	63	74%	85	100%

Table 23. Company ownership.

Company Ownership and Products Marketed

According to the data, there was not a significant relationship between company ownership (public or private) and companies having a product on the market (Logistic regression, Chi Square p=0.087). Sixty percent (38 companies) of the publicly-held companies had no products marketed while 40% (25 companies) indicated they did have products marketed. Eighty-one percent (17 companies) of the privately-held companies did not have products marketed but 19% (4 companies) did have products marketed.

Ownership	No Products	Products	Total
Private	17 (81%)	4 (19%)	21 (25%)
Public	38 (60%)	25 (40%)	63 (75%)
Total	55 (65%)	29 (35%)	84 (100%)

Table 24. Frequencies of companies and ownership (public/private).
(One value is missing from SAS analysis)

A4. Revenues

Sixty-five (76%) companies had revenues under $10 million. Seventeen (20%) companies had revenues in the $10-100 million range. Three companies had revenues over $100 million.

Origins	<10M	$10-100M	>$100M
Total	65	17	3

Table 25. Companies and revenues.

Revenues and Having Products Marketed

The data showed there was a significant relationship between company revenues and companies having a product on the market (Chi Square p=0.001). There is a higher probability that a company with higher revenues would have a product on the market. For example, for companies with revenues greater than $10 million, there is a 65% likelihood of having a marketed product, while the likelihood of having a marketed product is 25% for companies with revenues less than $10 million.

Categories of Approaches One - Five

Results of the five categories of approaches and outcomes are summarized in table 25 that follows. The data do not completely reject the hypothesis that approaches used by biotech companies for commercialization of technology significantly influence the success of these companies and a specific combination, outcome A, of the approaches defined would be the most indicative of success. Findings show there was a significant relationship between companies having a product on the market and approach category 1B, companies who did not acquire their technologies from academic institutions. (Logistic multiple regression analysis p=0.0495, alpha = 0.05. When alpha = 0.1, there was no change in significance of the data observed.)

There was no significant combination of approaches that would indicate success, and therefore, no predictive model could be shown relating a combination of these five approaches to companies with marketed products. The logistic regression backward

elimination procedure eliminated all variables from the model. When age was added as a variable and tested for significance with companies with marketed products, there was no change in statistical significance of the variables tested previously. However, age was statistically significant with companies having marketed products and remained in the model (logistic regression backward elimination procedure p=0.006).

The table below shows data from the logistic multiple regression analysis when each variable was tested individually with companies having marketed products. As can be seen from these data, except for outcome B, category 1, none of the outcomes was significant. All categories of approaches were used by the companies sampled.

Categories	Outcome	P=
1. Origins of technology		
	A Companies who acquired technologies from academic institutions	0.3232
	B Companies who acquired technologies from sources other than academia	0.0495
2. Protection of Technology		
	A Patent applications filed prior to out-licensing	0.5770
	B Patent applications filed after out-licensing	0.2965
3. Rights to Technology		
	A Rights to technologies acquired by another company for commercialization	0.1977
	B Rights to technologies not acquired by another company (in-house development)	0.1629
4. Sources of Funding		
	A Largest overall (%) funding from sources other than private placements	0.8684
	B Largest overall (%) funding from private	0.8684

		placements	
5. New Product Focus			
	A	Focus on innovative products (100% response)	-
	B	Focus on non-innovative products	0.8144

Table 26. Results using logistic multiple regression analysis. Each variable was tested individually with companies having a marketed product.

Observations:

All companies sampled:

- Used the five approaches tested, outcome A and/or outcome B.
- Had products marketed and/or technologies under development.
- Responding companies are representative of the total sample. (See section on Sample Representation.)

Frequencies

The table below summarizes frequency data of the 85 companies who participated in the survey and approaches they used to commercialize technology. According to these frequency data, categories 2, 4, and 5 support the hypothesis while categories 1 and 3 do not.

Category		Outcome	Percent
1. Origins of technology	B.	Technologies were not acquired from academic institutions.	80%
2. Protection of technology	A.	Patent applications were filed prior to licensing-out agreements.	54%
3. Rights to proprietary technology	B.	Rights to the company's proprietary technology were not acquired by another company (in-house development).	41%
4. Sources of funding	A.	The largest percent of funding overall was from sources other than private placements (IPOs, etc.).	59%
5. New product focus	A.	Focus was on innovative products.	100%

Table 27. Categories 1-5, summary of total number of approaches used.

Category 1. Origins Of Technology (Section C Data)

For category 1, Origins of Technology, analyses of the aggregated data showed there was a significant relationship between companies having a product on the market and origins of technologies from non-academic sources (outcome B), but not from academic institutions (outcome A). When tested in the logistic regression backward elimination procedure with the other four categories in the hypothesis, both outcomes A and B were eliminated from the model. When tested individually with companies having a marketed product, outcome B was significant, but not outcome A. Chi Square values are listed below for both outcomes.

	Outcome	P =
A	Technologies from academic institutions	0.3232
B	Technologies not from academic institutions	0.0495

Table 28. Category 1. Origins of technology, outcomes.

When each of the five variables relating to origins of technology was tested for significance with companies having marketed products there were no significant relationships (Logistic regression backward elimination procedure). All variables were eliminated from the model. The tech transfer office showed a marginal trend (p=0.07). However, when tested with age as a factor, a significant relationship was observed for younger companies with technologies from academia and having a product on the market

(Chi Square p=0.0382, see below). In addition, there was also a marginal trend of companies with technology transfer offices and age of the company (p=0.0631).

Origins of Technologies from Academia and Age of Company

There was a significant relationship between the age of the companies tested, technologies acquired from academic institutions, and having products on the market (Logistic regression, p=0.0382). With one or two academic-sponsored technologies, younger companies (ten years old or younger) have a greater probability of success than older companies (over ten years old). For example, if a young company has one academic-sponsored technology, there is a 74% chance of having marketed products, but only a 57% chance for an older company to have marketed products. If a young company has two academic-sponsored technologies, there is a 96% chance of having a product on the market while there is an 84% chance for an older company to have products on the market.

Eighty-one companies were tested in this model. Twenty-eight of these companies responded that they had marketed products. Fourteen of these were ten years old or younger (younger companies), while 14 companies were over ten years old (older companies). Fifty-three companies did not have products on the market, 42 were younger companies and 11 were older.

Table 29 shows companies with technologies originating from academia and age (ten years old and younger and older than ten years).The top line of numbers are the

numbers of technologies originating from academia. The bottom line represents the number of companies.

	NUMBER OF ACADEMIC-SPONSORED TECHNOLOGIES						TOTAL
Technologies	0	1	2	3	4	5	46 (techs)
Companies ≤10 yrs old	6	2	2	0	2	2	14
Companies >10yrs old	9	3	2	0	0	0	14
Total # companies	15	5	4	0	2	2	28 (companies)

Table 29. Frequencies of academic-sponsored technologies and age.

Equations

Predictive equations for probabilities of having marketed products for young and old companies with technologies from academic origins are described below.

A = Number of academic technologies in pipeline

Young companies:

$$P[\text{Marketed Products} \mid \text{young company}] = 1 - \frac{1}{1 + e^{-(1.1766 - 2.2078\,A)}}$$

Older companies:

$$P[\text{Marketed Products} \mid \text{older company}] = 1 - \frac{1}{1 + e^{-(1.1766 - 0.0486 + (-2.2078 + .8119)A)}}$$

(Logistic Regression estimates of probabilities and coefficients.)

Frequencies of Origins of Technologies

Forty companies (47%) responded that they had no technologies originating from academia. Ten (12%) companies had no technologies from sources other than academia. Three companies did not provide data or responded "not applicable" to the technologies from academic institutions response. The remaining 32 companies (38%) had technologies from both academia and other sources. Of the forty companies indicating no technologies originated from academia, 19 of the companies actually originated from academia. Table 30 below describes the number of companies with and without technologies originating from academia. (T, U refer to variables used in the statistical analyses.)

Companies	*Number Companies (% total)*	*Number of companies with products*
With no technologies originating from academia (T=0)	40 (47%)	15
With academia as only source of technologies (U=0)	10 (12%)	3
With technologies from both academia and other sources (T and U)	32 (38%)	10

Table 30. Number of technologies originating from academia.

The following table shows the number of companies using these origins of technologies and their total numbers of products marketed and technologies under development. For example, of the companies responding that they had in-house research, 25 of these companies had marketed products, 31 technologies under late development

(no products), and 13 technologies in early development (no products). The purpose of this table is to show that companies used combinations of approaches to acquire their technology.

Origins	Number of companies with Products Marketed	Number of companies with Techs under development (no products)	Number of companies with Techs in early development (no products)	Total Number of Company Responses
In-house research/ discovery	25	31	13	69
Collaborative research/joint development	15	23	10	48
Licensed from pharma. company	6	5	2	13
Other	3	5	1	9
Academia	15	20	9	44
Total	64	84	35	183

Table 31. Number of companies and their products marketed, technologies under late and early development using these approaches to acquire technology.

As can be seen from the data, companies combined approaches they used for their acquisition of technologies. All companies indicated that at least one of these approaches was used. An average of 2.15 different origins were used for each company. Note that in the "other" category the company's comments determined whether their technologies could fall under academia.

Origins and Number of Products/Technologies and Success

Each origin of technology (in-house development, collaboration/joint development, acquired from academia, licensed from pharmaceutical companies, or other non-academic sources) was tested as a group which included each of their number of products or technologies under development. The objective was to observe relationships between these groups of variables and companies having marketed products. Using the logistic regression backward elimination procedure, results showed a significant relationship between the in-house research group and companies having marketed products only. No significant relationships were observed between the other groups of origins and marketed products.

When tested as a group described above, the data showed significant relationships between companies with in-house research/ discovery ($p=0.0065$) and technologies in late development (0.0137), and with companies with marketed products. Technologies in early development was not a significant variable and fell out of the model. When these variables were tested individually (logistic multiple regression) with companies having marketed products, the findings were the same with the exception that the variable, companies with in-house research/discovery, was not significant ($p= 0.8610$), but that in-house research/discovery marketed products ($p=0.0003$) and technologies in late

development (0.0028) were both significantly related to companies having a product on the market.

The following table describes the probability values for each type of origin and their products and technologies.

Origin	Origin p =	Marketed p =	Late Development p =	Early Development p=
In-house research	0.0065	0.0001	0.0137	0.9387
Collaboration/ joint development	0.3990	0.8412	0.9552	0.9688
Academic Institutions	0.6050	0.9566	0.1537	0.4060
Pharmaceutical companies	0.3961	0.9472	0.9935	0.9050
Other - non-academia	0.8965	0.9857	0.9818	0.9854

Table 32. P values of probabilities of products and technologies in each of the origins of technologies (Logistic regression backward elimination procedure).

