

GROWTH STRATEGY FOR AN EMERGING BIOPHARMACEUTICAL COMPANY

by

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PROJECT SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF BUSINESS ADMINISTRATION

In the
Faculty
of
Business Administration

Executive MBA Program

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SIMON FRASER UNIVERSITY



Summer 2006

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ABSTRACT

Inimex Pharmaceuticals, Inc. is a privately held biopharmaceutical company dedicated to the discovery, development and commercialization of new human medicines based on the selective modulation of the innate immune response. Since Inimex's background is in human drug development, no formal animal health activities have been a part of Inimex operations.

This initial analysis shows that Inimex has opportunity in the animal health market. Inimex is in a good place to evaluate a potential revenue-generating growth opportunity that could also develop in-house capabilities and positively increase Inimex's public profile for future investors.

The primary recommendation is the strong encouragement for Inimex to pursue the development of a medicine for companion animal application. For maximum short term revenue, Inimex should bring the medicine into INADA trials then negotiate a deal before entering more resource intensive clinical field trials.

Keywords: animal health; biopharmaceutical; biotech; innate immunity; pharmaceutical.

EXECUTIVE SUMMARY

Inimex Pharmaceuticals, Inc. is a privately held biopharmaceutical company dedicated to the discovery, development and commercialization of new human medicines based on the selective modulation of the innate immune response.

This author was asked by Inimex's senior executives to identify whether there was a business opportunity for Inimex in the animal health market. Since Inimex's background is in human drug development, no formal animal health activities have been a part of Inimex operations. Therefore, this project is the initial analysis and screening of growth opportunities for Inimex in the animal health market.

Chapter 2 demonstrated two things. First, that Inimex has a drug technology platform with significant advantages. Namely, it promotes the innate immune system to rapidly fight infections while suppressing inflammation. Second, there is opportunity for Inimex drugs in both the livestock and companion animal segments of the animal health industry. The approach for the two animal health segments is different.

Chapter 3 showed that the climate for developing an animal health drug is favourable for Inimex. One of the key success factors for incumbent firms is constant innovation. Inimex can meet this need with its technology platform. One of the key Inimex success factors is sufficient capital to sustain development to product approval. If Inimex can show some efficacy and application, animal health firms will want to make a deal with Inimex.

In Chapter 4, an Analytic Hierarchy Process (AHP) tool was used to evaluate sample target indications. The criteria and their weighting were determined by the author. Should Inimex wish to use this tool any further, they need to evaluate the criteria and weightings based on their own perceptions and further market research.

Although many animal indications fit the Inimex medicine profile, a sample indication from a livestock and a companion animal segment was evaluated for discussion: bovine respiratory disease complex (BRD, shipping fever) and canine hemangiosarcoma (dog cancer). The AHP tool indicated that companion animal indications would be more favourable considerations for Inimex at this point in its development. Although limited industrial and clinical information was available for both indications, the main point is that companion animal clinical trials require less time and resources than for livestock.

In Chapter 5, the two sample indications were first valued using two techniques: industry standard and discounted cash flow (DCF). With a lack of animal drug valuation information, many assumptions and estimates were made based on the available data. More detailed market research is needed for more confidence in the valuations. Second financing options were presented. Out-licensing was the option with the most potential for shorter term revenue generation. Finally, the sample indications were discussed from the perspective of market potential, valuation, regulatory timeline and financing options.

Recommendations. The primary recommendation is the strong encouragement for Inimex to pursue the development of a medicine for companion animal application. For maximum short term revenue, Inimex should bring the medicine into INADA trials then negotiate a deal before entering more resource intensive clinical field trials.

The reasons for focusing on companion animals over livestock are three-fold. First, the upfront clinical costs that Inimex would bare are lower. Second, clinical trials are shorter. Third,

clinical trials can be managed more easily. These three reasons speak to the fact that regulatory and public perception are critical; as early trial data is available, Inimex can benefit from positive animal health drug development information or make adjustments in the event of negative data. The realization of short term revenue, no matter how small, will benefit Inimex in its operations and public perception.

Before jumping into such an undertaking, there are four activities that Inimex would need to consider. First, Inimex would need to put together a business plan to discuss the concept with its Board of Directors, which includes animal health experts. This would include determining whether this activity would distract the human drug development focus and the identification of mitigations to avoid distraction. Second, Inimex would need to earmark about US\$300K to IM for the INADA activities. Third, Inimex would need more market research on companion animals. Fourth, Inimex may need to hire at least one more person to assist in developing the business concept.

In conclusion, this initial analysis shows that Inimex has opportunity in the animal health market. Inimex is in a good place to evaluate a potential revenue-generating growth opportunity that could also develop in-house capabilities and positively increase Inimex's public profile for future investors.

For Robyn, lulu. Mama is back!

ACKNOWLEDGEMENTS

I am deeply indebted to Inimex Pharmaceuticals Inc. for allowing me to undertake this project and providing me with information and support to complete the work. In particular, Roger Graham has helped to clarify my understanding of Inimex and business development. He also provided comments and input regarding the possible strategic directions that could be taken.

I also acknowledge the teaching and administrative staff of Simon Fraser University's Executive MBA program. They have provided excellent support, assistance and guidance throughout the program. I am especially thankful to Ian McCarthy for his supervision, humour and perspective in this project.

Finally, I would like to thank my EMBA-2004 cohort group; I have grown through many brutally honest, hilarious and often-caring interactions. My own Fantastic Four study team will be the fondest part of my memories and an extension of my small family.

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GLOSSARY

AHP	Analytic Hierarchy Process
BCR	Benefit to cost ratio
DCF	Discounted cash flow
INADA	Investigation of a New Animal Drug Application
IP	Intellectual property
NADA	New Animal Drug Application
NPV	Net present value
UBC	University of British Columbia

1 INTRODUCTION

Inimex Pharmaceuticals, Inc. is a privately held biopharmaceutical company dedicated to the discovery, development and commercialization of new human medicines based on the selective modulation of the innate immune response.

This author was asked by Inimex's senior executives to identify whether there was a business opportunity for Inimex in the animal health market. Since Inimex's background is in human drug development, no formal animal health activities have been a part of Inimex operations. Therefore, this project is the initial analysis and screening of growth opportunities for Inimex in the animal health market.

1.1 Introduction to Inimex Pharmaceuticals

Inimex was founded in 2001 by University of British Columbia, UBC, Professors B. Findlay and R. Hancock after the discovery and patenting of novel immune system modulators. The Company's goal is to have its technology platform yield novel prophylactic and therapeutic agents, which will have a significant impact on the management of a wide range of disease indications for humans.

Inimex is developing non-antibiotic medicines that act on the patient/host rather than on infection-inducing bacteria. Antibiotic resistance has become a major issue in today's society, affecting many sectors including healthcare and agriculture. According to the Centers for Disease Control, CDC, septicemia was the 10th highest cause of death in the United States in 2003 (Hovort et al, 2006). Septicemia is the presence of disease-causing bacteria in the blood. If a person has any type of surgery, there is a risk that unfamiliar strains of bacteria may be

introduced into their body. In the hospital environment, the prevalence of antibiotic resistance and immune compromise are significant medical concerns. The known ability of plasmids to transfer antibiotic resistance between bacterial species reinforces these concerns (van Elsas and Smit, 1997). Furthermore, the livestock industry is under increasing scrutiny with findings that human antibiotic resistance can be the indirect result of antibiotics use in the production of animal products for human consumption (Mølbak et al, 1999). Inimex medicines are proprietary short peptides that selectively augment host innate immunity without triggering inflammatory responses that lead to tissue damage and sepsis.

Inimex is an emerging company with fewer than 25 employees. It has completed two rounds of private equity financing and it has been awarded non-dilutive government funding. As of early 2006, it has identified its first drug candidate to undergo formal pre-clinical studies. In the next five years, Inimex expects to build a portfolio of clinical programs addressing serious unmet medical needs associated with antibiotic resistant infections, broad spectrum prophylaxis in immune suppressed patient populations and the management of inflammatory disease. According to industry pundits (PhRMA, 2005), it can take from 12 to 18 years to move a product from discovery to commercialization. Preparing for its first pre-clinical trial, Inimex may not have a commercial drug for human use until 2016.

The time to market for veterinary pharmaceuticals is typically six to twelve years (AHI, 2006); much shorter than that for human drugs. It is likely that Inimex could have a commercial veterinary product before a human product. Therefore, it would be prudent to evaluate scenarios whereby eventual animal health revenue streams could fund Inimex pre-commercial activities. The benefit of such a strategy would be to reduce reliance upon venture capital funding, identify different sources of funding and develop in-house competencies. It is the intent of this project to identify animal health opportunities for Inimex. The following sections will detail the project aims and structure.

1.2 Statement of Project Objective and Aims

The overall objective of this project is to evaluate whether there is a viable animal health business opportunity for Inimex. To meet this objective, three aims to this project must be met. The first aim is to demonstrate a clear understanding of Inimex and the animal health industry. The second aim is to develop an opportunity evaluation tool for Inimex animal health medicines and then identify sample target animal indications. The third and final aim is to perform a comparative evaluation of potential revenue-generating scenarios for the sample targets. Through the analysis of the available information, Inimex will gain a business development process with which to target and evaluate animal drug opportunities.

1.3 Project Structure

The project objective will be met with the following structure. Chapters 2 and 3 will achieve the first aim of the project, which is to demonstrate a clear understanding of Inimex and the animal health industry. Chapter 2: Animal Health Opportunity, will discuss Inimex's technology platform and animal health opportunities by:

- describing the Inimex technology platform;
- discussing Inimex drug advantages;
- identifying opportunities through presentation of the customer profile, the animal population growth trends and perceived customer needs.

Chapter 3: A Look at Animal Health Industry Dynamics, evaluates the environment in which Inimex is entering by:

- introducing the market leaders and the current market sales profile;
- presenting the animal health industry value chain to put into context Inimex's value chain footprint and core competencies;
- performing an industry analysis with use of the Porter Five Forces Model (Porter, 1979);
- listing the key success factors.

In Chapter 4: Targeting Drug Opportunities, the second aim will be met, which is to develop an opportunity evaluation tool applicable to Inimex animal health medicines. The tool will use the available internal, industry and customer needs information to:

- identify key drug development milestones, including duration, costs and risks;
- specify selection criteria and their significance;
- build and demonstrate the evaluation tool using select sample target indications.

Chapter 5: Evaluation of Scenarios, will round out the project by achieving the third aim: to perform a comparative evaluation of potential revenue-generating scenarios for the sample target indications. The evaluation will include:

- valuation of Inimex animal health medicines;
- identification of financing options;
- evaluation of revenue-generating scenarios for indications.

Finally, Chapter 6: Summary and Recommendations, will summarise the project findings and make recommendations that pertain more to the development of the business strategy as opposed to the selection of the target indications.

2 ANIMAL HEALTH OPPORTUNITY

In this chapter, Inimex's technology platform and animal health opportunities will be discussed by:

- describing the Inimex technology platform;
- discussing Inimex drug advantages;
- identifying opportunities through presentation of the customer profile, the animal population growth trends and perceived customer needs.

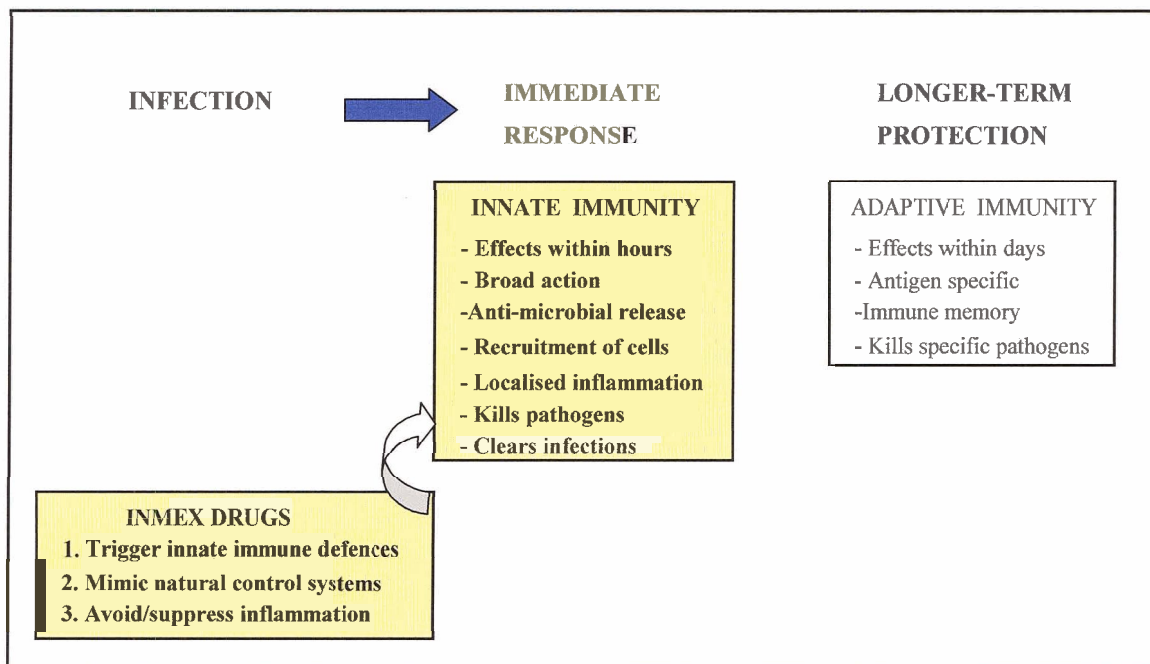
2.1 Inimex Technology

Inimex drugs are designed to trigger the innate immune system. The immune system has two general functional areas: innate and adaptive immunity. The two are broadly distinguished by their time of response and their action (Finlay and Hancock, 2005). The Inimex technology platform and the immune responses are summarized in Figure 2.1 below.

Adaptive immunity is more commonly known. It is the development of antibodies within a multi-cellular organism over days to fight antigens (infective agents). For example patients who have had chicken pox as children tend to be immune to the infection upon exposure later in life. Since adaptive immunity is antigen-specific, vaccinations have been developed as prophylactics to many debilitating diseases in both humans and animals.

The innate immune system recognizes an infection or threat thereof. The innate immune response is immediate and non-specific. The effect is broad spectrum treatment within hours. An aspect of the innate immune defence is inflammation, which clears away infections.

