



INTERNATIONAL BUSINESS

WHAT INTERNATIONAL MARKET ENTRY STRATEGY SHOULD KEREKIS FOLLOW TO ENTER INTO THE INDIAN CHRONIC DIABETIC WOUND MARKET?

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**WHAT INTERNATIONAL MARKET ENTRY STRATEGY
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Abstract

The author did this thesis with the objective of getting a Master's Degree in International Business. The reason for the study was to gain more knowledge into the diabetic market, internationalization, with focus on traditional and Born Global strategies. Kerecis is an innovative small to medium enterprise entering into international markets. Their products are designed for chronic diabetic wounds. The product base is designed from the skin of the cod fish and is unique in comparison to its competitors. The author chose India as a market due to the large growing diabetic population.

Keywords: Kerecis, India, Diabetes, Chronic Wounds, SME's, Entry Modes.

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Chapter1: Introduction and Research

Problem

1.1 Introduction

The global advanced wound care market is large and growing in developed and emerging economies and is predicted to be worth \$14.6 billion by 2021. In a report called World Market Prospects 2011-2021 by an independent business information provider Visiongain, physicians worldwide are using advanced wound care to treat burns, pressure and diabetic ulcers (Visiongain, 2012) .

Type II diabetes is one of the most common causes of chronic wounds in emerging economies. The three main forces driving this market currently are increased diabetic population, chronic wounds and longer healing processes. Worldwide roughly 347 million people live with diabetes. More than 80% of deaths occur in low-and middle – income countries. The World Health Organization predicts that deaths caused by diabetes will increase between 2008 and 2030 (WHO, 2012).

Diabetic wounds are on the rise and have a 15% higher chance of resulting in amputation than the general population due to chronic ulcers. The cost of chronic wound care is very high. In a United States study done by the Agency for Healthcare Research and Quality it was estimated that the cost of pressure wound management exceeded 1.4 billion dollars annually. The average cost to heal one leg ulcer was estimated at \$1,951 in 2011, whereas that for a diabetic foot ulcer was estimated at \$29,373 (WHCC, 2009).

India currently battles with a high population of diabetic patients. Although in general the elder population seems to be more affected, statistics show that diabetes affects all ages. The more acute the condition is, the more likely the chance of amputation, due to poor circulation and nerve damage.

There is a high demand for wound products all over the world due to the epidemic proportion of diabetes. In India alone the wound care market industry will reach \$179 million by 2016 (WDF, 2012).

The purpose of this thesis is to find out whether there is a suitable market in India for Kerecis MariGen Wound products with a focus on chronic diabetic wound sufferers. The author did a three month internship at Kerecis and could see huge potential for the

Kerecis chronic wound products while conducting research into the wound care markets in emerging economies. For this thesis, the author applied theories and information from the MSc International Business program with a focus on Business Markets in Asia and Entrepreneurship and Innovation. This is a Type A applied thesis starting with a body of theory, and applying it specifically to Kerecis.

Kerecis is a small Icelandic biochemical company that has been in operation since 2007. Classified under medical devices its focus is on the diabetic chronic wound care markets. The products are developed by a highly qualified team of tissue-healing experts, and the production is simple and inexpensive with raw materials readily available at very low prices. Kerecis has developed a medical device that is fish based. The active ingredient is collagen from the fish skin. The products are based on the distinctive material characteristic of fish skin tissues. The products compete with porcine and human tissue generated products that have high costs and complicated production processes.

Kerecis is a company that focuses on the biologics segment of the chronic wound prevention and repair markets. They are also focusing on the growing markets of diabetic patients.

1.2 Research Questions and Structure of the Thesis

Diabetes is the number one killer worldwide and India is at the top of the list with over 43 million diabetics. The healthcare industry is worth billions of U.S dollars and companies all over the world spend time and money to create new medical products to help cure diseases. Small to medium biotechnology companies have to compete with larger companies. Competition is very high and therefore entry into other markets is vital but it is important to evaluate markets carefully.

What International Market Entry strategy should Kerecis follow to enter in the Indian chronic wound diabetic market?

1.3 Objectives

- To determine there is a market for Kerecis wound care products in India.
- To determine if Kerecis and staff have the skills and resources for the Indian market.

- To determine if India's infrastructure and healthcare systems are adequate for entry by Kerecis.

Based on the above the research questions are as follows:

- a) What are the strengths and weaknesses of Kerecis?
- b) What are the conditions and characteristics of the Indian Healthcare system?
- c) What are the characteristics of the chronic wound diabetic market in India?
- d) Where should Kerecis place their products in this market?
- e) What are some of the Internationalization Strategies being used today with start-ups?
- f) What is the best entry mode strategy for Kerecis to select for India?

1.4 Justification

There is a lot of research being done on the medical markets within emerging economies. India has emerged as one of the biggest alongside of China. With a large population and booming economy, it is predicted India will surpass China. Economists term India's growth as the economic destination. Companies and workforce are solid financial markets and institutions (The Economist, 2010).

While emerging economies like India are seeing economic growth, they are also seeing a rise in Non Communicable Diseases such as diabetes. India currently has the highest diabetic population in the world and it is expected to get worse with the increase of urbanization. India's strengthening economy is allowing for more disposable income in the middle to upper-class brackets. Indian people are becoming ill with unhealthy diet and less activity which is increasing the rate of disease.

There are many new initiatives in India between government and health officials to counteract these problems. Affordable healthcare plans are being put in place as well as reduced drug prices, the construction of new hospitals and clinics, the latest technology and better trained staff.

India is becoming a very large player in global markets and continues to attract companies from the West owing to its strengths in Information Technology. Indians have a strong command of the English language and are providing many other services for global clients such as medical tourism. The growing potential in this industry is expected to grow into a \$2 billion industry by the end of this year (PWC, 2007).

In conclusion the author applies international and Born Global strategies to Kerecis translating the applications into practice to propose and support a viable entry mode.

Further the author will examine other known medical device companies from Iceland which are in or are considering entry in the Indian market to compare their strategies.

The thesis allows the author to use her knowledge from the International Business program to do relevant research and field work to investigate the opportunities and changes facing medical device companies from Iceland that may be going into larger markets.

The thesis enables the author to gain ample insight into the medical and healthcare industries which can be used in the future for other business proposals and projects. Finally the author intends for this thesis to give others new perspectives into International Business evaluation of new healthcare system strategies.

Chapter 2: Literature Review

2.1 Introduction

In this section the author has split the literature review into two parts. The first part reviews the company Kerecis in detail. Kerecis is a biotechnology company classified internationally under Medical Device that focuses on wound care products derived from cod fish to treat chronic diabetic wounds. They have one cosmetic cream for diabetic feet that is currently in the domestic market. The other wound product, Marigen Wound has just received CE (European Economic Drug Market) coding and they are still waiting for approval from the FDA (Food and Drug Administration) in the United States. They have another product for hernias that is still in development.

The competitors with Kerecis are porcine, bovine and human tissue based. Kerecis is the only fish based product on the market which would be favorable in countries with strong religious beliefs against animals like pigs and cows.

The second section focuses on the International and Born Global strategies. Research is suggesting that traditional internationalization models for corporations are being replaced by new strategies and models for companies that are called 'Born Global' 'Start-ups' and 'New Venture'. A comparison will be made to determine which may be preferable for Kerecis, leading to the most desirable market entry mode.

2.2Kerecis

Kerecis was founded in Iceland in late 2007. In 2010 the Icelandic New Business Venture Fund invested in Kerecis providing the company with capital for research and development, production, marketing and distribution.

The President and CEO is Gudmundur Fertram Sigurjonsson a former Head of Wound Management at Össur, the world's largest non-invasive orthopedics firm. He is an inventor with over 40 registered US patents. The company's Medical Director is Dr. Baldur Baldursson, M.D., Ph.D., is former Head of Clinical trials at Össur, a practicing M.D. for 25 years and Senior Consultant at the National Hospital of Iceland. He is the President of the Nordic Dermatological Association. The VP of Medical Sciences is Hilmar Kjartansson, M.D. He is a specialist in Emergency Medicine and Internal Medicine. Ernest Kennedy is Kerecis's Legal Counsel and a Director at Kerecis. He is a US Washington DC based patent attorney with over 40 years experience in the field. Dora Hlin Gísladóttir is the R&D Manager of Kerecis. She is a chemical engineer from the Swedish Royal Institute of Technology and UCSB California and formerly the laboratory manager of Agar Ltd (Kerecis, 2011).

The very strong qualifications and experience of key personnel and founders has enabled Kerecis complete product development and the start of three products within 3 years from the foundation of the company.

Mission and Vision, Goals

Kerecis focuses on two high growth markets: abdominal wall reconstruction and prevention and treatment of chronic wounds. Kerecis wound product is MariGen™ Wound, and Kerecis is committed to the prevention and treatment of chronic wounds (Kerecis, 2011). These wounds are often the consequence of diabetes and circulation complications. The targeting for the products is the growing niche markets for diabetics. Kerecis is committed to the prevention and treatment of chronic wounds. Chronic wounds cause patients severe emotional and physical stress and create a significant financial burden on patients and the whole healthcare system. Kerecis provides a unique solution that helps the wound regain balance and heal (Kerecis, 2011).

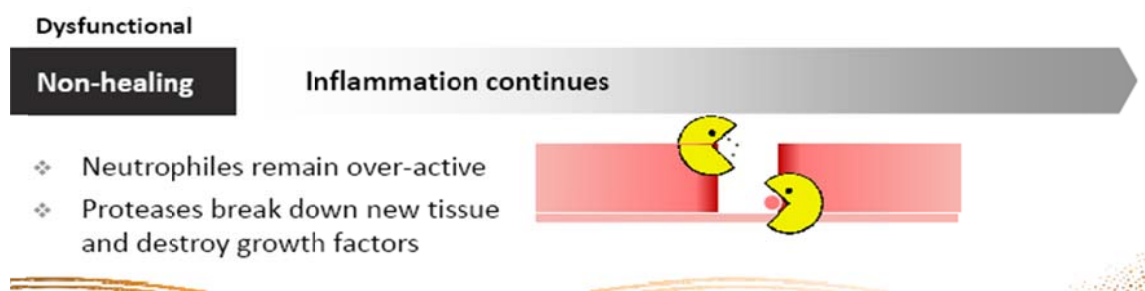
Biologics in Chronic Wound Prevention and Care

Traditional products in chronic wound prevention and care are lotions, gauzes and bandages. New and advanced products have been introduced during the last years such as hydrogels, colloids, alginates, foams and silicon coatings.

Biologics products are based on matrices, growth factors, grafts and auto grafts and differ significantly from other products in the field. Kerecis biologics products are based on the Lipid Enhanced Matrix technology, providing novel tissue regeneration material to accelerate repair of damaged tissue (Kerecis, 2011).

Chronic wound prevention and care and diabetes

Every year about 34.5 million chronic wounds are treated globally. Chronic wounds are often the consequence of diabetes and circulation complications. In chronic wound care the balance between production and degradation of molecules such as collagen is lost and degradation plays too large a role, see illustration in picture 1 below (Kerecis, 2011).



Picture 1-Illustration of dysfunction

Diabetic foot ulcer is one of the major complications of Diabetes mellitus. It occurs in 15% of all patients with diabetes and precedes 84% of all lower leg amputations. A major increase in mortality among diabetic patients has been observed over the past 20 years. This is considered to be due to the development of macro and micro vascular complications, including failure of the wound healing process (Kerecis, 2011).