The data showed that 33.33% of the companies with products marketed had one product marketed that originated from in-house research/discovery. Thirty-four percent had 2 to 40 products that originated from in-house research/discovery and 33.33% had no products marketed as a result of in-house research/discovery. The data also showed that 53.33% of the companies with products marketed had from one to eleven technologies in late development with in-house origins while 46.67% had no technologies in late development that originated from in-house research/discovery.

The data showed 101 products marketed, 89 technologies under late development, and 238 technologies in early development originated from in-house research/discovery. Seven products were marketed, 28 technologies under late development, and 82 technologies in early development originated from academic institutions. The following table describes the breakdown for each origin of technology and the number of products and technologies under development.

Origin	Products marketed	Technologies - late development	Technologies - early development	Total
In-house research	101	89	238	428
Collaboration/ joint development	23	21	108	152
Academic Institutions	7	28	82	117
Pharmaceutical companies	8	13	11	32
Other - non-academia	1	5	1	7
Total	140	156	440	736

Table 33. Products and technologies developed by type of origin of technology for companies sampled (85). Academic institutions includes "other" that were related to academic origins.

Company Comments

According to the data and the comments provided, companies may be acquiring their original technology from an academic institution and then developing products around it. While a company may have been founded to commercialize a technology

originating at an academic institution, once the company has been formed, the origin of the technology and any new technologies resulting from the parent technology can then be considered of the company's own origin. This could explain why companies originating from academia may have responded to the question asking how many technologies were "acquired" from an academic institution. Company 44 in the table that follows commented that this is a difficult question. Originally their technologies came from a university but developments have all been in house. Company 62 responded that they acquired patents from academic institutions and did not provide data on the number of technologies acquired. The following table summarizes company comments relating to the "other" origins of technologies response and general comments.

Company ID #	*Comments - Origins of technologies*	*Comments - General*
14	Public health service (NIH)	
18	Collaborative research agreement (CRADA) w/ NIH	
28	One product as a result of intercompany collaboration	
31	One product as a result of intercompany collaboration	
33	Licensed from patent holder at Harvard	
42	Licensed from academic institution	
44		Related to in-house research/discovery - This is complicated. Originally our technologies came from a university but developments have all been in-house. Licensing was

		from a from biotech company.
45	Academia	
58		Staff members handle tech transfer function.
60	In-house development. Our non-drug/non-invasive technologies were developed by our group of product development engineers and neuro-scientists.	
62		Acquired patents from academia.
64	Collaborative development with university co-inventors.	

Table 34. Company comments, other.

Agreements with Academic Institutions

Twenty-seven companies (32%) had standing agreements with from 1-7 academic institutions allowing options to all their new technology. Seventeen of these companies had agreements with one academic institution, six had agreements with two institutions, two companies with four institutions, one company with six institutions, and one company had agreements with seven academic institutions.

Number of Companies	Number of Agreements with Academic Institutions
15	1
6	2
2	4
1	6
1	7
2	no data

Total: 27 companies

Table 35. Companies with agreements with academic institutions.

When tested for statistical significance, there was not a significant relationship between having a standing agreement with an academic institution and companies with marketed products (Logistic regression, p = 0.2474).

Tech Transfer Office

Thirty companies had an office dedicated to technology transfer and commercialization such as a New Business Development or Licensing department. One company indicated that staff members handle this function. Fifty-four companies did not have dedicated offices to this function.

Companies	Frequency	Percent
With tech transfer offices	30	35.7
Without tech transfer offices	54	64.3

Table 36. Frequencies of tech transfer offices.

The data, when statistically analyzed, showed a trend in a relationship between companies with a marketed product and companies with tech transfer offices. The probability is greater than alpha at 0.05 (Chi Square p=0.0631). When tested with age as a factor, the results showed that companies 6.5 years old and younger have a greater probability of having a marketed product with a tech transfer office than companies the same age without a tech transfer office. This trend, however, reverses itself at 6.5 years of age. Companies older than 6.5 years have a greater probability of success without a tech transfer office than companies the same age with a tech transfer office. For example, a 2.5

year-old company with a tech transfer office has about a 12% probability of success while a company the same age without a tech transfer office has about a 5% probability of success. An eight-year old company without a tech transfer office has about a 28% probability of success while a company the same age with a tech transfer office has about a 19% probability of success.

Category 2 - Protection of Technology (Section F Data)

According to the data, patent applications were filed prior to out-licensing agreements for 526 technologies, 72% of the total 733 technologies from 46 companies, 54% of the 85 total participating companies (outcome A). Patent applications were filed after out-licensing agreements for 207 technologies (28%) by four companies (5%) (outcome B). Twenty-one companies (25%) provided no responses in this section. Responses were tied for 14 companies (16%). This section contains technologies in all phases including early-stage development.

Statistical Analysis

The data showed there was not a significant relationship between companies having a product on the market and filing patent applications prior to or following out-licensing agreements. When tested in the logistic regression backward elimination procedure with the outcome variables from the other four categories, both outcome A and outcome B were eliminated from the model. Outcomes and Chi Square values are described below.

	Outcome	P =
A	Patent applications were filed prior to out-licensing agreements.	p = 0.5770
B	Patent applications were filed after out-licensing agreements.	p = 0.2965

Table 37. Category 2. Protection of technology, outcomes.

When tested independently of the other categories the data also showed there were not relationships between either outcome and companies having a product on the market. (Outcome A, Mantel-Haenszel Chi-Square p = 0.158. Outcome B, Fisher's Exact Test two-tail, p = 0.172.)

According to the data, 70% of the companies with marketed products and 89% of the companies without marketed products filed patent applications before they licensed out their technologies (outcome A). Forty percent of the companies with marketed products and 57% of the companies without marketed products filed patent applications after agreements to out-license their technologies (outcome B). These differences are not statistically significant.

Patents Filed by Originator

According to the data, there was not a statistically significant relationship between companies having products on the market and patents filed by the originator if technologies were licensed in. (Mantel-Haenszel Chi Square p=0.886.)

Publishing Before Patenting

According to the data, there was a significant relationship between companies having products on the market and publishing before patent applications are filed. (Fisher's Exact Test 2-tail, p = 0.028.) For example, 96% of the companies with marketed products and 75% of the companies without marketed products did not publish before patent applications were filed. A total of 83% of the companies surveyed did not publish before patenting and 17% did publish prior to patenting.

The following are comments provided by companies in the questionnaire related to this section.

Company ID #	*Comments*
13	• Patents have been applied for prior to out-licensing to other companies for more than 200 technologies in early stage development (phase I, preclinical, or screening if FDA regulated, or trial phase if non-FDA regulated). • Patent applications have been filed following out-licensing to other companies for more than 50 early stage technologies.
21	• 100 patents prior to out-licensing agreements. • Numerous patents after entering into out-licensing agreements. • Numerous patents by originator.
31	Answered the yes/no questions regarding patents but would not provide data on the actual numbers of products or technologies saying this information is considered proprietary.

33	No license agreements at present.
44	We continue to apply for patents, but do not publish before the patent application has gone in.
81	Indicated that the 16 patents in the response related to filing patent applications prior to out-licensing, have been issued.
82	Patents for more than 50 technologies in early stage development were filed after out-licensing agreements.

Table 38. Company comments - protection of technology.

Category 3. Rights to Proprietary Technology (Section D Data)

Seventy-four percent of the companies sampled (63 companies) replied that rights to 215 technologies were acquired by other companies. Twenty-two companies indicated their technologies were not acquired by other companies. Sixty-six companies (78% of the total sample) had technologies under in-house development. Of these companies with in-house development activities, 55 companies had technologies that were acquired by other companies. This represents 83% of the companies with in-house development of technologies.

Statistical Analysis

The data showed there was not a significant relationship between companies whose rights to technology were acquired by other companies and companies having products on the market. (Fisher's Exact Test two-tailed p=0.122.) When tested in the logistic regression backward elimination procedure with the outcome variables from the

other four categories in the hypothesis, both outcomes A and B were eliminated from the model. See table 39 provided below.

	Outcome	P=
A	Rights acquired by another company	0.1977
B	Rights not acquired by another company (in-house development)	0.1629

Table 39. Category 3. Rights to proprietary protection, outcomes.

In-house Development of Technologies

According to the data, there was not a significant relationship between companies who developed technologies in house and companies having products on the market (Mantel-Haenszel Chi Square p = 0.957).

Sixty-nine companies were tested in this model. Sixty-six companies had in-house development activities while three companies did not. Of the companies with in-house development, 23 had marketed products while 43 did not. Of the companies without in-house development, one company had a marketed product while two did not. Of the companies tested with marketed products, 96% had products on the market and in-house development while 4% had products on the market and do not have in-house development.

Sixty-five percent of the companies with in-house development did not have marketed products while 35% did have marketed products.

In-house Development of Technologies and Rights Acquired by Other Companies

The data showed there was a significant relationship between companies who develop technologies in house and companies whose rights to technologies are acquired by other companies for development (Fisher's Exact Test 2-tail p=0.00695). There was a 42% correlation between having in-house development and other companies acquiring rights (Phi coefficient = 0.423). For example, companies without in-house development have a 100% likelihood of not granting out rights to their technologies. Companies who have in-house development have an 83% likelihood of granting out rights and only a 17% likelihood of not granting out rights to other companies.

Sixty-nine companies were tested in this model. Of the companies without in-house development, three companies (100%) responded that they had not granted rights to other companies while none of the companies who did not have in-house development granted out rights to their technologies. Of the companies with in-house development, 11 companies (16.7%) did not grant out rights while 55 (83.3%) did grant rights to their technologies to other companies for development. Of the companies who did grant out rights to other companies, 55 companies (100%) had in-house development while none of the companies without in-house development granted rights to other companies. Table 40 below shows companies with and without in-house development activities and rights to their technologies acquired by other companies.

	Rights not acquired by other companies	Rights acquired by other companies	Total
No in-house development	3	0	3
In-house development	11	55	66
Total	14	55	69

Table 40. In-house R&D and rights acquired by other companies.

Funding for Rights

Fifty-nine companies responded in the questionnaire that they received funding in exchange for rights to their technologies. Six companies responded that it was not applicable while 20 companies did not receive funding in exchange for rights. Questions regarded three types of funding: milestone payments, royalties, up-front payments.

Statistical analysis of the data showed there was not a significant relationship between companies with marketed products and companies with technologies that were acquired by another company for purposes such as research, development, and/or marketing in exchange for funding (Logistic regression, backward elimination procedure, Chi Square p=0.434).

Tables 41 and 42 below show frequencies of types of funding received and number of companies.

