FRAMEWORK FOR ANALYZING COMPONENTS OF ORGANIZATION DESIGN WITHIN THE BIOTECHNOLOGY SECTOR: THE INEX PHARMACEUTICALS CASE STUDY

by

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ABSTRACT

Biotechnology firms are founded on scientific technology and are often managed by scientific founders. These individuals often have limited experience in management processes. Although solid scientific technology is a key success factor for biotechnology firms, management processes are of equal importance. This paper systematically examines management processes at Inex Pharmaceuticals Corporation (Inex) using traditional tools and techniques. The framework employed in this analysis examines six components of Inex's organizational design: Strategy, Organizational Structure, Human Resources, Processes, Partnerships and Corporate Performance Measures as the Company navigated three phases of its lifecycle (i.e. Phase A: Research, Phase B: Development and Phase C: Commercialization).

Throughout Inex's evolution dynamic changes have taken place throughout the organization. Analyzing Inex's organization design during this evolution provides an excellent learning opportunity for small biotechnology companies. Based on the analysis, key learning points have been summarized within a conceptual framework that start-up biotechnology firms should deliberate in their growth and development. However, other factors such as the external environment, scientific perceptions and resource limitations should be considered in parallel with these learning points.

Major findings and learning points within the framework of analysis include:

Strategy: it is important for organizations to have strategic development processes in place and to ensure that strategy is driven and monitored by both internal scientific progress and external market conditions.

Human Resources: Core values of the organization should be communicated to all employees, from the outset, in order to provide common focus. In addition, appropriate systems should be in place to establish a consistent and quality approach to recruitment and selection of personnel.

Organizational Structure: Seek to build a harmonizing structure that is conducive to *innovation* (to cultivate research), while allowing for a level of *standardization* (to achieve regulatory compliance).

Process Development: Anticipate the need for infrastructure to support Development Research, (i.e. Preclinical, Analytical Development, Process Development, Clinical and Regulatory Affairs) well in advance.

Partnerships and Networks: Develop a partnering strategy that is aligned with company strategy and is executed through a business development team.

Corporate Performance Measures: Use the balanced scorecard as a tool for management systems, performance measurement and communication.

DISCLOSURE STATEMENT

This project represents the views and ideas of the authors. Inex Pharmaceuticals has not reviewed this project and does not endorse the ideas and views presented herein.

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1.1 Background of Biotech Industry

Biotechnology is generally defined as the use of cellular and molecular processes to solve problems or make products[1]. These products can be applied in the areas of biological, agricultural, and environmental science. However, biotechnology's most significant contributions have been, and continue to be, in the healthcare sector. Biotechnology (biotech) allows researchers to study diseases on a cellular level with the aim of gaining a better understanding of their intricate mechanisms. This insight has been used to create treatments for diseases previously considered untreatable, as well as to develop improved therapeutics for diseases where existing treatments were relatively ineffective. The definition of biotech for the purpose of this paper will be the healthcare sector of the industry and will pertain to companies that are focused on developing small molecule therapeutics for human diseases. This part of the industry accounts for 40% of all biotech companies, and comprises 73% of US biotech-derived product sales[2].

Canada has the second largest biotech sector in the world, with companies such as QLT, Aventis Pasteur, Iogen, and Millennium Biologix promoted as flagship firms. In 2001 the main clusters of Canadian biotech firms were in: Quebec (133), Ontario (119) and B.C. (81), with 75% of these companies employing less than 50 people; 14% employing between 51 and 150; and only 11% employing more than 150. The revenues

[1] Harp, D. Introduction to Biotechnology. Deutsche Bank, June 2002.
[2] ibid

from this sector were estimated to be $5 billion in 2002, and the value of exports was estimated to be $1.7 billion in 2002[3,4]. For this sector to mature and develop, it is recognized that sustainable biotech companies need more than good science and good technology. Appropriate firm design and good management practices are also required[5,6,7].

Biotech companies face a collection of challenges which make it inappropriate to simply apply existing operations and firm design thinking. For instance, at present relatively few biotech firms generate earned income from sales. They focus on creating intellectual capital and offering related testing and processing services. The time scale and route to create such outputs is typically long (five to fifteen years), highly uncertain, complex and requires investment in the order of tens of millions of dollars. With these conditions, it is difficult to understand how biotech firms should be measured, designed and operated; and theory and practice show that most new and small biotech firms are destined to remain small, fail, or be acquired by larger predatory competitors[8,9]. This problem is significant to Canada, because as Niosi (2003) cautions, only a few of Canada's biotech

[3] Statistics Canada. Features of Canadian Biotech Innovative Firms: Results from the Biotechnology Use and Development Survey. Cat. No. 88F0006XIE2003005, 2001.

[4] Statistics Canada. Innovation Analysis Bulletin. Cat. No. 88-003-XIE, 3.3, 2001.

[5] Prewitt, E. What You Can Learn From Managers in Biotech. Harvard Management Update. May: 3-5, 1997.

[6] Oliver, A. L. and K. Montgomery. Creating a Hybrid Organizational from Parental Blueprints: The Emergence and Evolution of Knowledge Firms. Human Relations. 53.1: 33 – 55, 2000.

[7] Niosi, J. Alliances Are Not Enough: Explaining Rapid Growth in Biotechnology Firms. Research Policy. 32: 737 –750, 2003.

[8] Oakey, R.P. High Technology Small Firms: Their Potential for Rapid Industrial Growth. International Small Business Journal. 9.4: 30-42, 1991.

[9] Walsh, V., Niosi, J. and P. Mustar. Small Firm Formation in Bio-technology: A Comparison of France, Britain and Canada. Technovation.15.5: 303-327, 1995.

firms will grow, unless they understand how to adopt and implement the correct strategy and mix of products.

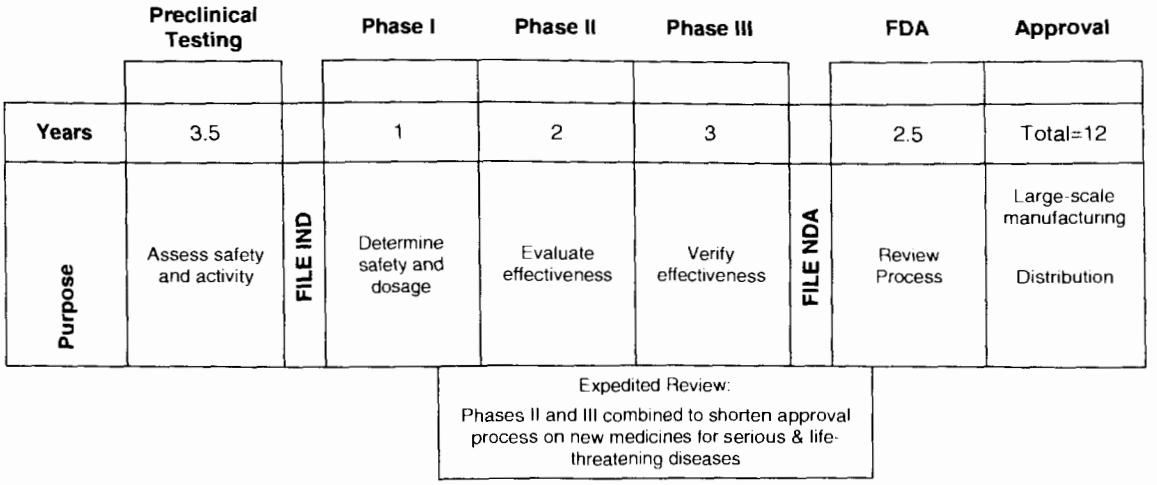
1.2 Overview of Drug Development

The drug development pathway is a multi-step process with many regulatory hurdles. To understand the systems and processes required in a biotech company, a brief introduction to the drug development pathway including preclinical and clinical development is required. Outlined below is a brief primer on the drug development process.

On average, it takes 10-15 years to develop a drug and can cost up to US $800 million[10]. Figure 1 below, outlines the drug development and approval process. It is important to note the drug approval process depicted in Figure 1 is a simplistic view of the process. Preceding the preclinical testing stage, are many years of discovery and preliminary research and development (R&D). This serves to identify a compound that is ready to be put through the rigors of the drug approval process. Since the US system for drug development is considered to be the "gold standard", organizations will usually market their drugs in the US first. The discussion below is based upon the US Food and Drug Administration (FDA) regulations.

[10] Regulatory Affairs Professional Society (www.raps.org/s_raps/sec_RANews_Detail.asp?TRACKID=&CID=116&DID=18858). (last accessed on June 2, 2004).

Figure 1: Drug Development and Approval Process[11]



1.2.1 Preclinical

Once a compound has been identified and tested in the R&D phase, *in vitro* (in an artificial environment, such as a test tube) and *in vivo* (in a living organism) pharmacology, efficacy, and toxicology work must be conducted to confirm that the compound is not toxic and will not cause side effects in humans. The toxicology studies are conducted in two animal species under the guidelines of good laboratory practices (GLP). Once these studies are completed, an Investigational New Drug Application (IND) can be filed in order to obtain approval to proceed with clinical trials in humans. In addition, manufacturing of the compound for preclinical studies and clinical trials is also conducted during this phase. Preliminary research phases require milligram quantities of compound for testing. However, as the compound advances towards commercialization, gram to kilogram quantities will be required. As a result, a cost-effective method for manufacturing must be considered well before commercialization. The preclinical phase

[11] Table adapted from Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, 2002.

takes approximately 3.5 years and both toxicology and manufacturing are usually outsourced to service providers[12].

1.2.2 Clinical Development

The clinical development phase is initiated with the filing of an IND that is submitted to the regulatory authorities. The IND compiles all the data from preclinical studies and it is the first step towards obtaining approval to start testing the compound in human subjects (clinical trials). Clinical trials are divided into three phases that occur in succession.

Phase I clinical trials typically involve 20-80 patients and the compound is tested to observe any toxicities, dose tolerance, maximum tolerated dose (MTD) and pharmacokinetic properties. If the compound is safe and non-toxic, Phase II clinical trials are initiated with diseased patients to test the effectiveness (efficacy) of the compound. Phase II clinical trials typically involve 100-300 patients and can take up to 2 years to complete. These trials also serve to identify possible short-term side effects and risks in a larger patient population. A larger form of the Phase II trials, often termed pivotal Phase IIb or Phase III trials, begins once the effectiveness of the compound has been established. Phase III trials involve conducting tests in an expanded patient population at geographically dispersed test sites (multi-centre trials) to establish clinical safety and effectiveness. Phase III trials also generate information from which the overall benefit-risk relationship of the drug can be determined and will provide a basis for drug labelling. These trials are conducted with 1000-3000 patients and can take up to 3 years to complete[13].

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[12] Alliance Pharmaceuticals Corporation (www.allp.com/drug_dev.htm) (last accessed on May 15, 2004).
[13] ibid

Upon successful completion of all three phases of clinical trials, a company can file a New Drug Application (NDA) with the FDA to obtain approval to manufacture and market its product. The application compiles all the preclinical, clinical and manufacturing data. The FDA will review the document and make a decision as to whether the product meets specific criteria and should be commercialized. If the FDA approves the NDA and the product is commercialized, post-marketing Phase IV clinical trial studies may still be required. Phase IV studies are designed to monitor patients who are being treated with the drug over a long period of time to confirm that no side effects occur with chronic administration. Furthermore, post-approval studies may provide additional data on safety and efficacy for indications other than that for which the product was initially tested.

As the preceding discussion illustrates, the process of drug development and approval is a lengthy one. Thus, the United States has adopted a statutory program to accelerate or "Fast Track" the approval of drugs to treat specific indications. The intention is to expedite the review of drugs that are anticipated to treat serious, life-threatening conditions and that demonstrate the potential to address current unmet medical needs. Upon obtaining Fast Track designation, the sponsor of the product can be considered for a number of procedures regarding marketing applications including priority review of a product approval application.

1.3 Project Aims and Objectives

Leaders of an organization have very few levers of change. Two key levers are: setting the business strategy, and designing and managing an organization to achieve the strategy. As outlined in Figure 2 below, strategy shapes the design of an organization, which is comprised of four key constructs: structure, processes, people and partnerships. These elements act synergistically to progress the company towards realizing its vision. Therefore, all of these factors must be in alignment with each other, as well as with the business strategy. Although specific processes and technologies may be easily imitated by competitors, the interconnections of the various subcomponenents within an organization are less amenable to imitation and give rise to competitive advantage.

High technology (high tech) and biotech firms are founded on strong technological and scientific know-how. However, success of companies in the high tech and biotech space is often limited. In fact, some statistics indicate that failure rates for high tech start-up organizations can be as high as 90%[14]. Although there is a large body of research that focuses on difficulties in financing, marketing, strategic planning and R&D as factors that contribute to the demise of organizations, little information is available on the management processes[15].

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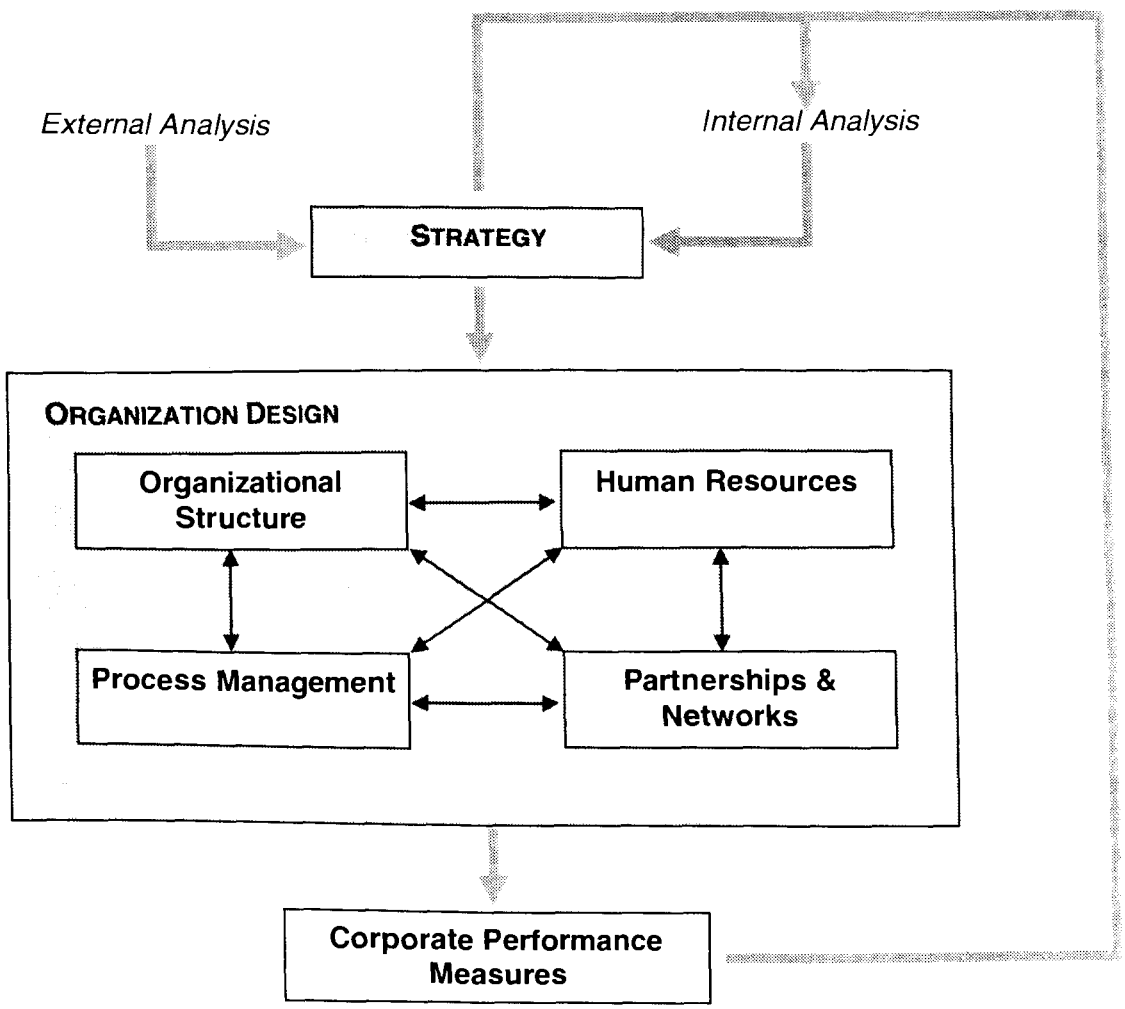
[14] University of Arkansas. Course Combines Business and Technology Education To Produce More Successful High-Tech Start-ups University of Arkansas. (http://advancement.uark.edu/news/NEWS_ARCHIVES/MAR00/failure.html) (last accessed on June 1, 2004).

[15] Tau Trends in Research. What makes a High-Tech Start-up Successful? (http://www.tau.ac.il/Research-Authority/trends/startup.html) (last accessed on May 11, 2004).

The objective of this paper is to employ a conceptual framework to examine management processes within biotech organizations. Using traditional tools and techniques, each component of organization design (organizational structure, human resources, process management, partnerships and networks) will be examined, together with strategy and corporate performance measures. This will provide a comprehensive view of the determinants of a successfully managed biotech organization. The findings of the analysis will identify specific practices and processes for early stage biotech firms to use as a point of reference in their growth and development.

Figure 2: Schematic Representation of Management Processes[16]



16 Figure adapted from Aaker, D.A. Developing Business Strategies. Wiley 6th edition, 2001.

2 METHODOLOGY

To accomplish the aims and objectives of this project, the organization design of Inex Pharmaceuticals will be examined. Inex provides an excellent model as it is one of the few companies in BC that has successfully made the transition from basic research, through development, and into commercialization. In 1998/99, the Company had to revise its strategy and restructure systems and processes to align with the new strategy. Therefore, an analysis of Inex will provide valuable insight into organization design within a small biotech firm.