The Kerecis MariGen Wound™

The Kerecis MariGen™ Lipid Enhanced Matrix technology provides a unique solution restoring growth factor balance and the healing process. Chronic wounds present an enormous physical, social and economic burden worldwide and their incidence is on the rise with an ageing population. It has been estimated that chronic wounds affect 120 per 100.000 people aged between 45 and 65 years and increases to 800 per 100.000 people aged over 75 year. Chronic wounds result from a number of different causes among them diabetes, pressure, arterial and venous insufficiency, vasculitis and burns. Additional complications, including infections, necrosis, tissue hypoxia, and exudates represent further challenges in dealing with a chronic wound. Poor nutrition, obesity, excessive alcohol consumption and smoking can then add an additional layer of complications to an already serious condition (**Kerecis, 2011**).

Normal wound healing progresses through three stages. The first is Inflammation which lasts 2 to 4 days from the time of injury. Upon injury homeostasis causes vascular constriction, and thrombus formation. Platelets in the wound release factors that recruit neutrophils and monocytes (macrophages), which in turn attract lymphocytes and fibroblasts to the site of injury. The proliferatory stage overlaps the inflammatory stage, starts at about day 3 and lasts for several days. It is characterized by angiogenesis, collagen formation and epithelialization mediated by fibroblasts, and is complete when balance is achieved in collagen formation and its continuous breakdown by matrix metalloproteases (MMPs). The Remodeling stage is the third and last stage and can extend over a year or more. Collagen remodeling continues, fibroblasts differentiate into myofibroblasts, vascularity decreases and tissue strength increases (Kerecis, 2011).

Technical Benefits

Chronic wounds fail to progress normally through these stages and arrest at the inflammation stage. In the chronic wound environment factors counteracting healing take control. The concentration of MMPs increases with detrimental effects on collagen formation and remodeling, and other proteins necessary for normal healing. Keratinocyte and fibroblast dysfunction is apparent, and angiogenesis and neovascularization is impaired. Reactive oxygen species, neuropathy and hypoxia also impede healing. This is a vicious cycle that can continue for years on end (Kerecis, 2011).

The Kerecis MariGen™ Lipid Enhanced Matrix is designed to refocus the healing process of chronic wounds. The matrix acts as a scaffold for revascularization and repopulation by the patient's cells. It is also a substrate for the voracious MMP curbing their appetite for native collagen. The natural lipids in the matrix serve to reduce inflammatory processes thereby allowing wound healing to progress normally (Kerecis, 2011).

Production

Production takes place in Isafjorður Iceland. Isafjorður is a fishing village in the north western part of Iceland.

The source material is fish skin from cod that is farmed in the pristine North-Atlantic Ocean off the northwest coast of Iceland. The supplier of fish skin, H-G is under contractual obligation with Kerecis not to use pesticides or penicillin in their cod farm supplying Kerecis's raw materials. The cod is farmed in clean sea that is monitored. The cod farm H-G supplying the cod skin, is situated 10 minutes from Isafjorður. The cod farm's production is quality controlled. The supply of raw material is plentiful in Iceland. The fish skin is a very inexpensive raw material as it is excess material in the production of filleted cod (Kerecis, 2011).

Kerecis's production in Isafjorður is at present employing 3 employees, providing non specialized labor for the production process. There is an ample supply of unskilled labor in Isafjodur, a low wage area with unemployment. There may be a future need to employ a specialist to handle quality control in Isafjorður. The Head Quarters are in Reykjavik. The company's specialized personnel work at the HQ. Supply of specialists for the HQ, for R&D, testing and registration of products is somewhat limited in Iceland and there may be a future requirement challenge (Kerecis, 2011).

The production facilities need to be sterile, special ventilation is required and the production area is sealed. The product is packaged completely sterilized. The production is quality controlled under the ISO 13 485 medical standard and has received standard accreditation. Production will be doubled from the current capacity in the current production personnel and investing in further production equipment and air ventilation system (Kerecis, 2011).

Product

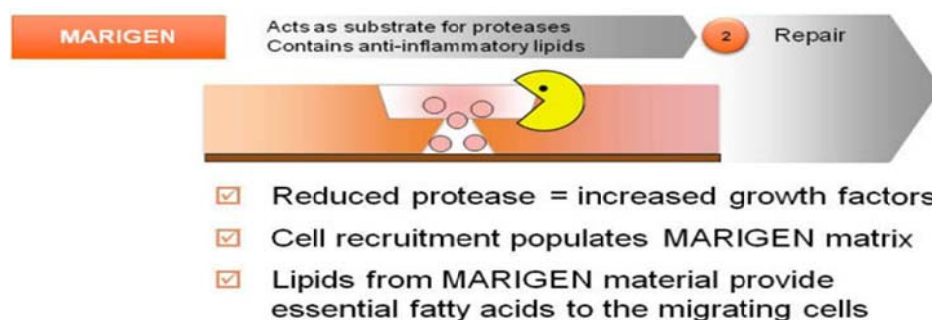


Picture 2 – Competitors Oasis from Health point (left) and Marigen from Kerecis (right) (Kerecis, 2011)

The Marigen lipid collagen matrix is a patent – pending, fish skin-derived, tissue-regeneration technology that is based on a unique biochemical and physical structure of fish skin. This is an innovative tissue growth and repair product for global medical markets (Kerecis, 2011).

Technical Basis

The **MariGen™ Omega3 Extra Cellular Matrix** technology is made from fish skin and contains lipids and proteins that in a concerted manner help the body regenerate damaged tissue. The lipids in MariGen™ include sterols, fat-soluble vitamins, and phospholipids as well as polyunsaturated fatty acids. The health benefits of polyunsaturated fatty acids have long been recognized and their positive impact on health is on sound scientific footing. These favorable effects are in large part mediated by the omega-3 (n-3) fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) found in high concentration in fish oil. One of the reasons why wounds remain chronic and fail to heal is the shortage of lipids which are formed in the Golgi apparatus of the keratinocytes (Kerecis, 2011).



Picture 3 - Restoration of normal wound healing process with Kerecis Marigen Footguard™ (Kerecis, 2011)

MariGen™ contains intact insoluble proteins from the extracellular matrix (ECM) of the fish skin. In all animals the ECM is the extracellular part of animal tissue that provides structural support to the cells in addition to performing various other important functions. Skin ECM consists of structural proteins (primarily collagen), adhesive glycoproteins, proteoglycans, and matricellular proteins. Scaffolds composed of ECM have been shown to be rich in bifunctional molecules such as fibronectin and various types of collagen, among other structural and functional molecules. Degradation products of the ECM molecules have as well demonstrated significant biological activity themselves. The MariGen™ Omega3 Extra Cellular Matrix scaffolds do not elicit an immune response since the major antigenic components present within cell membranes are removed during processing (Kerecis, 2011).

All commercially available ECM scaffolds to date derive from mammalian sources. Their use within many bioengineering fields has grown rapidly, due to their excellent biocompatibility, low antigenicity, high biodegradability and good mechanical, haemostatic and cell-binding properties. Non-mammalian derived scaffolds have so far not received much attention. A small number of aquatic and marine sources have been explored, including and fish scales for corneal regeneration, but fish proteins generally have received little attention as a suitable material in an ECM structure. Fish skin does, however, possess much the same features as mammalian derived ECM, among them an appropriate surface chemistry and microstructures that facilitate cellular attachment, competent mechanical strength and biodegradation rate without undesirable bi-products. Fish protein ECM from marine sources also has the added bonus of being free of potential human pathogens, and other confounding concerns, for instance religious beliefs and societal issues (Kerecis, 2011).

The company is actively seeking future licensing and distribution partners, while focusing on product development, intellectual property protection and clinical tests. Ideal potential technology licensees will have the ability to accelerate regulatory approvals and the market launch of these proprietary devices or provide access to key markets outside of the U.S (Kerecis, 2011).

2.3 International Market Entry Strategy

Literature

In this section the author will:

- Review Small to Medium Enterprises (SME's) Internationalization theory and Uppsala Internationalization Process Model.
- Review Born Global theory and Research Model.
- Review the SME biotechnology, innovation and entrepreneurship strategy.
- Review emerging economies, India and market entry for Kerecis.
- Make a comparison and discuss the findings.

2.3.1 SME Internationalization

The importance of SME's internationalization entry mode research has increased over the years and more insight has been given to the entry mode choices of these companies. Where much of the focus has been on the multinational companies, researchers (e.g. Nakos and Brouthers, 2002) believe the importance now has shifted to smaller and medium sized companies (Reinhold & Zhao, 2004). The definition 'Entry Mode' originated from the theory of multinational companies with many explaining it as a critical issue in international marketing. Regarded as the 'frontier issue', Wind and Perlmutter (1977) argue that the choice of entry mode has a strong impact on international operations whilst Root (1994) claims that entry mode choice is one of the most critical strategic decisions for multinational enterprises (Reinhold & Zhao, p.181 2004). Cavusgil and Nevin (1981) see the process of internationalization in four stages, domestic marketing, experimental, active, and committed involvement where the stages of involvement in international markets corresponds with the development of strategic thinking and long term resource commitment (Doole & Lowe, p.195 2001). The benefits are reduced costs, better training, higher research and development, improvements in quality control and lower perceptions of risk which increase a companies performance. Doole and Lowe (1997) suggest that the internationalization process of companies, is

not a gradual incremental process but a series of step changes. Many factors could play into this. Many researchers have different theories, however, some conclude the following could result in step changes. The recruitment of a chief executive, product and market success, failure within the business and markets, stakeholders and their expectations, not enough profit to owners and family interference.

Today SME's are growing faster as they compete on a global stage due the increase of business worldwide. Strategies are being developed, creating moderate growth and less risk. The advantage of being an entrepreneur is being flexible to new demands. Financial and Research and Development commitments are normally the biggest burden. Whilst some companies have good management, many are left with costly failures. Entering into new markets is the most challenging aspect of business of SME's. Culture as well as market structure and business practices are just a few problems for many companies. Some companies will not enter foreign markets out of fear. Those that do will risk and deal with the complications that arise or respond quickly to the difficulties that emerge. Evaluating, planning and managing operations and resources will make for a successful internationalization development plan.

Doole and Lowe (1997) continue that SME's who want generate revenue from foreign markets often use a number of alternative strategies that fit to the internationalization process:

- Selling domestic goods abroad.
- Creating a viable marketing mix for an internationally based niche product.
- Tapping into electronic commerce for marketability on a global scale.
- Participation in the international supply chain of an MNE, can lead to SME's piggybacking on the MNE's international development. This may involve either domestic production or establishing a facility close to where the MNE's new locations are established in other countries (Doole,p180 2001)

Doole and Lowe (1997) also stress that whilst strategies are changing as the approach to internationalization changes, that it is important to still look at the principal approach to strategy .The authors assess in three stages.

- Identification of the various segments that exist within the sector using various segmentation methods. It is important for the SME to define cross-border segments with clearly identifiable requirements that is able to serve.

- The firm must then target the segments which appear to be the most attractive in terms of their size, growth potential, the ease with which they can be reached and their likely purchasing power.
- In seeking to defend and develop its business the firm needs to position its products or services in a way that will distinguish them from those of its local and international competitors and build up barriers which will prevent those competitors taking it's business (Doole & Lowe,p.189 2001)

Following this the mode of entry into the foreign market is an extremely critical marketing decision. This is when the company chooses a selective method according to their overall needs. SME's entering the emerging economies will find this an important step as the risk is higher due to distance. Cultural, legal and political issues in different countries could lead SME's into using different strategies and entry modes for different environments.

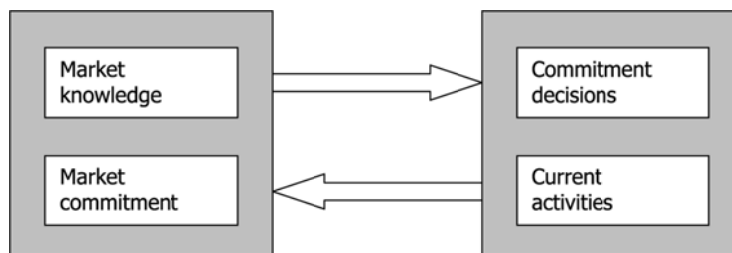
The author will look at the Uppsala Internationalization Process Model. This is an updated model from the original Uppsala model that was designed in 1977 by researchers Johanson and Vahlne.