Figure 2.1: Inimex Technology Platform



Based on Inimex Pharmaceuticals, www.inimexpharma.com/products/prod_tech_immunity.html, site accessed April 11, 2006.

As stated above, Inimex drugs are designed to selectively trigger the innate immune system. These drugs are synthetic peptide chains identified and optimized from the human host defence peptide LL-37 (Bowdish et al, 2005). Inimex drugs have been tested on cells *in-vitro*. *In-vivo* testing has also been performed on the murine animal model. Drugs administration has been through injection.

2.2 Inimex Drug Advantages

Four key competitive advantages to Inimex drugs have been identified:

- No resistance
- Avoid or suppress inflammation
- Fast acting and broad spectrum
- Effects present for days

Medical intervention for infections is usually through the administration of antibiotics. It is well known that antibiotic resistance has become an issue. Since Inimex drugs act on the host

innate immune system and not the infecting agents, drug resistance is not an issue. Moreover, Inimex drugs are not expected interfere with other drug treatments.

Under normal circumstances, inflammation is a non-threatening aspect of the healing process for the host. Unfortunately, for health-challenged individuals like chemotherapy patients, inflammation can inhibit healing and even cause death. The Inimex drugs selectively trigger the innate immune system, without causing inflammation.

Since Inimex drugs are fast acting their effect is broad spectrum, they are ideal for treating infections in high density populations. For example critical care patients and livestock being readied for shipment are all immune compromised and susceptible to infection. Under these circumstances it is often difficult to diagnose the specific antigen for treatment quickly. As a therapeutic, Inimex drugs would be used to treat quickly a broad spectrum of infections. As a prophylactic (preventative) treatment, the drugs are expected to prevent spread of the infection.

Finally, the effect of Inimex drugs can remain in the system for up to two days. This is an advantage over some antibiotics that need to be administered two to three times a day.

2.3 Animal Health Opportunities

This section considers the size of the animal market and whether there is capacity for Inimex animal health drugs. This is achieved by presenting animal populations and growth trends, as well as perceived customer needs. The animal health industry can be divided into two areas: livestock and companion animals. Livestock are animals intended for human food consumption. Companion animals are basically pets. Although horses can be used for consumption, for this discussion, they are considered a companion animal.

2.3.1 Livestock

Livestock include cattle, hogs sheep and poultry. Livestock are considered a commodity because of their high economic value and volume of consumption. For example, the estimated 2005 retail value for the USA beef and cattle industry was US\$78 billion (USDA, 2006a) and USA poultry was US\$29 billion (USDA, 2006b).

The USA 2004 cattle inventory was 94.9 million head with about 20 percent annual turnover for slaughter (USDA, 2006a). The Canadian cattle inventory as of January 2006 was somewhat less at 14.8 million head and a similar annual slaughter turnover (Statistics Canada, 2006a). The total 2005 poultry production was about 15.9 billion birds (85 percent chicken) in the USA (USDA, 2006c) and 647 million birds in Canada (Statistics Canada, 2006b).

Livestock value is based on weight. Animal health is focused on maintaining disease-free herds, while keeping costs as low as possible. Market opportunities for Inimex drugs would be realized in areas that increase livestock economic value. An example that fits well with a Inimex drug advantages is the substitution for antibiotics. Growing public concern over antibiotic resistance could be addressed by the use of Inimex drugs, which act on the host and not the infecting agents. A successful Inimex drug could increase demand for antibiotic-free meat.

Another area of opportunity is during weaning and shipping when animals are under immune stress. Stress induces the diversion of nutrients away from weight gain and growth. Scientists have attributed the cause of weight loss to pro-inflammatory cytokines that are released in the immune response (Spurlock, 1997). Inimex drugs suppress inflammation because they do not trigger the release of cytokines. With this advantage, trials should show that Inimex drug treatment prevents weight loss during periods of high immunological stress.

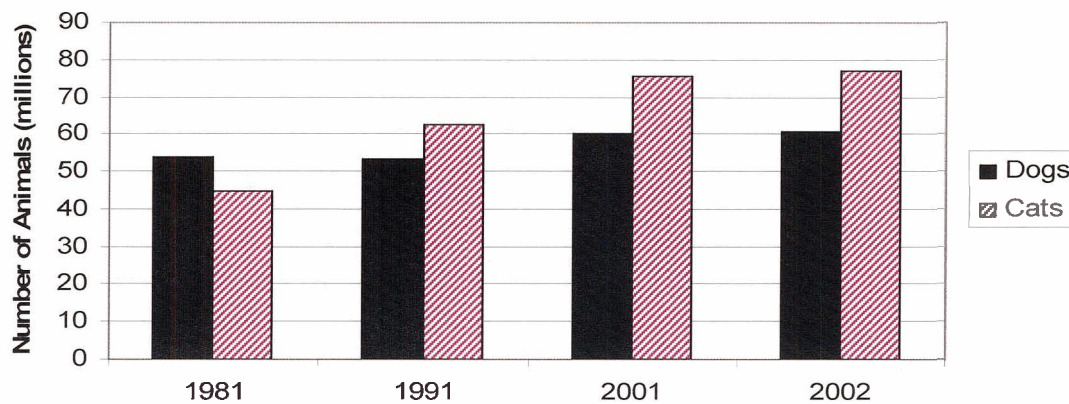
With billions of dollars in revenue at stake, the livestock industry should welcome animal drugs that will improve their returns. As a competing drug, Inimex would either have to prove economic value through a reduction of costs or an increase in revenues before adoption by the agricultural industry. At least one challenge for the drug itself is its formulation, which is

currently an injectable. Since a herd would be treated as a whole, bulk administration methods would likely find more ready adoption. An oral formulation that is administered in feed or drinking water would be preferred over the more time-consuming to administer injection.

2.3.2 Companion Animals

Companion animals are pets. By tradition, most small animals were working animals on farms: dogs to herd and cats to catch rodents. Since the urbanization of farm land in the 1950s, companion animal numbers have increased in urban centres. Since the USA companion animal market is larger than that of other countries, its animal population will be discussed here. As of 2004, USA pet population is about 60 million dogs and 75 million cats, as shown in Figure 2.2 below.

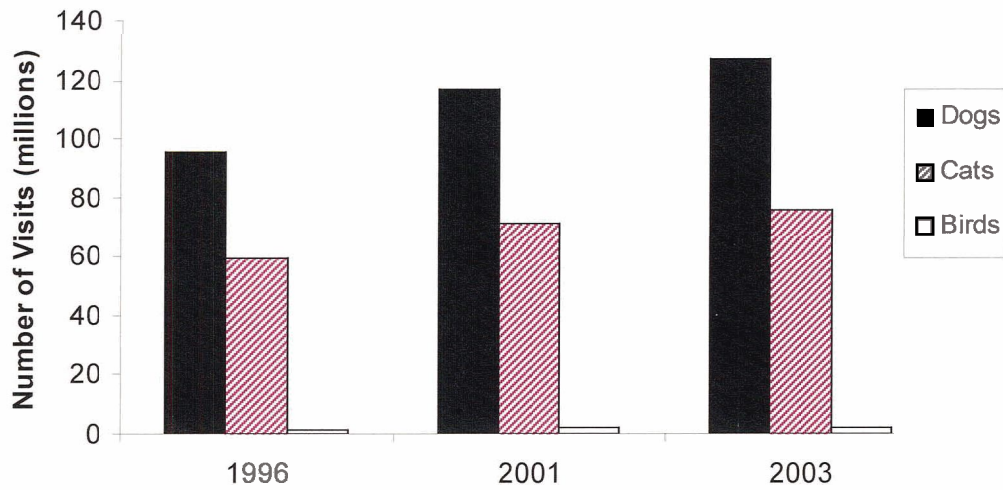
Figure 2.2: USA Population of Dogs and Cats, 1981-2002



Data source: Packaged Facts, 2004.

With the aging human population and couples having children later in life, the trend is to treat pets as members of the family. As such, people have been reported to bring their pets to the veterinarian more often than they see doctors themselves. With an increase in animal population, the number visits to veterinarians have also increased over time, as demonstrated in Figure 2.3 below. Birds, the third most common pet, are depicted in the figure to show that smaller pets represent a niche animal health market relative to cats and dogs.

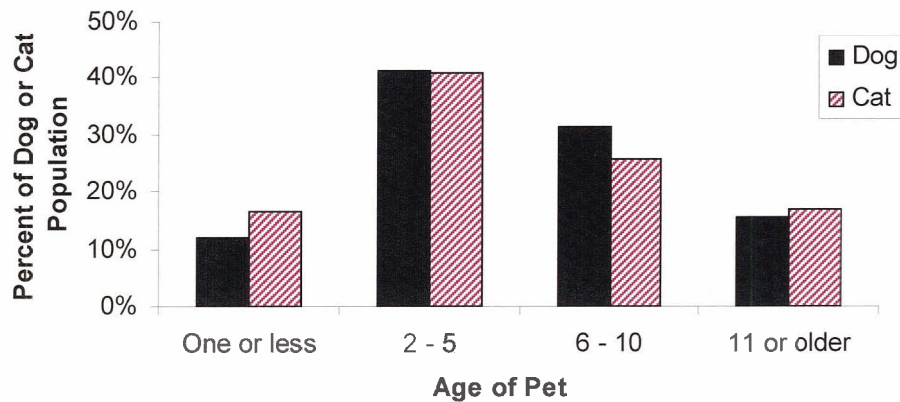
Figure 2.3: Visits to Veterinarian by USA Pet-Owning Households



Data source: Packaged Facts, 2004.

As a means to understand customer needs and demands for pets, the USA dog and cat populations for 2001 are further segmented into age groups; see Figure 2.4 below.

Figure 2.4: Share of Respective USA Animal Population by Age, 2001



Data source: Packaged Facts, 2004.

Older animals have an increased probability of developing an age-related disease. The most common ailments for older pets are cancer and obesity which could lead to heart and kidney disease and diabetes. Over 10 percent of the dog and cat populations are older than 11 years of age, representing about 14 million animals. Although this number of animals is not as high as that

for livestock, there is still market opportunity. Pet owners are more willing to pay large veterinary fees to keep their “family member” alive. A 2003 survey conducted by the American Animal Health Association (AAHA) shows that the price of services is not a priority; in fact it was 8th most important factor (Packaged Facts, 2004). Moreover, pet owners have used specialized, costlier services, as presented in Table 2.1 below.

Table 2.1: Specialized Veterinary Services Used by Pet Owners

Specialized Service	Percentage Used	Estimated Numbers¹
Ultrasound	16%	21.6 million
CT Scan	3%	4.1 million
MRI	2%	2.7 million
Endoscopy	2%	2.7 million
Chemotherapy	1%	1.35 million
Radiation Therapy	1%	1.35 million

¹ Number of animals based on assumption that survey is representative and a pet would receive the service once. Number obtained multiplying percentage by 135 million (approximate cats and dogs in 2002) from Figure 2.2 above

Data source: Packaged Facts, 2004.

Since it may be difficult to quantify to quantify improved quality of live, the types of companion animal indications to consider are acute cases where a measure of success could be the survivability rate. Acute cases could initially mimic that of the Inimex human drug program, which targeting immune compromised patients. For animals this could be cats or dogs that have undergone cancer treatment. Assuming that the above survey results are representative of the US animal population, the approximate number of pets that received chemotherapy in the United States was about 1.35 million for 2003.

As in the livestock case, other considerations are those situations that induce immune stress. Such situations would be periods in kennels, extended care in veterinary clinics or dog day cares where kennel cough (*bordatella bronchicarpa*) has been a common occurrence. Although

statistics were not available for this report, research should provide the numbers of pets under such care, the incidence of related infections, available vaccines and treatments.

2.4 Opportunity Summary

This chapter has demonstrated two things. First, that Inimex has a drug technology platform with significant advantages. Namely, it promotes the innate immune system to rapidly fight infections while suppressing inflammation. Second, there is opportunity for Inimex drugs in both the livestock and companion animal segments of the animal health industry. The approach for the two animal health segments is different. For livestock, the focus is to enhance economic value for food producers: high volume low cost. The companion animal focus is to increase quality and duration of pet life: low volume, high cost.

3 ANIMAL HEALTH INDUSTRY DYNAMICS

In the previous chapter, the soundness of Inimex's technology platform and the animal market size both indicate that there is potential for Inimex in the animal health industry. This alone will not decide whether Inimex has a business opportunity. The next step is to consider the animal health industry dynamics in which Inimex would enter. The environment for the industry is evaluated in this chapter by:

- introducing the market leaders and the current market sales profile;
- presenting the animal health industry value chain to put into context Inimex's value chain footprint and core competencies;
- performing an industry analysis with use of the Porter Five Forces Model (Porter, 1979);
- listing the key success factors.

3.1 Market Leaders and Sales Profile

The animal health market is a small portion of the overall health care industry. In 2004, US pharmaceutical sales were US\$215.0B for human use and US\$3.9B for animal health use (PhRMA, 2005). However, this does not discount the value of the growing animal health business where revenue is almost ten times greater than reported R&D expense. The estimated 2005 world animal health industry was valued at US\$14.9B with 8.8 percent growth over 2004 (Wood Mackenzie, 2006). A surprising statistic is that 45 percent of this share, US\$7.2B, belongs to generic products (Animal Pharm, 2006a). Table 3.1: below summarizes global animal health sales from 2000 to 2005.

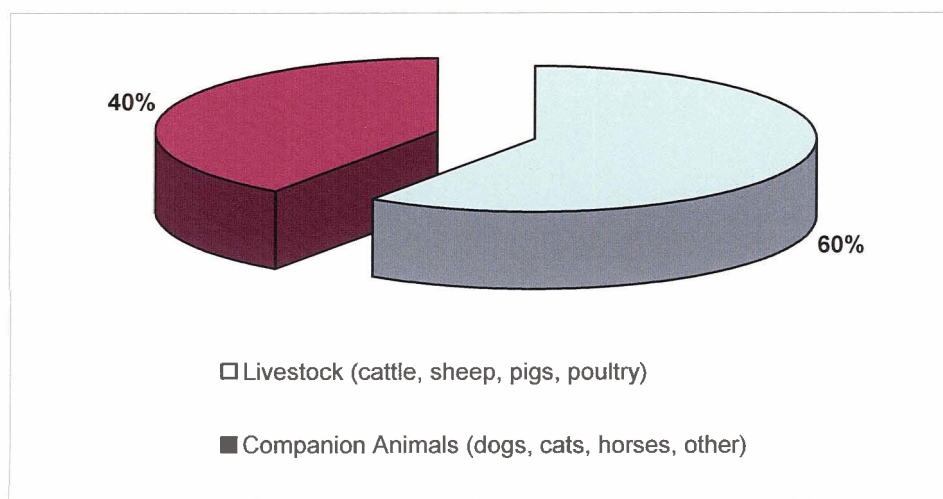
Table 3.1: Global Animal Health Sales, 2000 - 2005

Global Sales US\$B	2000	2001	2002	2003	2004	2005
Total World Market	\$11.0	\$11.1	\$11.3	\$12.5	\$13.7	\$14.9
Growth Over Previous Year	-	0.2%	2.5%	10.7%	9.3%	8.8%

Data source: Wood Mackenzie, 2006, www.ifahsec.org/Industry/animal_health_market.htm, site accessed April 26, 2006.