Type of Funding	Frequency (Number of Companies)		Per Cent	
	Yes	*No*	*Yes*	*No*
Milestone Payments (D7a)	56	29	66	34
Royalties (D8a)	56	29	66	34
Up-Front Payments (D9a)	53	31	63	37

Table 41. Granting rights and funding.

Type of Funding	Number of companies with Products Marketed	Number of companies with Techs under development (no products)	Number of companies with Techs in early development (no products)	Total products/ techs
Milestone Payments	11	31	10	52
Royalties	10	31	11	52
Up-Front Payments	9	32	9	50
Total	20	94	30	144

Table 42. Funding and products.

Milestone Payments

The data showed there was not a statistically significant relationship between companies having products on the market who received milestone payments for rights to their technologies acquired by other companies. In logistic regression, backward elimination procedure, the variable, milestone payments, was eliminated from the model ($p=0.2688$).

Royalties

The data showed there was a significant relationship between companies having products on the market who received royalties for rights to their technologies acquired by

other companies (Logistic regression, backward elimination procedure, Chi Square p=0.0042).

Of 70 companies tested, 64% received royalties while 25% did not receive royalties. Of the 26 companies with products marketed, 58% did not receive royalties while 42% did receive royalties. Of the 44 companies without marketed products, 77% received royalties while 23% did not receive royalties.

When tested with age as a factor, the data showed that at the same age the difference in likelihood in having marketed products was not significant between companies receiving or not receiving royalties from licensed-out products (Chi Square p=0.5378). However, the likelihood of having marketed products is greater at the same age for companies not receiving royalties from licensed products. For instance, at 10 years, there is a 68% chance of having marketed products if the company is not receiving royalties while there is a 32% chance of having marketed products for 10-year old companies receiving royalties for licensed-out products. However, the difference between 68% and 32% is not statistically significant.

Companies	Number of Companies	Royalties	No Royalties
With Marketed products	26	42%	58%
Without Marketed products	44	77%	23%
Total Tested	70	64%	25%

Table 43. Frequencies of companies and royalties.

Up-front Money

Logistic regression analysis, backward elimination procedure, eliminated up-front money from the model (p=0.2847). When tested alone, the data showed a significant relationship between companies with marketed products who received up-front money for rights to their technologies acquired by other companies. (Chi Square p=0.027). Of 70 companies tested, 63% received up-front money while 37% did not receive up-front money. Of the 26 companies with products marketed, 54% did not receive up-front money, while 46% did receive up-front money. Of the 44 companies without marketed products, 27% did not receive up-front money while 73% did receive up-front money.

Overall, companies not receiving up-front money were more likely to have products on the market. When tested with age as a factor, the data showed that at the same age the difference in likelihood in having marketed products was not significant between companies receiving or not receiving up-front money from licensed-out products (Chi Square p=0.9758). However, the likelihood of having marketed products is greater at the same age for companies not receiving up-front money from licensed products. For instance, at 10 years, there is a 60% chance of having marketed products if the company is not receiving up-front money while there is a 32% chance of having marketed products for 10-year old companies receiving up-front money for licensed-out products. However, the difference between 60% and 32% is not statistically significant.

Companies	Number of Companies	Up-Front Money	No Up-Front Money
With Marketed products	26	46%	54%
Without Marketed products	44	73%	27%
Total Tested	70	63%	37%

Table 44. Frequencies of companies and up-front money.

How Rights Were Acquired

Licensing

The data show a significant relationship between companies with marketed products and out-licensing technologies to other companies. (Fisher's Exact Test 2-tail, p=0.029.) There were not statistically significant results when age was tested as a factor (Logistic regression Chi Square p= 0.5748.)

According to the data, 50% of the companies with marketed products licensed them out while the other 50% did not. Of the companies without marketed products, 76% licensed out their technologies while 24% did not. Though the relationship to age is not significant, the data showed that the probability of having marketed products increases with age for both companies who licensed out their technologies and those that didn't. There is a greater probability of having a marketed product for companies who do not license out their technologies. However, as companies age the difference in probability of having a marketed product decreases. For example, a company that is about 13 years old

who has not licensed out their technologies has about a 78% probability of having a marketed product while a company that did license out has about an 45% probability of having a product on the market at the same age. At 20 years, a company without having licensed out technologies has a 98% probability of having a marketed product while a company who did license out has about a 88% probability of having a marketed product.

Additional Data Tested

The variables in the following tables are related to granting rights to technology to other companies and were tested for significance with companies having products on the market. No significance was observed from the data. Therefore, these variables are not indicative of having products on the market. Variables and probabilities are provided below. (Logistic regression backward elimination procedure. Alpha = 0.05.) Chi-Square frequency cross tabulations were also run on these variables without significant results.

Rights	P =
Joint venture	0.953
Parent company	0.9859
Other means	0.6150

Table 45. Rights and p values.

Rights	P =
Partial rights retained (yes/no)	0.3495
Co-marketing	0.5246

Therapeutic indications	0.6481
Other rights retained	0.5193
Profits shared with licensee	0.2763

Table 46. Rights to technology.

The following table summarizes comments made by survey participants related to this section.

Company ID#	Rights Acquired - Other Means (D5a)	Other Rights - D10h	Comments - General
9	Licensed to various"big pharmas"		
2		manufacturing	
12	Joint development agreement		
20			This is an out-licensing program for a technology we acquired. We have many licenses (non-exclusive and a few licenses with exclusivity). We charge cash for the licenses.
21		Manufacturing rights & rights in certain territories	
26		Manufacturing	
27			d2b international markets. d3b US market
30	marketing agreement		
40		Manufacturing	
42		Manufacturing	
44	marketing agreement	manufacturing, distribution, R&D	
46	negotiated	co-promotion	
47		technology outside field	
49	joint-development collaboration		
55		to utilize technology for internal programs and to establish new collaborations	
58	manufacturing and sales agreements		
63		manufacturing	
64	manufacturing and sales agreements	All rights except specified field of use.	

70		Manufacturing and future developments	
75			Funding. We had an early agreement like this with another company for $$ for rights and R&D $$ but this agreement ended.
81	License & research agreement	Use of technology	
82			Preclinical or screening, not related to specific products. Undetermined at this time.D2d D7d D8d >20
85	Research & licensing agreement (collaborative)	co-promote	

Table 47. Company comments, rights acquired by other companies.

Category 4. Sources Of Funding (Section E Data)

According to the data, there was not a significant relationship between companies having products on the market and sources of funding. When tested in the logistic regression backward elimination procedure with variables from the other four categories of the hypothesis, both outcome A and outcome B were eliminated from the model. Chi Square probabilities are provided below for both outcomes A and B.

	Outcome	P =
A	The company's largest overall (%) source of funding was from sources other than private placements (industry, government, IPOs, etc.).	p = 0.8684
B	The company's largest overall (%) source of funding was from private placements.	p = 0.8684

Table 48. Category 4. Sources of funding, outcomes.

The initial source of funding was private placements for 70% of the companies with marketed products and 82% of the companies without marketed products. Fifty-nine

percent of the companies with marketed products and 40% of the companies without marketed products identified public offerings as their second source of funding. The largest and second largest sources of funding for both groups were private placements. Table 49 below describes the major sources used by companies with and without marketed products.

According to the data, 50 companies (59%) obtained their largest percentage of overall funding from sources other than private placements (pharmaceutical industry, government, public offerings, equity investments, revenues from marketed products, revenues from licensing agreements, contract research, and other sources) (outcome A). Twenty-nine companies (34%) obtained their largest percentage of overall funding from private placements. Six companies (7%) provided no responses.

Sources of Funding	Companies with marketed products	Companies without marketed products
Largest source of funding:		
Private placements	37%	38%
Public offerings	19%	31%
Equity investments	19%	8%
Second largest source of funding:		
Private placements	28%	33%
Public offerings	16%	15%
Pharmaceutical industry	12%	17%
Initial source of funding:		
Private placements	70%	82%
Other	13%	11%

Second source of funding:	59%	40%
Public offerings	28%	25%
Private placements	3%	22%
Pharmaceutical industry		

Table 49. Sources of funding.

Additional Data

The variables in the table below were tested for significance with companies having products on the market. The data showed there were no statistically significant relationships between the variables and companies having marketed products. Data provided for the largest and second largest sources were compiled separately from data provided by the companies for each of the four sections. Data for the initial and second sources of funding are from the companies' responses to these specific questions. (Logistic regression, Mantel-Haenszel Chi-Square (rank scores)). Probabilities are provided below. (Numbers in parentheses refer to the SAS analysis data.)

Variables tested	P =
Largest overall source of funding (R)	0.220
Second largest source of funding (S)	0.288
Initial source of funding (T)	0.776
Second source of funding (U)	0.114

Table 50. Sources of funding, largest and initial.

Largest Source of Funding

While all of the sources of funding in the questionnaire were used by the participants in the survey, the largest sources of funding fell into seven out of the nine

options provided in the questionnaire. The other two sources, government and contract research, made smaller contributions to the companies' funding. These differences were not significant.

As can be seen from the data, the most frequently used source by both companies with and without marketed products was private placements. Public offerings were more frequent sources for companies without products on the market than companies with products (31% vs. 19%). More equity investments were obtained by companies with marketed products than without (19% vs. 8%). Both groups obtained funding from the pharmaceutical industry, with greater frequency by companies without products marketed. Companies with marketed products had revenues from other products. Companies without products indicated licensing revenues while companies with products did not.

The table below shows frequencies of sources of funding used by companies with products on the market and companies without products on the market. Percents are for each column.

Largest Source of Funding	Companies with Marketed Products	Companies without Marketed Products	Total
Pharmaceutical industry	2 (7%)	7 (13%)	9
Private placements	10 (37%)	20 (38%)	30
Public offerings	5 (19%)	16 (31%)	21
Equity investments	5 (19%)	4 (8%)	9
Revenues from other products	4 (15%)	0	4

Revenues from licensing agreements	0	3 (6%)	3
Other	1 (4%)	2 (4%)	3
Total	52	27	79

Table 51. Largest sources of funding. Values missing = 6.

Second Largest Source of Funding

For the second source of funding, all nine options were used. Data were compiled separately from the above section on largest sources of funding and statistically tested. The largest second source most frequently used by both groups of companies was private placements as in the case of the largest source discussed above. Other most frequently used sources were the pharmaceutical industry and public offerings. See the table that follows showing second largest sources of funding used by companies with and without marketed products. Percents are for each column.