2.3.2 Uppsala Internationalization Process Model.

Due to the changes in International Business the Uppsala Model has been revisited. The old Uppsala Model was created in 1977 by Johansson and Vahlne. The model referred to the empirical studies on Swedish manufacturing firms at the international business department at the Uppsala University. Johansson and Vahlne (1997) came up with the basic assumption that a lack of knowledge created obstacles into international business. The Uppsala model represents and acknowledges the learning aspects of knowledge and what it represents in the business world. Swedish manufacturing companies lacking market knowledge forced themselves to enter the international business sector in small stages, which slowed the rate of commitment and kept risks low due to psychic distance (Copignatti, 2012).

The current business environment is more heavily geared towards networking and less based on a psychic distance existence (relationships of independent suppliers and customers) which is currently known as 'Outsider ship'. On the other side there is

‘Insider ship’ which is the network of relationships in which firms are linked to each other in various complex invisible patterns (Johanson & Vahlne, 2009). The new Uppsala Model Johanson and Vahlne (2009) is essentially the same as the original version, with the addition of model trust-building, knowledge creation, and networking building relationships. The business network model consists of two sets of variables. State variables (stock) and change variables (flow), which are relevant to both sides of a relationship. The model thus depicts dynamic cumulative processes of learning, as well as trust and commitment building (Johanson & Vahlne, p.13 2009).



Source: Johanson and Vahlne (1977)

Model 1: The business network internationalisation process model

The following are a list and explanation of the variables as displayed in the model above (Johanson & Vahlne, p.13 2009).

Knowledge opportunities: This variable is regarded as the most powerful. It is being used and regarded as a viable source to opportunity. Along with this components like needs, capabilities and networks, it can impact a firm directly or indirectly. The authors added recognition of opportunities as another variable. They see that opportunity is an important element of knowledge which will drive the process.

Network Position: The authors assume that the internationalization process is pursued within a network. Relationships are characterised by specific levels of knowledge, trust and commitment that may be unevenly distributed among the parties involved, and hence they may differ in how they promote successful interationalization. If the process is seen as potentially rewarding, a desirable outcome of learning, trust and commitment building will be that the firm enjoys a partnership and a network position.

Learning, Creating, and Trust Building: The quick involvement, and efficiency of the process in learning, creating the knowledge, and building trust, commitment, and finding partnership opportunities is beneficial. Developing opportunities is a critical part of any relationship. High levels of knowledge, trust and commitment in a relationship result in a more effective creative process.

Relationship Commitment Decisions: The firm decides on the level of commitment to one or more of their networking relationships. The decision will be made through changes in entry modes, the size of investments, organizational changes, and definitely in the level of dependence. A change in commitment will either strengthen or weaken the relationship. The developing of new relationships, or working on an existing relationship is helpful.

Conclusion

Through a lot of empirical studies, research on internationalization has evolved over the decades. The business network internationalization process model was designed to incorporate the process model with the network approach. Studies by Caviello and Munro (1995, 1997), showed that network relationships have an impact on foreign market selection and entry mode choice in the context of ongoing network processes (Johanson & Vahlne, 2009). Johanson and Vahlne say that their model focuses on business networks as a market structure (Johanson & Vahlne, 2009).

2.4 Born Global

2.4.1 SME's and New Venture Strategies

In the field of international entrepreneurship there is a lot of discussion about 'Born Global' companies. Little research has been done on these companies. Most researchers have focused on internationalization theories over the past three decades. In a study dated back in 2002, Erik Rasmussen and Tage Madsen did a paper for the EIBA (European International Business Academy) conference. They spoke about the new changes and challenges for companies and entering international markets. Since the seventies much research has been done on export and internationalization in the U.S and Europe (Johanson & Vahlne, 1977; Johanson & Vahlne, 1990) and in North America (e.g. Bilkey, 1978; Casvugil, 1980). These research traditions viewed exporting in

incremental stages. Perception, expectation, experience and managerial capacity are the fundamentals and the firm is to assume it has to build a stable domestic position before starting international activities (Rasmussen & Madsen,p.4 2002).

Today things are different and it is claimed that international businesses does not always work in stages but that they may start international activities from birth (Rasmussen & Madsen, p.3 2002). Such firms have been labeled International New Ventures (Oviatt & McDougall, 1994), High Technology Start-Ups (Jolly et al., 1992), and Born Globals (McKinsey & Co., 1993; Knight & Cavusgil,1996; Madsen & Servais, 1997). The global market provides a new picture with a change of conditions. There have been many developments in the areas of transportation and communication technologies. The explanation for this new picture of internationalization of firms is claimed to be more about global market conditions and the rising number of people with international experience. Some authors, (e.g. Knight & Cavusgil, 1996; Oviatt & McDougall, 1994), have launched these empirical observations as a challenge calling for a new theory, whereas others (Madsen & Servais, 1997); (Knudsen et al., 2002) argue that firms which overtly behave differently, do not necessarily differ from other firms with respect to more fundamental processes (Rasmussen & Madsen,p.4 2002).

According to the latter argument, the phenomenon may not require new theories, but may be explained by already well known constructs. However, it may still be relevant to categorize such firms as something unique from a managerial point of view or with regard to governmental support programs (Rasmussen & Madsen,p.4 2002).

Technolgy and active entreprepeuship ideas and activities have created the name Born Globals producing breakthroughs with new and unique product invention (Doole & Lowe, 2001).

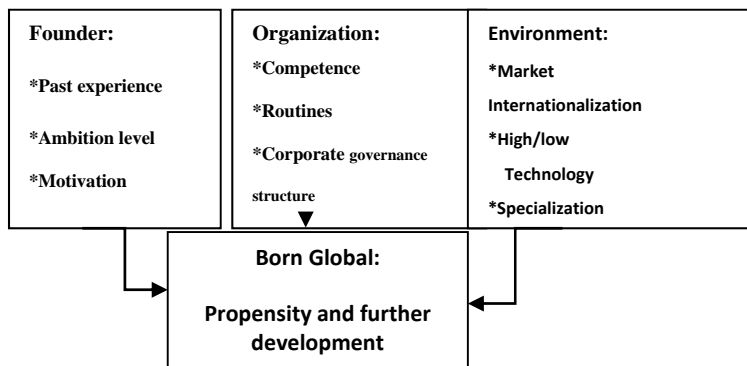
Knight and Cavusgil found that many trends have given rise to the emergence of Born Global firms:

- The increasing role of niche markets especially in the developed world.
- The growing demand from consumers for specialised or customised products.
- To compete with globalising markets and worldwide competition smaller firms must specialise.
- Recent advances in process technology means low-scale batch production can be economical and new technologies mean that SME's can compete with large firms to produce sophisticated products.

- Communications technologies allow SME's to manage across borders and information is more readily accessible to everyone.
- Quicker response time, flexibility, and adaptability to foreign tastes and specific customer requirements give these firms an immediate competitive edge.
- The means of internationalization, knowledge, technology, tools, and facilitating institutions have become more accessible to firms. SME's can access funding and introductions, joint research programmes technology transfer and cross-border educated students easier than ever before.
- Increasingly international business is facilitated through partnership with foreign businesses – distributors, trading companies, subcontractors allowing new specialist firms to participate in global networks (Doole & Lowe,p.202 2001)

2.4.2 A Research Model of Born Globals

The Research Model of Born Globals is modeled after the specific Born Global characteristics. This model deals with three main variables: Founder, Organisation and Environment, all of which ultimately make up the Born Global foundation.



Model 2: A research model of Born Globals (Madsen & Servais, 1997)

Founder: Many think it is important to explore the history of Born Globals.

McDougall *et al.* (1994) concluded that the history of the founder had a large influence on the appearance of International New Ventures. The ambition and motivation of the founder could be influential when trying to understand Born Global patterns and development (Madsen & Servais, 1997). These entrepreneurs also have extensive international experience and do not see their native country as the center of their lives. The international experience promotes motivation and drive in them to become Born

Globals and also changes perception of the distance to other countries (Madsen & Servais,p.14 1997).

Organization: The corporate governance structure carries the same importance. Looking at the history and experience of those involved in the process and their networks. How do these small firms make effective use of strategic alliances and networking activities on a worldwide scale. Not an easy task but a very important managerial issue (Madsen & Servais,p.15 1997).

Environment: The nature of the product line and competences in general may indicate whether the offer of the firm might be marked internationally. This should be seen in connection with the level of technology, specialisation, and market internationalisation (Madsen & Servais,p.15 1997).

Conclusion: The born global phenomenon is still evolving and changing. One thing is certain is that they are international at birth. The founder, organization and environment form a bond together before the lifecycle begins. The influences could or could not produce a thriving process, but the importance is to consider and evaluate these forms as one body. There is a certain ambiguity in the development of Born Globals in the future and while the research continues Madsen and Servais (1997) give seven propositions for future research that come from four leading questions: (Madsen & Servais,p.13 1997)

1. What are the antecedents of Born Global?
2. What are the necessary conditions for their emergence?
3. What are the sufficient conditions for their birth and expansion?
4. What is the impact of the national settings ?

Propositions:

1. The antecedent of a Born Global is one or several strong entrepreneur(s) with strong international experience. And perhaps in addition a strong product.
2. The extension of the phenomenon Born Globals is positively associated with the degree of internationalization of the market.

3. In comparison with other exporting firms, Born Globals are more specialised and niche oriented with products that are either more custom-made or more standardised.
4. The geographical location of activities in Born globals is determined by the past experience of founders and partners as well as economic and capability or customer-related factors – directly or in interaction.
5. The comparison with other exporting firms, Born Globals more often rely on supplementary competences sourced from other firms; in their distribution channels they more often rely on hybrid structures (close relationships, network partners, joint ventures, etc.)
6. The growth of a Born Global is positively associated with high innovative skills, including an ability to access affective R&D as well as distribution channels, often in partnerships with close collaboration in international relationships that involve frequent, intense, and integrated efforts across nations.
7. Firms in nations with small domestic markets have higher propensity to become Born Globals than firms in nations with large domestic markets. Therefore, Born Globals from small nations may rely on many different products whereas Born Globals from large nations may be limited to high tech industries. Also, nations with a high number of immigrants may have a higher proportion of Born Globals (Madsen & Servais,p16 1997)

2.5 Entrepreneurship, Innovation and Biotechnology

In this section the author will briefly discuss the area of biotechnology, specifically, why these companies have to internationalize? The author will also look at some of the entrepreneurial and innovation strategies that these companies are using to reach a global market.

2.5.1 SME's and Biotechnology

The vital role of SME's is unquestionable in the biotechnology field as they are an important source of innovation and are proving indispensable in emerging markets, particularly in the areas of health, industrial and agricultural technology. Tom Saylor of

EuropaBio's explained in an interview back in 2010, that these high risk companies need large investments and tend to be turned away by investors through economic downturn. The SME's are very important in the field of science and depend heavily on capital but make the most out of the resources that they have (Saylor, 2010).

Biotechnology is a field of applied biology that involves the use of living organisms and bioprocesses in engineering, technology, medicine and other fields requiring bi-products. (Wikipedia, 2012). Another name used is biotech and in 1919 a Hungarian engineer Karl Ereky defined it this way 'biotechnology is all about manipulating living things to solve problems'. Biotechnology is mostly effective in the three main groups – food, health and fuel. In the fields of medical research and pharmaceutical development modern Biotechnology plays a huge role (OECD, 2012).