Although the market was relatively flat in 2000, on average the industry has grown in sales about US\$1B a year to 2005 (Wood Mackenzie, 2006). The animal health market is dominated by the livestock industry. With current cases of Bovine Spongiform Encephalopathy (BSE, mad cow disease) and avian flu disease, related animal health product sales have decreased. However this is balanced by increased growth in the companion animal sector. Therefore, although market share is greater for livestock animals at 59.8 percent, the companion animal market is growing at a faster rate (Wood Mackenzie, 2006). The animal health market is presented by animal segment in Figure 3.1, below.

Figure 3.1: World 2005 Animal Health Sales by Animal Segment (Total US\$14.9B).

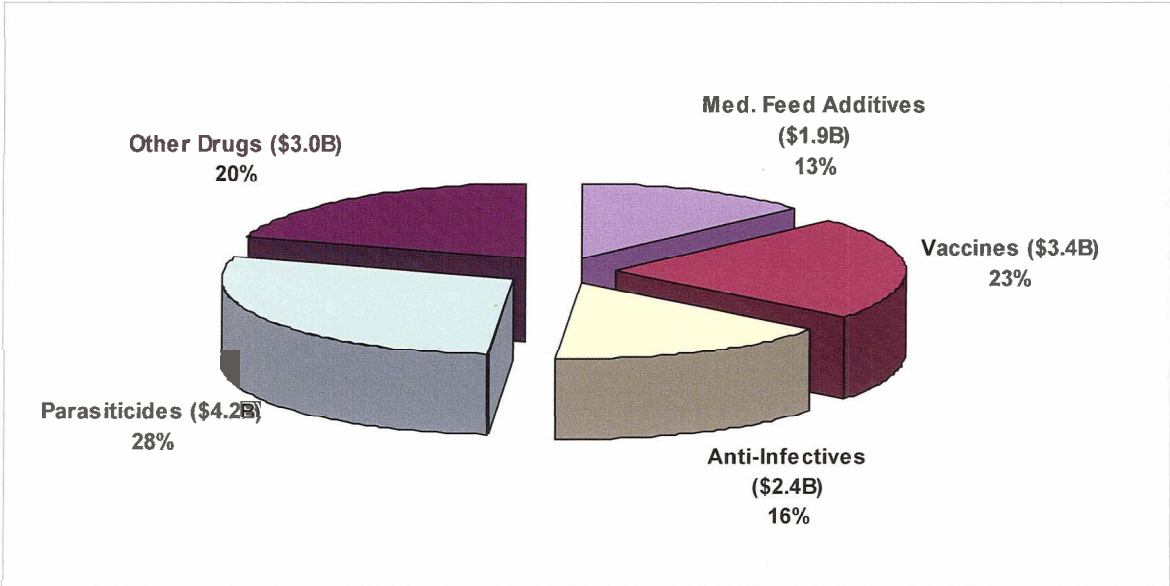


Data source: Wood Mackenzie, 2006.

Animal health products are divided into five major product segments: medicinal feed additives, vaccines, anti-infectives, parasiticides and other pharmaceutical drugs. The proportion of sales worldwide for each segment is presented in Figure 3.2 below. The highest sales, at US\$3.4B, are for parasiticides in both the livestock and companion animal categories. Parasiticides are medicines used to kill or prevent parasites such as fleas, ticks, mites and worms. The second largest sales are for vaccines, at US\$3.4B. The third largest segment, at \$3.0B, is other pharmaceutical drugs. This segment includes a broad range of pharmaceuticals like immune suppressants, neurological drugs, analgesics and cancer treatments. With worldwide sales at US\$2.4B, anti-infectives include antibiotics, antiviral drugs and fungicides. The last segment is medicated feed additives at \$1.9B.

Parasiticides and other pharmaceuticals are the higher growth rate product segments. Sales for the anti-infective product segment have the lowest growth rate. Anti-infectives include antibiotics which are centred in the antibiotic resistance debate associated with livestock production.

Figure 3.2: World 2005 Animal Health Sales by Product Segment (Total US\$14.9B).



Data source: Wood Mackenzie, 2006.

With very few exceptions, animal health companies are subsidiaries of larger human pharmaceutical companies. The top six animal health companies are identified in Table 3.2: below. These companies account for 51 percent of world animal health sales; all have global operations with thousands of employees.

Table 3.2: Top Six Animal Medicine Companies, Sales Worldwide

Animal Health (AH) Division	Parent Company	2005 Sales (US\$M)	Key Product Segments
Pfizer Inc., AH	Pfizer Inc.	2,206	anti-infectives, parasiticides, vaccines, pharmaceuticals
Merial Ltd	Merck & Co., 50%; sanofi-aventis, 50%	1,987	parasiticides, vaccines
Fort Dodge AH	Wyeth	881	parasiticides, vaccines
Elanco AH	Eli Lilly and Co.	864	anti-infectives, medicated additives
Bayer AH	Bayer Healthcare	856	anti-infectives, parasiticides,
Schering-Plough AH	Schering Plough	851	anti-infectives, vaccines, pharmaceuticals

Data source: www.pfizer.com, www.merck.com, www.Lilly.com, www.wyeth.com, www.bayer.com, www.sch-plough.com, all sites accessed April 29, 2006.

3.2 Inimex In Context

Inimex’s novel drug discovery technology platform is its single-most important asset. Any activities that support and protect this asset increases Inimex’s potential for success. Inimex is a drug development company, as such the focus is on pre-commercial operations and business development. Inimex’s goal is to take its drugs to a point that it will be attractive to big investors or large pharmaceutical companies. Therefore, it is important to look at Inimex in the context of the overall industry drug development process. From this perspective, we can identify where and how Inimex can add value to any animal health drugs it should choose to develop.

One of the goals of this Section and Section 3.3 is to provide information that will assist in identifying the key success factors for incumbent firms and Inimex, a new entrant to the animal health industry. Key success factors will be identified throughout and summarized in Section 3.4.

3.2.1 Drug Development Activity Value Chain

Six general activity categories can be identified in drug development for commercialization. These activities together make up the industry value chain, from start to finish. The industry-level value chain for the animal health industry is presented in Figure 3.3 below. The shaded area indicates pre-commercial activities and the unshaded area is for commercial activities. As an emerging drug development company, Inimex does not have any commercial activity. Its footprint in each category is expressed above each box.

Figure 3.3: Industry-Level Value Chain With Inimex Footprint

90% Inimex 10% Contract	40% Inimex 60% Contract	0%	100% Contract	10% Inimex Marketing	0%
Drug Discovery	Preclinical Studies	Clinical Field Trials	Manufacturing and Support	Marketing and Sales	Distribution

Activity Legend	
Pre-commercial	
Commercial	

Based on EMBA Strategy Seminar [EMBA 607 class notes]. Bukszar, Ed. Spring 2006.

The first category in the industry-level value chain is drug discovery; the process of evaluating lead drug development candidates. The activities in this category are basic research, which includes cell and molecular biology, bioassays and screening, synthetic chemistry and *in vivo* pharmacology. Typically 400 compounds are evaluated to obtain one lead drug candidate. Depending on the size of research group and funding, this process can take anywhere from 2 to 12 years. Constant innovation is one of the key success factors in this industry; without a viable drug candidate pipeline, commercial growth is compromised and shareholders will hold the company accountable. Inimex performs about 90 percent of these activities in-house the rest is through collaborations with organizations like Genome Canada and research laboratories at UBC.

The second category is preclinical studies are performed to determine the efficacy and safety of the drug candidate in disease models for the target animal species. Beginning at this point of development, the regulatory agencies in each country has a great deal of oversight. In the USA, the regulatory agency is the Food and Drug Administration, FDA, in Canada it is the Health Protection Branch, HPB. In the USA, formal preclinical studies would begin with an INADA (Investigation of a New Animal Drug Application). The regulatory pathway is summarized in Table 3.3 below.

Table 3.3: Regulatory Pathway for Drug Development to Commercialization

Stages	pre-INADA	INADA	NADA		Market
Discovery	<i>in-vitro, in-vivo</i>				
Companion		Safety Efficacy	Field Studies (Clinical Trials)		Market
Livestock		Safety Efficacy	Field Studies (Clinical Trials)	Human Safety Studies	Market
Timelines	2-12 years	1-3 years	2 - 5 years per species	2 - 5 years	
Successful Candidates	~1 in 400	~ 1 in 50	~1 in 5		
Comments	Basic research in academia or industry.	Infect healthy animals. Controlled laboratory Pivotal: target species. Pharmacokinetics dose finding etc. GLP	Naturally occurring indication. Usually 3 geographic sites. Sequential or in parallel for each species and animal product use. GMP, GCP	Analysis of residual drug. May include reproductive studies on animal or cell lines. Multi-species. Discovery data useful. Performed early or in parallel.	On-going monitoring

Data source: PhRMA, 2005 and Vaughn, 2006.

INADA studies are controlled laboratory settings where healthy animals infected and then treated under formal Good Laboratory Practices (GLP) conditions. Pharmacokinetics and toxicology studies are performed on animal models according to regulatory guidelines. Pharmacokinetics studies identify how quickly the drug moves through the body and where it resides when it is in the body. Toxicology studies determine the toxicity of the drug. Chemistry testing is also required to identify the active drug and drug metabolism by products. This is important in the determination of environmental safety as well as product stability and safety. Typically one in 50 drugs make it through this phase of development, which lasts from about one

to three year. Actual drug testing and evaluation periods are relatively short, however discussion with regulatory agencies and obtaining approval to continue can extend the duration of this phase.

Inimex is involved in the preliminary studies, which is about 40 percent of this category's activities. However, it lacks the infrastructure to perform the formal GLP studies as well as chemistry testing. These later activities will be contracted out. Once Inimex identifies a lead animal health candidate, Inimex will also need to determine the most appropriate formulation for its drug. Currently, the drug is formulated as a parenteral injection. If the drug is to be administered orally, Inimex will need time and resources to develop an oral formulation that will protect the amino acid peptide from being digested before it has an opportunity to act. The specified activities in this paragraph point to a key success factor common to all start up companies: experienced workers with specialized knowledge are required to move a drug candidate through the approval process. This requires either contracting with specialized organizations or hiring the qualified personnel.

Positive preclinical data enables a company to apply to the regulatory agencies to initiate drug efficacy and safety trials on naturally infected animals in the field (third category in Figure 3.3 above). These are clinical trials and are the most costly aspect of the drug approval process. Before filing for commercial approval (NADA, New Animal Drug Application), a company must first complete trials in three geographically different areas. These studies are costly because they require fully compliant GCP studies (Good Clinical Practices) which are resource intensive activities. About one in five candidates obtain market approval after this level of evaluation. Due to the high costs, this category in particular addresses the key success factors for both incumbent firms and start up companies. Incumbent firms need to use existing resources to manage the high costs and start up companies need to attract funding to sustain drug development through to approval and commercialization.

If the animal or animal products are intended for human consumption, additional trials are required to show safety in humans. This is also very costly and time consuming because it requires the highest number animals and successive generations of animals must be monitored for drug side effects. Even with Inimex's medicines that are amino acid peptides, which should not cause any harm to humans, this program could take up to seven years. Inimex would contract all clinical trial activities to CROs (Contract Research Organizations) except for program management.

The fourth category in the industry-level value chain is manufacturing and support. This aspect of the business activity is initiated in parallel with the trials. Since small amounts of drug are required for earlier development work, lab scale and pilot scale manufacturing is performed. With the escalation of activity towards commercialization, the manufacturing process is also scaled up towards commercial production. This increase in activity requires more manufacturing support controls, known as CMC (chemistry, manufacturing and controls). Regulatory agencies require that manufacturing is performed under GMP conditions (Good Manufacturing Practices). All of these CMC and GMP activities require a great deal of oversight and infrastructure.

Currently, Inimex is at the phase of development where in-house, lab scale synthesis is sufficient for their needs. Some analytical testing is contracted out. Inimex has expressed an interest in remaining a drug development company as opposed to a fully integrated organization. Assuming that this goal remains unchanged, Inimex will need to determine their involvement in this process when business opportunities are evaluated. For preclinical studies and clinical trials, Inimex will need to identify a manufacturer to perform the GLP and GMP manufacturing and CMC support. If in the interest of building drug value, Inimex decides to take drug development farther, the manufacturer will have to be a contract manufacturing organisation (CMO). However, Inimex may try to make a deal with a larger pharmaceutical company that would also serve as the manufacturer.

The fifth category in the industry value-chain is marketing and sales. Depending on the level of development, marketing and sales activities include research, advertising, detailing and direct sales. Advertising has been targeted towards veterinarians and livestock producers. Detailing is the process where the drug company provides educational information and support to veterinarians. Some examples of detailing are conferences and seminars. Since this category is about developing market share, protecting market share is also included in this discussion. Protecting market share includes defending against patent infringement; a critical success factor for incumbent firms who must maximize profit margins by keeping the period of drug exclusivity as competitor-free as possible. At Inimex's level of development, their current activity is market research to identify competitors and unmet medical needs. This activity is performed in-house.

The sixth and final business activity in the industry value-chain is distribution of drug product. Larger, established organizations dominate the distribution channels. Should Inimex change their strategy and be able to successfully commercialize their products, they would look to contract out or partner this activity with a larger company. This is a key success factor for all start up companies. Great medicines can fail without proper distribution and adoption by the veterinary community.