Second Largest Source of Funding	Companies with Marketed Products	Companies without Marketed Products	Total
Pharmaceutical industry	3 (12%)	8 (17%)	11
Government	1 (4%)	6 (13%)	7
Private placements	7 (28%)	15 (33%)	22
Public offerings	4 (16%)	7 (15%)	11
Equity investments	2 (3%)	2 (4%)	4
Revenues from other products	3 (12%)	1 (2%)	4
Revenues from licensing agreements	2 (8%)	2 (4%)	4
Contract research	1 (4%)	4 (1%)	5

Other	1 (4%)	1 (4%)	2
Total	25	46	71

Table 52. Second largest sources of funding. Values missing = 14

Initial Source of Funding

Companies were asked to select from five options showing their initial source of funding. Frequencies are shown in the table below. While the numbers were not significant, the greatest number of companies both with and without marketed products indicated private placements as their initial source of funding (70% and 82%), a total of 66 out of the total 85 companies. See the table below showing initial sources of funding used by companies with and without marketed products. Percents are for each column.

Initial Source of Funding	Companies with Marketed Products	Companies without Marketed Products	Total
Pharmaceutical industry	1 (3%)	3 (5%)	4
Government	3 (10%)	0	3
Private placements	21 (70%)	45 (82%)	66
Public offerings	1 (3%)	1 (2%)	2
Other	4 (13%)	6 (11%)	10
Total	30	55	85

Table 53. Initial source of funding.

Second Source of Funding

As in the preceding section, companies were asked to select from five options to show their second source of funding. The greatest frequency for both companies with and without marketed products was seen for public offerings as the second source of funding

(58% and 40%). The next most frequently used second source of funding was private placements (28% and 25%). Again, these data were not significant. See the table below showing second sources of funding used by companies with and without marketed products. Percents are for each column.

Second Source of Funding	Companies with Marketed Products	Companies without Marketed Products	Total
Pharmaceutical industry	1 (3%)	12 (22%)	13
Government	1 (3%)	2 (4%)	3
Private placements	8 (28%)	14 (25%)	22
Public offerings	17 (59%)	22 (40%)	39
Other	2 (7%)	5 (9%)	7
Total	29	55	85

Table 54. Second source of funding. Values missing = 1.

The following are comments provided by companies relating to their initial and second sources of funding, and general comments.

ID #	Comments - Initial Source	Comments - Second Source	Comments - General
4	-	(5) Other - R&D agreements (large medical device industry)	
7	-	(3) Private placements - Equity	
8	-	-	Pharmaceutical industry for this company is the diagnostics industry.
9	(3) Private placements - Equity	(3) Private placements - Equity	
14	-	Both pharmaceutical	

		industry and public offerings	
15	-	(5) Other - Licensing, contract research organization (CRO)	
16	-	(5) Other - merger with a pubicly-held company	
20	(5) Other - Personal funds of founder	-	Starting the company was 100% self-funded by the founder
21	(1) Pharmaceutical industry - parent company	(1) Pharmaceutical industry - parent company	Parent company provided funding
23	-	-	Debt
24	-	(5) Other - contract research	
26	(5) Other - Personal funds	-	
34	(5) Other - Subsidiary funding from parent company on a "line of credit" basis	Both pharmaceutical industry and government	Funded as subsidiary of parent company
37	(5) Other - From a chemical company	-	
44	-	-	These are not easy to break down. After 10 years, the company held an IPO so we added public offerings. Revenues have not yet been significant.
46	(3) Private placements but not venture capital	-	
54	-	-	Milestone payments
58	Both pharmaceutical industry and private placements	Both pharmaceutical industry and private placements	Did not know percents
62	(5) Other - A manufacturing company	(5) Other - A manufacturing company	A manufacturing company, Tredegor Industries, Richmond, Virginia, is their sole investor.

64	Personal credit lines		Credit card credit lines
66	-	(2) Government - State SBIR grants	
67	-	-	Debt/bond
75	Founders' personal investment	-	No idea of percents. "Other" is founders' personal investment
77	-	(5) Bank loans	
80	(5) Parent company	(5) Parent company	
81	Contract research	-	Research costs funding - "Other" is interest on cash. Manufacturing costs were available cash and general funds
82	-	-	1992-94 - Pharmaceutical industry funded 100%. 1994 - Pharmaceutical industry funding was 50%, private equity 30%, contract R&D 20%. 1995 - More pharmaceutical industry (equity & contract). 1996 - IPO.

Table 55. Comments regarding sources of funding.

Category 5. New Product Focus (Section G Data)

All companies responded to this section and all indicated innovation as their new product focus. Two companies also indicated a non-innovative product focus as well. Their comments are provided in tables 59 and 60 in this section.

According to the data, there was not a significant relationship between company product focus and companies having products on the market. When tested in the logistic regression backward elimination procedure with variables from the other four categories of the hypothesis, both outcome A and outcome B were eliminated from the model. Chi

Square probabilities are provided below. No probability was produced for outcome A, possibly due to the fact that all companies used this approach.

	Outcome	P =
A	Focus on innovative products. (All companies used this approach.)	-
B	Focus on non-innovative (me-too) products	0.8144

Table 56. Category 5. Product focus, outcomes.

Additional Data

With one exception, when the individual variables in this section were tested with companies having a product marketed, the results were not significant. According to the data, 37% of the companies (11) with marketed products had a new product focus to develop a new therapeutic class of drug while this was the focus of 65% of the companies (36) without marketed products. (Logistic regression backward elimination procedure, Chi Square p= 0.0175, and Fisher's Exact Test, 2-tail, p=0.013. Alpha=0.05%.)

All of the variables in tables 57 and 58 below were tested for significance using the above tests. Chi-Square probabilities (Logistic regression backward elimination procedure) and frequencies for companies with and without marketed products are provided. Percents are percents of companies for each group, those with or without marketed products.

New Product Selection Focus	Probability	Companies with marketed products	Companies without marketed products	Total
Technology for previously untreatable diseases (G1a) V	0.5304	53%	65%	52
New therapeutic class of drug (G1b)W	0.0175	37%	65%	47
New products similar to existing products but with an advantage (G1c) X	0.9736	53%	49%	43
Me-too products (G1d) Y	0.9713	7%	0	2
Enabling technology (G1e) Z	0.9735	50%	36%	35
Other (G1f) aa	0.9805	10%	7%	7
Total				186

Table 57. New product selection focus.

Overall New Product Focus	Probability	Companies with marketed products	Companies without marketed products	Total
Single core technology with potential multiple applications (G2a) ab	0.2293	80%	70%	62
Technology with a single therapeutic application with blockbuster potential (G2b) ac	0.9620	7%	11%	8
Service function (CRO, etc.) (G2c) ad	0.1917	10%	2%	4
Other (G2d) ae	0.9606	20%	20%	17
Total				91

Table 58. Overall new product focus.

The tables that follow are comments provided by the companies. Table 59 describes their comments to the "other" responses. Table 60 describes their comments regarding their advice to someone interested in commercializing their technology.

Company ID #	Comments - New Product Selection Focus	Comments - Overall New Product Focus
10	-	We concentrate on reproductive health therapy, diagnostic. This can include multiple technologies, applications & functions.
12	-	Developing multiple (not single) core technologies with potential multiple applications.
13	-	Developing a broad base of technology that may be used in a modular manner to provide for multiple product opportunities.
14		Developing drugs (multiple) for the treatment of patients with cancer.
20		Developing a technology with multiple indication potential and blockbuster potential.
23		Developing technology around central expertise of core people.
24		Multiple core technologies with multiple applications.
25	Developing technology for better diagnosis of diseases.	Developing technology that has multipurpose diagnostic application with blockbuster potential.
29	New diagnostic system.	
30		Developing "several" core technologies with potential multiple applications.
31		Developing multiple core technologies with multiple

		applications each.
33	Developing safer and more potent NMDA-receptor calcium channel blockers.	Developing a portfolio of product candidates based on expertise of company neuroscientist collaborators.
34	Discovery of new therapeutic targets, engineering, genes.	
46		Developing two core technologies with diversified product opportunities.
47	Drug discovery tools.	
50		Multiple core technologies and multiple applications.
58		Developing enabling technologies for products addressing multiple applications.
60	Our ABM (animal behavior modification) devices represent non-drug, non-invasive technology that mimic the effects of drugs that are administered exogenously.	
64		Developing a single core technology with potential multiple applications and providing a service function. We do both equally.
67		Developing more efficient/medically beneficial ways to deliver new and existing drugs.
70	Diagnostic imaging agents.	
71	-	Opportunistic, licensing opportunities for breakthrough or innovative products.
81	-	Developing "several" core technologies with potential multiple applications.
83	-	Developing three core technologies

		with potential multiple applications.
85	-	Opportunistic identification of technologies for new therapeutic classes.

Table 59. Comments - New product focus and overall product focus.

Company ID #	Company Comments - Suggestions for Commercializing Technology
10	Do not concentrate on any one thing. The technology that started this company was found not to work long ago. There needs to be multiple outlets for maximum flexibility. We have a number of technologies in process from many sources. At some point in this company history, we could have answered "yes" to almost every question you asked.
11	Work hard, keep your options open, try to have some single controlling leverage (e.g., patent, mfg. know-how, etc.)
46	Protect intellectual property, attention to details, add value, find early partner, leverage partnership for further financing, keep promises, project conservatively.
58	Raise plenty of $$. Hire entrepreneurs. Work hard.

Table 60. Suggestions for commercializing technology.

Summary of Results - All Categories

Table 61 summarizes the significant findings related to categories one through five of the hypothesis that were presented in this chapter. (Alpha = 0.05.)

Section/ Category	Results	p=
Origins of Technology	There is a greater likelihood of having a product on the market for companies with technologies originating from non-academic sources than from academic sources.	0.0495

	There is a greater likelihood that a company with a marketed product will have technology that originated from in-house research and discovery than from other sources.	0.0065
	There is a greater likelihood that a company with a marketed product will have technology undergoing late-stage development that originated from in-house research and discovery than from other sources and other stages.	0.0028
	Younger companies (≤10yrs) who have two technologies from academia have a greater probability (96%) of having marketed products than older companies (>10yrs) (84%) with the same number of technologies from academia.	0.0382
	Companies with tech transfer offices have a greater probability of having a marketed product than companies without tech transfer offices at 1- 6.5 yrs old. Companies older than 6.5 yrs without tech transfer offices are more likely to have a marketed product than companies with tech transfer offices.	0.0631 (marginal - trend)
Protection of Technology	Of the companies with marketed products, 96.4% did not publish their technology before filing patent applications. Of the companies without marketed products, 75% did not publish before patenting.	0.028

Table 61. Significant relationships with companies having marketed products.

Table 62 summarizes other significant findings presented in this chapter.