Biotechnology is a unique area and is now considered by big firms like Ernst &Young in their Biotechnology reports as the 'entrepreneurial life sciences sector' that uses 'modern biotechnological techniques to develop products or services' (OECD,p.2 2012).

There are many reasons that biotechnology companies start the internationalization process early. Gurau (2007) in his research paper on biotechnolgy Born Global companies reviews the reasons why:

- Biotechnology is global.
- Industries using biotechnology techniques are highly internationalized.
- Limited resources in the domestic market such as human, technological and financial can cause firms to look abroad to fill in the gaps in these areas.
- The domestic market is not filled with enough substantial customer and purchasing power. The return in investments could be low and therefore it is important to look into a global market segment with a homogenous demand. This will allow the company to compete effectively and further develop its R&D activities.
- Due to the high risks and technological development in this area, the complexities will determine the outcome of a system of transnational strategic alliances (Gurau,p.13 2007).

Strategy

In the industry of Biotechnology, entrepreneurship and innovation play a vital role. Biotechnology companies are dependent on funding to continue their R&D practices as innovation is what creates more success. Innovation strategies will help in industry

evolution and according to Gundry and Kickul in Entrepreneurship Strategy they recommend four main advantages and structural requirements for four distinct innovation strategies originally designed by Hickman and Raia (2002)

1. Improving Core Business: This strategy involves the development and incremental improvements to core products and services that can rapidly be developed and inexpensively implemented.

- Key strengths: Fast execution and cost efficiency as ‘new and approved’ ideas are added to the offerings of the company, these changes are often not on the radar screens of competitors.
- Key weaknesses: Potentially inadequate responsiveness to market and competitor changes.
- Structural requirements: This strategy requires innovation supports in the organization and encourage these types of improvements.

2. Exploiting Strategic Advantages

- This strategy moves the firm’s innovation focus beyond its current strategic scope. This enables the firm to leverage a unique brand and expand to reach a broader range of customers.
- Key strengths: Involves a relatively low- risk investment for potential high returns; high returns and strategic value/cost leverage.
- Key weaknesses: this innovation could easily be duplicated by competitors.
- Structural requirements. Use of external resources such as consultants, researchers, and advertising agencies.

3. Developing New capabilities

- This strategy involves developing or acquiring new technologies, competencies, services, and businesses to better serve the current strategic scope.
- Key strengths: Builds and sustains long term customer advantage and loyalty.
- Key weaknesses: High investment cost and execution time
- Structural requirements; this strategy demands an organization that is highly fluid and flexible. Including the use of joint ventures, strategic alliances and licensing and franchising.

4. Creating revolutionary change

- This strategy involves transcending the firm's current product and service lines to achieve fundamental changes to the strategic scope. Using this strategy, the firm envisions new business models, new markets and new industries.
- Key strengths: First mover advantage, ground breaking position.
- Key weaknesses: Lack of urgency may exist, high risk of imminent failure
- Structural requirements: virtual teams and alliance (Gundry,p.296 2007)

Conclusion

SME Biotech companies struggle due to the lack of human, technological and financial resources. They need to focus on what is their distinctive competitive advantage. Product development can be a lengthy and expensive one from the birth of the product idea until reaching its selected market or markets, therefore care needs to be taken when strategizing. For many the domestic market is not enough to develop full market potential and therefore the internationalization process must be considered (Gurau, 2007).

2.5.2 SME NewVenture Entry Strategies into Emerging Economies

The market entry process is the most vital part of any persons business after evaluating markets and strategies. For smaller to medium sized companies the choice of market entry mode is a big step. Each entry mode comes with its set of advantages and disadvantages. In this section the authour will:

- Describe what an emerging market is.
- A small brief on India as an emerging economy.
- Look at the entry modes most suitable for Kerecis

Emerging Economy

To define what is an emerging market is I have used the term from the Goldman Sachs Group, Inc. They are a leading global investment banking securities and investment management firm founded in 1869 and holds its headquarters in New York. They invented the concept BRIC (Brazil, Russia, India and China) which is a collective unit of the larger developing countries that will play a major role in the world economy in the future and have much larger investments than what is already predicted. In fact

Goldman Sachs predicts that in the long term these economies together could be larger than the G6 (U.S, Japan, U.K, Germany, France and Italy) (Sachs, Goldman, 2003).

To describe what the emerging market is Goldman Sachs looks at the following

- Economic size
- Economic growth
- Incomes and demographics
- Global demand patterns
- Currency movements

The focus of the author's research is on the emerging market India. India is an emerging market with a huge population and continues to grow as one of the fastest growing economies destined to overtake China who are currently leaders. Goldman Sachs predicts that India could be larger than all of U.S and China in 30 years. India has the potential to show the fastest growth over the next thirty to fifty years. Growth rate remains above 5% throughout the period. In comparison the developed markets G6 is expected to slow significantly over the next 50 years and India's GDP will outstrip that of Japan by 2032. (Sachs, Goldman, 2003). The conditions for growth rely on a set of core factors such as macroeconomic stability, institutional capacity, openness and education. American classical macroeconomist Robert Barro found through his research that the determinants of growth are enhanced by higher schooling, and life expectancy, lower fertility, lower government consumption, better maintenance of the rule of law, lower inflation and improvements in terms of trade. Barro also argues that it is 'institutions' meaning legal systems, functioning markets, health and education systems, financial institutions and the government bureaucracy that affect the 'efficiency' of an economy. Bad institutions lower incentives to invest, to work and to save (Sachs, Goldman, 2003).

Although India will experience growth there will always be poverty. Whilst there is an increase in disposable income; there is still half of the population that is below the poverty line. With an aging population and change in lifestyle there is more disease and this is having an impact on the country and its population. Investments in education and health care might have the largest multipliers per dollar of investment in economic development (Prahalad, 2006).

In business today the fault with CEO's is assuming business can be done the same in developed and emerging markets. Infrastructure plays a vital role and because it varies so widely amongst countries they need to be viewed differently. Companies need to use

strategies that work individually for the different markets. A strategy that may work in a western market will not work the same in an emerging market. Whilst evaluating new markets it is important to look and use tools like country analysis and political risk assessment which chiefly focus on the profits however they should focus on the infrastructure to get the full picture (Khanna & Palepu, 2006).

Market Entry Strategies

When a company is looking to expand into foreign markets, and has reviewed their market strategy, then they have to choose the right mode of entry that is suitable for them. Mode of entry into an foreign market allows the entry of a firm's resources, products, management, service and know how. Before looking at the entry modes there are some criteria that should be looked at. Doole and Lowe (2001) suggest the following.

- The company should look at its objectives and expectations relating to size and value of anticipated business.
- Size and financial resources.
- Existing foreign market involvement.
- Skills, abilities and attitudes of company management towards international marketing.
- The nature and power of the competition within the market.
- The nature of existing and anticipated tariff and non tariff barriers.
- The nature of product itself, its competitive advantage, trademark or patent protection.
- The timing of move in relation to market and competitive situation.

The following are the market entry methods that are used by companies both large and small. The diagram shows the levels of involvement these methods have in the international markets.

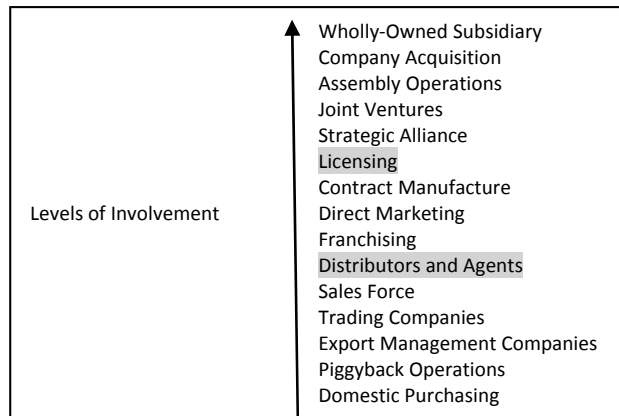


Figure 1: Market entry methods and level of involvement in international markets (Doole & Lowe, 2001, p. 248)

For the sake of this research the author will focus on the following entry modes:

- Licensing
- Distributors and Agents

After reviewing the literature the author feels these are the most appropriate choices of entry mode when reviewing Kerecis and entry into India. The reasons for these choices are explained below.

Licensing

Licensing is a management contract between the licensor and licensee where licensor has the exclusive rights to a Patent, Trade Mark, or copyright that has exclusive rights which excludes licensee from exploiting the idea, design, name or logo commercially. The licensee pays a fee in exchange for the rights to use the intangible property (Zekiri & Angelova, 2011, p. 6)

Licensing can be a useful entry method. Setting up manufacturing, retailing or marketing subsidiaries can be costly with some management difficulties. Licensing can also allow companies to avoid the tariff and non-tariff barriers. Companies see benefits in licensing in difficult markets where they are not so large and have very little involvement.

The advantages to both licensor and licensee are as follows:

- Low initial investments.
- Avoidance of trade barriers.
- Access to local data and information.
- Easier to respond to customer needs and wants.

The disadvantages are:

- Less control for licensor over operations.
- Difficulties with transfer price and monitoring transfer outcome.
- The licensee can end up being your competitor.

In order to minimize the potential problems of the problems of licensing Terpstra and Sarathy (1999) suggest that there be a clear policy and plan. Senior managers should be given the full responsibility for the licensing. Careful selection should be considered when choosing the licensees. Care should be given when drafting agreements looking specifically at duration, royalties, trade secrets, quality control and performance measures. The licensor should be an important part of the licensee's business operations, supplying the critical ingredients, obtain equity in the licensee, limit the product and territorial coverage and retain patents, trademarks and copyrights (Doole & Lowe, 2001).

Distributors and Agents

Distributor and agents follow similar roles with a few differences. Distributors will purchase goods from the exporter and then resale them in that current market. Agents act like the exporters abroad and are paid on a commission basis. Distributors take title ownership of the goods where agents will have territorial sales rights and may work with more than one company and carry many product lines (McAuley, 2001).

Advantages of Distributors

- Distributors take a higher price to cover their costs and risks as they outright buy the product from the manufacturer. More products sold more profit.
- Exclusive rights to sales territory and representation in all aspects of sales and servicing in that area.

Disadvantages of Distributors

- Distributors buy the product from the manufacturer which comes with risks if there are unsold goods in the market leaving less room for profit.
- Depending on the type of goods and modes of storage and transportation the capital investment could be very high in this exclusive form.

Advantages of Agents

- Provide the most common form of low cost direct involvement in foreign markets.
- Independent individuals or firms who are contracted to act on behalf of exporters to obtain orders on a commission basis.
- Represent a number of manufacturers and will manage non-competitive ranges.
- As part of contract to agree sales targets and contribute substantially to the preparation of forecasts, development of strategies and tactics

Disadvantages of Agents

- Agents usually work on a low commission taking a percentage of the orders.
- If there is lack of clarity in what is expected between each party then this can lead to poor business (Doole & Lowe, 2001).

In the next chapter the author will review the literature review section. This chapter uses the ideas, theories, concepts, beliefs and assumptions to support the research for this study. Miles and Huberman (1994) defined a conceptual framework as one that 'explains, either graphically or in narrative form, the main things to be studied – the key factors, concepts, or variables – and the presumed relationships among them' (Maxwell p.33).