3.2.2 Inimex Competencies

Founded in 2001, Inimex is very young but senior management has many years of industry experience with significant medical or scientific knowledge. It would be the task of the business development team to either bring in financing or licensee companies to enable development and commercialization of animal health drugs. Alternatively, the company could divert funds from the human drug development program. Inimex personnel expertise is in human drug development. Fortunately, the same regulations govern both human and animal drugs, therefore there is an overlap in competency requirements. A competency gap is that Inimex does

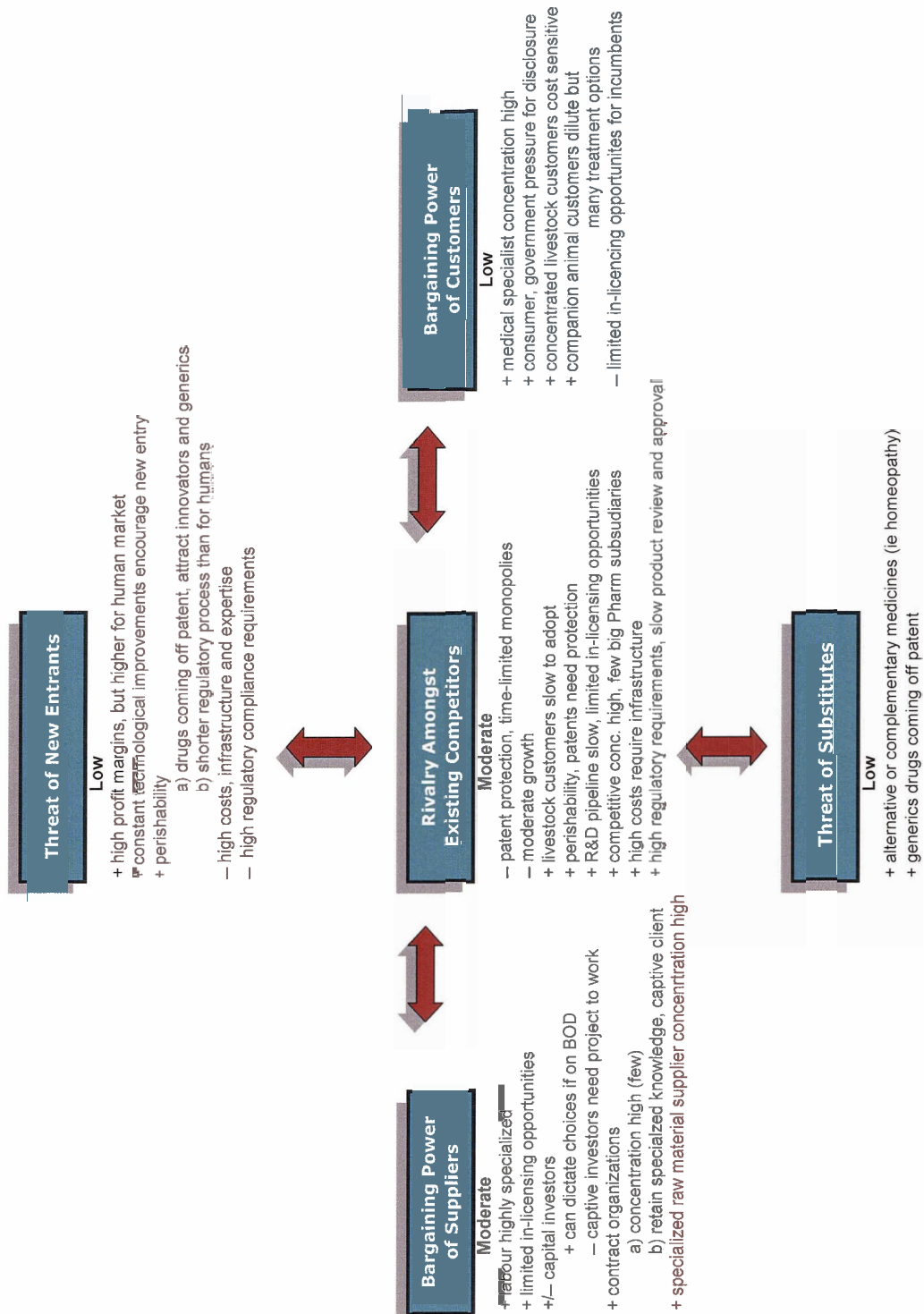
not have experience communicating with the veterinary medicine branch of regulatory agencies. Should Inimex pursue an animal health drug, it would need to either hire a senior manager experienced with animal health regulatory experience, or rely upon an outside party, be it a licensing partner or a CRO.

3.3 Industry Five-Factor Analysis

The competitive landscape of the animal health industry is presented in this section. By performing an industry analysis with use of the Porter Five Forces Model (Porter, 1979), key success factors will be identified for both Inimex, a new entrant, and established companies, which are potential licensing partners for Inimex.

Five competitive forces are used to evaluate the attractiveness of the animal health industry: rivalry amongst existing competitors; threat of new entrants; threat of substitutes; bargaining power of suppliers; and bargaining power of customers. For each force, key variables are identified and the overall influence is discussed. These forces are presented in Figure 3.4 below.

Figure 3.4: Competitive Forces In Animal Health Industry



Based on EMBA Strategy Seminar [EMBA 607 class notes]. Bukszar, Ed. Spring 2006. After Porter, 1979.

3.3.1 Rivalry Amongst Existing Competitors

Rivalry amongst existing competitors in the animal health industry is moderate. There is one key factor that reduces rivalry, namely patent protection. Growth is moderate, bolstered by the creation of time-limited monopolies with patent protection. Animal blockbuster drugs, which can generate over US\$100M in revenue per year, drive the growth rate. Examples of lead veterinary drugs are Merial's parasiticide products containing ivermectin (ie Ivomec[®],Eqvalan[®], Heartgard[®]) and fipronil (ie Frontline[®]) generated combined 2005 sales over US\$1.2B. Unfortunately, these values are traditionally overshadowed by the human drug growth rate and revenues. Therefore, there are constant expectations for profit margin improvement and intolerance for any reductions in growth, even if it remains positive.

There are two key factors that increase rivalry: perishability of patents and demands for innovation. It is common in the pharmaceutical industry for generic products to compete with an off-patent drug. Generic drugs will play a more important role for farmers and high volume production units, where cost reduction is a factor. Brand loyalty tends to be higher for veterinarians treating companion animals. However, other companies can gain market share by reformulating an off-patent drug into a presentation that is easier to administer to the animal. It is this aspect of innovation with generic drugs that is capturing the market share and which incumbent firms are adopting (Animal Pharm, 2006a).

Constant innovation is always a factor in this growing market. R&D is costly, and the process is slow. Innovation is often realized through the in-licensing of novel drugs from emerging biotech companies. In 2003, over 400 Canadian biotechnology companies were reported (Earnst & Young, 2004). Many of these companies are developing products for the human and animal health industries. Incumbent companies also compete to acquire the most promising new drugs. Alternatively a parent company's human drugs have been used for animal drugs. Veterinarians are permitted by regulators to prescribe human drugs for animals, if animal

drugs are not available. With a growing companion animal market, reformulating human drugs owned by the parent company is a common animal health R&D resource.

Overall, rivalry is moderate for the established animal health companies. The key success factors that reduce rivalry are:

- moderate growth through constant innovation and;
- patent protection.

Since new entrants provide drugs to the R&D pipeline it follows to further evaluate the impact of new entrants on industry dynamics in the next section.

3.3.2 Threat of New Entrants

The number of new entrants is high however the potential for them to be a threat is relatively low. As stated above, there are many emerging and start up biotech companies; most of which are spin-off companies from university laboratories. The allure of high profit margins in a growing industry will always attract new entrants. Constant technological improvements give rise to the possibility of more effective treatments. As existing drugs come off patent, more innovators of drug delivery or better target receptors encourages new entrants.

Basic research at the academic and government institution fuels this drive. Over 1500 pre-IPO biotech companies were working on new therapeutics to meet unmet needs. This is in extreme contrast to the observation that there were no new veterinary product launches at this year's annual forum for the American College of Veterinary Internal Medicine (Animal Pharm, 2006b). Typically, it takes five to ten years to move a new drug from discovery to commercialization. Although this a long period, it is half the time required for humans. This in itself would attract new entrants to explore animal medicines instead of or as well as human application.

New entrants tend to be smaller biotech companies with fewer than 25 employees. Barriers to becoming a fully integrated company are high. The costs to develop and bring a product to market are enormous. Animal toxicology, formulation development, clinical trials, manufacturing, marketing and sales are all costly and require a specialized workforce. Lacking infrastructure, smaller organizations must rely upon contract manufacturing and research organizations. Recent estimates state that these companies have 2 to 24 months of working capital at a time. Where there is good science, capital is readily available.

Even with patent protection, the road to commercial success is long. Usually the smaller companies look to larger, established organizations to acquire their company or partner in exchange for marketing rights. A sales force with the required marketing channels is critical to achieving full integration. Without depth and expertise, the separation between new entrant and a fully integrated organization is a quantum leap. Most of these companies remain small, do not get their product to market before bankruptcy or are acquired.

Overall, the threat of new entrants for the established animal health companies is low. The key success factors that improve the potential for new entrants are:

- capital to sustain development to product approval;
- attract experienced workers with specialized knowledge;
- product adoption and distribution.

3.3.3 Threat of Substitutes

The threat of substitutes in the animal health industry is low. Substitutes for vaccines are rare, aside from alternative husbandry practices. Substitutes for other livestock medicines are generic drugs. They offer the advantage of cost savings without affecting the level of care. However, since incumbent firms are actually adopting generic drugs into their pipeline, generic drugs are more a part of the existing firms' pipeline, as discussed in Section 3.3.1.

In the companion animal market, surgery, homeopathy and human drugs are all possible substitutes. In cases like joint dysplasia, surgery and drugs are both separate and complementary treatments. The cost of surgery is high and anaesthesia is risky for animals, especially smaller breeds. Pain management and anti-inflammatory drugs are areas of growth. As companion animals live longer, people are more willing to consider medical options for their pets.

Homeopathy is a growing area for animal care. Preventative medicine and non-pharmaceutical treatments all appeal to the concept of healthier living and long term cost reduction. This is especially relevant in health areas where animal disease is acute but not critical, as for dermatological indications.

Cheaper generic drugs are always an option for companion animals, but as discussed above, brand loyalty and recognition is common. Veterinarians tend to keep limited supplies of drugs on hand; a more common substitute is the prescription of human drugs for animals. This way, veterinarians do not need to maintain inventory.

Overall, the threat of substitutes is low. The key success factor for existing firms is to innovate in ways that provide complementary drugs for surgical applications or drugs that preclude the need for surgery. For start up companies, the key success factor is to ensure the innovative drug is adopted over other substitutes.

3.3.4 Bargaining Power of Suppliers

The bargaining power of suppliers in the animal health industry is moderate. To incumbent firms, suppliers provide R&D products, contract services and labour. To incumbent firms, suppliers also provide infrastructure support and capital.

For the animal health subsidiary, the parent company supplies infrastructure support. All but one of the top 20 animal health companies are subsidiaries of pharmaceutical companies. In

this high growth industry, parent companies do not tolerate reduced profit margins. When profits are not high enough, companies have divested their animal health units. For example, in 1995, SmithKline Beecham sold their animal health business to Pfizer. This rationalization gives the parent company (as a supplier) a great deal of power over the animal health organization.

Venture capital organizations (VC) and animal health companies supply capital to new entrants. Small firms have limited funding (two months to two years funding) and they are desperate to make financing deals. Where established animal health companies have power is when they decide early in a venture that the project would not have enough value and they withdraw support. Animal health company support is usually a combination of funding and internal expertise in exchange for marketing rights and a share of the profits. Venture capital, VC, funds exert their power by claiming positions on the Board of Directors. The VC then has decision making power in the organization.

Some organizations sell drug delivery platforms to established companies with drugs coming off patent. These companies are able to improve the existing line of care or provide novel drug delivery platforms. Whenever these organizations are able to add value to an existing drug, their bargaining power will be high.

Contract manufacturing organizations (CMO) and contract research organizations (CRO) supply manufacturing and research services, respectively. Smaller companies rely upon these firms so they do not have to commit to infrastructure before a product is approved and generating income. Small firms can also become dependent upon the expertise of these contract organizations. Established companies have also found utility in contract organizations to make up for under-capacity or to develop new manufacturing processes. Such contract organizations are growing in power because there are relatively few compared to the demand for their services.

Labour is highly specialized in this industry and it comes at a premium. The labour groups that have the most powers are the financial managers, employees with business development abilities and specialty innovation leaders.

Overall, the bargaining power of suppliers in the animal health industry is moderate. The key success factor for incumbent firms in this section is to manage high costs. For new entrants, the key success factors are:

- capital to sustain development to product approval;
- attract experienced workers with specialized knowledge.

3.3.5 Bargaining Power of Customers

The bargaining power of customers is low. With increased access to information and increased consumer advocacy, consumer power is increasing. This is reflected in the increased vigilance of regulatory agencies that decide whether a health product can go to market and when. Government organizations act in response to public concerns about safety. However, this is also offset by pet owners who are willing to buy drugs at any price to treat their beloved “family member”.

Animal health growth in the livestock industry is inconsistent because it is dependent upon public concerns. The most recent concerns with regards to animal medicines is about overuse of antibiotics in the livestock industry, which gives rise to fear of antibiotic resistance in people who eat the meat. Animal health companies are more heavily restricted in Europe over which antibiotics can be used in livestock but the impact is also felt in the rest of the world.

Livestock sales are commodity-like. Farmers and animal producers have narrow profit margins; they will not adopt animal medicines if the added cost does not improve their profit margin. This forces the drug companies to cap their prices.

Although customers also have power because they have more choice, they are also fragmented and don't have a strong voice.

The veterinarian is the gatekeeper to consumer choice. Companies able to inform and convince veterinarians of their drug product's efficacy will be successful. For new drugs and treatments to be adopted, veterinary specialists need to endorse the products to the community. Veterinary specialist concentration is high. With limited veterinary specialists, their bargaining power increases over that of the animal health company.

One other group of customers in the industry is the incumbent firms themselves. As the pressure to innovate increases, these companies turn to start up biotechnology and drug delivery companies for novel solutions. This was discussed in the previous section from the perspective of incumbent as supplier of capital. As a customer, their bargaining power is also moderate because the industry is heavily reliant upon innovation, of which there is currently very little. Moreover, incumbent firms' power decreases as the drug moves closer to approval. Few drugs make it to approval, the later the stage of development the greater the competition between incumbents to in-license the drug from innovating start up firms.