Section/Category	Results	p=
Origins of Company	There is a greater likelihood that older companies (>10yrs) will have a product on the market than younger companies (≤10yrs).	0.003
	There is a greater likelihood that companies with higher revenues (>$10M) will have a product on the market than companies with lower revenues (≤ $10M).	0.001

Rights to Technology	Companies with in-house development have an 83% likelihood of granting out rights to their technologies to other companies, and a 17% likelihood of not granting out rights to their technologies.	0.00695
New Product Focus	New product focus of 65% of the companies without marketed products was to develop a new therapeutic class of drug, while this was the focus of 37% of the companies with marketed products.	0.013

Table 62. Other significant findings.

Case Study - ILEX Oncology

As a case study, a meeting with Richard Love, CEO and President of ILEX Oncology, took place in San Antonio, Texas, on 7/29/97. The objective was to define approaches used by the company to commercialize their technology and to determine if those approaches support the approaches defined in categories 1-5, outcome A, of the hypothesis. Questions were prepared and written up in advance, designed not to exceed one hour. Questions related to starting and funding the company, acquiring technology, protecting their technology, arrangements to market their technology, and the company focus. He was also asked for advice to anyone wanting to start a company and for any other comments.

Results indicated the company (1) in-licensed technologies from academia, (2) holds exclusive worldwide rights to patents held by licensors, (3) had not yet out-licensed technologies they are developing, (4) obtained funding ($55M) from private placements

and public offerings, and (5) focuses on innovative products in a single therapeutic area, oncology.

The data obtained from Mr. Love indicated the company used outcome A for categories of approaches 1, 2, 4, and 5, but outcome B for category 3, which in part, support the hypothesis. These are defined in the table below.

Category		Outcome
1. Origins of technology	A.	Technologies were acquired from academic institutions (UTHSC/SA)
2. Protection of technology	A.	Patent applications were filed prior to licensing-out agreements.
3. Rights to proprietary technology	B.	Rights to the company's proprietary technology were not acquired by another company. Currently under in-house development but want to license out.
4. Sources of funding	A.	The largest percent of funding overall was from sources other than private placements ($25M in private placements. $30M from an IPO 2/97).
5. New product focus	A.	Focus was on innovative products. Only oncology products.

Table 63. ILEX Oncology, outcomes.

ILEX is a start-up company, founded in 1994, with academic affiliations and technologies under late-stage development and close to launch (awaiting FDA approval). ILEX also conducts contract research (testing in animals and humans) and contract manufacturing. This serves as a source of revenues to support their research activities. Questions asked during the interview and responses are described below.

1. How was the company founded?

Cancer Therapy and Research Center of San Antonio (CTRC)
UTHSC SA

Board of Governors

UTHSC SA	Cancer Therapy and Research Center of San Antonio	
↓	↓	↓
Medical School	Research	Treatment
↓	↓	
Medical Oncology	Ph.I/II clin.trials	

ILEX Oncology was formed out of the Cancer Therapy and Research Center of San Antonio (CTRC) which is closely tied to the University of Texas Health Science Center at San Antonio. CTRC is a non-profit organization. Doctors from UT Medical Oncology use the facilities at CTRC to treat patients. UTHSC/SA Medical School faculty members are also at CTRC. CTRC was licensing in technologies, conducting clinicals, and then licensing them out. Dollar returns were small (some royalties) but since technology was usually early-stage the value was low.

Mr. Love was the COO at CTRC. He had previously started a biotech company in the San Francisco Bay area. In 1991, Mr. Love and three persons from CTRC began organizing ILEX.

Founders:

- Richard Love - President, CEO
- Dan Van Hoff, MD, (over phase I, II clinical testing at CTRC) *

- Alex Weis (Director of preclinical studies- CTRC)
- Chuck Coltman, MD (CEO of CTRC) *

*UTHSC/SA Medical School faculty

In 1994, ILEX was formed. CTRC owned the technology. ILEX licensed it from CTRC in exchange for shares. The technology was appraised outside and a price was established for the stock. One hundred percent of the stock was divided between the four founders and CTRC.

Mr. Love explained the difficulties in going from non-profit to profit. The IRS closely scrutinizes this, termed "private eneurement". The SEC is not very interested at this early stage. Another model for doing this would be for the four founders to have split off from CTRC first and then bought the technology from CTRC. ILEX has the right first review all technology at CTRC.

2. Funding

When ILEX was formed in 1994, five private placements were made. Capital was obtained in exchange for stock. It took 12 months before finding their first investor. They were five weeks away from running out of money.

Private Placements:

$10M

$15M

$25M total

Venture capital was obtained from the local area initially and then from Boston and New York. Due to funding from a large pharmaceutical company, ILEX was able to leverage a deal with venture capitalists who were trying to buy shares at 50% of their value.

An IPO was filed in February 1997 and $30 million were raised. ILEX raised a total of $55M from 1994 to mid-1997. CTRC has benefited and could cash in their stock at a high premium and put it back into CTRC. ILEX now employs 115 people - double from a year previously. This will probably double again in another year.

3. Licensing-out agreements

- Later stage - more value - royalties, milestone payments, up-front money.
- Earlier stage - less value - usually only small royalties.
- Usually agreements are exclusive worldwide. They are considering changing this and assigning rights on a geographic basis, a country at a time, such as Japan. This will increase the value.

4. Focus

Their advantage over the larger pharmaceutical companies is that they are focused in one area only, oncology.

5. Agreements with academia

ILEX has an agreement for five years with CTRC. They have the right of first negotiation for CTRC's new technology. They have one-on-one agreements with other academic institutions for technologies licensed in.

6. Costs/time for approval

They have some in-house research, but mainly when compounds come to them, the IND has already been filed . Normally phase II, III is 2.5 to 3 years. If they conduct phase I-III it normally takes 6 years until approval.

7. Projected sales

Over the next 5 years (2002) they expect sales to reach $200M.

8. Product focus

a. Their new product focus includes:

- First on market, innovative
- Similar to existing products but with an advantage
- Disease states where no therapies exist
- No other products in a class
- MBAs (monoclonal antibodies), small molecules

b. Contract research - CRO

- Testing in animals

- Testing in humans
- Contract manufacturing

9. Funding for development:

- Funded by clients (contract) - profit.
- Marketing partner funds development for that product.
- Out of their own capital - for those compounds they're holding on to.

10. Product selection

ILEX has a team for new product selection, a Scientific Advisory Board, that is paid a consulting fee and given stock. ILEX has a Business Development office that looks at information including patents, etc., and determines economic and legal feasibility for licensing, and then passes it to the scientific staff and Scientific Advisory Board to determine scientific feasibility. The information is first carefully screened so that the scientists' time is not taken up unnecessarily. ILEX does have a small research staff to develop in-house technologies.

11. Patents/ownership of technology

The originators of the technology hold the patent. ILEX has an exclusive worldwide license with right to sub-license. Some R&D is conducted in-house. ILEX files patent applications as soon as possible. They don't wait and risk loosing it. They can request an extension if approval is delayed at the FDA.

12. Government funding

Government funding was not received. They received much help and assistance from venture capitalists who invested and provided networking. Investors want to add value since they have an interest in having the company do well. They can add value through their contacts.

13. Initial focus and strategy

Company Mission: Accelerating development of anticancer drugs

Company Strategy:

a. Provide services to pharmaceutical and biotech companies

b. In-license available products and take forward - build a product portfolio

c. Focus only on oncology.

Their long-term strategy, 5-10 years, is the same with the addition of cancer prevention. If early signs of cancer are present, treat it before it becomes cancerous. This would be something like a vaccine.

14. Management

All management has industry experience, both business and science.

15. Licensing out

The ideal collaborating company would want to do oncology, be committed, and financially strong - a "well-financed wannabe".

16. FDA

The FDA seems to be sliding backwards and is more conservative than before, and less interested in the patient than regulations. Regarding accelerated approval procedures, companies can market in phase II, but the FDA can make the company do phase III if data is not satisfactory. This has happened to them.

17. Advice

- Do it!
- Persistence - commit and do!
- Approach each barrier as it comes.
- This is a phenomenal time in the US for growth. Lots of investors are available.
- Investors are doing well and are more willing to invest more!

(ILEX is a type of oak tree native to the San Antonio area and was selected as the company's name because of its strength.)

Company Responses and Distribution

From the sampling of 354 companies included in the survey, 119 companies responded. Of these, completed questionnaires were received from 85 companies, 26%. The total response of 119 companies includes 34 companies who did not complete the questionnaire but responded to discuss the study (12) or decline (22) from participation. Of the 354 sent, 23 were returned by the Post Office without forwarding information. An

additional eight were returned by the P.O. with a forwarding address, or a new address was obtained and these were re-sent. The 23 companies were deducted from the total number of 354 potential participants leaving 331 companies contacted. This brings the response rate to 36%.

Total number of companies sent questionnaires	354	
Returned by Post Office	22	
Total deliverable	332	
Questionnaires completed and returned	85	25.7%
Companies declining	22	6.6%
Other responses	12	3.6%
Total responses	119	36%

Table 64. Number of Responses.

The 12 "other" responses indicated the questionnaires would be completed and returned but these were not received. Six additional companies who discussed the survey with me did return the questionnaire and these were counted with the 85 companies who returned the completed questionnaire. Most of the 22 companies declining who contacted me said there had been a change in management or corporate organization and apologized for the delay. One company replied that they did not have time to complete it but sent me a packet of information on the company to use in the survey instead. Six called for more information on the study.

Reasons for not participating are described in the table below. Primary reasons were that the person who would complete the questionnaire was out of town, the company cannot participate as a general rule, or that they consider the type of information

requested to be proprietary. It can be assumed that the 213 companies who did not respond had reasons similar to these for not participating in the study.

1.	Traveling - out of town (5)
2.	Do not/cannot/ prefer not to participate (5)
3.	Involved in a lawsuit with licensee (1)
4.	Bench research only (1)
5.	Manufacturing only (1)
6.	Not a biotech company (2)
7.	Biotech company but not biomedical (1)
8.	Part of a large pharma company (2)
9.	Consider the information requested proprietary (1)
10.	Not applicable (2)
11.	Supplier to biotech industry but not biotech company per se (1)

Table 65. Reasons provided (and number of companies) for not participating in survey.

Responses and Mailings

The percent of total responses to the total sample following each mailing was fairly equally divided, ~11% for each mailing. As a result of the first mailing to 354 companies, 40 (11.3%) total responses were received including 31 completed questionnaires, six declining, and three other responses. Thirteen of the mailings were returned by the Post Office. The second mailing, a reminder letter, was sent to 302 companies who had not responded to the first mailing. Again, 40 total responses were received. This included 23 completed questionnaires, eight declining and three other responses. This total represents 13.2% of the mailing or 11.3% of the total sample. Six were returned by the Post Office. It was not always clear which of these were responding

due to the reminder letter but considering a second wave of replies came in following that mailing it can be assumed this was a contributing factor. The third mailing, a reminder letter and questionnaire, was sent to 253 remaining companies. Of these, a total of 39 responses were received: 31 completed questionnaires, eight declinings, and no others. Three were returned by the Post Office. Since the questionnaires were numbered with a "1" prefix for the first mailing and a "2" prefix for the second mailing, it was clear these were received as a result of the second mailing.