Chapter 3: Conceptual Framework

Based on the literature review the author can propose relationships among critical variables for international market entry. A framework that provides guidelines for analyzing the opportunity for Kerecis to enter the Indian market

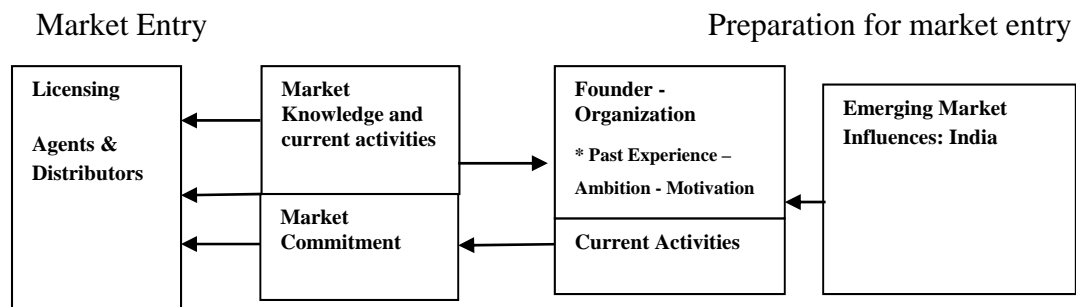


Figure 2: Conceptual framework for SME New Venture entering an emerging economy (Source: the author)

The end result of the research is to find the most viable market entry mode into emerging market India for Kerecis Marigen Wound product. The author prepared a set of sub-questions as a guideline to analyze the opportunity and come up with recommendations.

What are the strengths and activities required for successful market entry?

Looking at the Born Global Model there are three main independent variables, the founder, the organization and the environment. By doing an internal analysis of the firm, this will help to determine a firm's strengths and weaknesses and decide if the company is equipped for an international market. The Born Global Model considers the history of its founders and its organizational structure. A strong founding team for Kerecis is assessed from the track records, of the leaders, extensive experience and strong academic credentials. Some of the executives are from other countries and all of the Icelandic executives involved have lived, worked and studied in many countries. Another thing to point out is that many have worked at some point together over the last two decades and they have used their connections to form new bonds and business. Having a strong organization will produce excellent results. Two ways to get a strong organization is to offer excellent service to customers as well as beating the

competition. Forming networks that involve trust and commitment is vital for this company and can have a larger effect on the creative process.

In a Biotechnology world, the foremost current activity may be networking. A company's product must be perceived by the others in the marketing channel as a global product. Networking with others in the industry and supply chain is essential to move business forward. Kerecis is highly internationalized and looking for international markets with enough customer and purchasing power opportunities. Their products are characterized high technology, specialized for a niche market. They have plentiful resources such as hot and cold water, fresh farmed cod and the production is cheap.

Proposition 1: To achieve successful market entry, born global companies require a strong and qualified founding team and strong organizational structure.

Proposition 2: A strong founding team and organization structure are required to achieve commitment and engagement in appropriate activities (such as networking) leading to recognition of market opportunities.

What determines whether an emerging international market represents an opportunity for entry?

The Born Global and Business Network Process model acts in coherence. The updated internationalization model's variables of market knowledge and market commitment drive the process of a company becoming more internationalized. Evaluating your market helps to determine if this is the right market for your company. When investigating new markets, especially in emerging markets, generating as much knowledge about your external environment is vital. Analyzing the strengths and weaknesses in the market you are entering can give vital information and ultimately create your most suitable choice of entry into that market. A tool that has been used by many companies over the years is a SWOT analysis, which looks at the strengths, weaknesses, opportunities and threats in a new market. Today many new ventures are reversing this strategy and using TOWS. This is where the company starts with the external analysis first. Factors to be considered are the economic, socio-cultural, technological and political-legal factors.

Proposition 3: The viability of an opportunity in an emerging market requires gaining knowledge of the markets regarding economic size, and growth, incomes and demographics, global demands and currency movements.

Proposition 4: Market knowledge includes industry infrastructure including regulation, technology, economic conditions etc.

What are the characteristics of market in emerging economy?

Market knowledge and evaluation of the market will determine if the company is ready to commit. In this study the diabetic market is considered to be a niche market. 'International niche marketing occurs where firms become a strong force in a narrow specialized market of one or two segments across a number of country markets' (Doole & Lowe, p.183 2001). The model embraces the niche markets in new venture internationalization. In the born global model this can be perceived under high technology specialization. In order to be successful 'the product or service must be distinctive (highly differentiated) and be recognized by customers and other participants in the international supply chain and have clear positioning' (Doole & Lowe, p.183 2001).

Proposition 5: Niche market strategies are appropriate for born global companies when entering emerging economies.

Proposition 6: A founding team must require familiarity with the niche market targeted.

What tactics should a born global company employ when placing their products in an emerging market?

When considering international markets and placing its products it is valuable for a born global venture to consider the competition. Looking at the similarities, but what also separates you from the competition, is important. This can be found through generating market knowledge and evaluating your market, looking for the best ways your customers can access your products effectively.

A strategy called the four P's is a popular marketing mix. This stands for Price, Place, Promotion and Product. Having the right product sold at the right place, in the right place, using a suitable promotional package.

This model is suitable for Kerecis into finding the answers needed in making the conclusion to the research question at hand. ‘What is the best Entry Mode into India?’

The author did feel there was a gap that could be explored to do with Government influences particularly within emerging economies. Government in countries like India are participating more in the fields of health and technology. Networking and building close and trustworthy relationships could provide more opportunity with these growing markets. Iceland has embassy’s for both China and India, the two fastest growing economies in the world. This connection to Iceland is a favorable one and shows the commitment between the countries. Countries that show commitment to business and trade amongst each other create more business potential.

Price: Review competition and pricing, tax laws within India and other financial concerns

Place: Hospitals, clinics, diabetic institutions and Universities

Promotion: Web site, journals, health reports.

Product: Niche product

In the next section the author will explain the steps taken to gather information for this study.

Chaper4: Research Methodology

4.1 Literature Search

The research for this study started whilst doing a three month internship with Kerecis. The author used articles, journals, and wound market and health reports to look into India, it's healthcare and the diabetic and wound care markets.

The literature review involved information from the Kerecis website as well as confidential reports and business plans. The theoretical aspect of the literature review focused on international marketing, entrepreneurship and Born Global theory and strategy books and scholarly articles from the internet. The empirical section combines articles from the internet and International Business books.

The methods used in this research of the biotechnology/medical device companies in Iceland that have entered the Indian market were done through a series of telephone calls to government registry and the Icelandic Chamber of Commerce to find those companies registered as biotech/medical device SME'S.

In order to get a more detailed overall view of these Icelandic companies, in depth telephone interviews were conducted. After a brief telephone conversation, a list of questions was sent to the secretary of the Indian Diabetic Association. A scheduled meeting with the Indian Embassy occurred followed by a list of emailed questions.

4.2 Research Approach

The importance of qualitative research is to find out what goes on in an individual's mind. Whilst focus groups are most frequently used in this type of research they are not the only type of non-structured research. Today researchers need current information which can be gathered by in depth interviewing. There are other forms like grounded theory, protocol analysis, various projective techniques, and physiological measurements (Schmidt & Hollensen, 2006).

The author will be doing qualitative research in this field. The goal is to really get questions from those in some authority in the medical field like doctors and government health officials and representatives from the diabetic organizations. To use email questionnaires that will ask questions related to the future of healthcare in India, the progress made so far and the pitfalls that are still very much faced due to poverty and over population. Is there a potential market for wound care products of this capacity due

to the expense and if not is there a government initiative that might help in lowering costs?

4.3 The Choice of Topics and Forming the Research Model

The reason for choosing Kerecis and market entry into India was:

- During my three month internship at Kerecis the author was interested in the product and emerging economies.
- Marigen Wound reduced the healing process in chronic diabetic wounds, even more so than its competitors on the market and came in cheaper.
- The level of expertise and knowledge of the Kerecis staff seemed exceptional.
- There was a lot of outside support with funding which would influence research and development creating more innovative products.
- Kerecis is a high technology new venture company. Theories and strategies for internationalization and Born Global are constantly evolving. Research into these areas is continuing and as the world becomes smaller, companies are using the appropriate strategies and theories for their future needs.
- Emerging economies are in today's global plans. The author chose India as it has the largest diabetic population. Infrastructure is changing and more money is being put into the construction of new hospitals and facilities, better trained staff, lower drug prices and insurance plans. The government is getting more involved and can see the potential in the medical field.
- Although India is culturally very different from Iceland, they have a trading bond and embassy's in both countries.
- The legal system in India is based on the English law and the main language of business communication is in English. Their skilled workforce has been increasing in the healthcare field over the last few decades.

Chapter 5: Empirical Study

5.1 India's History

India's oldest Indus Valley civilization grew during the 3rd and 2nd millennia B.C. extending into the northwest part India. In 1500 B.C. Aryan tribes entered onto the Indian subcontinent. They merged with the Dravidian inhabitants creating classical Indian Culture. South Asia became united with the 4th and 3rd centuries Maura Empire reaching its zenith under Ashoka. India flourished in science, art and culture under the Gupta dynasty between the 4th and 6th centuries A.D. Over a period of 700 years Islam spread across the subcontinent. The Turks and Afghans invaded India in the 10th and 11th centuries and establish the Dehli Sultanate. In the early 16th century, Emperor Babur established the Mughal Dynasty which ruled India for more than three centuries. During the 16th century, European explorers began to establish footholds in India. By the 19th century, Great Britain had become the dominant political power on the subcontinent. In the World Wars the British Indian Army played a vital role. Independence formed in 1947 and was led by Mohandas Gandhi and Jawaharlal Nehru. Since independence the creation of two separate states occurred, India and Pakistan. They have been in conflict and have fought three wars since independence. The last was in 1971 which caused East Pakistan to become a separate nation which is today known as Bangladesh. India and Pakistan both did nuclear weapons testing in 1998 and in November 2008, Pakistan conducted a series of attacks in Mumbai, India's financial capital. India's economy continues to grow despite overpopulation, environmental degradation, extensive poverty and widespread corruption. In January 2011, India assumed a nonpermanent seat in the UN Security Council 2011-2012 (CIA, 2011).



Picture 4: Map of India

5.1.1 Demographics and Cultural Environment

India is the seventh largest country by geographical located in South Asia. The Indian Ocean lies south of India and the Arabian Sea on the southwest and the Bay of Bengal on the southeast. It shares land borders with Pakistan to the west, Bhutan, the People's republic of China and Nepal to the northeast; and Bangladesh and Burma to the east. In the Indian Ocean Sri Lanka, and the Maldives and its Andaman and Nicobar Islands all share a maritime border with Thailand and Indonesia with India being in close range. The Indian subcontinent home to the Indus Valley Civilization, historic trade routes and vast empires was identified with its commercial and cultural wealth for much of its long history. Four of the world's major religions – Hinduism, Buddhism, Jainism and Sikhism originated there, whereas Zoroastrianism, Christianity and Islam arrived in the first Millennium (CIA, 2011).

India is the second most populated country with 1.2 billion people of which, 30% of the population live in the urban areas. The average life expectancy for the total population is 67 years.

The Indian Cultural history spans over 4,500 years. The foundations of Hindu philosophy, mythology and literature were laid during the Vedic age 1700-500 BCE. Many of the same beliefs and practices still exist today such as dharma, karma, yoga and moka. India has a rich religious diversity with Hinduism as the predominant

religion. It has been shaped by many historical schools of thought such as Upanishads, the Yoga, Sutras, the Bhakti movement and the Buddhist philosophy (CIA, 2011).

Hindi is the main language with 41%. Other languages spoken are Bengali 8.1%, Telugu 7.2%, Marathi 7%, Tamil 5.9%, Urdu 5%, Gujarati 4.5%, Kannada 3.7%, Malayalam 3.2%, Oriya 3.2%, Punjabi 2.8%, Assamese 1.3%, Maithili 1.2% other 5.9%. English is the most important language for national, political and commercial communication (CIA, 2011).