To systematically evaluate Inex with respect to the framework outlined in Figure 2, a series of interviews were conducted with key members of the scientific and executive teams. Individuals within the organization were identified through a series of meetings with the Vice President (VP) of Human Resources and Information Systems at Inex. Subsequently, using theoretical material obtained from academic papers, textbooks and course work, a questionnaire was designed to address specific questions within each component of the framework. Questions were emailed to individuals prior to the interview so that expectations for the meeting were clearly understood. Each interview lasted 1-2 hours and a total of 8 individual interviews were conducted. Examples of persons interviewed include the President and Chief Executive Officer (CEO), VP of Research, Senior Director of Pharmaceutics and Director of Business Development. After completing the interviews, the data were summarized and follow-up interviews were conducted as required. In addition, reference materials (including company business plans), strategy documents and offering memoranda were used to gather

historical information about the Company as it moved through the various stages of its life cycle. Theoretical information, research and data collected from the interviews were used to prepare this report. Based on the findings, key learning points from Inex's experiences are summarized. These learning points will provide insight into the concerns that need to be addressed for the successful management of a biotech company.

3 ACADEMIC THEORY AND CONCEPTS

3.1 Strategy and the Strategic Planning Process

The strategy of an organization is the basis for all operations and administrative activities within the firm. Thus, strategic planning is an essential component of building a successful business. It is the strategy that forms the foundation of the organizational systems and design. In the case of biotech firms, since the technology is based on basic research, the strategy is often defined by the science. However, once the science has been established, an external analysis is required to confirm the market opportunity and competitive landscape.

Over the past several years the promise of strategic planning has been hampered by companies developing inadequate assumptions and the inflexibility of organizations in response to external signals[17]. The successful development, modification and implementation of strategies for organizations are based upon being able to manage change effectively.

3.1.1 The Strategic Planning Process

Basic strategic planning is focused on three key questions, which form the basis for analyzing a firms' strategy. These questions are:

[17] Rosenberg L.J. and Schewe C.D. Strategic Planning: Fulfilling the Promise. Business Horizons. July-August: 54-62, 2001.

1. Where is the firm, currently?

2. Where does the firm want to go?

3. How will the firm get there?

Where is the firm, currently?

When analyzing where the company currently is, it is important for the firm to have a mission statement and defined goals. This ensures that the firm has an overall objective that it can work towards and that it has a mechanism to track its progress. Other important questions to consider during this stage of the analysis include:

- Does the firm understand who its current customers are?
- Is the firm aware of its existing and potential competitors?
- What is the company's core business? Does it focus on R&D or Manufacturing? Is it a service provider?

Where does the firm want to go?

The second question focuses on identifying where the company wants to go. This involves an internal and external analysis. An internal analysis of the company seeks to identify the firm's strengths and weaknesses. Generally, this focuses on the firm's core capabilities and competencies. From an external point of view the company should identify opportunities and threats. The following is a list of questions to consider when conducting an external analysis:

- Are there emerging technologies that would be complementary to the firm's current technologies?
- What are the new markets that the firm could exploit?
- Is the firm aware of potential competitors in the new opportunities it is identifying?

How will the firm get there?

The third question addresses how the company is going take advantage of the new opportunities it has identified. The following questions should be considered:

- Will the firm develop novel opportunities internally, or contract them out?
- Does the firm need to acquire a company and/or license to gain rights to the novel technologies?
- Will the firm partner or collaborate to exploit the novel opportunities identified?

3.2 Human Resources

The manner in which an organization's human resources are managed has a profound impact on the effectiveness of its operations, and ultimately its success. Therefore, it is crucial that these systems are aligned with strategy, as well as the elements of organization design (organizational structure, human resources, process management, partnerships and networks). This section examines several elements of human resources (HR) management that are fundamental to ensuring effective operations within a biotech organization.

3.2.1 Culture

Culture is the adhesive component of organizations, and acts as the mechanism that guides and shapes the attitudes and behaviours of its members. The strength of a company and its culture is largely dependent upon the strength of its value system and its employees' commitment to those values. Therefore, the way in which HR management helps to develop and foster the culture of the organization – its shared values and beliefs, is of prime importance.

Over the past 10-15 years, the concept of teamwork has gained popularity within the area of operations management. Although most work has always had elements of group-based activities, the notion of teamwork assumes a shared set of objectives and responsibilities[18]. Since the biotech industry is knowledge-intensive industry that is comprised of "specialists" in various areas, completion of a single task may require the efforts of several individuals with very specific skill sets. These shared objectives tap into the unique skill sets of various members within the team. Therefore, creating an environment that emphasizes teamwork is essential to productivity within a biotech organization.

Perhaps the most important aspect of organizational culture is communication. Open communication; and an atmosphere of mutual trust, respect and responsibility are necessary for the proper development of a company's relationship with its employees.[19] Communication is especially important in the biotech industry since multiple groups must work together to develop a product. As a result, mechanisms such as regularly

[18] Daft R.L. Organizational Theory and Design. West Publishing Company, 1992.
[19] Inex Pharmaceuticals Corporation. Inex Corporate Policy Manual. Vancouver, 2002.

scheduled meetings, reports and memos should be in place to encourage communication and the sharing of information.

3.2.2 Recruitment and Selection

It is essential to technical and business success that a biotech company be able to attract, motivate and retain excellent people. The recruitment process should be designed to ensure a consistent and quality approach to hiring[20]. It is imperative that all individuals involved in the selection process are clear as to the job description and ideal candidate profile. Hiring should be based not only on finding the individual with the right combination of skills and experience, but one who is the right 'fit' with the company's culture and values.

In an industry such as biotech, current employees within an organization may be the most attuned to skills that are required within a particular department or function. Employees may be members of professional associations or have peers in the industry, or in academia. Therefore, it is important to tap into the networks of employees in order to seek out individuals with specific skill sets, rather than resting this responsibility in the hands of the HR department.

[20] Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, n.d.

3.2.3 Job Structure

The purpose of Job Structure is to provide a clear framework for two key HR system activities[21]:

1) To describe the competencies required for each position and level within the company, providing a guide for employee recruitment, development and promotion criteria.

2) To equate job groupings and roles within the company to aid in planning and managing the total compensation plan.

The first activity, and perhaps most important to the employees, defines the roles that each position within the company are to play, and illustrates the points of interface between the roles. Clarifying these roles early on puts them in contention with each other and manages expectations of job description. The second serves to equate different job families within an organization. In an industry such as biotech, it seeks to ease the disparity between the "scientific staff" and the "business staff" in order to create a sense of equity.

3.2.4 Objective Setting and Performance Management

Elements such as objective setting and performance management determine employees' expectations of what is required of them and influences their perceptions of how they contribute to the organization.

[21] Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, 2002.

Implementing a management by objectives (MBO) program will convert overall organizational goals into specific, more achievable objectives for each department and/or individual. There are four ingredients common to MBO programs: 1) goal specificity, 2) participative decision-making, 3) a defined time period, 4) feedback on performance. Goals must be tangible and measurable, and acceptance is more likely when the goal-setting process is participative. The fulfilment of each objective has an assigned time period, during which continuous feedback is provided.

3.2.5 Recognition and Rewards

Recognition and rewards link the metrics that define organizational success, with individual contribution. In addition, these systems should serve to encourage behaviours that are in line with the company's culture and its values. This section will examine how biotech companies should determine base and variable compensation and how rewards and recognition reinforce corporate culture.

3.3 Organizational Structure

The structure of an organization defines lines of authority and communication and specifies the mechanism by which tasks and processes are accomplished[22]. Therefore, it refers to the way in which people and processes are grouped into defined units. Grouping activities and positions into organizational units establishes common focus by creating standard processes, coordinating mechanisms, providing access to information and establishing a common chain of command. Finally, organizational structure that is in line with the business strategy facilitates the efficient use of resources.

[22] Aaker, D.A. Developing Business Strategies. Wiley 6th edition, 2001.

There are many factors that influence the configuration within an organization. These factors can be categorized as *structural elements* or *situational elements*. *Structural elements* include: job specialization, formalization of processes, training, grouping of units within the organization, span of control of managers, planning and control systems, liaison devices and centralization of authority[23]. *Situational factors* include: age of the company/stage of maturity, size, environment, and power systems (how tightly the organization is controlled externally).

All organizations function within an environment that is somewhat unique. Thus, understanding the nature of an organization's environment becomes imperative. Depending upon the complexity of their environments and the pace of change, firms should adopt different structures.

Companies within the biotech industry exist in dynamic environments – scientific advances continually give rise to new competitors and regulatory authorities are constantly tightening policies. Furthermore, a structure that fosters an environment for innovation is crucial to the success and competitiveness of a biotech firm. As a result, biotech firms require a different organizational structure to survive, when compared with firms that operate in simple and slow-paced environments.

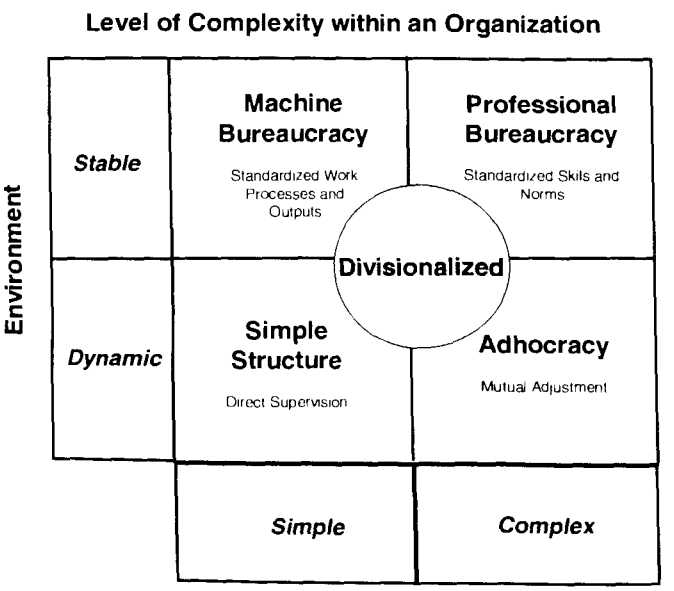
When designing an organization that is based on innovation, it must be both competitive and sustainable. Competitive, for biotech firms, refers to an organization that is effective and efficient, relying on innovation to maintain competitive advantage. Sustainable refers

[23] Mintzberg, H Organization Design: Fashion or Fit? Harvard Business Review. Jan-Feb: 1-16, 1981.

to an organization that is able to adapt to the complex and dynamic environment in which the biotech industry operates. Future growth for companies in dynamic environments can never be predicted with certainty. Consequently, biotech organizations must be organic, reconfigurable and able to recognize and respond to change rapidly. Such organizations are in anticipation of ongoing change and are able to evolve in response to the environment.

Henry Mintzberg identified five organizational configurations, based on the level of complexity within an organization and the environment in which a firm operates. These include: 1) Simple structure 2) Machine bureaucracy 3) Professional bureaucracy 4) Divisionalized form and 5) Adhocracy (See Figure 3). However, it is important to note that these configurations are "idealized" and that many firms exist as hybrids of the aforementioned configurations.

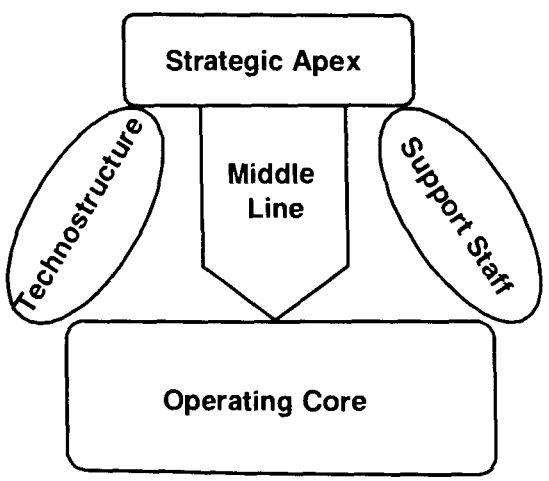
Figure 3: Environmental determinants of organizational structure[24]



[24] Figure adapted from Beshears F. Mintzberg's Taxonomy of Organizational Forms. http://ist-socrates.berkeley.edu/~fmb/articles/mintzberg/) (last accessed on June 12, 2004).

Within each of the five configurations, there are several basic components or subunits (Figure 4). The *strategic apex* consists of the President and CEO working with the Executive Committee and the Board of Directors. The essential functions of the company, such as Research, Clinical and Regulatory Affairs, and Commercial Operations are carried out in the *operating core*. The *middle line* is formed by middle managers, necessary as a company grows in size, and can be found dispersed amongst the various departments throughout the organization. To the left of the middle line is the *technostructure*, consisting of analysts who plan and control the flow of activities, such as Project Management. Finally, to the right of the midline is the *support staff*, which would consist of departments such as: Human Resources and Information Systems; Investor Relations and Corporate Communications, and Finance.

Figure 4: Basic Components of the Organization[25]



[25] Figure adapted from Mintzberg, H *Organization Design: Fashion or Fit?* Harvard Business Review Jan-Feb 1981

The simple structure is most often adopted by young start-up companies or entrepreneurships. This type of organization is very lean and there is little in the way of support staff and technostructure. In the simple structure, the managers in the strategic apex directly supervise the coordination of work. Little of the behaviour within this type of organization is formalized in any way.

In a machine bureaucracy, procedures and output are heavily standardized by its technocracy. The work of this type of organization is found in simple and stable environments (Figure 3), and is typical of mass production companies. Efficiency is a key goal, and is the focus of the middle line managers. Because of the requirement for stable environments, machine bureaucracies tend to be more vertically integrated than other organizational structures.

Where the machine bureaucracy relies heavily on standardization of procedures and outputs, the professional bureaucracy relies instead on the standardization of *skills* of highly trained specialists within the operating core. These employees have considerable autonomy in their work, and often belong to professional associations external to the company in which they are employed. This type of organization will typically have a large operating core and support staff, but will not require an extensive technostructure. Power tends to be decentralized, with decision-making authority extending throughout the organization.

The divisionalized arrangement consists of independent entities in the middle line of an organization. Each of these divisions is semi-autonomous in nature, and performance is

measured on the basis of output. This structure is most often seen within large organizations with a diversified product line.

The final form of organizational design described by Henry Mintzberg is that of the adhocracy. This is not a pure form, but rather one that has developed out of a need to incorporate certain aspects of the other forms. This form is preferred for innovative organizations that would otherwise be stifled by the constraints of the machine and purely professional bureaucracies, but could not operate under the direct supervision of the simple structure. In this form, there are interacting project teams operating within a dynamic and complex environment. In an adhocracy, there are many skilled employees. However, unlike the professional bureaucracy, which relies on the standardization of those skills, the adhocracy encourages the existing skill set as a base and a stepping stone upon which to build further knowledge, and to freely innovate. An adhocracy can be further broken down into two types: the operating adhocracy and the administrative adhocracy. The distinction between the two is that the operating adhocracy will innovate and solve problems directly on behalf of its clients (project planning and execution are not separated), whereas the administrative adhocracy innovates to serve its own needs.

3.4 Process Management

A value chain refers to the "series of value-generating activities"[26] performed by companies in a given industry. However, individual companies in an industry may participate in the value chain to varying degrees, depending upon their size, strategy and stage of maturity. Ideally, companies perform only the activities that give them a competitive advantage in producing their product (or delivering a service). Similarly, all

[26] NetMBA. www.netmba.com/strategy/value-chain/ (last accessed on June 15, 2004).

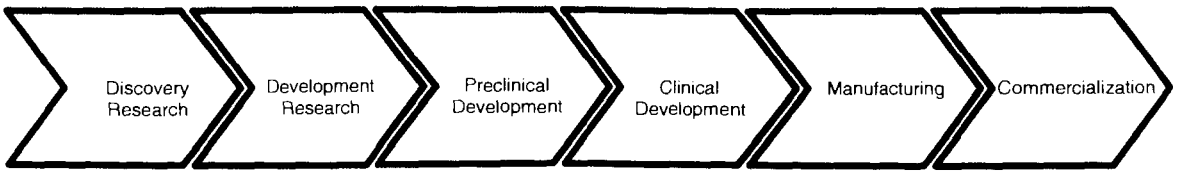
other activities performed by the company should be in support of its primary activities. A value chain analysis is an evaluation of whether a company's present and planned activities support its business strategy.

The biotech industry value chain is depicted in Figure 5. Value is added to drug candidates as they progress through each stage of the value chain towards successful commercialization. It is important to note that this value chain is a simplified modular representation with an array of activities within each module. Therefore, each activity shown in Figure 5 consists of many components, which together, make it possible to realize the potential value of that particular segment of the value chain.

Traditionally, biotech companies have partnered with large pharmaceutical companies (large pharma) in order to capture its strengths and expertise at the tail-end of the value chain (i.e. clinical development, manufacturing, and marketing). However, this model is now shifting as biotech companies are increasingly searching to establish the full value chain, internally[27]. The ensuing discussion gives a brief background on each activity within the biotech industry value chain.

[27] Berg C, Nassr R and Pang K. The evolution of biotech. Nature.1: 845-846, 2002.