Summary Total

Mailing	Total Number Responses Received	Responses Received	
		% mailing	% Total
1	40	11	11
2	80	13	23
3	119	15	34

Table 66. Responses per Mailing.

Geographic Breakdown

The 354 questionnaires were sent to companies that were located in 31 states throughout the United States. These states have been divided into six general regions: South Central (3), Southeast (6), Southwest (4), North Central (7), Northeast (8), and Northwest (3). The greatest number of companies were in the Southwest (117) and Northeast (116) regions. The individual states with the greatest number of companies were California (114), Massachusetts (54), Texas (39), New York (21), New Jersey (19), Washington (17), Maryland (15), and Pennsylvania (12).

The greatest number of questionnaires completed and returned were from the Southwest with 33 companies and the Northeast with 25 companies. This represents 28% and 25% respectively of the total number sent to these regions. The overall average percent of returns by regions was 24%. Other regions that completed questionnaires were the South Central region with ten companies (24%), the Southeast region with six companies (17%), the North Central region with six companies (30%), and the Northwest region with five companies (21%). The largest number of completed questionnaires was received from California with 32 companies (28%). Other states in that region, Hawaii returned a questionnaire (100%). Arizona and Nevada, also in that region, had no questionnaires returned. Other states with a large number of questionnaires returned are Texas (8 companies, 21%), New Jersey (6 companies, 26%), Massachusetts (6 companies, 11%), Pennsylvania (5 companies, 42%), and New York (5 companies, 24%).

This distribution of companies by region can be attributed to the concentration of companies located in these regions with the majority of biotech companies being located in the Northeast and Southwest regions. The following table summarizes the number of questionnaires and percents received by region. The numbers of questionnaires returned correspond for all regions with the number of questionnaires sent. The regions where the greatest number of questionnaires were sent had the greatest number of responses.

REGION	Number of States	Number of Companies - Total Sent	Number of Companies - Questionnaires Received	% Received
1. North Central	7	20	6	30
2. Southwest	4	117	33	28
3. South Central	3	42	10	24
4. Northeast	8	115	25	22
5. Northwest	3	24	5	21
6. Southeast	6	36	6	17
Total	31	354	85	24

Table 67. Questionnaires sent and received by geographic region. Sorted by percent received.

REGION	Number of States	Number of Companies - Total Sent	Number of Companies - Questionnaires Received	% Received
1. Southwest	4	117	33	28
2. Northeast	8	115	25	22
3. South Central	3	42	10	24
4. Southeast	6	36	6	17
5. North Central	7	20	6	30
6. Northwest	3	24	5	21
Total	31	354	85	24

Table 68. Questionnaires sent and received by geographic region. Sorted by number of questionnaires received (column 4).

Twenty-two questionnaires were not received by the companies and were returned by the Post Office. The following tables reflect this number. If this number is deducted from the total sent, then an actual 332 companies would have received the questionnaires. The "all responses" column in the table includes responses from companies who declined to participate or who wanted more information but did not send the questionnaire. When

this number is added to the total responses (column 7), these calculations then cause some changes in the percent of questionnaires received, and ranking of regions. The total response rate increases to 36% from 24%.

With this view of the data, the ranking of the two largest regions of companies participating remain as before, the Southwest with 42 companies responding (39%), and the Northeast with 37 companies responding (32%). There was some variation in the ranking of the other regions: Southeast with 13 companies (38%), South Central with 12 companies (32%), North Central with eight companies (42%), and the Northwest with seven companies (30%). The number of questionnaires returned does not correspond to the number of questionnaires sent.

Region	Number of States	Question-naires sent	Received	%	Sent minus Returned (P.O.)	All Responses	%
1. North Central	7	20	6	30	19	8	42
2. Southwest	4	117	33	28	109	43	39
3. Southeast	6	36	6	17	34	12	35
4. Northeast	8	115	25	22	109	36	33
5. South Central	3	42	10	24	38	13	34
6. Northwest	3	24	5	21	23	7	30
Total	31	354	85	24	332	119	36

Table 69. Ranking by percent total responses received to total questionnaires sent without returns (from P.O.). (column 8)

Region	Number of States	Question-naires sent	Received	%	Sent minus Returned (P.O.)	All Respons es	%
1. Southwest	4	117	33	28	109	43	39
2. Northeast	8	115	25	22	109	36	33

3. Southeast	6	36	6	17	34	12	35
4. South Central	3	42	10	24	38	13	34
5. North Central	7	20	6	30	19	8	42
6. Northwest	3	24	5	21	23	7	30
Total	31	354	85	24	332	119	36

Table 70. Sorted by all responses (column 7).

Region	Number of States	Question-naires sent	Received	%	Sent minus Returned (P.O.)	All Responses	%
Southwest	4	117	32	27	109	42	39
Northeast	8	115	26	23	109	37	32
South Central	3	42	9	21	37	12	32
Southeast	6	36	7	19	34	13	38
Northwest	3	24	5	21	23	7	30
North Central	7	20	6	30	19	8	42
Total	31	355	85	24	332	119	36

Table 71. Sorted by Questionnaires sent (column 3).

Non-Responding Companies

Of the total 354 company sample, 235 companies did not respond. No responses were received from eight states: Georgia (3), Arizona (1), Nevada (1), Illinois (2), Michigan (2), Delaware (1), Maine (2), Oregon (2). The two largest regions for no responses are the Northeast with 78 (68%) non-responding companies and the Southwest with 75 (61%) non-responding companies, which were the regions sent the greatest number of questionnaires. The breakdown by the other regions corresponds with the

number or questionnaires sent to companies: South Central (30 companies, 68%), Southeast (24 companies, 62%), Northwest (17 companies, 70%), and North Central (12 companies, 58%).

The following tables show the distribution by geographic region.

Region	Number of States	Question-naires sent	Recd	%	Sent minus Returned (P.O.)	All Responses	%	No responses	%
1. Northwest	3	24	5	21	23	7	30	16	70
2. South Central	3	42	10	24	38	13	34	25	66
3. Northeast	8	115	25	22	109	36	33	73	67
4. Southeast	6	36	6	17	34	12	36	22	64
5. Southwest	4	117	33	28	109	43	39	66	61
6. North Central	7	20	6	30	19	8	42	11	58
Total	31	354	85	24	332	119	36	213	64

Table 72. Non-responding companies. Sorted by percents of no responses.

Region	**Number of States**	**Question-naires sent**	**Recd**	**%**	**Sent minus Returned (P.O.)**	**All Responses**	**%**	**No responses**	**%**
1. Northeast	8	115	25	22	109	36	33	73	67
2. Southwest	4	117	33	28	109	43	39	66	61
3. South Central	3	42	10	24	38	13	34	25	66
4. Southeast	6	36	6	17	34	12	36	22	64
5. Northwest	3	24	5	21	23	7	30	16	70
6. North Central	7	20	6	30	19	8	42	11	58
Total	31	354	85	24	332	119	36	213	64

Table 73. Non-responding companies. Sorted by number of no responses (column 9).

Sample Representation

To determine if the sample in this study was representative of the population, data were tested relating to three areas, geographic region, ownership, and revenues. Data were obtained from the questionnaire or sources of published information referred to in Chapter 1, Introduction. Based on statistical analyses of the data, there was no significant difference between responding companies and non-responding companies in terms of geographic region, ownership, and revenues. (Chi Square, Cochran-Mantel-Haenszel statistics based on rank scores. See table below for probabilities. Alpha=0.05.)

It can, therefore, be concluded that the 85 responding companies in the survey are representative of the total sample of 354 companies, and can be considered representative of the population.

Variable	Value	Probability	Number Tested
Geographic Region	1.878	0.391	354
Revenue	1.068	0.586	354
Ownership	1.620	0.203	319

Table 74. Sample Representation.

Types of Companies

The sample included a total of 354 companies. All companies were in the biotech or biomedical industry. Companies were from the following specific industry sectors:

Agbio/veterinary	Enabling technology
Autoimmune	Gene/Cell therapy
Biomaterial/Skin/Wound	Hematology
Biopharmaceuticals	Infectious diseases/AIDS
Blood products/substitutes	Metabolic
Cancer	Musculoskeletal
Cardiopulmonary	Neurological
Dermatology	Transplant
Diagnostics/Imaging	Reproductive
Drug Delivery	Services
Drug discovery	

Table 75. Types of companies surveyed.

CHAPTER 4

DISCUSSION AND CONCLUSIONS

Results of the analysis of the data obtained in this study suggest a significant relationship of one of the ten possible outcomes of the five categories of the hypothesis tested with the success factor, companies having a product on the market. It is likely that a company with a marketed product will have acquired technology from sources other than academia including in-house research and discovery, collaborations and joint-ventures, the pharmaceutical industry, and other non-academic sources. Furthermore, it is likely that a company with a marketed product will have technology that originated from in-house research and discovery.

Analyses of the sub-category variables indicated significant relationships with companies having a marketed product and age, revenues, technology transfer offices, and publishing/patenting. It was shown that younger companies have a greater likelihood of success than older companies when technologies are acquired from academia, and it is likely that companies with in-house development will out-license their technologies. Other significant findings will also be discussed in this chapter.

These overall data tested suggest that approaches used by biotech companies are related in a significant manner to success. There is further evidence from the case study

that support these findings. Therefore, it can be concluded that approaches to commercialize technology used by biotech companies do influence the success of companies and a that combination of approaches can be indicative of success.

Categories One - Five

According to the data, there was a greater probability that companies with a marketed product acquired their technologies from sources other than academic institutions. Otherwise, there was no evidence in these data tested here to suggest a relationship between successfully bringing products to market and the approaches studied. Companies with and without marketed products used both outcomes A and/or B for approaches two through five. However, when individual variables in each category were tested individually with companies having marketed products, significance was found in several areas and are discussed later in this chapter.

The following conclusions can be made from the analyses of the data for categories one to five, outcomes A and B.

Category 1. It is likely that a company with a marketed product will have acquired technology from sources other than academic institutions including in-house research and discovery; collaborations and joint-ventures; pharmaceutical companies; and other non-academic sources.

There were no significant relationships between companies with a marketed product and either outcome A or outcome B of categories of approaches two to five. All responding companies used the following approaches.