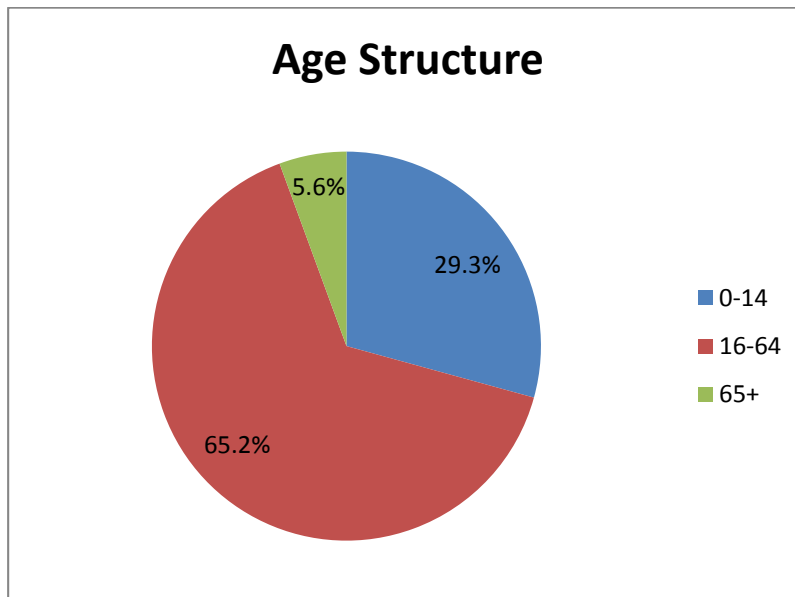


Figure 3: Segmentation of age structure.

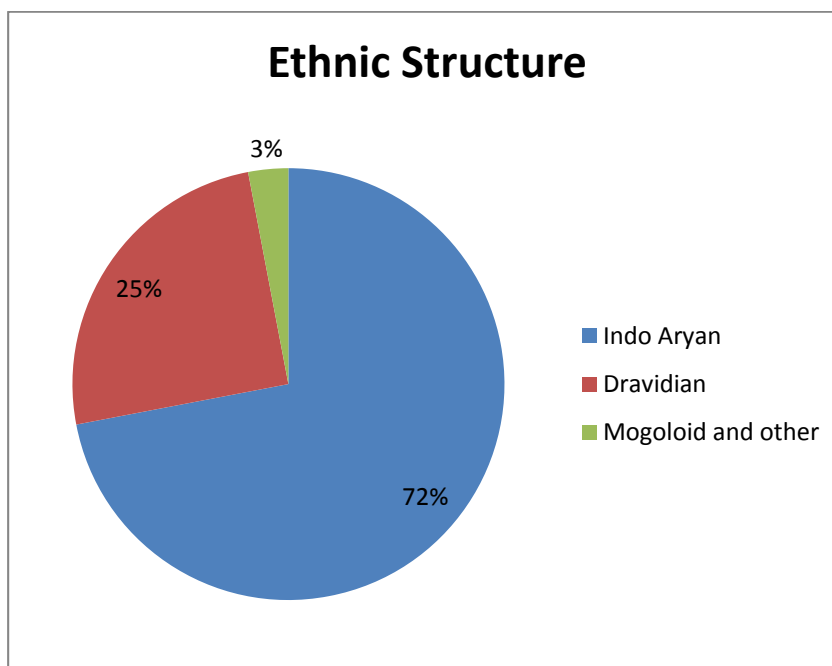


Figure 4: Segmentation of Ethnic Structure.

5.1.2 Political environment

India is the world's most populous democracy with a parliamentary republic and a multi-party system. India has six recognized national parties, including the Indian National Congress and the Bharatiya Janata Party (BJP) as well as 40 regional parties. India's political culture is considered center-left or 'liberal' (CIA, 2011).

5.1.3 Legal environment

India runs on a common law system based on the English model. There are separate personal law codes that apply to Muslims, Christians and Hindus (CIA, 2011).

5.1.4 Economical environment

In 1991 after a balance of payments crisis, India liberalized its economy moving it towards a free market system with emphasis on foreign trade and investment. India's natural resources are: Coal, Iron ore, manganese, mica, bauxite, chromites, thorium, limestone, barite, titanium ore, diamonds and crude oil (CIA, 2011).

Gross Domestic Product or GDP measures the changes in the market value of final goods and services within a domestic market within a given period of time. After the global financial crash India bounced back in 2010 primarily due to a good domestic market. However, in 2011 growth slowed due to high inflation and interest rates. Many corrupt legal scandals, high crude prices, high fiscal deficit and worsening account deficit have all contributed to weak economic reform and slow growth (CIA, 2011). In the third quarter of 2012 GDP grew 0.60% over the previous quarter. Services are the most important sector with trade, transport and communication, hotels, real estate, finance and insurance, and business, social and personal services all account for 60% of GDP. Agriculture, fishing and forestry make up 12 %of GDP and contribute to 50% of employment. Construction takes up 8% and the last 5% is mining, quarrying, water, gas and electricity (Economic, 2012).

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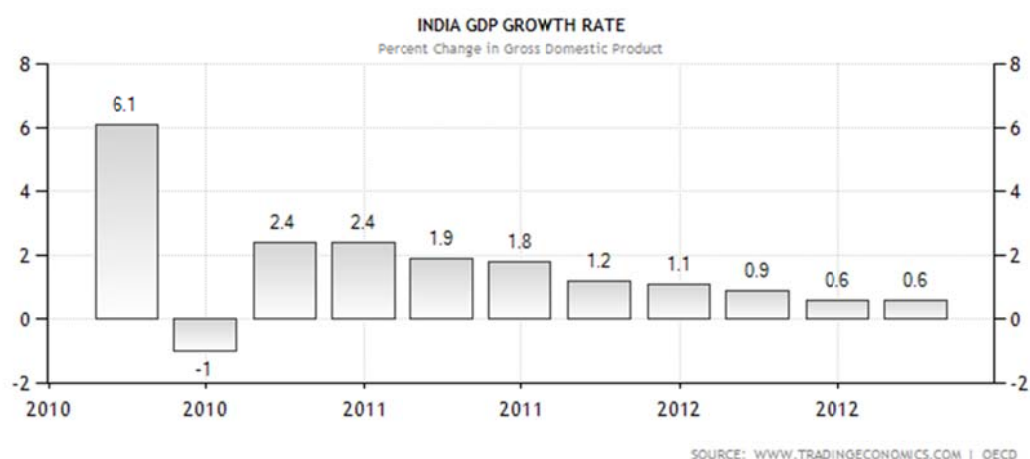


Figure 5: India's GDP Growth Rate 2010 - 2012

It is estimated that nearly 700 million of the population live on \$2 a day. However, a growing middle-class with more disposable income, show that more than 50 million Indians have incomes ranging from 200,000 to 1,000,000 rupees per year (\$4,166-\$20,000). By 2025 the middle-class will grow tenfold (U.S Department of State, 2012).

The Bombay Stock Exchange is the oldest and largest stock exchange in Asia by market capitalization (Wikipedia, 2011).

Table 1: competitive list 2011 – 2012

Country/Economy	GCI			
	GCI 2012 Rank	GCI 2012 Score	2011 Rank	Change 2011-2012
Hong Kong SAR	1	5,31	1	+0.15
Australia	5	5,01	5	+0.08
Sweden	10	4,71	11	+0.20
Korea Rep.	15	4,14	18	+0.29
Ireland	20	4,84	22	+0.04
Bahrain	25	3,93	24	+0.04
Italy	30	3,69	27	-0.16
Czech Republic	35	3,48	34	+0.08
India	40	3,29	36	-0.00
Morocco	45	3,15	42	-0.00

In the world list of competitiveness, India ranked 36 in 2011 and 40 in 2012 as seen above in table one (Forum, 2012).

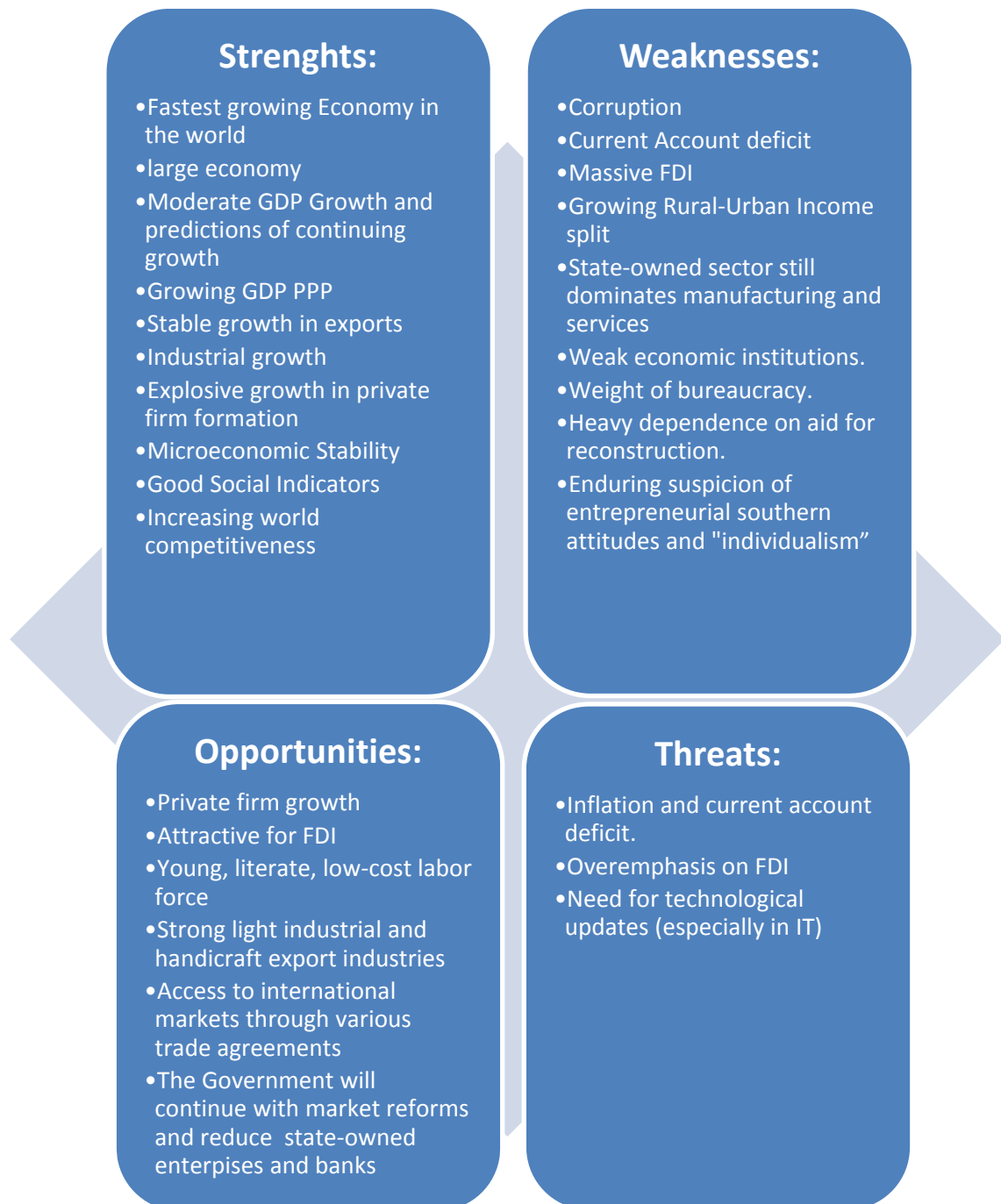


Figure 6: SWOT analysis of India

Looking at India's strengths, weakness, opportunities and threats helps a company to see if it is worth the risk or at least level out the most important risks involved. While

India's economy is growing and healthcare is developing, there is still a lot of corruption, financial issues and infrastructure issues.