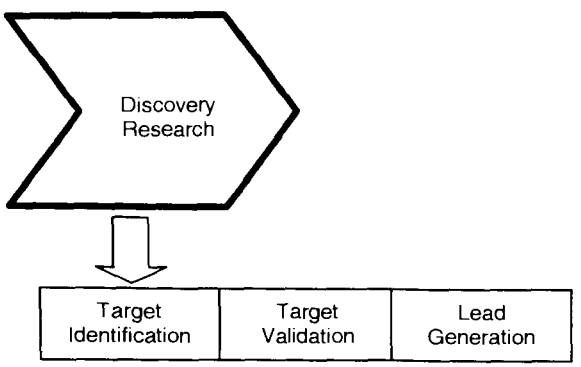
Figure 5: The Biotechnology Industry Value Chain[28]



3.4.1 Primary Activities

3.4.1.1 Discovery Research

Figure 6: Schematic Representation of activities within Discovery Research[29]



Basic science research, which is an endeavour simply of exploration and characterization, is the most common source for the identification of compounds (targets) that have the theoretical potential for therapeutic use. It is common in the biotech industry for target identification to occur in an academic institution. Since academic institutions consider it beyond their scope to develop competencies along the subsequent modules of the value chain necessary to realize the potential of the targets they routinely identify, it has become commonplace for a university to license the technology relating to the target they have identified. This is an interesting feature of the biotech industry model, because the initial module of the value chain in this industry –

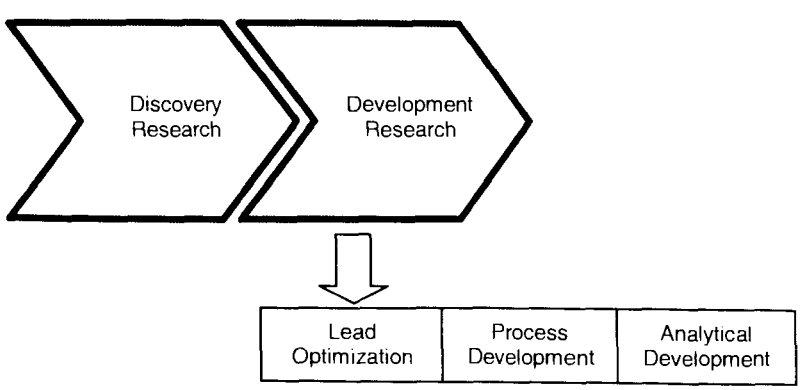
[28] Figure created by authors (Zahra Dhanji and Parimal Nathwani)
[29] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

Discovery Research, begins as a harvesting process that results in the in-licensing of promising therapeutic entities.

A degree of target validation occurs prior to the transfer of the technology, often involving basic, but critical, proof of principle studies. Thereafter, the biotech company typically drives the target validation with expanded research characterizing the performance of the target as a therapeutic entity. This process involves *in vitro* work to facilitate rapid screening of numerous variables associated with the activity of the compound, as well as *in vivo* work to elucidate the effects of the target in living systems, and in specific disease models. The expanded research during this phase culminates in the generation of a lead compound that has validated therapeutic potential (Figure 6).

3.4.1.2 Development Research

Figure 7: Schematic Representation of Activities within Development Research[30]



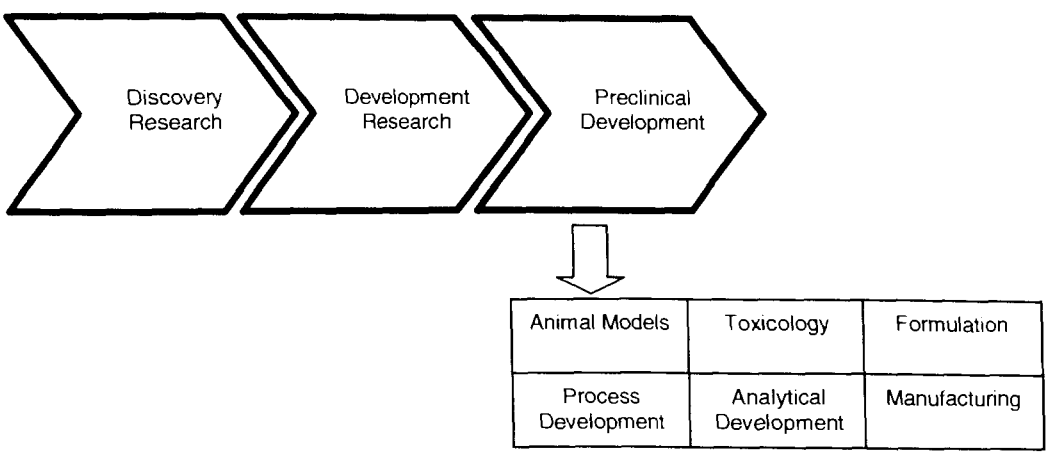
[30] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

Development Research consists of a wide range of activities from evaluating and optimizing the lead compound, through to devising more convenient formulations. The metabolic profile, safety and efficacy of compounds are evaluated in laboratory animals.

At this stage, the increasing supply requirements of the drug candidate necessitate the involvement of Process Development in order to scale-up manufacturing methods. Further, the involvement of Analytical Development is critical in order to establish highly reproducible and FDA-"validate-able" techniques for all aspects of testing and manufacturing (Figure 7). Establishing these reproducible techniques is essential in order to move a drug into human trials.

3.4.1.3 Preclinical Development

Figure 8: Schematic representation of activities within Preclinical Development[31]



Preclinical Development is an extension and formalization of the testing that is carried out in the Development Research phase (Figure 8). Animal studies are expanded into multiple animal species and multiple disease models. These models will serve to assess the bioavailability and pharmacokinetics of potential drugs and will provide an indication

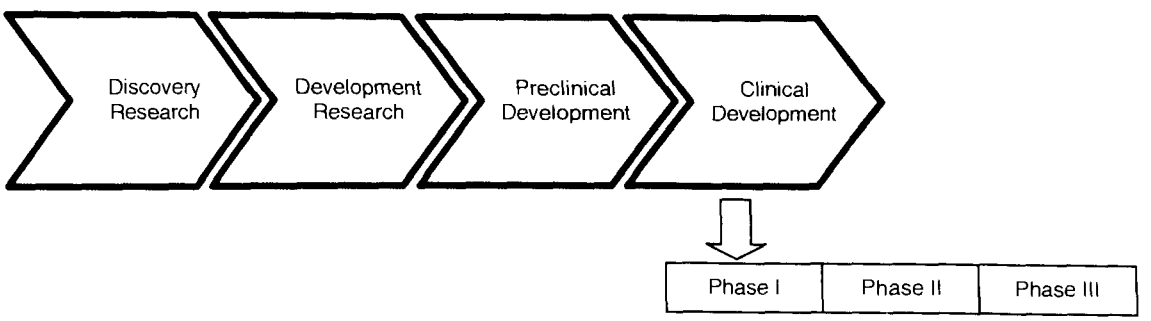
[31] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

as to the most promising therapeutic area. Toxicology studies must be performed at a GLP level of compliance.

Preclinical development researchers also investigate dosage form (e.g. tablet, inhaled, intravenous) and develop formulations to enhance the drug's effectiveness. Processes and supporting analytical methods for drug synthesis and formulation are refined, ultimately leading to the technical transfer of the processes and methods to Manufacturing. Manufacturing is then entrusted with synthesizing the clinical batches (i.e. drug that will be used in human clinical trials).

3.4.1.4 Clinical Development

Figure 9: Schematic representation of activities within Clinical Development[32]



Clinical development (Figure 9) is an area that is highly regulated by external authorities. Scientists and physicians design and execute clinical trials which may involve hundreds to thousands of patients. It requires the testing of a drug, in human subjects, to confirm safety and efficacy. Data are collected, analyzed and summarized to demonstrate the therapeutic activity and characterize the various effects of the drug candidate, and to compile the regulatory dossiers necessary to gain approval.

[32] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

This stage of the biotech value chain is one that is subject to immense scrutiny by all stakeholders of a company, as it is the "make it or break it" stage in the drug development process. Each regulatory hurdle that is overcome translates into reduced risk and greater probability of success. Consequently, successful progression through these phases results in a substantial increase in the value of a drug candidate. Conversely, failure at any of these stages can be detrimental and can destroy value that was created in preceding stages of drug development.

3.4.1.5 Manufacturing

Once the NDA has been approved by the FDA, the company must be able to manufacture the product on a commercial scale for sale and distribution. The manufacturing process is regulated by good manufacturing practices (GMP) and manufacturing facilities are audited by the FDA. In general, most companies will contract out manufacturing services rather than build internal capabilities due to the significant cost of drug manufacturing plants, especially if the company only has a couple of products on the market.

3.4.1.6 Commercialization

Commercialization of the drug allows the company to generate a revenue stream from sale of the product. However, given that the drug development process can take from 12-15 years, and patent protection only lasts for 20 years, the company only has a limited number of years to recover its costs and make a profit before patent expiration. Simply stated, commercialization involves building a sales force, establishing distribution channels and setting up a marketing department to promote the product. However, due to the significant cost and expertise that is required for commercialization, smaller

companies typically forge strategic alliances with larger pharmaceutical partners who have a large marketing muscle, established distribution channels and vast sales forces.

3.4.2 Supportive Activities

In the case of biotech companies, the primary activities consist of those discussed in the industry value chain, to varying degrees. However, supportive activities also play a crucial role in facilitating the primary activities and complement the companies' strategies. Supportive functions may include 1) A multi-disciplined management team 2) Boards and Consultants 3) Legal 4) Business Development 5) Marketing 6) Finance & Accounting 7) Human Resources Management 8) Information technology (IT) development and 10) Procurement of supplies.

3.5 Strategic Partnerships and Networks

Partnerships and networks can be extremely valuable to firms as they can provide capabilities that do not exist internally within a firm. This is especially true for smaller organizations that have limited internal resources. When performance gaps associated with core capabilities have been identified within an organization, partnerships may be a viable option to fill these gaps.

As outlined in the Figure 10, organizations can enter into various types of relationships. However, it is important to note that not all relationships should result in partnerships. In fact, partnerships should be driven by the firms' strategy and capabilities[33].

[33] Blumberg L. How to engage in a Strategic Outsourcing Relationship. Pharmaceutical Technology North America. 26: 74-80, 2002.

Figure 10: A Continuum of the Types of Relationships Between Organizations[34]

Forming partnerships is a time consuming and expensive process. As a result, it is extremely important that prior to entering into negotiations, firms should have a clear understanding of the partnering objectives and expectations. Moreover, once partnerships have been formed, managing the relationship appropriately is crucial to ensure their longevity. One study indicated that out of 50 alliances studied, only 50% of the relationships between large and small firms within the high tech sector lasted more then 4 years[35]. Therefore, an accurate evaluation of strengths and weaknesses of firms entering into a partnership is required to ensure that the objectives are met.

When considering whether or not to partner, organizations should consider if there will be an expected benefit from the partnership. More specifically, an analysis of the partnership drivers should be conducted by asking the following questions[36]:

Will the partnership provide improvement in the firm's assets and cost efficiencies?

- Will there be a marketing advantage from the partnership?

Does the partnership provide an opportunity for increased profits and growth?

- Will the partnership provide improved customer service?

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[34] Figure adapted from Business 759 Lecture 9, Ian McCarthy, Simon Fraser University, 2003.
35 Slowinski G. The Human Touch in Successful Strategic Alliances. Mergers and Acquisitions. 27: 44-48, 1992.
36 Gardner J.T., Lambert D.M., Emmelhainz MA. Partnership Facilitators Guide: Developing and Implementing Successful Partnerships in Supply Chain. International Center for Competitive Intelligence, 2002.

Once the decision to partner has been made, based upon the driver analysis, firms should identify potential partners and conduct a facilitator analysis. Facilitators are factors that increase the potential for a successful partnership. The following factors should be considered in a facilitator analysis:

- Will the firms involved in the partnership have corporate compatibility? Are the firms' cultures similar?
- Are the management philosophies between the two firms going to mix?
- Does the partnership benefit both sides?
- Are the firms comparable with respect to size, productivity, financial strength etc.?
- Is the relationship exclusive?
- Are both firms in similar time zones and geographic locations?

It is important to note that not all of the questions mentioned above must be addressed, but the more facilitators there are, the greater the likelihood of success for the partnership.

Partnerships are extremely important for biotech organizations. Early stage biotech companies will try to negotiate joint ventures, or Phase II or III partnerships, to mitigate risk. Early stage biotech companies do not have any products, and as a result there is always a push to market. Since the drug development process is very risky and extremely expensive, partnerships or joint ventures that minimize the risk for a small biotech organization are desired. However, as the company becomes more mature and

has multiple products in development, the biotech company will take on more risk by negotiating deals that allow for more control of the final product. Thus, the type of partnerships that biotech organizations enter into depends on the stage of the firm's lifecycle.

Most biotech organizations will negotiate partnerships with pharmaceutical companies for mid to late stage development activities (i.e. Phase II or III clinical trials), sales and marketing. In this scenario, the drivers for a partnership are clearly favourable. For example, the partnership will allow for profit and growth since small biotech companies do not have core competencies in late stage trials, sales or marketing. The marketing advantage is not only for the product, but the partnership with a large pharmaceutical company also provides credibility to the biotech organization. In addition, the partnership will provide the biotech company with access to the large pharmaceutical company's distribution channels, thereby being able to reach the end user (i.e. patients or doctors) more effectively.

In the case of a biotech-pharmaceutical partnership, the partnership facilitators are more difficult to satisfy than the drivers. Generally, large pharmaceutical companies have different corporate cultures, management styles, size and financial strength. However, one very important facilitator is the fact that the partnership is mutually beneficial. As discussed previously, the partnership provides a small biotech organization with the access to resources and systems that it does not have internally. By the same token, the partnership also benefits the pharmaceutical company as it provides the firm with access to clinical candidates, especially since large pharmaceutical companies' internal product pipelines are drying up.

3.6 Corporate Performance Measures

Once the strategy has been devised and implemented, mechanisms must be in place to monitor strategy and confirm its effectiveness. In fact, effective strategy measurement is a vital element of management processes[37]. In the past, financial measures such as profits, stock price and earnings per share (EPS) have been used to measure successful strategy implementation. Although these measures were sufficient for the industrial era, companies today are much more knowledge-intensive and derive much of their value from intangible skills, processes, and patents. "A*s little as one third of a company's stock market value is based upon hard asset value. The growing share lies in soft attributes (i.e. patents, processes, and customer/employee satisfaction).*"[38] Therefore, it is becoming increasingly important for managers to assess other aspects of performance to account for "value-creating" activities.

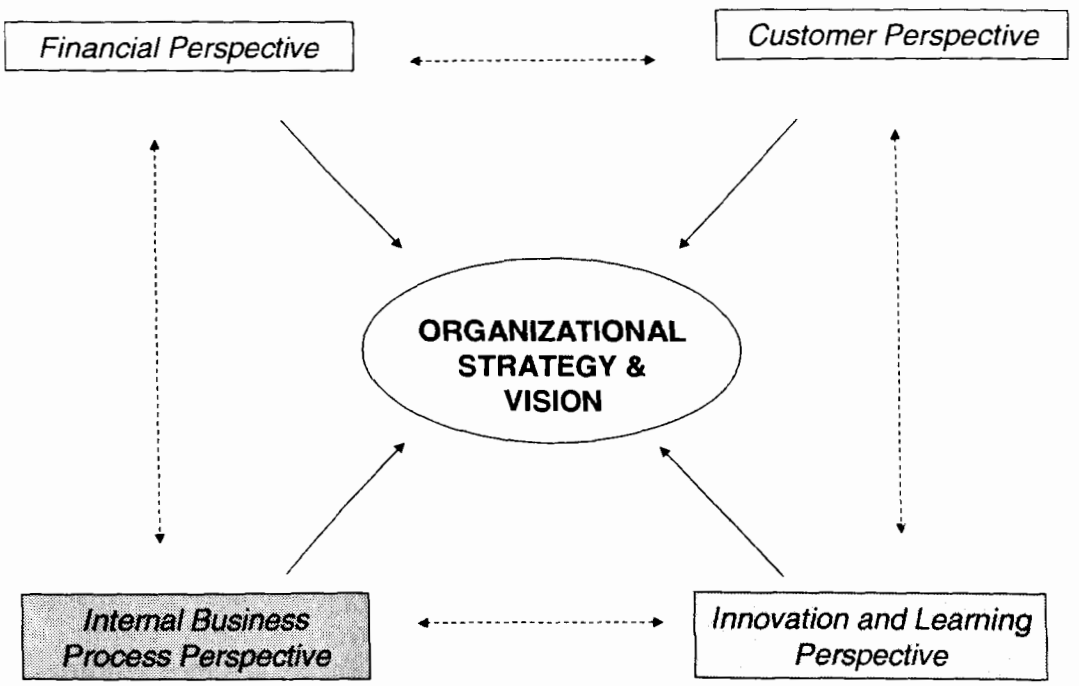
Young biotech firms are no exception. They are not profitable and have volatile stock prices. Furthermore, the bulk of their assets are "soft" or intangible and competencies lie in scientific know-how, in the form of patents and processes. As a result, financial measures alone can be misleading when attempting to measure the effectiveness of strategy implementation.

The balanced score card (BSC) is a tool introduced by Drs. Kaplan and Norton in 1992. The BSC puts strategy at the center and provides managers with a comprehensive view of the organization from four perspectives: customer, financial, internal business

[37] Kaplan R.S. and Norton D.P. Putting the Balanced Scorecard to Work. Harvard Business Review. September-October: 134-142, 1993.
[38] Financial Sense Online. www.financialsense.com/stormwatch/oldupdates/2001/110901.htm (last accessed on June 15, 2004).

processes, innovation & learning (See Figure 11) [39]. Within each of these areas, one can identify key performance indicators for the organization to monitor. In fact, the BSC is used to translate corporate strategy into performance measures that can guide operational plans. This provides managers with a balanced view of both financial and operational measures relating to a company's critical success factors. Furthermore, it helps managers to understand their interrelationships in order to transcend functional barriers, ultimately leading to improved decision-making and problem-solving[40].

Figure 11: Schematic Representation of the Balanced Scorecard[41]



[39]Kaplan R.S. and Norton D.P. The Balanced Scorecard-Measures that Drive Performance. Harvard Business Review. January-February: 71-79, 1992.

[40] Kaplan R.S. and Norton D.P. Putting the Balanced Scorecard to Work. Harvard Business Review. September-October: 134-142, 1993.

[41] Figure adapted from Kaplan R.S. and Norton D.P. The Balanced Scorecard-Measures that Drive Performance. Harvard Business Review. January-February: 71-79, 1992.