Category 2. Filed patent applications prior to and/or after agreements to license out their technologies.

Category 3. Granted rights to proprietary technologies, such as through licensing agreements, to other companies and/or they are developing their technologies in house.

Category 4. Obtained funding from sources tested such as the pharmaceutical industry, government (grants, loans, etc.), private placement (venture capital, friends, associates, etc.), public offerings, equity investments, revenues from marketed products, revenues from licensing agreements, contract research and other sources.

Category 5. Focused on innovative new products such as for the treatment of previously untreatable diseases, a new therapeutic class of drug, products with an advantage over currently marketed products, rather than me-too products.

Category 1. Origins of Technologies

According to the data, there is a greater likelihood of having a product on the market for companies with technologies originating from non-academic sources than academic sources. There was also evidence that it is likely that a company with a marketed product has technologies that originated from in-house research and discovery rather than other sources.. It is also likely that a company with a marketed product has technologies in late-stage development that originated from in-house research and discovery.

It can, therefore, be concluded that it is possible that a company's original technology may have originated from academia, but any technology the company developed around it is considered the company's own proprietary technology. It is then this technology that reaches the market. The number of products that have reached the market with origins from in-house research and discovery relative to other origins also supports this. This was confirmed by company comments.

It could also be that technologies acquired through other biotech or pharmaceutical companies could be in a later stage of development where there is a higher probability of reaching the market in a shorter timeframe than technology acquired from academia which could be earlier-stage technology.

Origins of Technologies from Academia and Age of Company

Younger companies who acquire technologies from academia are more likely to have a product marketed than older companies who acquire technologies from academia. Younger companies benefit from research conducted and funded by an academic institution. It can also be that these younger companies were started with the intention of commercializing an academic institution's technology.

An equation was developed that can predict probabilities of having a marketed product related to company age and number of technologies from academic institutions.

Tech Transfer Offices

Companies with tech transfer offices have a greater probability of having a marketed product than companies without tech transfer offices until they are about six and a half years old. The reverse occurs for companies older than six and a half years old, when companies are more likely to have a marketed product if they do not have a tech transfer office. A reason for this could be that younger companies are focused on bringing in new technologies to the company and also finding licensing partners at the appropriate time to complete the commercialization process. Older, more established companies may have assigned tech transfer responsibilities to various departments within the company. They may not need to pursue tech transfer activities to bring in new technologies or license out their technologies already in house to the same degree as younger companies.

Category 2. Protection of Technology

The likelihood for a company to have a product on the market is not significantly different for companies who patent their technologies before or after entering into an agreement to out-license their technology to another company.

The decision when to patent a technology can be based on various factors. The value of the technology and the valuation of the company increases with patent protection. However, considering the cost of patents, a company may want to wait for a licensor to take on those costs. Also, a larger company who licenses in the technology may have more experience in intellectual property and may be in a better position to protect the technology, therefore, maximizing the technology's commercial potential and financial returns.

Patents Filed by Originator

The likelihood of having products on the market is not significantly different for companies whose technologies were patented by the originator when the technologies were licensed in from another source. The case study showed that ILEX has exclusive worldwide rights to technologies from an academic institution who holds the patents.

Publishing Before Patenting

There is a greater likelihood that a company will have a product on the market if it does not publish before patenting its technologies.

There was some controversy regarding this issue. While publishing new findings may increase the company's value, it can place its proprietary rights to its technology in jeopardy.

Category 3. Granting Rights to Technology to Other Companies

There is not a significant difference in the likelihood of having a product on the market for companies who grant rights to their technologies to other companies for commercialization and those who do not grant rights. However, the data showed there was a significantly greater likelihood that companies with in-house development activities will grant rights to other companies for commercialization activities. This is described later in this section..

There are advantages to both licensing out a technology for another company to develop and market, thus taking on the most expensive part of product development, and developing technology in-house and marketing it. The goal of some biotech companies is to develop a technology to a point where it becomes attractive to potential licensors. Revenues from royalties or other licensing arrangements can then provide the resources needed to continue R&D on current and new technologies. ILEX commented that their objective is to out-license their technology currently under development. Many of the companies surveyed may not yet have found a licensor or their technology may not be at a stage where they are ready to consider out-licensing. On the other hand, in-house development and marketing provides a high return on investment since royalties usually provide a small percentage of the actual product sales.

The timing of when to license out is also significant. The value of the technology increases the further along it is in the development cycle.

In-house Development of Technologies and Rights Acquired by Other Companies

According to the data, companies with in-house development did not have a greater probability of having products on the market than companies without in-house development. However, there is a greater likelihood that companies with technologies under in-house development will enter into arrangements with other companies to out-license their technologies than companies without in-house development. Companies with active in-house development activities often are focused on research through early phase development, making out-licensing arrangements advantageous.

Funding for Rights

Overall, the data showed there was no significant difference in likelihood that a company will have marketed products if they receive funding or do not receive funding in exchange for rights to their technologies. However, the data did show there were significant relationships between companies without marketed products and the sub-categories, royalties and up-front payments (discussed below).

Royalties

Companies not receiving royalties were more likely to have products on the market. When tested with age as a factor, the data showed that at the same age the

difference in likelihood in having marketed products was not significant between companies receiving or not receiving royalties from licensed-out products.

Up-Front Money

Companies not receiving up-front money are more likely to have products on the market. When tested with age as a factor, the data showed that at the same age the difference in likelihood in having marketed products was not significant between companies receiving or not receiving up-front money from licensed-out products. However, the likelihood of having marketed products is greater at the same age for companies not receiving up-front money from licensed products.

Licensing

Though the relationship to age is not significant, the data showed that the probability of having a marketed product increases with age for both companies who license out their technologies and those that don't. There is a greater probability of having a marketed product for companies who do not license out their technologies. However, as companies age the difference in probability of having a marketed product decreases.

Category 4. Sources of Funding

There was no significant difference in likelihood of having a product on the market and the source of funding. In addition, four other variables tested, described in Chapter 3, were not statistically significant. Both companies with and without marketed

products used similar approaches for funding. Both groups of companies obtained their initial funding from private placements and their second source of funding was from public offerings.

From the data, it can be seen that all the types of sources of funding tested were used. Each of the companies obtained funding from several sources for various stages of the development process. Companies have access to the same type of sources. From whom they obtain funding depends on factors such as the commercial value and type of technology, the company's business plan, and the ability and experience of the company's management to attract investors.

Category 5. New Product Focus

There was no significant difference between companies with marketed products and those without marketed products, and the companies' new product focus. Therefore, this cannot be used as an indicator of having products on the market. All 85 companies in the sample indicated innovative new products as their focus for selecting products for development. Two companies also said their focus was directed towards both innovative and non-innovative products. However, the data were significant relating to companies developing a new class of drug, but these companies did not have marketed products. This could indicate the high degree of difficulty in discovering new classes of therapeutics for diseases and getting such a product to market.

Overall, these findings are consistent with the general goals of the biotech industry. Companies are looking for small niche products where there is an unmet need or products offering an advantage, such as cost, efficacy, comfort, safety, over those products already on the market.

ILEX Oncology

In four of the five categories, the outcomes (A) supported the research hypothesis of this thesis. Category 3, outcome B, did not support the research hypothesis . While they have not licensed out their technologies, they plan to do so at some point. The company was formed to commercialize technology that originated at an academic institution, who holds the patents. The company obtained funding from both private placements and public offerings. They also conduct contract research services that produce income for the company's R&D activities. ILEX is focused on one therapeutic area, a small niche in oncology.

Origins of the Company

This section is not part of the hypothesis. However, when the data were analyzed the following conclusions were observed.

Origins and Products

There is not a difference in likelihood of having a product on the market for companies with academic origins and companies with non-academic origins. However, the data showed that more companies with academic origins had products on the market

than companies with non-academic origins. For example, of the 29 companies with products on the market, 59% were from companies with academic origins while 41% were from companies that did not have academic origins. This, however, was not significant.

Age and Products

There is a greater likelihood that older companies will have a product on the market than younger companies. This shows the longer the survival rate of a company the greater the probability of success.

Ownership and Products

The data suggested a trend of relationship between company ownership and having products on the market. There may be a higher likelihood that a publicly-owned company would have a product marketed than a privately-held company.

Revenues and Products

There is a greater likelihood that companies with higher revenues will have a product on the market than companies with lower revenues.

Conclusions

The following conclusions can be made based on analysis of the data tested related to the categories of approaches in the hypothesis and the success factor, companies having products on the market.

- It is likely that a company with a marketed product acquired its technology from sources other than academic institutions, and in particular, through in-house research and discovery.

- Younger companies with one to two academic-sponsored technologies are more likely to have a product marketed than older companies with the same number of academic technologies.

- Younger companies with tech transfer offices are more likely to have a product marketed than companies of the same age without tech transfer offices, and older companies without tech transfer offices are more likely to have a product marketed than a company the same age with a tech transfer office.

- Companies that do not publish before patenting are more likely to have a marketed product than those that do publish before applying for a patent.

- Older companies and companies with higher revenues are more likely to have a product marketed than younger companies and companies with lower revenues.

The following are other findings of interest:

- It is likely that companies with in-house development of technology will grant rights to their technologies to other companies for commercialization.

- Companies that are focused on developing products in new therapeutic drug classes are less likely to have a product on the market than companies focused on other areas.

In conclusion, these data support the hypothesis that approaches used by biotech companies for commercialization of technology do significantly influence the success of these companies. These findings are futher confirmed by a case study.

APPENDIX

EFFECTIVE APPROACHES OF BIOTECH COMPANIES TO COMMERCIALIZE TECHNOLOGY

Research Conducted by: Patricia M. Cappelletti

Graduate Student, Biomedical Sciences

University of North Texas Health Science Center at Fort Worth

3500 Camp Bowie Boulevard

Fort Worth, Texas 76107

The following survey is being conducted to define approaches biotech companies are using to commercialize their technology into new products.

Please answer all questions that apply to your company. Your responses will be completely anonymous.

If you wish to make additional comments please use the margins or a separate sheet.

Please return this questionnaire to Pat Cappelletti, Department of Pharmacology, University of North Texas Health Science Center at Fort Worth, 3500 Camp Bowie Boulevard, Fort Worth, Texas, 76107-2699.

A. Origins of the Company

First, we would like to ask you how your company was started and some general background questions. An "academic institution" includes any college, research institute, or university, whether for profit or non-profit.