In general, the bargaining power of customers in the animal health industry is low. The key success factor for incumbent firms in this area is to constantly acquire innovation from other firms, usually start up companies. For new entrants, the key success factors are to ensure product adoption and distribution to customers.

3.3.6 Overall Industry Attractiveness

The animal health industry is a moderate growth industry. Patent protection and innovation are key to the animal health industry. Patent protection defines the duration of the

product life cycle, which is the basis for the competitive landscape. Due to patents, incumbents know how long they can keep monopoly pricing, and when they need to make innovation.

The industry attractiveness is reflected in the many start-up biotechnology companies. Barriers to entry are low and capital is available for good science. The challenge in this industry is the transition from being an emerging company to full integration. Barriers to integration are most intense once products are approved and a sales force is required to find or make distribution channels. However, the product would either be commercialized or soon to be approved and incumbents are always available to in-license and make marketing deals. This is what sustains the industry attractiveness: incumbents gain access to late stage drugs, reducing risk and R&D costs.

The threat of substitutes is a low force because for the most part, generic drugs have been adopted by incumbent firms as key drugs about to come off patent. This effect is more significant for the livestock category than for companion animals. Other substitutes like homeopathy and human drugs prescribed by veterinarians reflect more the potential for the companion animal market. In particular this indicates an area where genomic and proteomic research will target and identify more effective species-specific drugs.

Moderate consumer power means that companies have to put significant resources towards working with regulatory bodies, medical specialists and veterinary groups. High profit margins drive the industry, being able to find the right product to in-license is also critical for the industry to remain attractive for incumbents. This reduces overall customer power because incumbent firms compete heavily to buy innovation from start up companies.

On the supply side, the industry attracts investors for good science. Similarly, the industry attracts good science workers because the pay scale tends to be higher and job security is higher in growth industries. This reflects moderate supplier power.

3.4 Key Success Factors

Inimex is a new entrant to the animal health industry, as such, the competitive forces can act differently on Inimex than on the incumbent animal health firms. The above value chain analysis in Section 3.2 and the five-factor analysis in Section 3.3 are instrumental in identifying the key success factors for both Inimex and incumbent firms. Inimex can use this information to determine how it can most strategically target development partners or firms to license Inimex animal health drugs.

3.4.1 Incumbent Firms

Three key success factors for incumbent firms to maintain growth and market share are:

1. Constant innovation
2. Manage patent protection
3. Manage high costs

The first success factor- constant innovation- is most relevant to Inimex. This was discussed in greater detail in Sections 3.2.1, 3.3.1 and 3.3.3 and 3.3.5. Investors expect consistent growth, this requires constant innovation. As the number of new chemical entities dwindles, biotechnology opens up in-licensing or acquisition opportunities. Incumbent firms have many opportunities to in-license products. The challenge is in selecting the products at the right time in development. Early development products are riskier investments but can be obtained at a lower price. Competition to acquire late phase products is high and the cost is a premium.

The second success factor- manage patent protection- ensures marketing exclusivity and expanded market share. This was discussed in Sections 3.2.1 and 3.3.1, and to a lesser extent in Section 3.3.3. The third success factor for incumbent firms – manage high costs- pertains to maximizing the profit margin, as discussed in Section 3.2.1 and 3.3.4.

3.4.2 Inimex

Three key success factors for new entities and therefore Inimex are:

1. Capital to sustain development to product approval
2. Attract experienced workers with specialized knowledge
3. Product adoption and distribution

The first key success factor is capital, as discussed in Sections 3.2.1, 3.3.3 and 3.3.4.

Although Inimex is not interested in commercializing its drugs, their goal is to add value to developing drugs and license or sell the products to larger firms at a premium. This revenue would then be used to fund Inimex human drug development. Inimex needs to know how much to invest into an animal health drug development program before trying to make a deal with an animal health firm.

The second success factor is attracting experience workers with specialized knowledge (Sections 3.2.1, 3.3.3 and 3.3.4). Inimex has highly qualified personnel who know the human pharmaceutical industry and science to discover successful products. Although there are many similarities between human and animal drug development processes, regulatory and clinical animal health expertise is lacking. This can be obtained through contract organizations or in partnership with a larger firm.

The third success factor is product adoption and distribution (Sections 3.2.1, 3.3.3 and 3.3.5). Product approval is wasted without both, requiring resources in sales and marketing. This last factor is often what keeps new entities small and it is the biggest barrier to full integration. Resolving this issue through partnerships with larger companies will overcome the challenges. As long as Inimex chooses to remain a specialty development organization, this should not be a deterrent to success.

3.5 The Next Step

This chapter contains a very rigorous and systematic analysis of the animal health industry dynamics. As a result, a number of trends were identified. First, livestock health sales worldwide are greater than those of companion animals. However, the companion animal growth rate is increasing more rapidly in the USA. Second, the top animal health companies are actually minor but significant subsidiaries of human health pharmaceutical companies. Third, there is a dearth of new drug innovation from incumbent firms. Moreover, incumbent firms rely upon small biotechnology firms to provide innovation in the form of new drugs and drug delivery systems.

Combined with the previous chapter, the first aim had been met, which is to demonstrate a clear understanding of Inimex and the animal health industry. The climate for developing an animal health drug is favourable for Inimex. If Inimex can show drug efficacy and application, animal health firms will want to work with Inimex.

The next step is to identify possible indications and target animal species and make a business case for development. This will be achieved in the following chapter.

4 TARGETING ANIMAL HEALTH OPPORTUNITIES

In previous chapters, it was established that there is an animal health market and opportunity for Inimex animal health medicines. In this chapter the second aim of this project will be met, which is to develop an opportunity evaluation tool. The purpose of such a tool is to assist in the decision process for determining whether there is a business opportunity for Inimex with animal health medicines, and if so, which indication to target, for which species. Such decisions are the result of a complex process that requires the consideration of many variables. It is a complex process; for each decision there are consequences and rewards. Anything that simplifies and objectifies the decision process could be a useful tool.

The tool will be developed using available internal, industry and customer information to evaluate medicine opportunities. In this chapter, the following will be accomplished:

- identify key drug development milestones, including duration, costs and risks;
- specify selection criteria and their significance;
- build and demonstrate the evaluation tool using sample target indications.

4.1 Development Milestones

The foundation of the drug development roadmap is rooted in regulatory guidelines. Therefore, drug development milestones, timelines and risks are defined around the regulatory pathway as presented in Chapter 3. Although there are regulatory agencies for each country, the USA process is presented here because it has the largest global animal health market. As a reminder, there are three major development stages before market approval can be obtained: discovery (pre-INADA), laboratory-based evaluation (INADA) and clinical field trials (NADA).

Regulatory requirements increase with successive stages. The result is an increase in duration and cost for each stage. Since people consume livestock or their products, human safety studies must also be performed, therefore, the duration and costs are greatest for livestock. Table 4.1 below is an expansion of Table 3.3 (p18) to include costs with milestones, timelines and risks.

Table 4.1: USA Animal Health Drug Development Milestones

Stages	pre-INADA	INADA	NADA		Market
Discovery	<i>in-vitro, in-vivo</i>				
Companion		Safety	Efficacy	Field Studies (Clinical Trials)	Market
Livestock		Safety	Efficacy	Field Studies (Clinical Trials)	Human Safety Studies
Market					Market
Timelines	2-12 years	1-3 years	2 - 5 years per species		2 - 5 years
Successful Candidates	~1 in 400	~ 1 in 50	~1 in 5		
Costs	Varied	US\$1M - 5M	US\$3M - 30M	US\$10M - 30M	Varied

Data source: PhRMA, 2005 and Vaughn, 2006.

The costs are estimates based on available industry information. Drug companies and lobbyists quote a Tufts University study finding that it costs US\$802M to develop one human drug (DiMasi et al, 2003). These are capitalized costs that also factor unsuccessful drug development costs in the estimate. Mean out-of-pocket clinical period phase costs for approved drugs were closer to US\$176M. These values are for human drugs, which require three clinical phases. Animal health drug development requires one clinical phase and has been estimated at one tenth that of humans (PhRMA, 2005).

A range of costs was estimated for each stage in Table 4.1. Drug discovery costs are presented as varied because there are no discovery guidelines, each research group, development laboratory and company has its own criteria and threshold for what constitutes a valid drug candidate.

For an INADA, where the first formal safety and efficacy trials are conducted, the cost is lower relative to clinical trials. The minimum requirement before the FDA will allow clinical trials is: one single dose and one multiple dose toxicity study to evaluate safety plus a study to show efficacy. All the studies are performed on the target animal species according to specified and government-approved protocols. A review of the FDA freedom of information (FOI) database shows that safety studies use about 20 to 30 animals. The duration of the safety and efficacy studies, which contributes to cost, depends upon many factors including dosing regime, dose range and biological drug distribution (pharmacokinetics). An industry cost estimate is about US\$150K to 200K for a dog study (Anonymous, 2006a). Assuming that sufficient data is acquired for both of the safety studies and the efficacy study, the clinical INADA cost would be about US\$600K. Allowing for overhead, application fees and drug manufacturing, the low estimate for an INADA is about US\$1M. If insufficient data was obtained for any of the studies, the regulatory agencies may require more studies and the cost will increase. For livestock, the costs are higher because livestock are more expensive to house than small animal species and more thorough drug residue studies must be performed. The upper cost range was estimated at US\$5M.

For a NADA, safety and efficacy are confirmed in field clinical trials for naturally infected animals at three geographically different sites. The size of the animal population tested is dependent upon a number of factors that include, indication, class of drug and animal segment. Clearly observable outcomes from treatment allow for better statistics and require fewer test animals. Since companion animal trials tend to be performed in veterinary hospital clinics, there is a higher degree of control over trials and fewer animals are required. In general, companion animal drug trials tend to use 100 to 300 animals. The lower NADA cost range applies to companion animals and is estimated at US\$3M. This number is based on the previously

mentioned ratio of animal to human cost; the companion animal cost estimate is 1/10th the capitalized mean costs for human phase I clinical trials (DiMasi et al, 2003).

About 10-times more livestock than companion animals are required for clinical field trials for two reasons. First, since livestock trials are conducted in working farms, the variables are harder to control. Second, livestock animals require more thorough evaluation because they will be consumed by people. For example, with injectable drugs, injection-site infection studies must also be performed on livestock but are not required for companion animals. The upper NADA cost range is an order of magnitude higher to reflect the 10-fold higher number of animals for livestock. The second part of a NADA applies to livestock only. Human food safety trials are reputed to be the most costly aspect of the trial (Craigmill, 1992). A US\$10M to 30M range was estimated for this part of development. The total upper estimate range of livestock development costs, excluding discovery is US\$65M. This benchmark estimate is between 1/10th the estimated out-of-pocket costs for human drug development and the capitalized costs, US\$126M and US\$802M, respectively. Given the available data, it is not an unreasonable estimate for the purposes of this study.

The main perspectives to keep in mind for this project are that INADA studies are significantly less costly than clinical field trials. In addition, total companion animal drug development costs are considerably lower than those for livestock. These costs do not factor manufacturing. Manufacturing costs are essentially the same for human as for veterinary drugs because they fall under the same regulatory guidelines.

4.2 Selection Criteria

One of the reasons why professors-turned-entrepreneurs take their discoveries out of the laboratory and into the drug development arena is because they realize they have a solution for a medical problem. With Inimex medicines, the drugs are broad acting and therefore the situation is

a bit like a solution in search of a problem. A number of factors need to be considered before keying in on a lead drug candidate. These factors are technical, regulatory and financial. A number of criteria significant to each factor can be identified and are discussed below. When making target indication selections, Inimex management would need to determine the significance of each criterion.

4.2.1 Technical

The selected indication must meet technical requirements. First and foremost, there must be some confidence that the drug candidate meets an unmet medical need. As stated earlier, the Inimex medicine platform is a fast acting, broad spectrum anti-infective with anti-inflammatory properties. Since the drug acts on the host and not the infecting microbes, antibiotic resistance is not an issue. The drug candidate must be a suitable formulation for delivery to the animal. The current formulation is as an injectable, which can be intravenous (IV), intramuscular (IM) or intraperitoneal (IP). This is not the most critical criterion because an oral formulation may be developed but time and costs would need to be a consideration. Finally, a broad category is the competitive landscape. This requires a consideration of conditions where the existing vaccines or treatments are not as effective as needed. Also, if existing vaccines or treatments are effective, it is important to consider whether there is opportunity under specific conditions.

The technical criteria are summarized as follows.

- Unmet medical need to fit Inimex medicine profile (fast acting anti-infective, broad spectrum, anti-inflammatory properties, no antibiotic resistance)
- Formulation(IV, IP, IM, oral may be developed)
- Competitive landscape

4.2.2 Regulatory

There must be confidence that the drug candidate can meet regulatory requirements. The wrong choice of candidate can not only use scarce resources, it can also cause harm to animals

and deleteriously affect Inimex's reputation. The first criterion to satisfy is whether there is sufficient discovery data. Although this is a technical issue, it also bears relevance in the regulatory arena. Pre-INADA data provides objective information on drug safety and it allows for the efficient design of trial protocols. Since drug approval is based on statistical analysis of treated animals compared to control animals, the better designed studies will give more clear outcomes. The second criterion is related, this is the clarity of outcome. A target indication must have distinguishable or quantifiable outcomes, which will also improve statistical analysis. Examples of this are: increased productivity for livestock, reduced morbidity or for companion animals, higher survival rates. Finally is the very important time to market. Longer trial periods cost more money, delay revenue generation and shorten patent protection periods.

The regulatory criteria are summarized as follows.

- Sufficient discovery data
- Clarity of outcome in regulatory trials
- Time to market

4.2.3 Financial

One of the final hurdles to identifying a drug candidate is finance. Without the required capital, no ingenious drug idea will be realized. The cost of development is an important criterion. A reasonable estimate of costs enables management to weigh development options. An awareness of organizational capacity gives confidence in the ability to get a drug developed. It is included as a financial criterion because without adequate head count or workforce skill, outside support or more recruitment will be required. The counterpoint to costs is the availability of capital. Although a start up company may not have sufficient funds to develop a drug, the ability to source funds that gives most value to the company is critical. Finally, the potential market is also an important criterion. An ability to make sales and earn some type of return is critical.

Developing a drug for a minor indication or a minor species may seem the easiest path. However if there is no market potential, it is most unlikely that a company will develop the drug.