3.6.1 Financial Perspective

The financial perspective is the most conventional perspective and measures the impact of the company's strategy, implementation and execution on the bottom line. Depending upon the company, financial measures can be very detailed. However, as mentioned in the preceding discussion, the financial perspective alone is not a good performance measure for the corporation. This perspective aims to address the question: How do we look to shareholders?[42]

3.6.2 Customer Perspective

All companies are producing a product or service that is targeted towards customers. As a result, customer service is a major component of all businesses. Concerns for the customer revolve around time, quality, performance and service. As a result, the customer perspective of the balanced scorecard should articulate performance measures which take these concerns into consideration. Therefore, the customer perspective should address the question: How do customers see us?[43]

3.6.3 Internal Business Process Perspective

The internal business perspective focuses on what the company must accomplish internally to satisfy its customers. These processes are often referred to as the core competencies of the firm. However, as the organization grows, or customers' needs change, the company must build a new internal infrastructure and modify its processes accordingly. Thus, measures in this category are derived from business processes that influence the customer and include measures such as productivity, product quality and

[42] Kaplan R.S. and Norton D.P. The Balanced Scorecard-Measures that Drive Performance. Harvard Business Review. January-February: 71-79, 1992.
[43] ibid

employee skills. Overall, this perspective should address the question: What processes and competencies should our firm excel at?[44]

3.6.4 Innovation and Learning Perspective

With new technologies and pressures from the market, it is extremely important for technology firms to constantly learn and improve processes. This is especially true since firms must be able to launch new products, create value for their shareholders and improve operating efficiencies. However, innovation and learning is not limited to new products; it also applies to existing products. The innovation and learning perspective seeks to answer the question: What improvements to products and processes can be made?[45]

It is extremely important for firms to have a BSC to ensure that: 1) all internal processes are aligned with the strategy 2) firms are able to monitor their progress and 3) firms are able to learn from past mistakes.

[44] ibid
[45] ibid

4 CASE STUDY: INEX PHARMACEUTICALS

4.1 Company History and Background

Inex Pharmaceuticals Corporation is a Vancouver-based biopharmaceutical company that was originally founded under the name Lipex Pharmaceuticals in 1992. Shortly thereafter, the Company changed its name to Inex Pharmaceuticals (Inex). The business strategy for the organization had been to utilize approved chemotherapeutic agents and enhance them with Company's proprietary drug delivery systems to develop and commercialize therapies for the treatment of cancer. Inex has two technology platforms: 1) Targeted chemotherapy for oncology applications and 2) Targeted Immunotherapy to stimulate immune responses towards cancer and infectious disease. The Company has filed an NDA for its lead product, Vincristine Liposomal Sulfate Injection (VSLI), with the FDA for relapsed aggressive non-Hodgkin's lymphoma (NHL). Inex is a publicly traded company with operational competencies in Research, Regulatory Affairs, Manufacturing and Clinical Development. The organization has also developed strategic partnerships for its key programs to facilitate further R&D and commercialization activities.

4.2 Core Products and Technology

Inex's core technology focuses around liposomal drug delivery technology for oncology applications. Existing treatment strategies administer chemotherapeutic drugs intravenously as free molecules which distribute to all regions of the patient's body, leading to substantial systemic toxicity, and limiting the dose that can be administered to the patient. Encapsulation of conventional chemotherapeutic agents in a lipid envelope targeted preferentially to the tumour site ameliorates the toxicity induced by the free

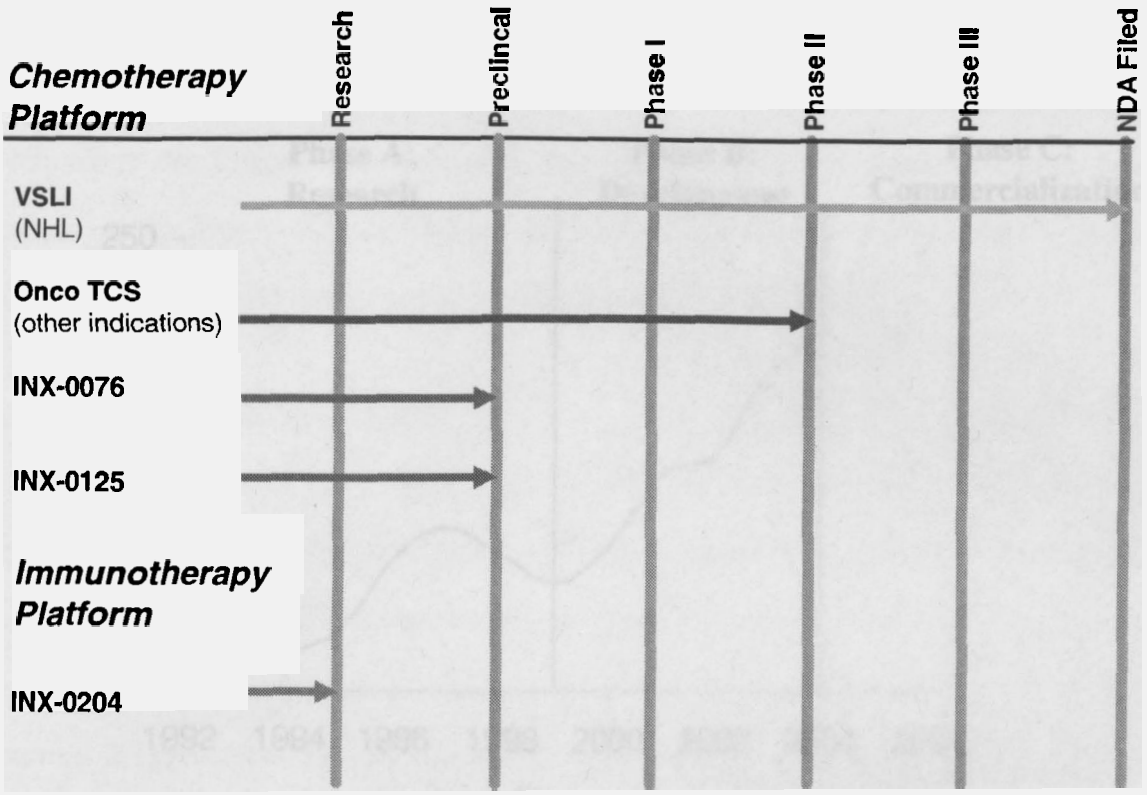
chemotherapeutic drug, and thereby permits dosing at a higher level for that patient. The Company's technology platform facilitates loading of high concentrations of chemotherapeutic agents into lipid vesicles that are targeted towards the tumour. This not only allows for targeted delivery, but also allows for more of the active agent to be delivered to the tumour site thereby increasing efficacy while reducing toxicity. Thus, encapsulation of conventional chemotherapeutic drugs, which have a well-characterized safety and efficacy profile in humans, with a proprietary drug delivery technology represents a low risk near-term commercialization strategy for the organization.

The Company's lead product, VSLI, is comprised of off-patent anti-cancer drug, Vincristine, encapsulated in a proprietary liposomal formulation for the treatment of NHL. Inex completed pivotal clinical trials in June 2003 for VSLI and has filed an NDA with the FDA. The Company anticipates a decision from the FDA in Q1 2005. In preparation for approval, the Company has setup a strategic partnership with Enzon Pharmaceuticals to commercialize VSLI. In addition, VSLI is being evaluated in Phase II clinical trials in combination with other agents as part of a first line treatment for aggressive NHL. Seeking FDA approval for relapsed aggressive NHL was a strategic decision intended to facilitate fast-track approval of the drug. However, it was anticipated that, once approved, off-label use of the drug by physicians in first line NHL, and perhaps in other indications, would represent a much greater patient population and be the primary profit generating opportunity. The efficacy of VSLI in other indications such as small cell lung cancer, Hodgkin's disease, acute lymphoblastic leukaemia and paediatric malignancies is also being tested to expand the market opportunity.

In addition to VSLI, the Company also has two other lipid encapsulated technologies for its chemotherapeutic platform. INX-0076 is lipid encapsulated topotecan hydrochloride and is being developed in partnership with GlaxoSmithKline. The conventional topotecan hydrochloride (trade name Hycamtin) has been approved for the treatment of recurrent ovarian cancer and small lung cancer. The liposomal formulation of Hycamtin is ready to enter Phase I clinical trials. The third lipid encapsulated anticancer agent to be developed as part of Inex's targeted chemotherapy platform is INX-0125. The active ingredient in INX-0125 is the off patent anti-cancer drug Vinorelbine. The conventional chemotherapeutic properties of Vinorelbine are used to treat breast and non-small cell lung cancer. The lipid formulation of Vinorelbine (INX-0125) is being developed by Inex and is at the preclinical stage.

In addition to the Targeted Chemotherapy platform, Inex is also developing a Targeted Immunotherapy platform using its proprietary lipid delivery system. The product INX-0204 (formerly known as OligoVax) is a lipid encapsulated oligonucleotide compound with disease specific antigens. This compound can elicit an immune response and help stimulate the body's immune system to treat conditions such as cancer and infectious diseases. INX-0204 has shown promising results in various models and is in research phase (see Figure 12 for summary of Inex's product pipeline).

Figure 12: Inex Pharmaceuticals' Drug Development Pipeline[46]

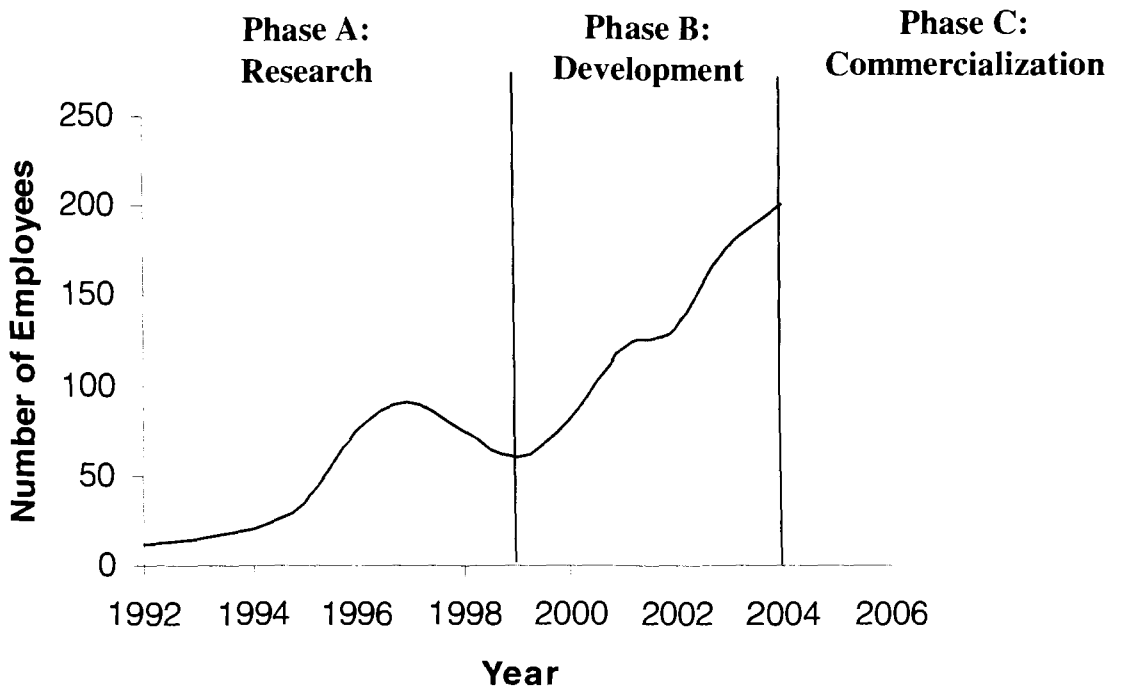


4.3 Key Transition points in the Company's Life Cycle

Since its inception in 1992, Inex has undergone significant change as it has developed its products from early stage research into development. Today, the Company is on the verge of another transition as it prepares for commercialization of its first product. In order to systematically evaluate the Company, three distinct phases have been identified as outlined below (See Figure 13). These three phases generally represent the transition points for most biotech firms (i.e. Research, Development and Commercialization). Using the framework discussed in the introduction, an analysis will be conducted for each phase of the Company's growth to obtain an understanding of how systems and processes evolved as Inex progressed through various stages of its life cycle.

[46] Figure adapted from Inex Pharmaceuticals' website (www.inexpharm.com) (last accessed June 13, 2004).

Figure 13: Schematic Representation of Phases in Inex Pharmaceuticals' Life Cycle[47]



4.3.1 Phase A: Research

The first phase spans the period from 1992-1999, during which time Inex was a research-based biopharmaceutical company. In fact, the early stages of the Company focused on developing drug delivery platforms to deliver many different types of therapeutics including DNA for gene therapy, antisense oligonucleotides, proteins & enzymes and traditional pharmaceuticals. The Company had active programs in disease areas such as oncology, metabolic disorders, cardiovascular, antibacterial agents and inflammatory disease.

[47] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

As the Company developed its technology, it was clear that too many programs across the technology platform were being pursued and not enough resources were being focused on core programs. As a result, in 1998/99, Inex spun out its gene therapy technology into Protiva Biotherapeutics, a subsidiary company focused on using lipid delivery technology to delivery DNA and plasmids for gene therapy. Inex then decided to focus its resources on further development of its lead product, VSLI.

4.3.2 Phase B: Development

The second phase of the Company spans from 1999-2004, during which time Inex forward integrated to add later stage development capabilities including manufacturing and later stage clinical development. For a company that was focused on research, expanding drug development capabilities was a major task that required significant internal infrastructure. Key developments during this time were: the formation of a strategic partnership with Elan Pharmaceuticals as a development partner for VSLI, completion of pivotal clinical trials for VSLI, reacquisition of Elan's interest in VSLI due to Elan's refocus, and expansion of the clinical pipeline.

4.3.3 Phase C: Commercialization

The Company is currently on the cusp of its third phase of growth. With the NDA for its first product submitted, Inex is preparing to commercialize its first product with its strategic partner Enzon Pharmaceuticals. Under the terms of the agreement, Enzon Pharmaceuticals will commercialize VSLI in North America for all indications in exchange for upfront, & milestone payments along with a certain percentage of sales revenue. In addition, Inex can develop a sales force in North America to complement Enzon's sales force in a co-promotion agreement. As a result, Inex will integrate forward

and build internal infrastructure into the commercialization component of the industry value chain.

5 PHASE A: RESEARCH

5.1 Strategy

During the first few years after inception, Inex was a small biotech organization that was founded on a drug delivery technology. Initially, the Company's main focus was on using its delivery technology for gene therapy. However, Inex also had projects in antisense and conventional therapies. As a start-up organization trying to mitigate risk, Inex had gene therapy projects in multiple therapeutic areas. This resulted in the organization's resources being spread too thin and not enough focus on any one project. In addition, during the early stages, the Company strategy was driven by the science and internal capabilities. Not a lot of resources were dedicated to actively "crafting and implementing" strategy. As a result, the Company did not have formal strategy development processes in place.

The Company's strategy was based on an enabling technology that facilitated the employment of a differentiation strategy and yielded a competitive advantage for the firm. Internal organizational capabilities were built on basic research and facilities were designed to include standard laboratory equipment found in most academic labs. In addition, the Company employed research scientists and technicians from academic settings, thereby fostering a culture of innovation. Examples of some basic research capabilities included: 1) Molecular biology tools to manipulate DNA and plasmids 2) *in vitro* cell biology tools to validate technology and 3) i*n vivo* animal testing to confirm *in vitro* data. Although there were clinical trial capabilities with the organization during

Phase A, most of these activities were contracted out or carried out in conjunction with a strategic partner.

Externally, Inex was aware of its competitors in the field of gene therapy. However, since the biotech industry is fragmented and there are 200 diseases[48] currently targeted by companies, direct competition is often not a major concern. In the case of Inex Pharmaceuticals, major competitors in the area of gene therapy included GeneMedicine Inc, GeneVec Inc, Megabios Inc and Vical Inc. However, due to Inex's proprietary lipid drug delivery technology, there are no direct competitors in each segment of its business.

Since the Company was based on an enabling technology, to develop a product Inex had to license, collaborate or acquire genes to combine with its technology. Identifying genes internally would be a time consuming and risky process, and as a result Inex had to build relationships to realize its strategy of developing targeted gene therapeutics.

5.2 Human Resources

5.2.1 Culture

At inception, and for several years into the Company's growth, the culture was informal and entrepreneurial. Although this sounds appealing, in retrospect, this culture led to a lack of focus as researchers pursued multiple opportunities. The Company had neither established, nor communicated its core values to employees. Therefore, each division of the Company acted as an independent entity, not cooperating or seeking the expertise of other departments. As discussed in section 5.1, three research divisions evolved

[48] Harp, D. Introduction to Biotechnology. Deutsche Bank, June 2002.

within a fairly small company. Due the attention that the field had been receiving, both in the scientific world as well as in the media, the Gene Therapy division received the most resources as investors looked favourably upon this area. It is important to note that scientifically, this division was not producing immediate results because the hype of the field had exaggerated the scientific plausibility, in the near term. This created division amongst employees and the realization that there would be a shortage of resources. Consequently, there was competition for limited resources, thereby leading to infighting.

In 1999, Inex was forced to focus its resources and scale back the Gene Therapy program. With this shift in strategy, the Company was forced to lay off 25% its staff. Naturally, in downsizing, the remaining employees felt threatened and there was tremendous mistrust of management. This presented significant challenges as Inex embarked upon the next phase of its growth.

5.2.2 Recruitment and Selection

Although there were no formal procedures and practices in place for the recruitment and selection of employees, the analysis revealed some trends in how staffing was accomplished. The majority of scientists originated as post-doctoral fellows in the VP R&D's University of British Columbia (UBC) lab. On the business side, the Company benefited from skilled personnel at QLT – a more developed, local biotech company. Due to the relative maturity of QLT compared to Inex, these individuals had survived many of the same challenges that Inex was facing. They had the experience to understand what a company at Inex's stage of maturity needed, and how the Company had to adapt in order to meet these challenges. Therefore, knowledge spill over from the

local cluster, specifically from QLT and UBC, was instrumental in building Inex during its early stages.