5.2 India and Iceland

Iceland and India established a diplomatic relations in 1972. The president of Iceland Ölafur Ragnar Grímsson's first diplomatic mission visit to India was back in 2003. Iceland was the first Nordic country to support the New Delhi's candidature for a permanent seat in the United Nations Security Council. In May 2005 the President of India A.P.J Abdul Kalam came to Iceland. In 2006 an Icelandic embassy opened in New Delhi appointing Gunnar Pálsson as ambassador. India then appointed S. Swaminathan as first resident ambassador in March 2008. They signed a double taxation avoidance agreement to strengthen ties of economic cooperation. They have also signed a memorandum of understanding for cooperation in renewable sectors in 2007 as well an agreement with MOU (memorandum of understanding) on sustainable fishing development and bilateral investment protection agreement (Wikipedia, Iceland-India, 2012).

In May 2011 the president of Iceland spoke at the Iceland-India business promotion Seminar that was organized by the Indian embassy in Iceland. CEO's of Icelandic companies and business members of the Confederation of Indian Industry attended. The seminar discussed opportunities amongst the following industries, renewable energy such as Geothermal and hydro power projects, ITC, Pharmaceuticals, biotechnology, Tourism and outdoor filming production. Innovation and technology was a main thread that ran through these discussions. Many projects are already in the making. There are three main sectors that continue to see growth, such as Century-Clean energy, IT, and Pharmaceuticals. The President of Iceland acknowledged India as the ideal partner for Iceland. Iceland is creating first class 21st Century technology and India is exposing it to the rest of the world (CII, 2011).

Indian Ambassador to Iceland H.E Mr.S. Swaminathan concluded that in the whole discussions of cooperation between India and Iceland, one strategic area remains that of skills development. Indian companies should benefit from R&D and Innovation that takes place in Icelandic Universities and use this for new product and design development, making the process of cooperation a win win for all (CII, 2011).

5.3 Indian Healthcare

India's medical traditions date back as far as two thousand years, and although there are vast improvements currently going on in India's healthcare system, the poor in rural areas depend heavily on traditional beliefs. India has four medical systems as well as dozens of localized and tribal ones that depend on herbal treatments. Ayurveda, Siddha and Unani are the three of the oldest of the four medical systems. These treatments are more holistic based and normally done through careful reading of the pulse and herbal and psychological holistic treatment is used. These three systems attribute disease to an imbalance in the body. The fourth system is most widely used and this is the Biomedicine or scientific medicine. India has 140 medical colleges and biomedicine has been used in cities for over three centuries. It is practiced in the best hospitals and colleges throughout India (Culture, 2011).

Positives

Development: Emerging economies like India are seeing huge developments in healthcare. It is one of the largest sectors in India both in employment and revenues. The private sector does account for 80% of total healthcare spending according to the healthcare report by PricewaterhouseCoopers in 2007.

With an estimated value of \$34 billion roughly 6% of GDP, the healthcare industry will continue to grow rapidly. The population will continue to boom currently at 1.2 billion and increasing 2% every year (PWC, 2007).

Medical Tourism: India over the last years has depended very heavily on medical tourism. The number of tourists has been growing annually 25-30%. Currently the medical tourism sector is driving growth in India. With over 2 million researchers on google investigating medical tourism in India, it is obvious that this is a popular new trend for patients seeking medical treatments. Recently India's healthcare sector has seen a positive shift in the level of education in these institutions, level of English is above average, and hospitals and institutions are world class treatments at an affordable price in comparison to the U.S.

India's private hospitals excel in fields such as cardiology, joint replacement, orthopedic surgery, gastroenterology, ophthalmology, transplant and urology (PWC, 2007). The medical Indian tourism industry was worth \$350 million in 2006 and is estimated to Indian Industries reach \$2 billion by 2012. In 2002 180,000 medical

tourists were treated in Indian facilities in 2004 which was a 10,000 patient increase in five years. The increase has been 25-30% annually. According to the Confederation of Indian Industries the medical tourist industry can contribute 5 billion dollars to the Indian economy (PWC, 2007).

The government of India has initiatives to support medical tourism with sustained private and public partnerships in the hospitals. On the outskirts of Delhi in Gurgaon, a 'Medi-City' is being built that includes a 900 bed hospital that supports 17 super specialties, a medical college and para medical college. The 'Medi-City' will incorporate alternative treatments with traditional medicine at a cost of \$493 million (PWC, 2007).

The government of India is encouraging medical tourism with many incentives like lowering import duties and higher depreciation rates on medical equipment as well as expedited visas for overseas patients seeking medical care in India.

Table 2: Cost of Key Health Procedures (PWC, 2007)

Currency USD	U.S	Thailand	India	India HC
Cardiac Surgery	50,000	14,250	4,000	12,5
Bonemarrow transplant	62,500	62,500	30,000	13,33
Liver transplant	500,00	75,000	45,00	11,11
Orthopaedic surgery	16,000	6,900	4,500	3,56

Government Initiatives: In India the government has taken great initiatives so far to implement different medical programs. One that has proven successful so far is National Rural Health Mission. 2005 – 2012. The government's aim is to instill better healthcare facilities, trained healthcare workers and to build better bonds with the private sector to create affordable healthcare plans for people in these areas. The market for private health plans is expanding in some instances and the government is partnering with the private sector to provide coverage at low cost. Private healthcare plans are increasing with the middle class, new enforced healthcare insurance plans like GIC (Group Insurance Mission) along with 4 other subsidiaries The New India Assurance Company, Oriental and Fire Co., National Insurance Co., and The United India Insurance Company. Foreigners are not allowed to own insurance companies outright and that is

why many have joint venture operations on the go. The GIC is able to obtain underwriting from other countries. Only 1% of the population was covered by private health insurance in 2002-2005. Group Insurance accounted for 35% of the total health insurance business (Deloitte, 2010).

Pharmaceuticals: The pharmaceutical market is the fastest growing market. In 2006 sales increased to \$7.3 billion. Most recently Federal government used price controls to ensure that vital drug were affordable (PWC, 2007).

Clinical Testing: India is becoming more attractive for clinical testing. The government amended the drugs and cosmetic act to make rules more consistent with international practice. India has a huge patient population and genetic diversity. It has also the largest pool of diabetic patients Indian clinical trials market was estimated to be around \$1 billion in 2010 (PWC, 2007).

Negatives

Affordability: Many tier one hospitals buy quality medical supplies and devices and equipment, however most of the country's population cannot afford adequate healthcare. This then causes a lot of the smaller hospitals, tier II and III in cities and rural areas to purchase cheaper products on the market (Deloitte, 2010).

Accessibility: Low investments in healthcare have left poor infrastructure which creates inefficiency and inadequacy. In rural parts of India the lack of medical devices and equipment is high. This then causes a problem for distribution of materials throughout these areas (Deloitte, 2010).

Availability: India is lacking in innovation and therefore this creates a reduction in production of goods and services. This has led to a huge gap between the needs of the Indian consumer and what is available on the market (Deloitte, 2010).

Awareness: Ignorance about disease control lies heavily within the rural areas of India. The wealthier cities in India have more access to information about chronic diseases. Programs have been implemented in these cities and therefore more can be done to control diseases like diabetes (Deloitte, 2010).

Medical Technology: India cannot just focus on infrastructure and increasing of medical care professionals without investing time and money into medical technology (Deloitte, 2010).

Conclusion

Although the market figures vary, it is predicted that currently the medical technology market is worth 5 billion U.S dollars and will have an annual growth rate of 15 %. This is a highly competitive market and whilst in the past MNC's continued to start up joint ventures and whole own subsidiaries most now choose to import through local agents and set up subsidiaries. In 2007 it was estimated that 25 medical device companies received licenses to import medical devices in India through subsidiaries (Deloitte, 2010). Although Kerecis is a small to medium enterprise the author thinks it's important to take this knowledge into hand. Local agents normally have good networking channels and can get through some of the red tape difficulties that are presented.

5.3.1 Regulations

In India the Department of Health under India's Ministry of Health and Family Welfare departments take care of the regulatory system for medical devices. Most medical devices can move freely in and out of India. However products that are considered implantation devices as well as diagnostic kits and sterile devices are required to be registered. There are no quality systems for medical devices within India so therefore, India sees CE marking from Europe and FDA approval marking from the U.S as a certified code, however if companies have neither there are ways to get what is called an ISI Mark certification or import license from the Bureau of Indian Standards.

CE Marking or European Conformity has been legal since 1993. For medical device products on the Market in Europe is its essential that they have the CE mark on the product. This is to show that the product has conformed to the essential requirements of European Economic Area (Wikipedia, CE Mark, 2011).

FDA is the federal agency in the U.S that is responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe, and electronic products that emit radiation are safe. FDA also ensures the public that these products are honestly, accurately and informatively represented (FDA, 2012).

Operational standards are as follows:

The DCG(I) (Drugs Controller General) of India, want applicant's details such as name, address of manufacturer and manufacturer premises, the importer, the local authorized representative and the local manufacturer if there is one. A copy of the Plant Master File is described in the Clarifications on Guideline for Import and Manufacture of Medical Devices (CDSCO, 2011).

Information on approval in other countries such as U.S clearance, CE certificate or approval in Australia, Canada, or Japan shall be documented and copies of ISO (International Organization for Standardization) or EN (European Committee for Standardization) certificates submitted. A list of countries where the product is sold and a list of countries where the product has been withdrawn from the market and the reasons for the withdrawal are required (CDSCO, 2011).

Product information, a GMP (Good Manufacturing) certificate and a master file are necessary. The master file shall have a description of the components and materials used and information on the manufacturing process. Included, should be flow charts, quality assurance procedures and process controls as well as a risk management report. According to ISO14971 and test protocols and reports for stability, bio compatibility, toxicology and validation/verification of sterilization where these tests are applicable should be provided (CDSCO, 2011).

The Medical Devices Safety Bill 2008 - Definition by Government of India

Medical device: is an instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means (AIMED,p.1. 2012).

Medical device intended for clinical investigation: means any medical device intended for use by a duly qualified medical practitioner or by a person authorized to use the same by virtue of his professional qualifications for conducting investigations in inadequate human clinical environment. (AIMED,p.1. 2012)

Medical device testing laboratory: means any medical device laboratory or Institute established by the Central or a State Government or any other agency and accredited to the National Accreditation Board for Testing and Calibration Laboratories (NABL) or an equivalent accreditation agency. (AIMED,p.1.2012).

5.3.2 Reimbursements

Wound Care Product Reimbursement: refers to the payment for a product, technology and service (Motta, 2011).

There are many complex issues when it comes to reimbursements and seems to be high on the agenda with medical companies. The following information is vital when looking into this area.

- Where was the wound care product used?
- How was it paid?
- Specific patient insurer information, including verification of coverage benefits.
- Coverage policy for the payer for the product or technology in question.
- Medical necessity requirements for coverage.
- Patient diagnosis that supports the medical necessity for the dressing, technology or service.
- Codes verified by medical companies.
- Fee schedules (Motta,p.1 2011).

Medical reimbursement is very low in India which causes many problems for patients and companies. Money that is earned from different sources is taxed differently. Section 17 of the income act defines salary to include wages, pensions and annuities, gratuities, advance of salary, commissions, encashment of leave salary and any amount of credit

- This exemption is available in respect of reimbursement up to Rs (Rupees) 15,000 for medical treatment of employee and family members.
- Reimbursement of expenditure incurred by an employee and family members in approved hospitals.