The financial criteria are summarized as follows.

- Development costs
- Organizational capacity
- Available capital
- Potential market

4.3 Decision Tool

The decision tool that is being developed is based on the theory and method of Analytic Hierarchy Process (AHP; Saaty, 1977 and 1980), a relative evaluation mathematical method. The AHP model contains both objective criteria and subjective judgement. The objective criteria are taken from the drug development milestones and drug selection criteria presented in the previous sections. Each criterion is subsequently compared with each other criterion; then, each alternative (highest level) is evaluated with each of the other alternatives. Finally, weights are assigned to these criteria according to a priority measure. This last step is one subjective aspect of the model. The second subjective feature is when the model is used as a tool by the user to rank indications for their suitability for each criterion.

The advantages of the AHP model include the use of a flexible modelling and measurement approach to decision making; consistent objective decisions can be made or adjusted based on shifting priorities for an evolving company; and the model is simple to use.

Limitations of the method might be a function of the imposed structure of decision making. For example, a rational decision can be assumed to be derived from a linear, stepwise process, whereas human preferences are more often the result of irrational comparisons (Raiffa, 1968). The model also does not consider judgemental heuristics and biases. Therefore it is

important to be clear about what information is used to form an opinion and what other data would be useful to have when challenging an opinion or assumption.

Ultimately, the subjective choices will be determined by Inimex management insight and priorities. For this project, the weighting of each criterion was assigned by the author; they are based on preliminary discussions with various industry representatives and Inimex executives. Although commercial software is available using the AHP process (*Expert Choice*TM), the tool developed here is a simplified, manual process. The frame for the tool is presented in Table 4.2 below.

Table 4.2: AHP Decision Tool For Inimex Animal Health Drugs

Factor	Criteria	Criteria Weighting (W)	Indication Ranking (R _i)	Values (W * R _i)
Technical	Unmet need	0.15		
	Formulation	0.05		
	Competitive landscape	0.1		
Regulatory	Discovery data	0.05		
	Clarity of outcome	0.05		
	Time to market	0.2		
Financial	Development costs	0.2		
	Organizational capacity	0.05		
	Available capital	0.05		
	Potential market	0.1		
Total Weighting:		1.0	Total (5 max)	

Source: Author

During criterion prioritization, the weightings (W) were scaled such that their weightings add up to one; this simplifies the math in the shaded area. Rationale for the actual weightings is provided in Section 4.3.1 as follows. The shaded area of the table represents the indication-specific ranking for each criterion, which is also subjective. The ranking can be out of whatever value the organization wants, for this project, the maximum ranking will be 5. For this project, the ranking will use a Likert scale where the more favourable assessment of a criterion for the

indication will be given the higher ranking. When the indication rankings (R_i) are multiplied by the criteria weightings (W) and then summed, the maximum total value will be 5. When the scores for different indications are compared, the higher scores are the more suitable indications to target given the criteria used. In Section 4.4 below, this tool will be applied to sample indications to demonstrate its utility.

4.3.1 Criteria Rationale

All weightings are with the perspective that Inimex animal health medicines are concepts at this point in time. Should animal health projects evolve, criteria prioritization could and probably should change. At the highest level, the three categories were prioritized. No matter how great an invention, if the capital is not available, the drug will never make it to market. Therefore the financial category was given the highest priority. Not to be discounted, the technical and regulatory hurdles can also be deal breakers later in the process. They were rated equally, second to finance. Out of one, the weightings for the categories were: technical, 0.3; regulatory, 0.3; and financial, 0.4. Within each category, the criteria identified in Section 4.2 above were further prioritized.

Technical (0.3). The technical criteria discussed in Section 4.2.1 and listed in Table 4.2 are:

- Unmet medical need to fit Inimex medicine profile (0.15)
- Formulation (0.05)
- Competitive landscape (0.10)

The three criteria are not equally important. Although it would affect the timeline, a formulation can always be modified; it is ranked lower than both unmet need and competitive landscape. A competitive landscape can be daunting but Inimex's focus is on drug development, not commercialization. Any partner or company that ultimately commercializes an eventual drug,

will manage competition. Therefore, unmet medical need is the strongest driver upon which that Inimex should focus on now.

Dividing the technical weighting of 0.3 between the three criteria, the weightings are: unmet need, 0.15; formulation, 0.05; and competitive landscape, 0.10.

Regulatory (0.3). The regulatory criteria discussed in Section 4.2.1 and listed in Table 4.2 are:

- Sufficient discovery data (0.05)
- Clarity of outcome in regulatory trials (0.05)
- Time to market (0.20)

The most important criterion and major deterrent to innovation in the animal health industry is the time to market. Some animal drugs can take as long to obtain regulatory approval as a human drug but human drugs are at least ten times more profitable. Having discovery data gives the confidence to enter formal trials. Clarity of outcome in regulatory is important in minimizing trial size and duration. Although clarity of outcome will become critical in later development stages and a factor in the design of trials, it is not as significant now. Therefore, both discovery data and clarity of outcome were prioritized equally, a distant second to time to market.

Dividing the regulatory weighting of 0.3 between the three criteria, the weightings are: discovery data, 0.05; clarity of outcome, 0.05; and time to market, 0.20.

Financial (0.4). The financial criteria discussed in Section 4.2.1 and listed in Table 4.2 are:

- Development costs (0.20)
- Organizational capacity (0.05)
- Available capital (0.05)
- Potential market (0.10)

It can not be overstated, that without capital, no great drug will be commercialized. Therefore, the development costs criterion is the highest priority in this category. Of the remaining three criteria, potential market addresses the concerns of potential suppliers of capital.

This, then, is the second priority in the category. Although important, available capital and organizational capacity they are not as critical as the previous two criteria.

With a financial weighting of 0.4, the weightings are: development costs, 0.20; organizational capacity, 0.05; available capital, 0.05 and potential market, 0.10.

Note that the focus for the financial is on costs and market potential. The determination of drug value is not included in this tool, rather valuation is discussed in detail in Chapter 5. At this point in the decision process, an indication of potential market is sufficient information.

Also note that there are three criteria that related to commercialization, which in later development may become a separate category in the tool. These criteria are: unmet medical need, competitive landscape and market potential. This is a reminder that the goal of this AHP tool for Inimex is to assist in the decision process for determining whether there is a business opportunity for Inimex with animal health medicines. Should Inimex use this tool any farther it would need to refine more thoroughly the criteria and their weighting. The next step in the process for this project is to identify sample indications and work through the application of the tool, which follows in the next section.

4.4 Sample Indications

In discussions with local veterinarians, specialists at the Ontario Veterinary College (OVC), and after a review of the animal health literature, several indications have been identified that could possibly be treated using Inimex animal health medicines.

Stress-related indications are associated with all livestock species. All have an associated economic impact costing billions of dollars. Shipping fever or bronchopneumonia, is the leading cause of illness and death in US feedlots; it is a challenge for goats, sheep, cattle and poultry. It is generally accepted that shipping fever results from a combination of stress, immunity and

infectious pathogens. Porcine reproductive and respiratory syndrome (PRRS) remains the most costly infectious disease to US swine producers. Clinical signs associated with the syndrome are associated with late-term abortions, stillborn or weak pigs, delayed farrowing rates and pneumonia in growing to finishing pigs. Persistent infections are a major factor in the inability to eliminate the disease. Treatment regimens vary, involving one or more antimicrobials. Vaccination programs are also in use but their effect is limited because new pathogens are identified in association with these diseases.

Stress in confinement is not limited to livestock; infectious tracheobronchitis (ITB) or kennel cough is a highly contagious inflammation of the trachea (windpipe) and bronchial tree caused by a contagious virus (adenovirus, parainfluenza virus, canine distemper virus) or bacterium (*Bordetella bronchiseptica*). The disease is associated most often with dogs housed in a high-density population or boarding kennel. The infectious agents can be transmitted through the air or by contact with contaminated surfaces. Puppies and younger dogs are at greatest risk, but even old dogs can acquire kennel cough. Vaccinations provide very good protection against ITB in most dogs. However, like all vaccinations, protection is not 100 percent and some dogs will contract ITB despite vaccination.

Specific to companion animals is the occurrence of cancer in older pets. Treatment for cancer includes surgery, chemotherapy and radiation therapy. Chapter 3 identified 3 million pets receive chemotherapy or radiation therapy a year. During and after treatment, the pet is immune compromised and therefore susceptible to infection. The application for Inimex drugs in these situations is parallel to that of the current human drug target: as a prophylactic and anti-infective adjunct to treatment.

For a perspective on the broad applicability of the medicines, one indication from each of the livestock and companion animal segments are discussed here.

4.4.1 Bovine Respiratory Disease Complex

Economic loss due to cattle and calf death or significant weight loss resulting from Bovine Respiratory Disease Complex (BRD), also known as shipping fever or bronchopneumonia, is estimated at billions of dollars (Storz et al, 2002). Mass treatment of a herd is warranted when an outbreak of BRD is anticipated or present in a group of cattle. Treatment regimens vary, involving one or more antimicrobials. Vaccination programs are also in use but their effect is limited because new pathogens are identified in association with BRD.

The AHP table for BRD is presented in Table 4.3 below; the BRD score is 2.6. The explanation for the rankings follows Table 4.3. The significance of the score is relative, not statistical. The score indicates a moderate inclination towards developing the drug given the nature of the technical regulatory and financial risks as perceived by the individual or organization using the model. In this case, it is the author's perceptions that are used. This number is more relevant when compared with the score for other indications using the same criteria and weightings.

Technical ranking explanation. With such a high economic cost attributed to BRD, the ranking is high for unmet need. The formulation ranking is moderate because the current formulation is an injectable and administration would be more facile if an oral dosage form were used. Inimex may need to reformulate before going into trials, this would need to be confirmed through industry sources. The competitive landscape is high, other treatments and vaccines are available, which may make adoption a challenge. The advantage for Inimex medicines is no antibiotic resistance, which should be a positive adoption influence. The ranking for this criterion is moderate.

Table 4.3: AHP Values for Bovine Respiratory Complex

Factor	Criteria	Criteria Weighting (W)	Indication Ranking (R _i)	Values (W * R _i)
Technical	Unmet need	0.15	4	0.6
	Formulation	0.05	3	0.15
	Competitive landscape	0.1	3	0.3
Regulatory	Discovery data	0.05	3	0.15
	Clarity of outcome	0.05	4	0.2
	Time to market	0.2	1	0.2
Financial	Development costs	0.2	1	0.2
	Organizational capacity	0.05	3	0.15
	Available capital	0.05	2	0.15
	Potential market	0.1	5	0.5
Total Weighting:		1.0	Total (5 max)	2.6

Note: Indication ranking is out of 5, where 5 is strongly agree or favourable.

Source: Author

Regulatory ranking explanation. To date, discovery data are available for rodents. This is helpful and a moderate ranking is assigned. The clarity of outcome would be a reduction in cattle death and economic loss. Quantification would be fairly straight forward, the ranking is high. The final criterion, time to market, has the highest weighting. The ranking is low because the regulatory path in livestock is lengthy. This is one of the main challenges for developing Inimex medicines in animals.

Financial ranking explanation. Associated with a long regulatory path is cost. This criterion is also heavily weighted and the ranking is low. Inimex's capacity for developing animal drugs is moderate, as reflected in its ranking. There is some level of expertise in senior management, but more support will be required. Limited capital is available for animal health projects, this ranking is low. Finally, the cattle market is large and if Inimex animal health medicines can be approved and adopted, Inimex would have access to a high volume market. Competition would be based on cost of production relative to economic benefits.

4.4.2 Canine Hemangiosarcoma

Hemangiosarcoma is a malignant cancer of the cells that form blood vessels. Because these tumours start in blood vessels, they are frequently filled with blood. Consequently, when a blood-filled tumour ruptures, it can cause problems with internal or external bleeding.

Hemangiosarcoma is considered to be a very aggressive tumour and can spread rapidly to other organs. Hemangiosarcoma is more common in dogs than in cats. It usually occurs in middle-aged to older dogs 9 to 11 years of age. Golden Retrievers, German shepherds and Boxers appear to be predisposed to developing this cancer. The most common primary location of this cancer in dogs is the spleen. These tumours usually spread to the lungs, liver and heart. Even with immediate treatment prognosis is poor. Inimex medicines could improve survivability rates as a prophylactic and anti-infective adjunct to treatment.

The AHP table for canine hemangiosarcoma adjunct is presented in Table 4.4 below with a score of 3.5 out of 5. The score indicates a favourable inclination towards developing the drug relative to the shipping favour case above. The explanation for the rankings follows.

Table 4.4: AHP Values for Canine Hemangiosarcoma Treatment Adjunct

Factor	Criteria	Criteria Weighting (W)	Indication Ranking (R _i)	Values (W * R _i)
Technical	Unmet need	0.15	3	0.45
	Formulation	0.05	5	0.25
	Competitive landscape	0.1	3	0.3
Regulatory	Discovery data	0.05	3	0.15
	Clarity of outcome	0.05	4	0.2
	Time to market	0.2	5	1.0
Financial	Development costs	0.2	3	0.6
	Organizational capacity	0.05	3	0.15
	Available capital	0.05	2	0.1
	Potential market	0.1	3	0.3
Total Weighting:		1.0	Total (5 max)	3.5

Note: Indication ranking is out of 5, where 5 is strongly agree or favourable.

Source: Author

Technical ranking explanation. As with human cancer treatments, complications due to infections and inflammation can expedite death. There is a valid application for Inimex medicines, the ranking is for unmet need is moderate. The formulation ranking is high because the current formulation is an injectable which would be ideal for administration during chemotherapy. The formulation could be used as is. The competitive landscape is high because antibiotics are available for use. However, antibiotic resistance, microbial specificity and inflammation concerns are always issues, which are addressed by Inimex medicines. The ranking for this criterion is moderate.

Regulatory ranking explanation. The same moderate ranking was assigned as for livestock. The clarity of outcome would be an increase in survivability rate. Outcomes can be quantified for this acute condition in controlled clinical field trials, the ranking is high. The final criterion, time to market, has the highest weighting and ranking. The regulatory path for companion animals is short relative to livestock and humans. The entire process could be as short as years. This is a very attractive feature of Inimex medicines for companion animals.