5.2.3 Job Structure

At this phase of Inex's development, the Company had only addressed the first aspect of Job Structure as discussed in section 3.2 on Human Resources – Academic Theory and Concepts (i.e. to describe the competencies required for each position and level within the Company, providing a guide for employee recruitment, development and promotion criteria). As such, the Company had successfully outlined detailed job descriptions (major duties and responsibilities and qualifications) and classifications in the areas of Research & Preclinical Development, Development, and Corporate Services by the end of Phase A.

What remained unclear, however, was how the positions across the different areas were related and what their impact was in terms of compensation. Questions such as, "If I'm a scientist, am I more or less important than a manager? How does that impact my compensation?" arose and continued to perplex the culture within the organization. The advent of such attitudes was likely a result of the downsizing and was contributing to the lack of morale within the Company. Clearly, this was an area that needed to be addressed in order to establish equity between the different areas of the organization.

5.2.4 Objective Setting and Performance Management

During the first few years of Inex's growth, survival was at the forefront. Therefore, the Company-wide objectives were financially motivated – i.e. "get the data, so we can get the money". Towards the end of Phase A, objectives were set quarterly, but remained at the corporate level. The objectives could not be cascaded to the individual level due to

the instability within the Company and its shifting strategy and therefore, shifting objectives.

Performance Management was a formality more so than a formalized process, particularly in the earlier years. To some extent, this can be attributed to the lack of a unified site for the Company's operations. The science was being conducted at UBC, and the business and administrative side was managed off-campus. This disconnection made performance management an arduous task as the two sides of the Company had very different cultures and had very little interaction. Towards the end of Phase A, Inex had moved its operations under a single roof and began to implement an annual system for performance management. Although reviews were done on annual basis, they were not well-structured and consisted only of a manager's review of his/her subordinates. The review form consisted of a simple checklist and a rating system from 1 to 4 (4: excellent, 3: above average, 2: satisfactory, 1: below expectations).

5.2.5 Recognition and Rewards

Up to this point, Inex hadn't spent any money on compensation evaluation to ensure alignment with market rates. Base salaries slightly out-competed salaries within academia in order to attract individuals from academia to industry. Employee benefits were mediocre and not competitive enough to attract and retain key people. For example, the Company did not have an RRSP-matching plan, and extended healthcare benefits were limited. Inex did not have a bonus structure in place to reward employees based upon achievement of objectives. The Employee Stock Option Plan (ESOP) did not explicitly quantify allocation of options. Achievement of corporate milestones determined whether or not stock options were granted to all employees. Therefore, two

individuals, who put forth varying degrees of effort, could both have options granted to them if the Company met its milestones. This translated into a lack of individual accountability as objectives were too broad, being set at the corporate level. Therefore, the sentiment among employees was that the lack of transparency indicated subjectivity in allocating the number of options to each individual. Naturally, these sentiments further exacerbated the mistrust after the downsizing.

5.3 Organizational Structure

Based upon the research findings and the industry dynamics in which Inex finds itself, an evolutionary continuum of the structure for Inex will be presented. The range of structures that Inex has adopted since inception, was created by assessing the elements which Mintzberg contends affect organizational structure (both structural and situational factors).

As most organizations have at inception, and throughout its early years, Inex had a very simple and flat organizational structure. The firm was a start-up organization with a small number of employees that reported directly to the CEO. In 1996, the Company's premises grew modestly from existing in a small UBC lab, to a slightly larger facility off-campus. Thus, the CEO and VP R&D were still able to directly supervise and coordinate the Company's activities. The organization's structure was essentially flat as power was concentrated in the hands of the CEO, Chief Operating Officer (COO), VP R&D and the Board of Directors, which was controlled by investors.

A simple structure afforded the company a great deal of flexibility. It was able to adapt to change rapidly, which is essential in the dynamic environment of biotech. With the focus

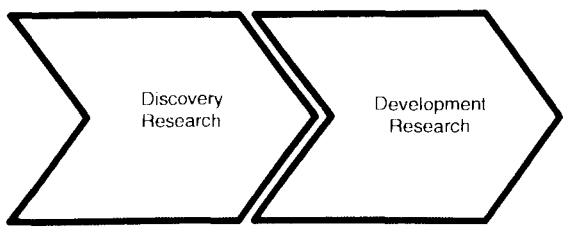
on science as opposed to product development or manufacturing, there were few technical systems, policies, standard operating procedures or highly defined job descriptions. Thus, behaviour was informal and the only obvious grouping was that employees were either administrative or scientific and reporting was to the CEO, COO or the VP Research. The simple structure was suitable for Inex during this phase of its existence, as it was a start-up organization that required flexibility and was driven by the results from the laboratory.

5.4 Process Management

In order to examine Inex's growth along the biotech value chain, it is helpful to examine a snapshot of the organization's functionalities at the beginning and at the end of each phase. This will provide a visual depiction as to what processes were added to the Company during each phase of its growth. The analysis will seek to address the motivation behind incorporating each of these processes and whether doing so was aligned with the corporate strategy during each phase.

Inex, like many of its biotech peers, was founded at the Development Research stage of the value chain. The Discovery Research was conducted at UBC and a target was identified and ready to be spun-out into a company for development. As such, in 1992, the Company was primarily focused on Development Research (See Figure 14).

Figure 14: Inex's Primary Activities: Beginning of Phase A – Research[49]



[49] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

From the outset, Inex had adopted a framework for the required infrastructure for a company of its size. The Company's primary activities consisted of Development Research, which was conducted by the scientific team. However, Inex recognized the importance of developing an infrastructure of the supportive functions that would enable the organization to drive its Development Research. Consequently, "departments" (typically consisting of one individual) such as Business Development, Finance, IP were added to complement and support Development Research activities (refer to Table 1).

Business Development, as a support function, lends itself to establishing goals and partnerships or alliances that will foster the growth of the company. Partnerships and alliances are critical to biotech firms that are focused on early stage drug development. During this stage, Inex didn't have a formal Business Development group, but rather one individual who was responsible for facilitating partnerships around the Company's delivery technology.

Financing is a prerequisite to growth, and therefore, is an integral support function. It requires the constant evaluation of needs in both primary and support activities, where long term capital requirements for the next phase of growth need to be identified. In addition, accounting activities are critical in tracking capital resource allocation and needs. This is accomplished by establishing and maintaining departmental budgets. These budgets are necessary, not only to forecast future needs, but also to monitor and evaluate current spending activities to avoid downstream inefficiencies in capital allocation. Initially, Inex's finance department was small and primarily focused on

administrative activities. However, as the Company grew during Phase A, senior level financial experts were added to aid with fund raising and budgeting processes.

In most start-up biotech firms, IP is typically not internalized until later stages. However, the function is critical to a company's success, as it not only impacts future revenue streams, but also influences investment capital that can be raised in early stages. Successful patents form a barrier to entry for competitors and therefore perceived as core assets by potential investors, financiers, and partners. Inex had a lot of IP coming from UBC and its collaborators and therefore, it needed to carefully manage what would become the Company's currency for many years before revenues could be realized.

Table 1: Snapshot of Departments at Inex: Phase A - Research[50]

1992	End of 1998
Business Development	Business Development
Finance	Finance
Intellectual Property (IP)	Intellectual Property (IP)
Research	Research
	Human Resources
	Preclinical Development
	Product Development
	Manufacturing & Process Development
	Quality Control (QC)/ Quality Assurance (QA)
	Regulatory Affairs
	Facilities' Management
	Investor Relations

Note: Newly created departments are indicated in bold font.

As the Company progressed through the early years, positive data necessitated growth in the primary activity of Development Research. In order to sustain its primary activities, Inex had to be proactive in building its supportive activities. Furthermore, the Company

[50] Table created by authors (Zahra Dhanji and Parimal Nathwani)

had to envision those activities which would become primary in the short-to-medium term and build those capabilities accordingly.

This growth was facilitated by hiring an individual to manage the human resources and to fill the organization's staffing needs. Other roles of the HR department included supporting the education and training of employees, granting fair compensation, dealing with personnel issues, and motivation of employees. HR management adds value across all levels of primary and support activities, and therefore along the entire value chain.

Preclinical and Product Development, together with Manufacturing & Process Development and Quality Control/Quality Assurance, became increasingly important as Inex propelled its lead candidate towards Clinical Development. All of the processes involved in these areas were conducted internally, with the exception of GLP-compliant toxicology studies. These studies were outsourced due to the stringent regulatory requirements of GLP compliance. Rather than going through a steep learning curve and investing resources in performing GLP studies internally, it was more feasible to outsource this aspect of preclinical development.

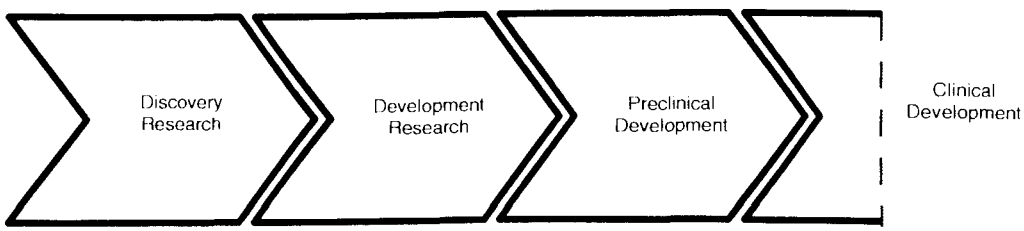
Regulatory Affairs was done on a consulting basis for the first couple of years, but became a full time position within the Company by 1994. Although the regulatory function was introduced during this phase, it remained very small. It is important to note that Inex was already in Phase I clinical trials for its lead product, yet the Company had not expanded the regulatory function to prepare for subsequent phases of the drug

approval process. This was consistent with Inex's strategy at this stage, in that it was spread over 3 research divisions, with the focus being on Gene Therapy, not on its current lead product, VSLI.

Supportive activities of Facilities' Management and Investor Relations also became valuable during this stage. Inex had moved into a larger facility with more equipment which needed to be maintained. Furthermore, the Company had gone public in 1997.

Therefore, although there was substantial growth during Phase A, the processes that were introduced during this phase needed to be refined. In addition, the Company had to consider developing capabilities further along the value chain. By the end of Phase A: Research, Inex had built internal capabilities, along the value chain up to Phase I of Clinical Development (See Figure 15).

Figure 15: Inex's Primary Activities: End of Phase A – Research [51]



5.5 Strategic Partnerships and Networks

During the Research Phase of Inex's history, all collaborations and partnerships focused on basic research activities to augment internal capabilities. Since the Company's core platform at this stage was based upon an enabling technology, the partnership strategy was to combine Inex's proprietary drug delivery technology with a specific gene target

[51] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

from a partner to develop targeted gene therapies. Thus, the relationships that Inex formed during this phase of its lifecycle were critical to the success of the Company as it tried to execute its strategy of becoming a biopharmaceutical company developing proprietary drugs using its technology platform.

Inex's technology was developed in Dr. Pieter Cullis' (scientific founder of Inex) academic lab at UBC. As a result, Inex developed strong relationships with UBC and other academic institutions early on. In addition, the Company also developed a number of partnerships with pharmaceutical and biotech companies for its enabling delivery technology. Outlined below is a list and brief description of major academic and commercial partnerships that Inex was engaged in during Phase A.

5.5.1 Academic Partnerships

1. *University of British Columbia:* Inex contracted out basic research functions, such as optimization of new lipid formulations for its drug delivery technology to Dr. Cullis' academic lab. This partnership allowed Inex to access the expertise of scientists and technicians who had discovered the founding technology and Inex would receive first right of refusal to any IP derived from the academic research.

2. *BC Cancer Agency:* Similar to its relationship with UBC, Inex had strong scientific ties to academic researchers at the BC Cancer Agency. As a result, academic labs within the agency were funded by Inex to conduct research related to its core technology, in exchange for IP derived from the research.

3. *University of Groningen:* In order to mitigate some of its risk, Inex setup a collaboration with an academic institution in the Netherlands to investigate alternative drug delivery technologies. This collaboration focused on modifying viral membranes as an alternative to the "synthetic" lipid formulation drug delivery technology. The structure of the partnership resembled that of the aforementioned academic relationships.

5.5.2 Commercial Partnerships

1. *Schering Plough/Canji Pharmaceuticals:* This partnership focused on developing cancer therapeutics using two novel cancer genes as targets. In this relationship Inex would have access to Schering and Canji's cancer genes to develop targeted lipid based vesicles to facilitate the delivery of the two genes to specific tumours, thereby leading to inhibition of tumour growth. This partnership would also allow Inex to have access to a large pharmaceutical company's (Schering Plough) expertise in drug development and commercialization. However, due to technical hurdles this partnership dissolved.

2. *Isis Pharmaceuticals:* Isis is one of the leaders in the discovery and development of antisense compounds. As a result, the signing of this deal was an important event in establishing credibility with investors. Like the Schering Plough partnership, this partnership provided Inex with access to an antisense molecule for the treatment of inflammatory disease. Inex would combine the molecule with its delivery technology to develop a targeted

antisense therapeutic. Although there were some initial promising data coming from Inex's R&D efforts, Isis decided to terminate the partnership for strategic reasons.

3. *Other partnerships:* Inex had developed various other partnerships with similar structure and function to the Isis and Schering Plough partnerships described above. These included partnerships with Genzyme, Chiron and Bayer. However, these relationships were dissolved due to technical and/or strategic concerns by the partner.

4. *Lynx Therapeutics:* In 1997, Inex decided to acquire Lynx therapeutics to gain control of some cancer genes for further development. This was not a true partnership but rather an integration of Lynx Therapeutics into Inex. The primary reason for the acquisition was due to Inex's experiences with previous partners in that the Company did not control all of the assets required for product development.

As can be seen from the partnerships described above, Inex was able to secure relationships with large pharmaceutical and biotech companies who were leaders in the field of gene therapy and antisense therapeutics. The ability of Inex to secure high calibre partnerships can be attributed to the credibility of its technology. The scientific founders of Inex were experts in the field of lipid-mediated drug delivery and had published data in top-ranked journals and presented at international conferences. In addition, the drug delivery technology had been validated by other groups and products

using similar technology were in clinical trials. As a result, clinical proof of concept data was available, adding to the credibility of the technology that Inex was developing.

Although Inex was able to secure high profile partnerships early on, it was not able to extract significant value out of many of the relationships. Part of the reason for this was that a clear partnership strategy had not been put into place. In fact, at this stage the Company did not have a Business Development team that was responsible for conducting due diligence activities on potential partners. A formal analysis of drivers and facilitators of partnerships was not conducted for the early stage partnerships in Phase A. The partnerships were basically sought out, and entered into, by the scientists at Inex. Since most scientists are intrigued by new R&D projects, the partnerships were viewed as a way of conducting more R&D in new and exciting areas. As a result, some of the partnerships were dissolved due to the strategies of Inex and its partner not being aligned. However, if a more formal partnering strategy had been in place, due diligence activities with respect to potential partners may have resulted in exclusion of some of the early stage partnerships. This may have allowed Inex to focus on specific areas and to build longer lasting and more applicable partnerships.

In retrospect, a driver analysis for the early stage partnerships that Inex was engaged in appears favourable. The partnerships were designed to increase the firm's assets from a product development standpoint. In addition, the partnerships were set up such that if specific milestones were attained then royalties would be paid to Inex, thereby providing an opportunity for growth. Moreover, as the R&D progressed, Inex could leverage the expertise of the large pharmaceutical partner in the area of drug development. Finally,

positive data from R&D efforts could be presented at international conferences and used to gain credibility in the scientific community.

However, the facilitators of partnership development were not well addressed. Since the large companies that Inex was partnering with had divergent management structures, cultures and financial strength and spanned different geographical regions, building a successful partnership was difficult. In addition, Inex was more reliant on the partner and this put the firm in a situation of vulnerability. Further, it is important to note that although Inex had access to the assets of its partners, Inex did not control the assets since the active ingredient in the potential therapeutic (i.e. gene or antisense molecule) did not legally belong to Inex. Thus, although the potential did exist for a positive R&D relationship, if the partner did not want to pursue the relationship for strategic or other internal reasons, the partnership was dissolved.

In order to retain control of the assets and mitigate risk, Inex employed an alternative partnership strategy towards the end of Phase A. As mentioned previously, the Company acquired the assets of Lynx Therapeutics. This allowed Inex to control both the technology platform and the active ingredient (i.e. antisense molecule) to develop a therapeutic for specific types of cancer. Today, the technology acquired from the acquisition of Lynx Therapeutics forms the foundation of the Company's OligoVax program.

In summary, although Inex was extremely successful in seeking partnerships and collaborations, the organization did not have a formal partnering strategy and a Business

Development group. More careful consideration of the partnership facilitators as part of the due diligence process may help to identify partners that are more aligned, thereby facilitating the development of more prolonged and fruitful partnerships. In addition, retaining control of all assets involved in generating the product at the R&D stage is critical to a successful partnering strategy.

5.6 Corporate Performance Measures

During the first phase of Inex's business, formal corporate performance measurement systems were not in place. Since the Company was primarily focused on basic research, the inherent uncertainty made it difficult to set performance measures. In addition, during the early phases of a research-based company, it is important to remain innovative and flexible, thereby allowing the firm to adapt based on the results from internal research, as well as the external landscape. Having strict top-down corporate goals can inhibit the culture of a research organization and can consume people with administrative processes. Consequently, goals were mostly driven by scientific progress.

6 PHASE B: DEVELOPMENT

6.1 Strategy

The second phase of the Inex's lifecycle represents a transition from research into development. To facilitate this transition, a new CEO was appointed by the Board of Directors. With the gene therapy area proving to be challenging from a scientific perspective, Inex decided to change its product development strategy to focus on conventional small molecule and oligonucleotide compounds for the treatment of cancer. Thus, Inex shifted its strategy from a technology platform company to a product-focused company. With the Company's lead product (VSLI) in phase II clinical trials and an additional program at the IND stage, and no partner to facilitate clinical and regulatory development, it was evident that Inex needed to start developing these competencies internally. From 1999-2003, Inex built up many internal capabilities related to drug development including Manufacturing, QC, QA and a Clinical Research group in order to support the shift in strategic direction.