A1. Was the company founded as a result of a(n): (Circle the letter of your answer(s).)

a. Research discovery that originated at an academic institution

b. Initiative with an academic institution

c. Partnership of an established company and an academic institution

d. Divestiture from a larger company

e. Merger of two or more companies

f. Joint venture with another company

g. Newly-created subsidiary or spin-off from another company

h. Industrial cluster or incubator of companies

i. Academic consortium

j. Initiative of patent holder(s)

k. Other (please explain)_____

_____

A2. What is the approximate age of your company, in years? (Circle number of years.)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 23 24 25

If other please specify_____

A3. Is your company: (Circle the letter of your answer.)

a. Privately held b. Publicly held

A4. How would you rank your company in terms of overall revenues (1995): (Circle the letter of your answer.)

a. Less than $10 Million b. $10 M to $100 Million c. More than $100 Million

B. Number of Technologies

We would now like to ask you about your company's products under development or launched. In this questionnaire, "technology" will be used to include compounds, devices, instrumentation, equipment, procedures, methods, or uses.

B1a. Does your company have technology such as compounds or medical devices subject to FDA approval (NDA's, PMA's...) under clinical development? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number B2a.)
2. YES

If yes, how many are in the following phases of development? (Circle the number of technologies or specify the number in "other".)

1b. Phase I	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
1c. Phase II	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
1d. Phase III	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
1e. Awaiting registration	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
1f. Technologies not included in the phases above	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

B2a. Does your company have technology under development that is <u>not</u> subject to FDA approval such as class 1 and 2 devices? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number B3a.)
2. YES

If yes, how many technologies are in the following phases of development? (Circle the number of technologies or specify the number in "other".)

2b. Trial phase	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
2c. Pre-manufacturing (necessary documentation such as safety and efficacy data ready)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
2d. Manufacturing	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
2e. Technologies not included in the above	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

B3a. Does your company have products on the market? (Circle 1 for no, 2 for yes.)

1. NO (Go to question C1a.)
2. YES

3b. If yes, how many products? (Circle number or specify the number in "other".)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

3c. If yes (question B3a), how many of your products were launched in the past ten years? (Circle number or specify the number in "other".)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Other_____

What were the approximate annual dollar amounts of 1995 sales for each of your products launched in the last ten years? (US$ Millions)

3d. Product 1	_____
3e. Product 2	_____
3f. Product 3	_____
3g. Product 4	_____
3h. Product 5	_____
3i. Product 6	_____
3j. Product 7	_____
3k. Product 8	_____
3l. Product 9	_____
3m. Product 10	_____
3n. Product 11	_____
3o. Product 12	_____
3p. Product 13	_____
3q. Product 14	_____
3r. Product 15	_____

C. Origins of Technologies

Next, we would like to ask you where your proprietary technologies originated. This includes products launched and under development.

Did any of your company's technologies originate from the following: (Questions C1-C5)

C1a. Your company's in-house research or discovery departments?
(Circle 1 for no, 2 for yes.)

1. NO (Go to question number C2a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

C1b. Marketed.....	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C1c. Late phase development... (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C1d. Earlier stages..... (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

C2a. Collaborative research efforts with another company for joint development of a product or products? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number C3a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

C2b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C2c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C2d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

C3a. Acquired from an academic institution? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number C4a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

C3b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C3c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C3d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

C4a. Licensed from a pharmaceutical company? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number C5a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

C4b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C4c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C4d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

C5a. Did any of your company's technologies originate from other sources?

1. NO (Go to question number C6a.)
2. YES

If yes, please explain_____

_____

_____

If yes (question C5a), how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

C5b. Marketed.....	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C5c. Late phase development... (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
C5d. Earlier stages..... (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

C6a. Does your company have a standing agreement with an academic institution allowing options to all their new technology? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number C7.)
2. YES

6b. If yes, how many academic institutions?
(Circle the number of institutions or specify the number in "other")

1 2 3 4 5 Other_____

C7. Does your company have an office dedicated to technology transfer and commercialization? (Circle 1 for no, 2 for yes.)

1. NO
2. YES

D. Rights to Proprietary Technology

Next, we would like to ask you how your technology reaches the market.

D1a. Were any rights to your technology acquired by another company for purposes such as research, development, and/or marketing? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D11, pg 10.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D1b. Marketed.....	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D1c. Late phase development... (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D1d. Earlier stages..... (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

If yes (question D1), how were they acquired by the other company? (This includes questions D2 - D5.)

D2a. Licensed out to the other company? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D3a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D2b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D2c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D2d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

D3a. Your company and the other company formed a joint venture? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D4a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D3b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D3c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D3d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

D4a. The other company is/was your parent company? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D5a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D4b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D4c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D4d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

D5a. Your company's technologies were acquired by the other company or companies through some other means? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D6.) 2. YES

If yes, please explain_____

_____

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D5b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D5c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
D5d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

D6. If any of your technologies were licensed to another company, did the licensee agree to provide your company with funding in exchange for rights to your technology? (Circle 1 for no, 2 for yes, or 3 for not applicable.)

1. NO (Go to question number D10a.) 2. YES 3. Not applicable (Go to question number D10a.)

If yes, were any of the following types of funding provided?

D7a. Milestone payments? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D8a.) 2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D7b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D7c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
D7d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

D8a. Royalties? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D9a.) 2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D8b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D8c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
D8d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

D9a. Up-front payments? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D10a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D9b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D9c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
D9d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

D10a. If licensed out, did your company retain any form of rights to the technology? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number D11a.)
2. YES
3. Not applicable (Go to question number D11a.)

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D10b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D10c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
D10d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

If yes, What kind of rights to your technologies were retained? Circle the letter of your answer(s).)

D10e. Co-marketing rights?

D10f. Geographic areas?

D10g. Therapeutic indications?

D10h. Other rights (Please explain)_____

_____

D11a. Does your company have any agreements to share profits with another company for any of your technologies? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number E1.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D11b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D11c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D11d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

D12a. Does your company have technologies that are under in-house development?

1. NO (Go to question number E1.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

D12b. Marketed	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D12c. Late phase development (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
D12d. Earlier stages (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____

E. Sources of funding

We would now like to ask you about your sources of funding for starting the company, for research, development, and manufacturing costs.

In terms of dollar amounts, which of the sources below provided funding for the following and what were the approximate percents of funding?

E1. Starting the company: (Circle all numbers that correspond with the following sources for each answer, or explain, and give per cent.)

Source	Per Cent
1. Pharmaceutical industry	
2. Government (grants, loans, etc.)	
3. Private placements (venture capital, "angels", friends, associates, etc.)	
4. Public offerings	
5. Equity investments	
6. Revenues from marketed products	
7. Revenues from licensing agreements	
8. Contract research	
9.* Other sources (please explain)	

*Please explain_____

E2. Research costs: (Circle all numbers that correspond with the following sources for each answer, or explain, and give per cent.)

Source	Per Cent
1. Pharmaceutical industry	
2. Government (grants, loans, etc.)	
3. Private placements (venture capital, "angels", friends, associates, etc.)	
4. Public offerings	
5. Equity investments	
6. Revenues from marketed products	
7. Revenues from licensing agreements	
8. Contract research	
9.* Other sources (please explain)	

*Please explain_____

E3. Development costs: (Circle all numbers that correspond with the following sources for each answer, or explain, and give per cent.)

Source	Per Cent
1. Pharmaceutical industry	
2. Government (grants, loans, etc.)	
3. Private placements (venture capital, "angels", friends, associates, etc.)	
4. Public offerings	
5. Equity investments	
6. Revenues from marketed products	
7. Revenues from licensing agreements	
8. Contract research	
9.* Other sources (please explain)	

*Please explain_____

E4. Manufacturing costs: (Circle all numbers that correspond with the following sources for each answer, or explain, and give per cent.)

Source	Per Cent
1. Pharmaceutical industry	
2. Government (grants, loans, etc.)	
3. Private placements (venture capital, "angels", friends, associates, etc.)	
4. Public offerings	
5. Equity investments	
6. Revenues from marketed products	
7. Revenues from licensing agreements	
8. Contract research	
9.* Other sources (please explain)	

*Please explain_____

E5. Which was your company's initial source of funding? (Circle a single number.)

1. Pharmaceutical industry
2. Government (grants, loans, etc.)
3. Private placements (venture capital, "angels", friends, associates, etc.)
4. Public offerings
5. Other (Please explain)_____
_____

E6. Which was your company's second source of funding? (Circle a single number.)

1. Pharmaceutical industry
2. Government (grants, loans, etc.)
3. Private placements (venture capital, "angels", friends, associates, etc.)
4. Public offerings
5. Other (Please explain)_____
_____

F. Protection of Technology

Now, we would like to ask about your company's views on protecting proprietary technology.

F1a. Were any patent applications filed by your company prior to entering into agreements to license your technologies to other companies? (Circle 1 for no, 2 for yes, or 3 if no licensing agreements .)

1. NO (Go to question number F2a.)
2. YES
3. Not applicable (Go to question number F3a.)

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

F1b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
F1c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
F1d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

F2a. Were any patent applications filed <u>after</u> entering into agreements to license your technologies to other companies? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number F3a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

F2b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
F2c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
F2d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

F3a. Were any patents filed by the originator(s) of the technologies if your company licensed them in? (Circle 1 for no, 2 for yes, or 3 for not applicable.)

1. NO (Go to question number F4a.)
2. YES
3. Not applicable (Go to question number F4a.)

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

F3b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
F3c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
F3d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

F4a. Was data published on any of your company's technologies before patent applications were filed? (Circle 1 for no, 2 for yes.)

1. NO (Go to question number G1a.)
2. YES

If yes, how many are in the following stages at present? (Circle the number of technologies or specify number in "other".)

F4b. Marketed.....1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____
F4c. Late phase development...1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase II, III, or awaiting registration if FDA regulated, or premanufacturing/manufacturing if non-FDA regulated)
F4d. Earlier stages..... 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 Other_____ (phase I, preclinical, or screening stages if FDA regulated, or trial phase if non-FDA regulated)

G. New product focus

Finally, we would like to ask you about your company's focus for selecting technology for product development.

Does your company's new product focus include: (Circle the number of all that apply.)

G1a. Developing technology for treatment of previously untreatable diseases
G1b. Developing a new therapeutic class of drug
G1c. Developing products similar to those currently marketed but with an advantage such as efficacy, safety, or cost
G1d. Developing "me-too" products
G1e. Developing enabling technology (drug delivery system, etc.)
G1f. Other (please explain) _____

Your company's overall focus for new products can best be described as: (Circle the number of the single most appropriate answer.)

G2a. Developing a single core technology with potential multiple applications
G2b. Developing a technology that has a single therapeutic application but with blockbuster potential
G2c. Providing a service function (contract research, etc.)
G2d. Other (please explain) _____

Do you have any comments or suggestions for someone interested in commercializing their technology? (Please use a separate sheet.)

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Affiliations of References

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Table 76. Affiliations of references.