Financial ranking explanation. Associated with a shorter regulatory path is lower cost, the ranking is moderate. Inimex's organizational capacity ranking is the same as for livestock. Limited capital is available for animal health projects, this ranking is low. Finally, it was estimated that there about 1.5 million companion animal cases in the USA each year. Even though this market is small relative to livestock, dogs with hemangiosarcoma are pets that have been in the family for many years. The onset of the disease is fast and families have shown a capacity to pay what it takes to keep their pets alive as long as possible to adjust to the inevitable loss of the pet. Inimex medicines should be able to sell at a premium. This criterion was given a moderate ranking.

4.5 Conclusions

In this chapter, key drug development milestones were identified, including duration, costs and risks. Target drug selection criteria were then presented and their significance was discussed. The AHP tool was used to evaluate target indications. Although many animal indications fit the Inimex medicine profile, a sample indication from a livestock and a companion animal segment was evaluated for discussion.

With the stated assumptions and explanations for the rankings, the AHP scores for the two sample indications, bovine respiratory disease complex (BRD) and canine hemangiosarcoma were 2.6 and 3.5 out of 5.0, respectively. This suggests that there are animal health opportunities for Inimex medicines and that companion animal indications would be more favourable considerations for Inimex. Although limited industrial and clinical information was available for both indications, the main point is that companion animal clinical trials require less time and resources than for livestock.

In the following chapter, financial scenarios will be identified and evaluated for Inimex to consider when exploring Inimex medicine opportunities for BRD and canine hemangiosarcoma.

5 EVALUATION OF SCENARIOS

The groundwork for developing an Inimex growth strategy was laid in the previous chapters. It was established that there is an animal health market and opportunity for Inimex animal health medicines. A very simple opportunity evaluation tool was developed and two sample target indications were selected – one from each animal segment: bovine respiratory disease complex (shipping fever) and canine hemangiosarcoma (dog cancer). This chapter will round out the project by achieving the third aim: to perform a comparative evaluation of potential revenue-generating scenarios for the two sample target indications.

The evaluation will include:

- valuation of Inimex animal health medicines;
- identification of financing options;
- evaluation of revenue-generating scenarios for indications.

5.1 Valuation of Inimex Animal Health Medicines

Determining the value of Inimex animal health medicines is a critical aspect of a decision whether to continue development or not. In the previous chapter, Section 4.3, market potential is a criterion in the AHP tool to select target indications. This section goes deeper. Knowing or at least having a clear understanding of a drug's value is one of the more significant pieces of information to have when deciding whether to continue with a project, financing a project or negotiating a business deal.

Table 5.1 below adds the final layer to the animal health drug development summary that has been built over the past two chapters. The final layer, is drug value. Instead of specific values,

a qualitative depiction is offered. In general, the one universal statement about valuation to be made is that as a drug moves through the development milestones, its value to investors increases.

Table 5.1: USA Animal Health Drug Development Summary with Value Indication.

Stages	pre-INADA	INADA	NADA	Market
Discovery	<i>in-vitro, in-vivo</i>			
Companion		Safety Efficacy	Field Studies (Clinical Trials)	Market
Livestock		Safety Efficacy	Field Studies (Clinical Trials)	Human Safety Studies Market
Timelines	2-12 years	1-3 years	2 - 5 years per species	2 - 5 years
Successful Candidates	~1 in 400	~ 1 in 50	~1 in 5	
Costs	Varied	US\$1M - 5M	US\$3M - 30M	US\$10M - 30M Varied
Value	Lowest	⇒	⇒	⇒ Highest

Data source: PhRMA, 2005 and Vaughn, 2006.

Valuation is both a science and an art. Inimex medicines are in an early stage of development, they are concepts supported by scientific data. Moreover, Inimex has no commercial products against which financial performance can be measured. Therefore, it is difficult to assign one true value to Inimex animal health medicines. In this project, two methods will be discussed: industry standards and discounted cash flow. These two methods are used because they are most commonly used for early-stage products by venture capital organizations (Foragen, 2001).

5.1.1 Industry Standards

The industry standards valuation method is the use of benchmarking, where a drug or technology platform is valued relative to other industry deals. The details of early stage development deals are highly guarded secrets. Therefore, there is no publicly available information on animal health early development deals that would give insight into valuation

benchmarks. It is also generally accepted that technology almost by definition is unique with few pre-existing examples.

Insight can be gained from a 2003 survey of human pharmaceutical deals (Pharmalicensing, 2003). According to the 2003 survey, early-stage deals ranged from US\$1M to 4M for up-front and milestone payments with royalty rates of up to 10 percent. McKinsey & Co. (McKinsey, 2002) had similar estimates for early development valuation. McKinsey estimates an average US\$17M up-front, and 7 percent royalty rates.

An estimation of the deal size- headline valuation- is based on the upper royalty rate, a range of annual revenues and assuming a five-year period of market exclusivity. Allowing for the human drug to earn annual revenue of between US\$100M and US\$1B, the total royalties could range from US\$50M to US\$500M over 5 years. The approximate valuation range for early stage human drugs is US\$51M to US\$504M, where projected royalty payments make the most dramatic figures for the deal.

Since the animal health market is about 5 percent of the human health market, a reasonable estimate of early stage valuation of Inimex animal health medicines is 5 percent of the human drug range (US\$50M to US\$500M). The Inimex medicine valuation for both the canine cancer and shipping fever indications is US\$2.5M to US\$25M using available industry standards.

5.1.2 Discounted Cash Flow

The discounted cash flow (DCF) method determines the relative worth of a future investment by discounting (at a required rate of return) the expected net cash flows from the project. Two calculations are presented below: net present value (NPV) and benefit to cost ratios (BCR). NPV is the difference between discounted future cash flows and the present investment. BCR is the ratio between discounted future cash flows and the present investment. Both are

useful in giving project valuation perspective. The values obtained in the following calculations are estimates based on assumptions, which will be discussed with the results.

The use of a company’s income statement is necessary to calculate a reasonably representative DCF. Since Inimex has no commercial products, any estimate of cash flow would be pure speculation based on variables such as investment requirement, market size, anticipated market share, sale price, gross margin and timeframe for the product lifecycle. Nonetheless, DCF calculations in this instance are useful for understanding sensitivity to the identified variables.

5.1.2.1 Sample Target Indication: Shipping Fever.

In the case of Bovine Respiratory Disease Complex (shipping fever), a range of NPV and benefit to cost ratio (BCR) results are presented in the lower section of Table 5.2 below. Before discussing these speculative values, an explanation of the choice of variable values in the upper section of Table 5.2 is first provided.

Table 5.2: Livestock shipping fever discounted cash flow calculations

Year	0	1	2	3	4	5	6	7	8
Investment (US\$M)	-12	-6	-6	-6					
Revenue (US\$M)					50	85	90	90	90
25% Gross Margin					12.5	21.3	22.5	22.5	22.5
Cash Flow (US\$M)	-12	-6	-6	-6	12.5	21.3	22.5	22.5	22.5

Discount Rate	0.1	0.2	0.28	0.5
NPV (US\$M)	29.6	9.0	-0.1	-11.0
BCR	3.5	1.7	1.0	0.1

*Note: investment and cash flow are estimates based on Table 5.1.
 NPV is net present value. BCR is benefit to cost ratio.
 Source: Author*

The timeframe of the calculations are spread over 8 years. Year 0 is a relative time point. It marks the point where, all things being equal, the same drug for companion animals would be

approved for market. In other words, the investment associated with Year 0 would include INADA and partial NADA costs for the bovine target animal species. Years 1 to 3 cover the extensive clinical field trials which could last over three years longer than that of companion animal trials. The total estimated bovine development costs were set at US\$30M- an intermediate cost identified in Table 5.1 above. For the calculations, the Years 1 to 3 investments were discounted with the revenues to Year 0.

Assuming a 5-year period of exclusivity, Years 4 to 8 include cash flow estimates. Using the 2004 inventory and slaughter rate used in Section 2.3.1, it is possible that approximately 15 to 19 million cattle are shipped for slaughter each year. It has been established that adoption in the livestock industry is sensitive to cost; the gross margin was set fairly low to 25 percent to reflect this. Since blockbuster drugs can realize annual sales of US\$100M, a confident but conservative maximum of US\$90M was estimated. Allowance for a 1-year adoption period to reach peak sales was included to account for the possibility of rapid adoption once economic proof was realized.

Four sets of NPV and BCR values are presented in the lower section of Table 5.2 with their associated discount rate. For established companies, a 10 percent discount rate is used and for illustrative purposes, the NPV and BCR values would be US\$29.6M and 3.5, respectively. As stated above, Inimex has no commercial track record, therefore a higher discount rate is applied. Venture capitalists tend to use a 20 percent discount rate for late-stage products and 50 percent for early-stage products. The NPV and BCR values are US\$9.0M and 1.7, respectively, at 20 percent; lower than at 10 percent. The NPV is most dramatically affected with the 50 percent discount rate, demonstrating the sensitivity to the time element of discounting. The NPV and BCR values at 50 percent are -US\$11.0M and 0.1, respectively; an unattractive investment under these conditions. The break even point is at a 28 percent discount rate for the given variables.

5.1.2.2 Sample Target Indication: Dog Cancer.

In the case of Canine Hemangiosarcoma (dog cancer), the range of NPV and BCR results presented in the lower section of Table 5.3 below. The established company 10 percent discount rate NPV and BCR values are US\$8.8M and 2.8, respectively. The NPV and BCR values are US\$5.5M and 2.1, respectively, at 20 percent. The NPV and BCR values at 50 percent are - US\$0.5M and 1.1, respectively; a positive investment under these conditions. The break even point is at a 55 percent discount rate for the given variables.

The timeframe of the calculations are spread over 5 years, reflecting a shorter time to market period, relative to livestock. Year 0 is market approval. The estimated development costs were set at US\$5M- an intermediate cost identified in Table 5.1 above.

Table 5.3: Canine cancer discounted cash flow calculations

Year	0	1	2	3	4	5
Investment (US\$M)	-5					
Revenue (US\$M)		4	6	8	10	10
50% Gross Margin		2	3	4	5	5
Cash Flow (US\$M)	-5	2	3	4	5	5

Discount Rate	0.1	0.2	0.5	0.55
NPV (US\$M)	8.8	5.5	0.5	0.0
BCR	2.8	2.1	1.1	1.0

Note: investment and cash flow are estimates based on Table 5.1.

NPV is net present value.

BCR is benefit to cost ratio.

Source: Author

Assuming a 5-year period of exclusivity, Years 1 to 5 include cash flow estimates. It has been established that the potential market size is small but a premium price can be charged; the gross margin was set to 50 percent to reflect this. Since other cancer treatment adjuncts can be used, a very conservative maximum of US\$10M was estimated. Allowance for a 3-year adoption period to reach peak sales was included to account for slower adoption in a more fragmented segment.

5.1.3 Valuation Discussion

As a discussion aid, the industry standard values and the NPV values from Tables 5.2 and 5.3 above are presented together in Table 5.4 below. Given the highly speculative nature of the estimates used to make the valuations, the values are surprisingly consistent with each other. For this project, the median DCF values for each indication will be used: US\$20.6M, shipping fever; US\$4.6M, canine cancer.

Table 5.4: Summary of industry standard and discounted cash flow valuations

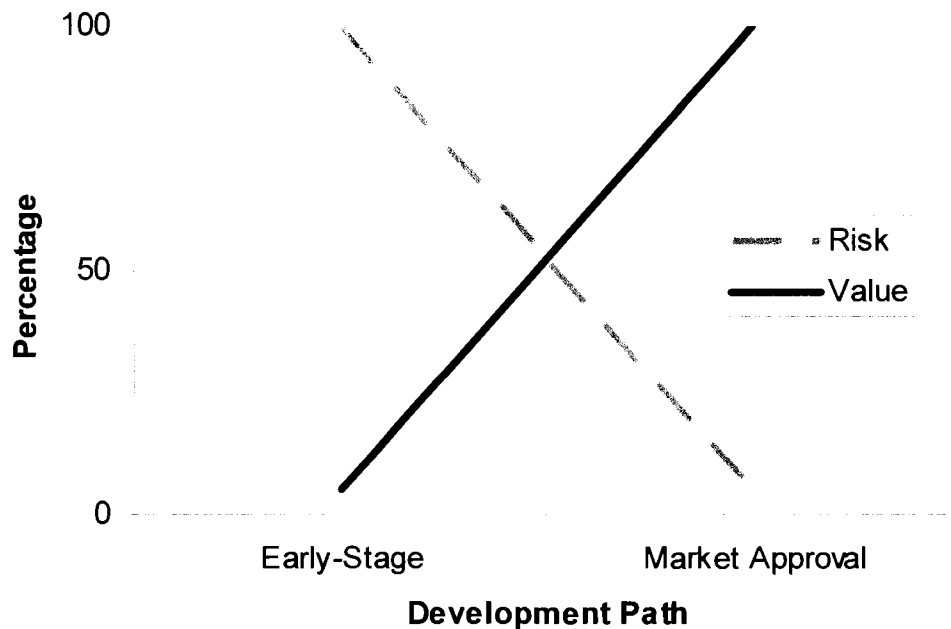
Indication	Values for Valuation Methods (US\$)		
	Industry Standard	Discounted Cash Flow ¹	(median)
Shipping Fever	2.5M to 50M	-11.0M to 29.6M	(20.6M)
Canine Cancer	2.5M to 50M	0.5M to 8.8M	(4.6M)

Source: Tables 5.2 and 5.3, ¹ NPV results using 10% and 50% discount rates.
Source: Author

The valuations indicate three points. First, the livestock scenario can be overlooked because long clinical trial periods and high development costs make the opportunity less attractive, especially when valued at a high discount rate. Second, even though the dog scenario projects reduced revenues relative to livestock, the opportunity is still attractive due to relatively low development costs and a shorter development period.

The third point is that given different variable values, a wide range of values can be determined. The most difficult aspect of valuation is taking risk into account. Examination of Table 5.1 above indicates a relationship between value and the rate of successful candidates, also known as risk. In early stages of development, there is little data; the risk of failure is high, therefore the value is low. As clinical data is acquired, risk decreases and product value increases. This reciprocity, demonstrated in Figure 5.1 below, will play an important role in valuation.