Inex's technology continued to employ a differentiation strategy. However, since the Company was larger, a more formal and top-down strategy development process was implemented. The strategy development process was driven by a benchmarking analysis of companies within the industry. Inex looked at 100 biotech companies with respect to the following criteria:

1. Therapeutic focus
2. Founding year

3. Number of employees
4. Market capitalization
5. Commercialization capabilities
6. Number of products on the market
7. Number of products in clinical development

Based on this analysis, Inex's strategy was to become a biopharmaceutical company developing and commercializing targeted therapeutics. The Company would take a product-focused strategy with the lead product for commercialization being VSLI. In addition, Inex had to establish a pipeline of products through internal R&D efforts, licensing and acquisition.

6.2 HR

6.2.1 Culture

In 1999, the new CEO of Inex wanted to reinvent the Company and began by addressing the culture, particularly so because of the lack of employee morale after the downsizing in the previous year. The CEO conducted one-on-one interviews with every employee within the organization in order to assess employee satisfaction and to communicate to them that the people were of utmost importance to the success of Inex. This was the first step in beginning to foster an environment of open communication and transparency.

In order to rebuild trust within the organization, monthly "What's Up" meetings were held. These were general staff forums where management had an opportunity to share

information on a wide variety of topics such as rolling out new policies, corporate information, changes which affected large groups, or common interest items. During these meetings, employees had the opportunity to ask questions on any topic on which they wished to seek clarification. An example of the agenda of such forums is the introduction of a new department or function within the organization. The individual leading that group would give a presentation to explain who they were, what they were doing, who would be in their department and how it would fit into the process. This was of great significance, particularly so due to the rate at which the Company was growing. Communicating in this regard served to proactively ease feelings where people might have felt that their positions were threatened. Initially, these meetings were held once a month, but as the Company grew, the meetings were held on a quarterly basis.

The importance of cooperation and teamwork was instilled in the organization by training 120 people within the Company on project management. Up to this point, individuals had worked on their own and within their respective departments. Therefore, there were some rigid mindsets to change in order to coordinate activities and increase cooperation. The group was trained on a specific way of thinking about project management so that there was a unified approach to planning. People were encouraged leverage the expertise of other departments' activities and even to define the output of their component of the project in a coherent fashion. This training also served to achieve buy-in on the creation of the department of Project Management at Inex. This department was created to implement systems and processes to lead project planning such that people could appreciate the value and interconnectedness of the various departments within the firm. The addition of the Project Management department was instrumental in transforming the Company into a development organization.

In July of 1999, the Company published its core values (Results, Teamwork and Initiative[52]) that govern its approach to work and interactions with individuals inside and outside the Company. These values are instilled into all of the people systems, including recruiting, rewards and promotions, performance management and training and development.

6.2.1.1 Values

Results: Productive

Measurable and timely results that meet company goals strengthen the Company's relationship with external stakeholders and reinforce the mission and vision of Inex. Results are based upon rigorous business planning, decisiveness, employee dedication and teamwork[53].

- Show superior ability to manage workflow and deliver results on time
- Solve difficult problems quickly and effectively
- Demonstrate commitment to innovation
- Challenge 'the way things have always been done'; identify patterns or connections between ideas; create ideas, concepts, products that are new to Inex

[52] Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, 2002.
[53] ibid

Teamwork: Supportive

Results are achieved through teamwork that recognizes the value of each individual's contribution. The Company strives to create a work environment that leads to cooperation, trust and respect. Good communication is an essential component of teamwork. Each individual acknowledges his/her personal responsibility to contribute to teamwork and for achieving the Company goals. Inex employs many teams that cooperate in order to support and drive the collective organization[54].

- Participate willingly; support team decisions, act to surface and resolve conflicts, share needed resources, publicly credit others who have performed well
- Demonstrate enthusiasm and commitment to the company and team goals, set high standards and hold self and team members accountable for performance
- Communicate clearly and concisely and share relevant information in a timely manner

Initiative: Proactive

A feeling of ownership is conducive to carrying out responsibilities to the Company and its shareholders. The Company employs and rewards individuals who take initiative and demonstrate commitment to results and teamwork[55].

- Demonstrate commitment to continuous performance improvement
- Actively seek out and welcome feedback on personal performance; assume responsibility for personal growth and development; approach issues with respect, honesty and integrity for self and others

[54] ibid
[55] ibid

- Embrace and champion change, easily switch gears in response to changing job requirements

6.2.2 Recruitment and Selection

As the Company experienced immense growth during this phase, it had to remain sensitive to the attitudes following the downsizing at the end of the previous phase. Therefore, the principle on staffing was that it should be sustainable. As the lead product moved forward it became necessary to review the organizational chart, box by box, to understand what positions needed to be filled on a priority basis.

Although Inex experienced tremendous growth during this phase, the bulk of the growth was in the area of Clinical Development and Regulatory Affairs. Therefore, Inex had to hire the necessary expertise to move the product through clinical trials. This posed a recruitment challenge for Inex because the biotech industry, locally and across Canada, was too young to have such expertise to draw from. That being said, the industry was relatively more mature in Eastern Canada than in British Columbia. Consequently, the Company began to do a lot of advertising in Canada and looked to the United States and Europe to fill these positions. Inex established and developed relationships with head-hunters in the US, who were biopharma experts. These experts had a lot of experience in the industry and had sufficient knowledge as to what was required for a company of Inex's size. These head-hunters began to send in resumes of individuals with such qualifications – even before Inex had realized that it would need such expertise.

Internally, people who had worn broad generalist hats were realizing that, by necessity, their roles were narrowing down and focusing. Thus, when new departments were being

created, the process was highly participative and tapped into the experience of current employees who were most attuned to skills that were required to fill gaps within the organization. A broad panel of individuals from the functional area most related to the proposed department would define the function of the new department. For example, in the formation of the new Analytical Development (AD) department, a number of people from Quality Control (QC) (who were carrying out a lot of these responsibilities) sat down to sketch out what "*new QC*" would look like and which of their responsibilities would go to AD. Furthermore, the same people were involved in defining individual job descriptions, establishing criteria for selecting successful candidates, and participating in the selection process.

Employee referrals are some of the most successful hires for a company because the individual being referred is usually well known to the current employee and as such, has already been screened for a skills and culture fit. Inex provided an incentive to all of its employees in the recruitment process. In order to seek out individuals with specific skill sets, the Company tapped into the networks of its employees (through professional associations, peers in the industry – in academia or industry) by implementing a "Referral Bonus". The implementation of this type of an incentive encourages employees to network at conferences, trade shows, professional association meetings or training programs. Many employees also develop relationships on-line in industry chat rooms. A bonus is issued to an employee if the candidate is hired and successfully completes three months of employment. The "Impact Level" (discussed in the subsequent section) of the hire determines the amount of the taxable bonus that the employee is eligible for. This is a simple, yet clever way, to engage employees in the recruiting process and allows a company to exploit the networks of its employees.

6.2.3 Job Structure

During this phase, Inex had 2 major objectives:

1. To revisit the job descriptions which were defined in Phase A in order to provide clarity in performance expectations and promotion criteria.
2. To address the issue of equity between the different areas of the organization.

To accomplish the first objective, Inex began by addressing the job descriptions and by creating "Job Families" which groups positions with similar skill sets and core competencies based on internal and external comparison of responsibilities. While one or more job families have competencies in common, there is a different level of relative emphasis in each.

There are three major job families at Inex[56]:

1) Science

- Encompasses those positions dedicated to scientific research and new breakthroughs
- Work is conceptual and abstract, requires independent judgment and discretion

2) Technical/Operations

- Work is generally well defined and follows generally accepted business practices, requires job/skill specific knowledge, judgment, creativity and discretion

[56] ibid

3) Management

- Work is focused on people (internal or external) and/or business processes

The second objective was much more challenging to deal with and had underlying roots in the culture of the organization. Attitudes such as, "Is a scientist more, or less important than a manager?" had emerged towards the end of Phase A. Consequently, the Company had to implement a system that would provide a consistent way of viewing all employees within the organization. Such a system would equate job groupings and roles within the Company to aid in planning and managing the total compensation plan.

Inex implemented a system of Impact Levels (Table 2) to recognize the level of responsibility and accountability of any given position against other positions within the organization. Impact levels reflect planning horizons and the impact of errors on the overall functioning of the Company. Progression through impact levels is based on both responsibility and accountability, and on job knowledge and experience. As one progresses through the impact levels in each job family, knowledge, skills and behaviours are cumulative, each level building on the next. Due to the definition of impact levels, they are also used to gauge variable pay, stock option allocation and other incentives that are linked to responsibility levels.

Table 2: System of Impact Levels at Inex Pharmaceuticals[57]

Impact Level	Job Family		
1	***Executive***		
	Management	***Science***	***Technical/Operations***
2	Senior Director Director Associate Director	Principal Scientist	
3	Senior Manager	Scientist IV	
4	Manager II	Scientist III	Associate V
5	Manager I	Scientist II	Associate IV
6		Scientist I	Associate III
7			Associate II
8			Associate I
9			Assistant

6.2.4 Objective Setting

Planning is an ongoing activity at Inex and detailed plans are developed twice per year. Corporate level objectives are determined by the Executive team. Each department then cascades the corporate objectives into department and individual objectives.

At Inex, objective setting for individuals is an interactive and participative process between managers and employees, and is used to develop SMART objectives: Specific, Measurable, Achievable, Realistic and Timely. This is carried out on a quarterly basis for each employee. At the end of each quarter, results against established objectives are

[57] Table adapted from Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, 2002.

documented and this provides input for determining payout of the variable compensation.

6.2.5 Performance Management

Inex views Performance Management as critical to developing both individuals and the Company as a whole. Since bonuses are tied to performance, formal and well-structured reviews are conducted twice per year (half-way through the year and at the end of the year). Inex's review system has three components: self-review, manager's consolidated review and third party reviews.

The performance review form, used for self and manager evaluations, is composed of three sections[58]: 1) "Key Accomplishments", which highlights notable accomplishments and activities from the past year, 2) "Shared Values and Skills" reviews the employee against the corporate values, 3) "Job Family Specific Skills" rates performance against the core competencies specific to the employee's job family.

Inex's third party reviews reflect a 360° system. Two to three peers review an employee: one within his/her functional group, one within the same department and another from any department within the Company.

The final stage of the review process focuses on career and skill development. Short-term goals that are critical to the employee's present position are documented along with longer-range career advancement objectives. From the list of career objectives for both

[58] Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, 2002.

the long and short term, an action plan is created outlining development activities and timelines for completion. This is known as an Individual Development Plan and is revisited on a regular basis to ensure that the desired training and development is occurring[59].

6.2.6 Compensation

As discussed in the preceding section on "Recruitment and Selection", Inex had to attract expertise from the US and Europe for positions in Clinical Development and Regulatory Affairs. However, Inex decided not to stretch beyond the market salary ranges to attract this expertise, as this would cause dissent within the organization. The executive team thought it critical that, if the salary numbers were put up on a wall, they could be justified and would be perceived as being fair –irrespective of where individuals were recruited from. Instead, the Company provided other incentives such as: housing loans, relocation packages and tax attorneys who would prepare a dual tax filing for the employee in the first year.

Therefore, the Company has maintained that base salary be driven by the market conditions and not by job titles, impact level or where an individual is recruited from. For example, at Impact Level 5, the salary range will be different for the employees in the three job families. At the beginning of this phase, the Company approved a number of base salary adjustments in order to align with market rates. Inex participates in a variety of commercial compensation surveys to ensure that its compensation program is market competitive within the industry in the Canadian market. In addition, Inex implemented an

[59] Inex Pharmaceuticals Corporation. Inex Employee Handbook. Vancouver, 2002.

RRSP-matching plan to encourage employee contribution and to increase the overall attractiveness of the compensation package.

Variable compensation is an area that went through a major re-invention during Phase B. The variable compensation includes stock option allocations and bonuses, and is driven by impact level. Although stock options were also granted in the previous phase of the Company's growth, it had become much more transparent and less subjective, as allocation now depended upon an individual's Impact Level within the organization.

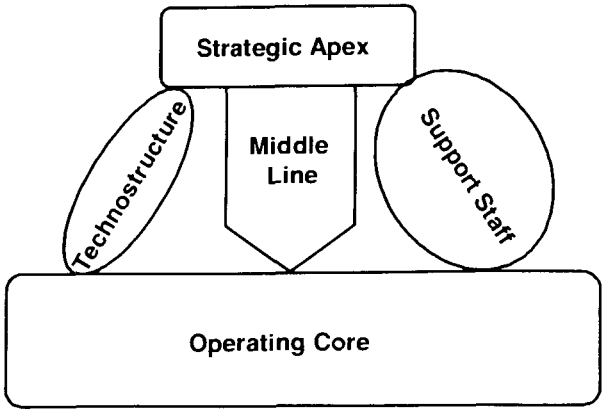
A new introduction to variable compensation was the idea of "bonuses' (cash and/or options). The introduction of the bonus system was designed to communicate and align corporate objectives with an employee's day-to-day work activities. The plan rewards the performance of individuals and teams as related to the achievement of corporate objectives. The criteria for achievement are based on a combination of corporate, department/team and individual objectives, thereby rewarding behaviours that are aligned with the corporate values. The percentage weighting on each level of performance varies with impact level (i.e. the more senior you were, the more heavily you were weighted on the achievement of departmental and corporate objectives, rather than on individual objectives).

6.3 Organizational Structure

At the beginning of this phase, the Company was focused on three areas of research, and all scientific staff including the VP of Research spent a great deal of hands-on time in the lab. Towards the end of this phase, in 1999, the Company's strategy shifted to narrow the focus from three research areas to one. Consequently, the simple structure

that prevailed throughout Phase A was no longer optimal and it became necessary to formalize the organizational structure. By 2000, the 5 basic parts of the organization, as described by Mintzberg became clear and the Company has continued to build upon the structure established during this critical phase. The strategic apex consists of the Board of Directors, CEO, Chief Financial Officer (CFO) and the VP of R&D. The operating core of the organization is represented by the Research Scientists (RS's), and Associates (RA's) who execute daily research activities. The technostructure is made up of the more senior level Research Scientists (RS's) as they are responsible for controlling the activities of the RA's and implementing new technologies. The Directors of the various departments act as the middle line and coordinate and communicate between the strategic apex and the operating core. Finally, functions such as Information Technology (IT), HR, Legal and Finance provide support to the overall organization. A diagrammatic representation of Inex's organizational configuration can be seen in Figure 16. This figure illustrates a slightly less pronounced technostructure and proportionally greater support staff (suggestive of an adhocracy) and a large operating core (suggestive of a professional bureaucracy) during this phase of the Company's growth.

Figure 16: Schematic Representation of Inex's Organizational Structure: Phase B - Development[60]



[60] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

The functional groups within the departments are headed by Senior VPs or Directors. An Executive Committee, consisting of the CEO and senior executives, provide the overall strategic direction of the Company. Corporate decision-making rests in the hands of ad-hoc committees and cross-functional teams such as the Portfolio Management (PM) Committee. These cross-functional teams ensure that projects are executed in a well-structured, flexible and timely manner. Additionally, PM Committees take into consideration the broader issues related to feasibility of a project in terms of IP, Business Development, PD and Manufacturing. It is this involvement from various departments that determine whether or not allocating further resources to a project is justified.

Table 3: Structural and Situational Dimensions of Mintzberg's Configurations[61]

	Simple Structure	Machine Bureaucracy	Professional Bureaucracy	Divisionalized Form	Adhocracy
Key means of Coordination	Direct supervision	Standardization of work	**Standardization of skills**	Standardization of outputs	**Mutual adjustment**
Key part of organization	Strategic apex	Technostructure	**Operating core**	Middle line	**Support staff (with operating core in operating adhocracy)**
STRUCTURAL ELEMENTS					
Specialization of jobs	Little specialization	Much horizontal and vertical specialization	**Much horizontal specialization**	Some horizontal and vertical specialization (between divisions and headquarters)	**Much horizontal specialization**
Training and indoctrination	Little training and indoctrination	Little training and indoctrination	Much training and indoctrination	Some training and indoctrination (of division managers)	**Much training**
Formalization of behaviour Bureaucratic/Organic	**Little formalization (organic)**	Much formalization (bureaucratic)	Little formalization (bureaucratic)	Much formalization (within divisions - bureaucratic)	**Little formalization (organic)**
Grouping	Usually functional	Usually functional	**Functional and market**	Market	**Functional and market**
Unit Size	Wide	Wide at bottom, narrow elsewhere	Wide at bottom, narrow elsewhere	Wide at top	**Narrow throughout**
Planning and control systems	Little planning and control	Action planning	Little planning and control	**Much performance control**	Limited action planning (esp in administrative adhocracy)
Liaison devices	Few liaison devices	Few liaison devices	Liaison devices in administration	Few liaison devices	**Many liaison devices throughout**
Decentralization	Centralization	Limited horizontal decentralization	Horizontal and vertical deccentralization	Limited vertical decentralization	**Selective decentralization**
SITUATIONAL ELEMENTS					
Age and size	Typically young and small	Typically old and large	**Varies**	Typically old and very large	**Typically young (operating adhocracy)**
Technical system	Simple, not regulating	**Regulating but not automated, not very complex**	**Not regulating or complex**	Divisible, otherwise like machine bureaucracy	Very complex, often automated (in administrative adhocracy), not regulating or complex (in operating adhocracy)
Environment	Simple and dynamic; sometimes hostile	Simple and stable	Complex and stable	Relatively simple and stable; diversified markets (esp products and services)	**Complex and dynamic; sometimes disparate (in administrative adhocracy)**
Power	Chief excecutive control; often owner managed; not fashionable	**Technocratic and external control; not fashionable**	Professional operator control; fashionable	Middle-line control; fashionable (esp. in industry)	**Expert control; very fashionable**

[61] Table adapted from Mintzberg, H Organization Design: Fashion or Fit? Harvard Business Review. Jan-Feb: 1-16, 1981.