Figure 5.1: Schematic of Risk and Value Relationship in Drug Development



Source: Author

To some extent, the different discount rates used in the DCF calculations reflect an acknowledgement of risk. More sophisticated valuation tools factor gradation of risk at each development milestone. Although not presented here, the following advanced methods merit mention: Monte Carlo simulations, Real Options and decision trees. The methods involve iterative DCF calculations that take into account both development stage risk and ranges of variable values based on industry information, experience and probabilistic reasoning (guessing). Valuation expert, Richard Razgaitis, has identified six primary valuation methods (Razgaitis, 2003): industry standards; rating/raking method; rules of thumb; discounted cash flow; advanced iterative methods; and auctions. For a detailed understanding of valuation and early-stage valuation, the reader is directed to Razgaitis writings (Razgaitis, 1999, 2003a and b).

5.2 Financing Options

This section follows the next logical step after valuation in a strategic business process, which is to identify financing options. For small companies that do not have a source of revenue to fund the activities required to bring a product to market, there are several financing options. They are as follows and will be discussed in this section:

- Venture capital;
- Loans;
- Out-licensing;
- Small miracles.

5.2.1 Venture Capital Funds

Venture capitalists invest in start-up companies by providing seed money and management expertise to get a new company off the ground. In Canada for example, Foragen Technologies Management specializes in forestry, agriculture and aquaculture technologies. They typically fund ventures in the range of CDN\$0.5M to 3M, requiring 40 to 60 percent control of the company. Foragen values early-stage projects with a 50 percent discount rate (Foragen, 2001).

Inimex has highly qualified senior management, including board members with animal health experience. Therefore, managerial support from a venture capital firm in this capacity should not be necessary. If Inimex were to consider venture capital funding for animal health medicines, it would mean giving up equity in this growth opportunity. This may not be looked upon favourably by Inimex stakeholders.

5.2.2 Loan

Another source of capital is a loan. Since Inimex's assets are intangible intellectual property (IP), it may be difficult obtaining a loan from a conventional source for the entire

amount required to get a product to market. Larger pharmaceutical companies however, value IP as an asset. These companies provide loans in these circumstances but often these loans are convertible to equity.

5.2.3 Out-Licensing

Out-licensing animal health medicines is an option that could generate revenue for Inimex without diluting equity. To fill pipeline gaps, pharmaceutical companies rely on drug innovation from smaller companies. In-licensed drugs accounted for 30 percent of large pharmaceutical organizations human health revenues in 2001 (McKinsey, 2002). Although the trend has been for larger pharmaceutical companies to in-license late stage drugs, with increased shareholder demand for innovation, early-stage deals have been increasing (Pharmalicensing, 2003). As discussed in Section 5.1.3, early-stage products are associated with more risk, so they have a lower valuation than late-stage products where there is more certainty of success.

The typical licensing deal involves the exchange of IP rights for cash or royalties or both (Brousseau, 2005). Non-monetary benefits such as shared research management, manufacturing and clinical support are often negotiated in deals. The cash is usually in the form of up-front and milestone payments. Royalty payments vary depending upon the stage of development. Although published animal health deals were not available to this author, early-stage licensing deals for human drugs have reported up-front cash and milestone payments totalling between US\$0.5M to 5M and royalty rates of up to 10 percent (Pharmalicensing, 2003). In many respects, this could reflect animal health deals because at early stages there would be lower perceived risk of failure for animal drugs than human drugs. This is because early-stages of development are before regulatory trials begin, therefore data could be available for target animal species but not for humans.

For comparison and completion of information, late stage deals in the human market on average include up-front and milestone payments of about US\$265M and a 25 percent royalty (McKinsey, 2002). At late stages, human drugs are valued more highly than animal drugs, and this could be reflected in the cash payments; on one hand the animal market is 5 percent human drug sales, on the other, animal block buster drugs generate about 10 percent that of human block buster drugs. Therefore cash deals ranging from US\$13M to 26.5M would not be surprising for late stage animal health deals. With regards to royalty rates, it is not unreasonable to negotiate for similar royalty rates as humans- 25 percent on average- because the sales will ultimately determine the payment size.

Another licensing arrangement is with smaller companies that “incubate” products. In these arrangements the licensor takes a drug from an early stage to a later pre-commercial stage. After moving through the development process- formulation and some or all of the clinical trials- larger pharmaceutical companies license the IP at a higher valuation. The benefit of an incubator company is they tend to have regulatory and drug development expertise, whereas the innovator who is often a bench scientist may not. In these cases, the incubator company is usually small and resource-limited, therefore the licensing deal may only involve royalties and an assumption of development costs by the licensor. The benefit of such arrangements is the innovator can focus on their core competencies and drug development may move faster with the incubator company.

A recent, relevant example of an incubator-type arrangement is the deal between a privately-held bioscience company, Imulan BioTherapeutics and a Calgary start-up biotech company, SalPep Biotechnology (Animal Pharm, 2006c). This is relevant because while Inimex is focused on initiating formal preclinical trials for a small peptide anti-microbial human therapeutic, SalPep is doing the same for a small peptide, non-steroidal anti-inflammatory. Inimex is considering growth in the animal health domain, SalPep’s licensed drug will target animal species. The details of the Salpep-Imulan deal were not disclosed but SalPep confirmed

that their goal is to use the animal health regulatory exposure to augment the company's human drug efforts (Anonymous, 2006b). It is likely that the deal was based on royalty payments in exchange for IP rights and the licensor, Imulan, assumes the burden of development cost and risk.

5.2.4 Small Miracles

The final option is reserved for the likes of angel investors and various grants. It is feasible for example that a company committed to the elimination of antibiotics use in livestock may invest in clinical trials for shipping fever. Or a philanthropist, after losing their beloved pet to cancer, may grant funds necessary to make pet cancer treatments more effective. These sources of capital are sometimes a product of fortuitous happenstance, and although rare, they should not be discounted.

5.3 Evaluation of Scenarios

With an awareness of valuations and financing options, it is now time to evaluate each of the sample target indications. This not necessarily about selecting either of these particular indications, rather the intention is to identify a strategy for animal health opportunities.

5.3.1 Bovine Respiratory Disease (Shipping Fever)

The efforts in this project have shown that there is consumer interest in antibiotic-free livestock products. Shipping fever is a condition that has a significant economic impact and it occurs within a finite timeframe and set of conditions. There is a large volume of animals that could be susceptible to shipping fever each year; crude estimates in Section 5.1.2.1 suggest as high as 15 million to 19 million cattle. Although the livestock industry is large, it is cost sensitive. With market approval and acceptance, this drug can prove to generate a very high sales volume for millions of cattle. Based on the available information, the approximate NPV for the drug is \$US20.6M (Section 5.1.3). Moreover, with approval in cattle, other livestock species can be targeted like swine, sheep and poultry.

The limitations of the drug are its long regulatory approval path, which could take over 10 years to market. The formulation is currently an injectable, which may be a deterrent to adoption. The drug may need to be reformulated into an oral dosage form before beginning costly regulatory trials. This will add to cost and extend the approval timeline.

Of the above financing options, the venture capital funds and pharmaceutical loans are not attractive because they include loss of equity. Out-licensing would be an option if Inimex had some data on cows: either on cell lines (*in-vitro*) or on actual animals (*in-vivo*). Moreover, if Inimex can get an INADA initiated with safety data, the product valuation would increase and Inimex would be in a stronger bargaining position with licensing partners. This scenario would require about US\$1M to 3M in clinical and manufacturing costs. It would also require Inimex resources when Inimex is also initiating formal preclinical trials for their human drug candidate.

5.3.2 Canine Hemangiosarcoma (Canine Cancer)

Canine hemangiosarcoma is an acute and insidiously invasive cancer. As discussed in Section 2.3.2, the approximate number of pets that received chemotherapy in the United States was about 1.35 million for 2003. Not all of these treatments would have been for hemangiosarcoma, but it reflects an adoption of the treatment method. It is also known that cancer treatment adjuncts are critical in the reduction of inflammation and infection, both of which are lethal susceptibilities with cancer. Although the companion industry is small, it is cost insensitive in these circumstances. Based on the available information, the approximate NPV for the drug is \$US4.6M (Section 5.1.3). With approval in dogs for cancer, the market is opened to other companion animals and indications.

Product valuation is much lower than for livestock, however the companion animal approval path is much shorter, which could take 3 to 5 years to market. The formulation is an

injectable, which would be the dosage form of choice in chemotherapy; saving time and money in the approval process.

As for livestock, out-licensing is the strongest financing option. The situation would be most advantageous if Inimex had either *in-vitro* or *in-vivo* data or both on dogs. Negotiations could commence fairly quickly. Moreover, INADA safety and efficacy costs could be as low as US\$200K per trial. It is conceivable that Inimex could either initiate an INADA themselves or partner with an intermediary incubating firm to produce INADA data within the year. This would put Inimex in the strongest bargaining position with a larger licensing partner.

5.4 Chapter Lead Points

A sample scenario was evaluated for both a livestock and companion animal indication. In each scenario, a drug valuation was performed and then financing options were identified.

Valuation. Inimex animal drugs were valued using industry standards and discounted cash flow (DCF). For this project, the median DCF values for each indication were used: US\$20.6M, shipping fever; US\$4.6M, canine cancer. With a lack of animal drug valuation information, many assumptions and estimates were made based on the available data. Other more advanced valuation methods were identified. More detailed market research is needed for more confidence in the valuations.

Financing options. To overstate the obvious, without capital, drugs will not make it to market. Four financing options were identified: venture capital, loans, licensing, small miracles (angel investors and grants). Most of the options involve giving up equity. Out-licensing seems to be the option with the most potential for shorter term revenue generation.

Scenario evaluation. The sample indications were discussed from the perspective of market potential, valuation, regulatory timeline and financing options.

6 SUMMARY AND RECOMMENDATIONS

6.1 Summary

Inimex is an emerging biopharmaceutical company dedicated to the discovery, development and commercialization of new human medicines based on the selective modulation of the innate immune response. Inimex's current focus is on initiating formal preclinical trials for its lead human drug candidate. Inimex has secured funding through two rounds of private equity financing and it has been awarded non-dilutive government funding, all of which should move the drug into later stage clinical trials. The goal of this project has been to perform initial analysis and screening to determine whether Inimex has a business opportunity in the animal health industry.

Chapter 2 demonstrated two things. First, that Inimex has a drug technology platform with significant advantages. Namely, it promotes the innate immune system to rapidly fight infections while suppressing inflammation. Second, there is opportunity for Inimex drugs in both the livestock and companion animal segments of the animal health industry. The approach for the two animal health segments is different. For livestock, the focus is to enhance economic value for food producers: high volume low cost. The companion animal focus is to increase quality and duration of pet life: low volume, high cost.

Chapter 3 showed that with fewer than 25 employees, Inimex has limited resources but the company's core competencies are drug discovery and business development. The climate for developing an animal health drug is favourable for Inimex. Through an animal health industry analysis, one of the identified key success factors for incumbent firms is constant innovation. Inimex can meet this need with its technology platform. One of the key Inimex success factors is

sufficient capital to sustain development to product approval. If Inimex can show some efficacy and application, animal health firms will want to make a deal with Inimex.

In Chapter 4, the main drug development milestones were identified, including duration, costs and risks. Target drug selection criteria were then presented and their significance was discussed. An Analytic Hierarchy Process (AHP) tool was used to evaluate target indications. The criteria and their weighting were determined by the author. Should Inimex wish to use this tool any further, they need to evaluate the criteria and weightings based on their own perceptions and further market research.

Although many animal indications fit the Inimex medicine profile, a sample indication from a livestock and a companion animal segment was evaluated for discussion: bovine respiratory disease complex (BRD, shipping fever) and canine hemangiosarcoma (dog cancer). The AHP tool indicated that companion animal indications would be more favourable considerations for Inimex at this point in its development. Although limited industrial and clinical information was available for both indications, the main point is that companion animal clinical trials require less time and resources than for livestock.

In Chapter 5, the two sample indications were first valued using two techniques: industry standard and discounted cash flow (DCF). For this project, the median DCF values for each indication were used: US\$20.6M, shipping fever; US\$4.6M, canine cancer. With a lack of animal drug valuation information, many assumptions and estimates were made based on the available data. More detailed market research is needed for more confidence in the valuations. Second financing options were presented. Out-licensing was the option with the most potential for shorter term revenue generation. Finally, the sample indications were discussed from the perspective of market potential, valuation, regulatory timeline and financing options. It is the accumulated information from all chapters that lead to the recommendations presented in the next section.

6.2 Recommendations

Based on the findings in the previous chapters, the main recommendation to be made is the strong encouragement for Inimex to pursue the development of a medicine for companion animal application. For maximum short term revenue, Inimex should bring the medicine into INADA trials then negotiate an exclusive licensing deal for all animal rights.

Inimex has enough in-house capability to serve as its own “incubating company”. Initiating INADA companion animal trials will increase Inimex’s price for an eventual licensing deal. The reasons for focusing on companion animals over livestock are three-fold. First, the upfront clinical costs that Inimex would bare are lower. Second, clinical trials are shorter. Third, clinical trials can be managed more easily. These three reasons address the fact that regulatory and public perception are critical; as early trial data is available, Inimex can benefit from positive animal health drug development information or make adjustments in the event of negative data. Also, the realization of short term revenue, no matter how small, will benefit Inimex in its operations and public perception.

The license price can be made even higher if the license is inclusive of all animal applications that the licensor would pursue. Although valuation of a companion animal drug will likely be more modest than for livestock, negotiations should include royalties for each drug to market. There should also be a limited period of exclusivity in which the licensor would initiate trials for other animals. This last condition would protect Inimex from competitors attempting to squash competing innovation.

Before jumping into such an undertaking, there are four activities that Inimex would need to consider. First, Inimex would need to put together a business plan to discuss the concept with its Board of Directors, which includes animal health experts. This would include determining whether this activity would distract the human drug development focus and the identification of

mitigations to avoid distraction. Second, Inimex would need to earmark about US\$300K to IM for the INADA activities.

Third, Inimex would need more market research on companion animals. Focus groups with veterinary specialists and commercially available pet owner surveys could give complementary detailed information for expanding the AHP decision tool in the selection of a target indication. Industry research can be purchased which could identify current clinical initiatives, competitors and potential licensors. Although not discussed in the project, canvassing pet insurance carriers may provide useful market research. Fourth, Inimex may need to hire at least one more person to assist in developing the business concept.

In conclusion, this initial analysis shows that Inimex has opportunity in the animal health market. Inimex is in a good place to evaluate a potential revenue-generating growth opportunity that could also develop in-house capabilities and positively increase Inimex's public profile for future investors.

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