6.3.1 Elements of Adhocracy and Professional Bureaucracy

As shown in Table 3 (Dimensions of Mintzberg's configurations), Inex's organizational structure during this phase exhibits characteristics most consistent with an administrative adhocracy. However, during this stage, the Company's core activities were in drug development and moving towards clinical trials. This requires specialized expertise and Inex had to adopt formal procedures in order to be in compliance with regulatory standards. Product Development and Clinical Affairs were functions that constituted a key part of the organization and were concentrated within the operating core, which is indicative of a professional bureaucracy.

In adhocracy configurations, coordination and control occur by mutual adjustment through both informal communication and interaction of competent experts. The R&D focus of the company requires these experts to work together to create new ideas and products through mutual adjustment. This is exemplified in the deployment of liaison devices such as task forces, cross-functional teams such as Portfolio Management Committees, and project committees, all of whom draw upon one another's expertise in order to enhance innovation. By the same token, the Clinical focus of the Company requires standardization of the skills of various experts dispersed throughout the Clinical and Regulatory affairs departments. Such standardization is imperative to ensure that the Company conforms to regulatory standards and is reflective of a professional bureaucracy.

Power, in adhocracies, is constantly shifting between experts, in a task-dependent manner. In Inex's case, there are three, separate - but non-mutually exclusive, operating

departments (Research, Commercial Operations, and Clinical/Regulatory Affairs). An example of the fluidity within the organization is seen within the Clinical Research and Regulatory Affairs Departments. Clinical Research has the power to determine whether trials or projects should proceed based on their analysis of clinical data and scientific opinion. Similarly, Regulatory Affairs has the power to make all decisions in relation to their area of expertise. On the other hand, decisions to undertaking new therapeutic markets or entertaining new alliances are made by the executives in conjunction with the supporting departments such as Business Development.

The structure of Inex revealed many managers with narrow "spans of control" which is also characteristic of an adhocracy structure. An example of this would be the project managers who coordinate the preparation of the NDA. This involves a coordinated effort of various small project sub-teams, who are responsible for completing specific sections of the NDA. In this case the manager is most concerned with combining the expertise of the various project teams, as opposed to direct supervision and control.

With respect to decentralization, Inex's structure is again, best characterized as an adhocracy in that there exist both selective vertical and horizontal decentralization. The strategic apex (CEO, Board of Directors, and Executive Team) makes strategic and major financial decisions. Department Directors are entrusted with making decisions regarding project timelines and direction. Outside the strategic apex and middle line, decision-making also varies in that Senior Research Scientists make decisions as to which compounds to move forward within their division. However, non-managers within the operating core do not have much decision-making authority. Therefore, Inex is most accurately described as exhibiting selective decentralization.

In an adhocracy, the organizational structure is complex and non-standardized, in a dynamic environment. Though Inex's structure is complex in a dynamic environment, there is a certain degree of standardization, thereby incorporating some elements of a professional bureaucracy. External controls in the form of regulatory compliance necessitate this degree of standardization within the quality and regulatory functions of the firm and these activities must be standardized in order to progress towards market clearance. Furthermore, the standardization of regulatory compliance and procedures is under the directive of highly trained professionals within the Company.

Although standardization is required in certain areas of the organization, it inhibits innovation in research. Due to this need for the presence of both standardization and non-standardization, Inex cannot be defined as a "pure" adhocracy. As the preceding discussion illustrates, Inex's organizational configuration is reflective of primarily, an adhocracy, with elements of a professional bureaucracy.

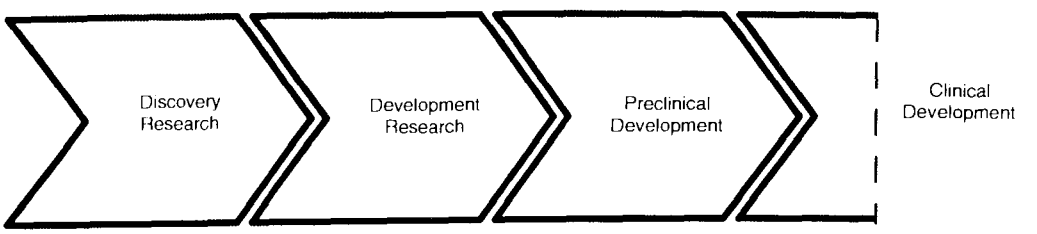
6.3.2 Traces of Simple Structure and Machine Bureaucracy

Inex has a very informal and organic structure that is able to adapt to the complex and dynamic demands of its environment. This is particularly apparent within the Research division of the Company. Despite the Company's formidable growth during this phase, it was successful in maintaining an informal structure in order to prevent bureaucratizing the innovative core of the organization. This is of critical importance in successfully growing an organization whose livelihood depends upon innovation. Bureaucracy and standardization counter innovation and it is imperative that these elements be left out of Research.

Within the Regulatory Affairs department of Inex, the technical systems fall into the "machine bureaucracy" configuration. As the activities of this department are heavily regulated by external authorities, it becomes necessary to regulate these activities internally, as well. Though these systems are not automated by any means, they are complex and require some level of standardization such that the organization is able to gain efficiencies. Well-planned and extensive technical systems within the Regulatory will enable biotech companies, such as Inex, to capture "lessons learned" and to improve regulatory strategies with downstream products.

6.4 Process Management

Figure 17: Inex's Primary Activities: Beginning of Phase B – Development [62]



During Phase B, the new strategy set forth in 1999 mandated the Company to refocus on the Conventional Drug Program. As a result, the Discovery Research processes were scaled back such that sufficient resources could be dedicated to driving the lead candidate (VSLI) through Clinical Development. VSLI was ready for Phase II Clinical Trials and Inex intended to take it through the Phase IIb pivotal trials as well. Further, the Company realized that if a large pharma partner did not come through, Inex would have to file the NDA for regulatory approval to market. This called for a very different set of

[62] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

processes and capabilities, which Inex had not developed over previous years (See Figure 17).

In alignment with the new strategy and vision of the Company, Inex experienced tremendous growth within the Clinical Development function of the Company. In order to prepare for filing of the NDA, a company must have processes such as: Information Systems, QC/QA for document control and AD (currently referred to as Pharmaceutics, by Inex) (See Table 4). Although some of these processes were already in place, they needed to be formalized such that the systems would pass an FDA audit. Therefore, the level of regulatory compliance at this stage of clinical development required a higher level of sophistication and compliance.

Table 4: Snapshot of Departments at Inex: Phase B - Development[63]

Beginning of 1999	2004 (Current)
Business Development	Business Development
Finance	Finance
IP	IP
Research	Research
Human Resources	Human Resources
Preclinical Development	Preclinical Development
Product Development	Product Development
Regulatory Affairs	Regulatory Affairs
Facilities' Management	Facilities' Management
Investor Relations	Investor Relations
Manufacturing & PD	Manufacturing & PD
QC / QA	QC / QA
	Clinical
	Information Systems
	Supply Chain Management
	Pharmaceutics
	Project Management
	Technology Development & Licensing
	Marketing

Note: Newly created departments are indicated in bold font

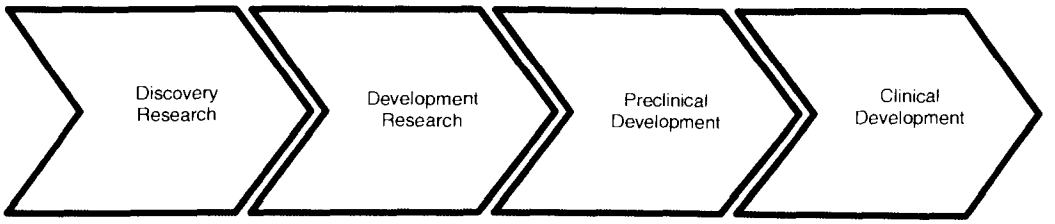
[63] Table created by authors (Zahra Dhanji and Parimal Nathwani)

Support activities such as Supply Chain Management became critical as the Company was approaching commercialization. Project Management also became significant in order to coordinate processes within the Company in a coherent and efficient manner. This was particularly significant due to the change in Corporate Culture in 1999. During Phase A, the culture was focused on results and management assumed that teamwork and initiative would follow. However, scientists were inward thinkers and kept data to themselves because everyone wanted to be the "inventor". This attitude couldn't be tolerated in the Development Phase due to the complexity in the regulatory approval process. Therefore, coordination of processes became essential and the Company needed to exploit expertise from many different areas within the organization in order to move VSLI forward.

Technology Development & Licensing was required to advance research activities consistent with the Company's strategy. This included both in-licensing as well as out-licensing opportunities. Finally, a Marketing function was introduced into Inex to ensure that the Company did its own diligence and was able to challenge a partner on assumptions related to market size.

Currently, Inex is approaching the end of Phase B has expanded internal capabilities along the Industry Value Chain as depicted in Figure 18. During this period Inex experienced significant growth as it redefined its strategy from a technology platform company and to a product-focused company.

Figure 18: Inex's Primary Activities: End of Phase B – Development[64]



6.5 Strategic Partnerships and Networks

In addition to the gene therapy technology that the Company was focusing on in Phase A, Inex was also developing VSLI as a cancer therapeutic. VSLI was made up of Vincristine, an approved chemotherapeutic agent and a proprietary lipid formulation that facilitated delivery of the active ingredient (Vincristine) to specific types of tumours. By 1999, the Company had brought VSLI through to Phase I clinical trials and had some promising clinical data. Consequently, as described in the strategy section, the Company decided to focus its resources on VSLI. This refocus resulted in the recruitment of a Business Development group and a partnering strategy to fill gaps in Inex's core competencies. Since Inex was primarily focused on research activities, it had limited competencies in late stage clinical development and commercialization. As a result, the partnering strategy was to identify a corporate partner with experience in designing and conducting late stage clinical trials in oncology. In addition, the partner would have a sales force and distribution channels to be able to service the market and commercialize the product.

[64] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

Outlined below are the major academic and commercial partnerships that Inex was engaged in during Phase B of its lifecycle.

6.5.1 Academic Partnerships

1. *University of British Columbia*: During the second phase of Inex's lifecycle, the Company continued to maintain a strong relationship with UBC by funding research in Dr. Cullis' academic lab in exchange for IP that was filed. This relationship ensured that Inex maintained connections to its roots and fostered innovative research capabilities that were not possible in a commercial setting. Other academic partnerships were dissolved in Phase B due to the refocusing efforts on VSLI.

6.5.2 Commercial Partnerships

1. *Elan Pharmaceuticals*: Established in 2001, Inex's partnership with Elan Pharmaceuticals is an excellent example of a partnership between a biotech and pharmaceutical company. Under the terms of the agreement, Elan would finance and provide intellectual capital for late stage clinical trials of VSLI. In addition, Elan had an established sales force in the oncology market, and was therefore a good fit. Elan was providing financial support to the clinical development program for VSLI. However, Elan was not providing support, in terms of intellectual capital, for clinical trial design. As a result, Inex had to expand its internal infrastructure and build clinical competencies. The lack of support, in terms of intellectual capital, from Elan was based on internal restructuring and refocusing of Elan's strategy. In fact, in 2002 Elan announced that it will focus on autoimmune disorders, pain management and neurology. As a result, Inex re-acquired the rights to VSLI from Elan in 2003.

2. *GlaxoSmithKline (GSK):* This partnership is based upon using Inex's drug delivery technology in combination with GSK's topotecan hydrochloride (a drug on the market for ovarian cancer), to develop a targeted oncology therapeutic. Although this partnering strategy is similar to the strategies employed in Phase A, a key difference was that Inex had independently conducted basic research with topotecan and its drug delivery technology and observed promising results. As a result, when Inex approached GSK for a potential partnership, Inex had a convincing argument about the potential of its technology with GSK's compound. Today, this partnership is still intact and the drug candidate is entering clinical development.

Phase B of Inex's life cycle had a clear partnering strategy that was operationalized by the Business Development group. In both partnerships described above, the drivers are quite favourable and easy to see. Both Elan and GSK are large pharmaceutical companies with significant experience in clinical development, sales and marketing. In addition, both companies had deep pockets and provided Inex with access to financial capital. From the facilitator aspect of the partnership model, both partners were large pharmaceutical companies that had different structures and management styles relative to a small biotech firm. However, interaction between Inex and the partners was funnelled through pre-assigned individuals to ensure maximal level of communication. In addition, steering committees with members from all parties involved would meet face-to-face regularly to address progress and concerns. As a result, although some of the facilitators were not favourable, they were managed appropriately. Unfortunately, Elan ran into financial difficulties and Inex re-acquired the rights to VSLI. However, without the

Elan partnership Inex would not have been in a financial position to develop VSLI and as a result, the partnership can be seen as being somewhat successful.

In summary, the partnering strategy for Phase B of Inex's lifecycle was much more focused and defined. The Business Development group was actively able to conduct driver and facilitator analyses to identify partnerships that would have the greatest chance of success. Although the drivers were clearly favourable, the facilitators had to be well-managed and clearly defined in the contractual relationship. In short, focusing resources on programs that will provide near term cash flow in a biotech company and concentrating partnering efforts around the program is crucial to a successful partnering strategy.

6.5.3 Corporate Performance Measures

When the Company decided to focus its resources on developing VSLI in 1999, the corporate performance measurement systems became more formalized. Although the Company did not use the balanced scorecard as a method for developing and measuring performance, individuals had goals and objectives that would line up with their superiors'. Inex's goals during Phase B focused primarily on operational objectives. More specifically, the Company's goals were concentrated on Clinical Development of VSLI, including Manufacturing, QC, Regulatory and Research functions to support product development.

7 PHASE C: COMMERCIALIZATION

7.1 Strategy

Inex's strategy has not changed significantly from Phase B to Phase C. The Company's strategy is still to develop and commercialize targeted therapeutics using its proprietary drug delivery technology. However, now that the Company has completed clinical development of its lead product, it must focus on the commercialization aspect. Strategically, Inex will have to establish relationships with other pharmaceutical and biotech companies that have sales forces and distribution channels. During this process, Inex will be able to learn from its partners and develop commercialization capabilities of its own. This will allow Inex to fulfil the commercialization aspect of its business strategy, since to date, the Company has been focused on development.

To build a long-term business model, Inex must be able to extract value from its existing products. In keeping with the Company's current strategy, Inex will develop VSLI for alternative oncology applications to expand the market opportunity and increase revenues. In addition, the Company should actively pursue in-licensing opportunities. This will allow Inex to build a pipeline to ensure that the internal infrastructure that the Company has built can be used for additional value-generating activities.

In summary, Inex's business strategy in Phase C will focus on:

1. Commercializing VSLI for aggressive non-Hodgkin's lymphoma
2. Increasing the potential of VSLI in alternative indications
3. Building a strong pipeline of products to ensure continual growth of the business

7.2 HR

The groundwork that was established in revamping the HR policies and procedures during Phase B, have faired well and will likely carry forward as the Company moves towards commercialization of its first product. The corporate values of *Results, Teamwork and Initiative* have been communicated and the HR systems have been built around these values. Communication within the organization remains informal and open.

Moving forward, the Company should continue to survey employees as to their satisfaction and stay attuned and open to potential areas of unrest. Although the basic systems and processes are in place, the organization must remain flexible and embrace change as the needs of its people, its environment, and its business evolve. It is apparent that Inex is continually advancing and seeking to improve its effectiveness. One such example is observed in the determination of bonus allocation. Whereas in the previous phase, bonuses were weighted on corporate, departmental and individual objectives, the Company has now eliminated the departmental weighting. This was done because Inex was beginning to realize that there were too many variables in terms of evolution – some departments were growing faster than others (due to the stage of drug development and the needs required further along the value chain) and were scoring higher on the achievement of departmental objectives than others. It was becoming

increasingly difficult to use departmental objectives as an equitable measure of achievement in all areas of the Company.

7.3 Organizational Structure

Inex currently employs approximately 200 people, distributed over various functional departments headed by the Senior VPs or Directors. The Company houses a full complement of drug development capabilities, namely: research, preclinical development, process development and manufacturing, clinical and regulatory affairs. However, from a structural perspective, Inex has simply built upon the structure that was established towards the end of Phase B. Consequently, the organizational configuration remains a blend of adhocracy and professional bureaucracy.

In view of the complex nature of drug discovery, it is important that the groups within the R&D department be able to interact, share knowledge and have the flexibility to react quickly to changes in the Company's environment. Thus, the key means of coordination is mutual adjustment and, as such, there are few planning and control systems. This remains consistent with an administrative adhocracy as discussed in Phase B. Similarly, the key functions within the organization remain within the operating core, suggestive of a professional bureaucracy.

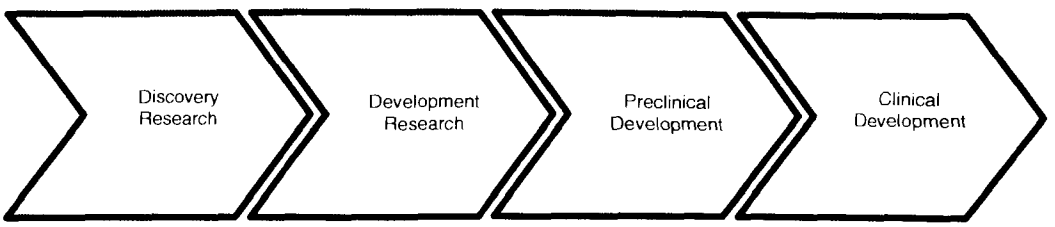
As the Company expands its operations to become more vertically integrated, it must remain cognizant of the extent to which it bureaucratizes. The overall configuration within the organization, particularly in early-stage research, must retain an adhocracy; whereas, later-stage development and commercialization must be standardized in order to achieve efficiency. Herein lies the greatest challenge for Inex: if the Company intends

to become a fully integrated organization, it must be able to manage a structure that not only provides a climate conducive to innovation, but one that simultaneously mandates standardization in areas such as Regulatory Affairs, Manufacturing, QC and QA. The Company must remain cognizant of the pressures, both internally as well as externally, to bureaucratize and standardize as the Company matures. Standardization for knowledge creation is always a double-edged sword: although standardization acts to capture acquired knowledge in order to increase efficiency, formal procedures in scientific research can inhibit innovation at the discovery phase. By the same token, the informal and non-standardized structure of adhocracy is ideal at the locus of innovation, but will present inefficiencies where regulatory compliance and commercialization are required.

Moving forward, a recommendation to Inex's management would be to maintain a simultaneous and hybrid structure of primarily an adhocracy, with some elements of professional bureaucracy. As the Company matures, management must strive to ensure that internal synergies are maintained and that there is consistency between the processes being undertaken and the configuration of the Company. Future growth for companies in dynamic environments, such as the biotech industry, can never be predicted with certainty. That said the configuration of Inex will certainly evolve as the Company grows. Currently, Inex is awaiting regulatory clearance for its first product. As other drug candidates attain the same status, the organization may consider divisionalizing by product in order to standardize processes in the *later phases* of a drug's development.

7.4 Process Management

Figure 19: Inex's Primary Activities: Beginning of Phase C – Commercialization[65]



During Phase C, the Company will be entering the last stage of the value chain. The area of commercialization requires significant infrastructure and expertise. Inex will be relying on its corporate partner, Enzon Pharmaceuticals to initiate the commercialization process. However, consistent with Inex's strategy, the Company plans co-promotion for VSLI to support Enzon's sales force. As a result, the marketing division within Inex will have to be expanded to include sales analysts, a sales force and call centres. The sales analyst group will be responsible to assess customer behaviour and buying patterns. A small ground sales force will be established to complement Enzon's sales force and will support product sales to clinics and hospitals. The call centre will be responsible for providing information to concerned patients and doctors and to close the sales cycle circuit.

In addition, a Medical Liaison division will have to be added as part of the commercialization infrastructure. This division will be made up of physicians and key opinion leaders within the oncology area that will speak at conferences about Inex's lead product. Furthermore, the medical liaison group will work closely with the rest of the marketing team to ensure that customer concerns are accurately addressed.

[65] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

Support activities such as Information Technology systems are critical to the marketing and sales of the lead product. A database of potential customers, sales and inquiries will have to be developed to support the marketing efforts for VSLI.

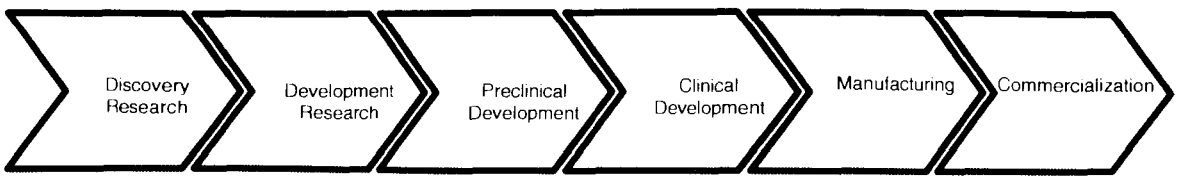
Outlined in Table 5 are the areas that Inex will have to develop within the commercialization component of the value chain as it co-promotes its lead product with Enzon Pharmaceuticals in North America.

Table 5: Snapshot of Departments at Inex: Phase C - Commercialization[66]

2004 (Current)	2005 (Commercialization)
Business Development	Business Development
Finance	Finance
IP	IP
Research	Research
Human Resources	Human Resources
Preclinical Development	Preclinical Development
Product Development	Product Development
Regulatory Affairs	Regulatory Affairs
Facilities' Management	Facilities' Management
Investor Relations	Investor Relations
Manufacturing & PD	Manufacturing & PD
QC / QA	QC / QA
Clinical	Clinical
Information Systems	Information Systems
Supply Chain Management	Supply Chain Management
Pharmaceutics	Pharmaceutics
Project Management	Project Management
Technology Development & Licensing	Technology Development & Licensing
Marketing	Marketing
	Marketing Expansion to include:
	-Sales Analysts
	-Sales Force
	-Call Center
	Medical Liaison Division
	Expansion of IT division to include:
	-Databases for customer
	concerns and sales

Note: Newly created departments are indicated in bold font

Figure 20: Inex's Primary Activities: End of Phase C – Commercialization[67]



[66] Table created by authors (Zahra Dhanji and Parimal Nathwani)
[67] Figure created by authors (Zahra Dhanji and Parimal Nathwani)

7.5 Strategic Partnerships and Networks

With the NDA for VSLI filed with the FDA, Inex now sits on the verge of the commercialization phase of its lifecycle. The Company has and will continue to maintain its academic partnership with UBC. In addition, the research collaboration with GSK is showing promising data and the technology is moving through the value chain. However, when the partnership with Elan dissolved, Inex had no infrastructure in place to commercialize VSLI in the event of approval from the FDA. Since sales and marketing functions are not core competencies for Inex and are extremely expensive to add to the Company's capabilities for only one product, a partnering strategy would be a viable option for the Company. However, by partnering at the sales and marketing stage Inex not only loses control of its product, but the Company will also have to share profits with a partner. Moreover, since Inex has multiple products coming through its pipeline, building expertise in sales and marketing would be a beneficial investment for downstream products. As a result, the Company's partnering strategy for the commercialization phase has been to develop relationships with partners that have competencies in sales and marketing, and from whom Inex can learn. Subsequently, based on this learning, Inex can begin to develop its own internal commercialization capabilities.

The following is a description of the partnership that has been formed to date in the commercialization phase:

1. *Enzon Pharmaceuticals:* In January 2004, Inex signed a strategic partnership with Enzon Pharmaceuticals for the commercialization of VSLI. Under the terms of the agreement, Enzon will use its sales force and distribution channels in the oncology market to commercialize VSLI for aggressive non-

Hodgkin's lymphoma in North America. However, in keeping with Inex's partnering strategy under the terms of the agreement, Inex has the right to co-promote VSLI in North America with Enzon's sales force by developing its own sales and medical liaison infrastructure. This strategy allows Inex to mitigate risk in that it relies on the expertise of an already established sales force, while being able to develop internal infrastructure to move towards vertical integration.

In the commercialization phase of Inex's lifecycle, the Business Development group has grown to 3 full-time dedicated Business Development staff and additional supplementary Business Development roles from various departments. This growth has been the result of a focused partnering strategy and the development of various relationships on the manufacturing, preclinical & clinical research and regulatory affairs side. To date, Inex has not publicly announced the formation of any additional partnerships. However, as the Company moves into the final phase of the industry value chain partnerships with for sales and marketing functions for Europe, Asia and other markets will inevitably be valuable and support the Company's strategy of becoming a biopharmaceutical company developing and commercializing targeted therapeutics.

7.6 Corporate Performance Measures

With the Company preparing to commercialize its first product and generate revenues, it will be extremely important for Inex to measure corporate performance in a systematic way to ensure that the Company's stakeholders, potential investors and customers can monitor the firms performance. In addition, since the Company may be generating revenues, financial performance measures will become increasingly important to the

organization. Using the balanced scorecard model, coupled with an understanding of Inex's strategy, a balanced scorecard with goals and measures within each of the 4 perspectives has been generated (section 7.6.1, below).

Since the balanced scorecard is derived from a company's strategy, recall that Inex's strategy is to create new proprietary products using conventional products that have already been approved and combining them with a lipid-based drug delivery platform. More specifically the Company wishes to:

1. Commercialize VSLI for aggressive non-Hodgkin's lymphoma
2. Increase the potential of VSLI in alternative indications
3. Build a strong pipeline of products to ensure continual growth of the business

Based on the Company's strategy, the following balanced scorecard was derived:

7.6.1 Internal Perspective

GOAL	MEASURE
• Expand technology application	• Acquisition or formation of a partnership with a company that has an approved compound in oncology to combine with Inex's technology for product development
• Manufacturing excellence	• Approved FDA inspections at contract manufacturing sites • Setup partnership with pharmaceutical company for manufacturing lipid vesicles
• Excel in basic research capabilities	• Product advanced from basic research to preclinical program • Publications in referred scientific journals and invited presentations at conferences
• Clinical Research excellence	• Key medical opinion leaders as consultants/staff • Successful clinical trial design and approval from FDA to proceed with various phase of clinical trials
• Expand market for VSLI	• Off label use of VSLI (use in other oncology indications) • Clinical proof of principle for VSLI in alternative types of cancer

7.6.2 Customer Perspective

GOAL	MEASURE
• GMP-compliant supply	• Low batch reject rates • FDA approval of manufacturing sites • Low customer complaint rates
• Reliable supply of product	• On time delivery to partner for distribution
• Efficient supply	• Decreased cost of manufacturing per batch • Increase rate of productivity
• Availability of product information	• Time to disseminate clinical information • Development of call centre for questions/concerns

7.6.3 Innovation and Learning Perspective

GOAL	MEASURE
• Discover new drug delivery technologies	• Expansion of therapeutic programs into new clinical indications other than oncology • Approvals for new indications
• Motivation of employees	• Satisfaction surveys • Company social events
• Increase R&D Capacity	• Number of research programs running in parallel • Developing therapeutics in new indications to expand pipeline
• Time to Market	• Decreasing product development timelines • Comparison of new product introduction relative to competitors

7.6.4 Financial Perspective

GOAL	MEASURE
• Increase Revenues	• Regional sales growth per quarter • Number of sales representatives • Actual to Budgeted Sales
• Manage Expenses	• General and Administrative expenses
• Increase Market Capitalization	• Stock price increase • Earnings per share

In summary, as the Company builds competencies at the tail-end of the industry value chain, development and formalization of a BSC will prove extremely valuable to investors, other companies and customers.

8 CONCLUSIONS AND KEY LEARNING POINTS

This paper examined the systems and processes at Inex Pharmaceuticals as the Company progressed through three key phases of its lifecycle: Research, Development and Commercialization. Through a series of interviews and research, the Company's strategy, organizational structure, human resources, processes, partnerships & networks and performance measurement systems were examined. Based on Inex's experiences, a series of key learning points have been complied, within the organization design framework of the analysis. These key learning points provide a frame of reference for the growth and development of a start-up biotech firm.

KEY LEARNING POINTS:

STRATEGY

- During the discovery research phase, executive team should allow strategy to be influenced by scientific findings in order to foster an environment of innovation. However, there should be systems in place to approach strategic planning at the executive level, taking into consideration market needs and the external environment. Once a target has been identified, formal strategy development processes should be in place within the biotech organization. These can include strategic retreats with senior management, company planning sessions with managers and operations' staff and/or generation of a formal strategy document that clearly defines corporate strategy.

- Focus on one or two core research programs. Although diversification may seem attractive in mitigating risk, in the biotech industry it can often lead to lack of focus and missed timelines and milestones. Further, focusing on too many programs may overburden financial resources.

- Clearly identify a feasible path towards commercialization. It is important to have a product-focused strategy to maximize value. In the case of Inex, the Company's initial strategy involved an enabling technology that required combination with genes or conventional therapeutics. Since Inex did not own these technologies or have control over them, the company technology relied heavily on its partners' technologies to be used in conjunction with Inex's enabling technology. Although this type of commercialization pathway can be more direct, it often leaves companies vulnerable and dependant upon their partners. A less obstructive path could be pursued by owning/controlling all components of the technology that are required for commercialization.

HUMAN RESOURCES

Culture

- Establish core values and communicate these to employees early in the company's development. In the case of Inex, the core values were not published, nor were they communicated to employees until 1999 – seven years after the Company's inception. Introducing corporate values at later stages in a company's development proves to be challenging as individuals and departments become entrenched in their ways of thinking.

- Emphasize the importance of teamwork in a knowledge-intensive industry such as biotech, where the completion of a single task may require the input of several individuals with specific skill sets.

Recruitment & Selection

- Careful consideration should be given to both: 1) having appropriate skill sets and 2) suitability to the company's culture and values when selecting individuals to join the organization.

- Biotech companies should tap into the networks of their employees in order to recruit individuals with very specialized skill sets. "Specialists" within the functional groups of the company may be more attuned to the gaps within the organization and the skills required to fill these gaps.

- New technical departments within the Development group (i.e. Preclinical, Clinical, Regulatory, QC, QA, Analytical Development and Process Development) should be staffed with experienced managers from more developed biotech/pharmaceutical companies. Because these departments must abide by the regulations imposed by the FDA, standardization in these areas is imperative to obtain regulatory approvals. Experienced individuals in these areas may then be entrusted with training less experienced members of the team. In Inex's case, during Phase A, scientists with little or no experience in later stage development processes were assigned to head up new departments. This created significant confusion as to the tasks involved and

the Company eventually hired senior managers to reconstruct and re-configure the departments. Consequently, Inex spent a lot of time mending such structures and implementing systems to ensure compliance with the regulatory authorities. In contrast, more generalist type management roles, such as HR, IT, Operations and Administration do not necessarily need biotech experienced management. In fact, companies should keep an open mind about recruiting individuals from different industries for such positions as these individuals often bring new insight and experiences.

Job Structure

- Due to the level of complexity in accomplishing tasks in biotech, coordination between "specialists" must be clearly delineated. Therefore, it is critical to define roles and points of interface within the organization to ensure efficient operations.

- Find a system to equate different job families within the organization. Inex implemented a system of impact levels in order to view employees in different job families, in a consistent manner.

- Implement a participative management by objectives system, where corporate objectives are translated into departmental and individual objectives. Inex has introduced a bonus system, in its variable compensation structure, that rewards the accomplishment of these objectives.

Recognition & Rewards

- Ensure rewards reinforce the desired behaviours and the corporate culture.

ORGANIZATIONAL STRUCTURE

- Balance the need to standardize (for regulatory compliance) with the need for innovation (research). Therefore, within a small biotech company, policies and procedures should be minimized to cultivate an environment that is conducive to innovation.

- Ensure that the organization remains flexible and reconfigurable in order to respond to the dynamic environment in which biotech exists.

PROCESS MANAGEMENT

- GLP and GMP required processes should be outsourced, as these activities are not primary for a small biotech company. Furthermore, the learning curve for these processes is very steep and would heavily tax resources in a small company.

- Regulatory Affairs should be incorporated into the organization just before embarking upon the preclinical development stage. This ensures that the company is well-positioned and has met regulatory requirements further along in the drug approval process.

- Analytical Development and Process Development should be considered prior to commencing preclinical development. This will allow the company to deal with challenges in manufacturing and testing methods, prior to be held accountable by regulatory authorities. Inex had not established these departments prior to preclinical development. As a result, the Company had to address concerns at a much later stage of development. These matters could have been resolved earlier in development with the relevant expertise.

PARTNERSHIPS AND NETWORKS

- Develop a partnering strategy that is in line with the company's overall strategy. It is important to ensure that if, and when, the company's strategy changes that the partnering strategy is adjusted accordingly.

- Ensure that Business Development is involved in identifying and defining partnerships. Although it is important for scientists in different organizations to work together, processes and systems must be put in place to facilitate interaction between parties involved. In the early stages, Inex's scientists were actively involved in identifying and forming partnerships without conducting an analysis of partnership drivers and facilitators. Thus, these partnerships may have been hampered by mismanaged expectations.

- Ensure that there is enough scientific validity and credibility to your technology before engaging in a partnership. For Inex, this was instrumental in gaining exposure and credibility from its early days.

CORPORATE PERFORMANCE MEASURES

- The balanced scorecard provides an excellent mechanism to develop corporate performance measures across all aspects of the business. However, for the BSC to work effectively, the goals and measures must be communicated to everyone within the organization to obtain "buy-in". In addition, since the BSC is based upon the company's strategic objectives, the goals should be translated into tangible functions that everyone can related to and work towards. Finally, in addition to a measurement system, the BSC can be used as a strategic management system and communication tool.

These key learning points establish a sound foundation for management processes in a young biotech company and will help position the company for future growth and development. However, it is important to realize that having these elements alone does not guarantee success. Various factors should be considered to complement the guidelines discussed in this paper. These may include: financing strategy, management style, marketing strategies, etc. to build a successful start-up biotech company.

It is important to note the limitations to the analysis described in this paper:

- The analysis presented is based upon the experiences of one company. Many times, lessons learned from one company cannot be extrapolated to others due to differing circumstances. An analysis of multiple biotech companies would provide a more comprehensive view of learning points within the framework. However, the time and resource limitations of this project, did not make it feasible to engage in a thorough analysis of more than one company. Therefore, this project provides a framework for others to build upon by analyzing other firms.

- External factors play a critical role in contributing to the success of a biotech company. Market conditions can often govern the success of biotech firms. Access to capital is critical since start-up biotech companies do not have products from which to generate revenues. Thus, if market conditions are poor and access to capital is limited, even the best management systems and processes will not be sufficient to build a successful biotech company.

- The biotech industry often goes through phases of "sexy" science. During Phase A of Inex's lifecycle, gene therapy was "sexy" and held significant promise. Consequently, financiers were investing large amounts of money into companies that were involved in gene therapy research. Today, the potential of gene therapy has not been realized and funding gene therapy platforms has become very difficult. Therefore, biotech companies are often susceptible to conceding to "sexy" science in order to obtain the attention and funding necessary to grow and develop the organization.

- In biotech firms, science is seen as the value driver. Building management systems and processes such as an HR or IT department are not considered major value drivers. As a result, when firms are strapped for financial resources, companies will hire and build scientific infrastructure, often at the expense of systems & process infrastructure. Start-up biotech firms are often so entrenched in obtaining proof-of-concept data, that they will not expend resources to execute on the key learning points identified in this project.

In conclusion, this project presents a systematic way of analyzing organization design within a biotech company. Based on the encounters and experiences of Inex Pharmaceuticals, key learning points within the framework have been recommended. Although these key learning points provide a solid foundation, other factors such as the external environment, scientific perception and resource limitations should also be considered when growing and developing a biotech company.