- Group medical insurance for an employee and family members or reimbursement of premium paid by an employee for medical insurance.
- For medical treatment abroad, the actual expenditure incurred, including on travel and stay abroad of the patient and one attendant (if permitted by the RBI Reserved Bank of India) (India L. S.,p.1 2012)

5.4 Hospitals

Investment in healthcare in India is at an all time high. India has some of the best world class hospitals. In the past hospitals were restricted to just treating disease but now are equipped with the latest medical technologies to protect and prevent future ailments to. The foundation of these hospitals are doctors who have many years of global experience and have now returned to India to build top notch institutions. People today are willing to pay more for better treatments and this contributes greatly to the great financial costs. Other contributions come from the public sector, health organizations, health insurance companies and charities. Colleges have now specially tailored courses to educate the best of the best for these highly developed medical positions. (Squidoo, 2011)

Table 3 :Medical Independent Sales Representatives and Distributors (Network, 2011).

All India Institute of Medical Sciences, New Delhi – Government of India Undertaking
Apollo Hospitals, Chennai – The Apollo Chain
Fortis Hospitals – The Global Chain of Fortis Hospitals
Global Hospitals
Tata Memorial Centre, Parel, Mumbai
National Institute of Mental Health and Neuro Sciences, NIMHANS; Bangalore
Rajiv Gandhi Cancer Institute and Research Centre
LV Prasad Eye Hospital (LVPEI)
CMC Vellore
Breach Candy Hospital, Mumbai

Table 4: Top 10 Hospitals in India (Squidoo, 2011).

Dr. V Mohan's Diabetes Specialties Centre, Chennai
Diabetes Specialties Centres

Kanungo Institute of Diabetes Specialties Pvt.Ltd.
Dr. Raj Kumar Lalwani
Pondicherry Diabtes Centre
Diabetes, Thyroid and Endocrine Centre
Vinod K. Gujral
Diabetes Treament Centre

Table 5: Diabetes Hospitals in India (Onlymyhealth, 2011).

BTM Layout – Bangalore
CR Metditech Pvt. Ltd – Pranay Shah – Diratoe – Mumbia
Drake Medical Products – Yashesh Shah – Director of Sales – Mumbai
Event Medi Systems – J.P Shetty – Director - New Dehli
Saket Compex C – Dr. Pradeep Hule – Director – Thane
Ginetix Labs – Pratima Roy – CEO – Dhanbad
Glass Agencies – Anil Chopra – Propietor – Ambala cannt
Glowtech Consultancy Services Pvt. Ltd. – Sibananda – Director – Bhubaneswar
HealthShare – Rahul Madn – Proprietor
Vision Medical Technologies – Shivanand Skeruid – Bangalore
ZAP Cardiotronics – Pranah Shah – Owner – Mumbai
ZaveriSurgical Co – ZaveriMahta – Partner – Mumbai

5.5 India's Health Insurance Plans

The market for private health insurance plans are growing steadily in India and a variety of health plans are becoming available. Liberalization, growing middle class and more disposable income has allowed for emerging insurance health care plans. Healthcare in India is split between high quality medical care for the middle class Indians and medical tourists and then the rest of the population. Only 25 % of the population has any type of access to the Western medicine (PWC, 2007).

The government is partnering with the private sector to provide a low cost coverage for rural areas. The National Rural Health Mission 2005-2012 was born in April 2005, and the aim and mission of this program is to provide effective healthcare to India's rural population. The focus is on 18 of the lower public health states throughout India that

have low public health indicators and inadequate infrastructure. Normally 98.4% of total health expenditures are paid out of pocket by the people (PWC, 2007).

Public private partnerships involve schemes like Yashaswin Insurance scheme which was launched in 2002 in the state of Karnataka. This coverage is for major surgical operations, including those pertaining to pre-existing conditions, to Indian farmers who had no access to insurance. The cost of the premium is around 60 Rupees annually, approximately U.S 1.50 which most workers can afford and government contributes annually an additional 30 Rupees annually for each policyholder (PWC, 2007).

Medical Tariffs

In 2007 the Insurance Regulatory and Development Authority (IRDA) removed tariffs on general insurance back in January 2007. This is a positive move for those that are interested in medical health in Asia. According to a study by the New-Delhi based PHD Chamber of Commerce and Industry, the IRDA believes that eliminating tariffs will encourage scientific rating and adoption of better risk management practices, and lead to independent pricing for each line of business, so that all premiums will be based on actual risks and costs (PWC, 2007) .

India has some advantages with a high education pool and low-cost manufacturing, there are many competitive opportunities. India's pharmaceutical industry is the fourth largest producer of pharmaceuticals by volume accounting for around 8 % of global production. This attracts many in the different fields of medicine. There are great opportunities offered by the loss of patent protection on many products. India is now trying to reduce costs and compete on a global scale with major medical firms from companies in the U.S. (Epicom, 2012)

Table 6: International property index (International Property Rights Index, 2012)

Category	Score	Global Rank	Regional Rank (AO)
Legal and Political Environment	4.4	74 of 130	12 of 19
Judicial Independence	6.2	46 out of 130	8 of 19
Rule of law	4.9	61 out of 130	10 of 19

Control of Corruption	4	85 of 130	13 of 19
Political Stability	2.4	115 of 130	18 of 19
Physical Property Rights	6.5	46 of 130	11 of 19
Protection of Physical Property Rights	6.1	65 of 130	12 of 19
Registering Property	8.5	58 of 130	12 of 19
Access to Loans	4.8	34 of 130	9 of 19
Intellectual Property Rights	5.4	55 of 130	9 of 19
Protection of Intellectual Property	5	65 of 130	14 of 19
Patent Protection	0		
Copyright Piracy	3.8	54 of 130	9 of 19

5.6 Diabetes in India

The prevalence of diabetes is rapidly increasing and is expected to reach epidemic proportions. India accounts for almost 45 million of those diagnoses. This number is expected to increase to 73 million by the year 2025 and India is deemed the diabetic capital of the world at the International Diabetes Federation Conference in Copenhagen in November 2006 (O-WM, 2011).

With a lifestyle change including more exercise and a better diet, diabetes can be prevented. More prevention and control programs need to be in place or diabetes will continue to rise. Insulin is very important to Type 1 diabetic patients and sometimes to Type 2 patients also. The World Health Organization has insulin on its Essential Medicines list but in some developing countries insulin is still not available (WDF, 2012).

Diabetes creates huge financial burdens for families and societies. Depending on the economic status and social insurance policies of that particular country, it is the poorer

countries that bear the brunt with costly healthcare. Latin – Americans pay 40-60% of medical care expenditures from their own pockets.

Expressed in international dollars, the expenditure on dollars was at least ID 418 billion in 2010. In 2020 it will be at least ID 561 billion. In 2010 there was an estimated average of ID 878 per person spent on diabetes globally (WDF, 2012)

Diabetes has large economic burdens limiting growth. The largest economic burden is the monetary value associated with disability and loss of life as a result of the disease itself and related complications (WDF, 2012).

There are large net losses in national income from diabetes and cardiovascular disease. Between 2005 and 2015 figures have been, China ID 557 billion, in the Russian federation is was ID 303 billion, in India 336, Brazil ID 49 billion and ID2.5 billion in Tanzania.

Globally NCD'S will continue to increase unless the issues of these diseases are addressed. WHO predict that deaths caused by health problems will increase by 17% over the next decade with the greatest increase in low-middle income countries mainly in Africa and the Eastern Mediterranean (WDF, 2012).

India's Diabetic Research

In 1972 the Indian Council of Medical Research conducted a study of diabetes prevalence in major Indian cities. Looking back four decades Almedabad was the only city with 3% of the population suffering with this disease in comparison to other cities that had 2%. With the increase in urbanization it is assumed that if the situation is the same today Gujarat will emerge diabetic capital of the world (TimesOfIndia, 2012).

In another study done by medical practitioners 16,607 people from Maharashtra, Tamil Nadu and Jharkhand and Chandigarh were evaluated and it found that Maharashtra 6 million were diabetic with 9.3 million prediabetic. Tamil Nadu had 4.8 million diabetics and 3.9 prediabetics. Jharkhand with 0.96 million diabetics and 1.5 million prediabetics and Chandigarh with 0.12 million diabetics and 0.13 million prediabetics. So the total diabetics predicted for the country are 62.4 million diabetics and 77.2 million prediabetics (TheTimesOfIndia, 2012).

In the same study it showed that 11 million people developed diabetes in just one year between 2010 and 2011. Diabetes has always been known to be the 'rich man's disease' but is now seen mainly amongst middle-class societies.

The cause is primarily do to affluence and urbanization in rural areas. Lifestyle changes including poor diet, obesity, sedentary lifestyle and genetic reasons (TheTimesOfIndia, 2012).

5.6.1 Diabetic Wound Care

There is a high demand for wound products all over the world due to the epidemic proportions of diabetes. India is now considered to be in the same position as the rest of the world.

Asia's epidemiological transition is occurring at a faster rate which means that the burden of communicable diseases such as HIV-AIDS is far less than the current burden of non-communicable diseases (NCDs) like diabetes. NCD's are now 62% of the total disease burden in India. Asia is quickly catching up with the USA and Europe in this regard and cannot pay for the costs associated with care, patient education or professional training (Elizabeth, 2010).

The Diabetic Foot

In India 20% of hospital visits are due to chronic wounds related to Diabetes¹¹ and the diabetic foot. The diabetic wound creates serious tissue deterioration and if the appropriate healing strategies are not put in to place to treat this severe condition then amputation is likely. The tradition in India many centuries ago was when a visitor would visit the host of the home that the host would wash the feet of his guest. This gesture was to show his guest that he was welcome, showing kindness and respect (Shankhdhar, 2011).

People in India have become less traditional and tend to neglect the feet. Many still revert to home remedies or visit traditional doctors that apply alternative medicine. The main problem with the diabetic wound is the healing process. In medical terms it is called 'therapeutic inertia' in which the patient is simply delaying proper investigation and treatment. If the healing process can be reduced then this saves more treatment, less burden in costs to individuals and healthcare systems (Shankhdhar, 2011).

On a positive note there is huge research potential for the diabetic foot and currently India has the largest manufacturers in the world for footwear and the potential is there to help create more awareness for diabetic foot wound management and the products needed to treat and heal this problem.

Organizations Fighting Diabetes

The International Diabetic Federation (IDF) is playing a vital role in attacking the diabetic pandemic worldwide. Diabetes is up there with other non-communicable diseases like cardiovascular disease, chronic respiratory diseases, TB, Malaria and HIV/AIDS. The IDF wants to strengthen the global disease response by implementing special goals which include poverty eradication, gender equality and reducing child mortality and infectious disease. The way to lower the diabetes worldwide is for different groups within society to come together and work together to fight this problem. Governments with the support of the United Nations system, international aid agencies, business philanthropic organisations and researchers can help to reverse this disease (IDF, 2011).

It is important to find ways to reduce the costs that burden people and society due to diabetes and provide the right medicines to prevent the complications of this disease.

The role of the World Health Organization (WHO) plays a large role in global health. They help in many different areas of health such as shaping health research, setting norms and standards, articulating evidence based policy options, providing medical technology support and monitoring and assessing health trends. The WHO quote on their website that in the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats (WHO, 2012).

WHO has implemented a Diabetes Programme in the view of eradicating the disease wherever possible. The WHO use effective surveillance, prevention and control of diabetes in mainly low – middle income countries to help prevent further complications (WHO, 2012).

Core functions within the WHO are as follows. Overseeing, developing and adopting international standards and norms for the diagnosis and treatment of diabetes as well as the complications and risk factors that come along with it. Continuing to help educate societies about diabetes, the complications and risk factors involved. Creating awareness globally about diabetes and advocating towards the prevention of this disease, particularly in those societies which are vulnerable.

5.7 Competitors in the Market

Products on the market at this time for acute diabetic wounds are similar but made from the skin and intestines of pigs, cows and human cells. This can give Kerecis a

competitive edge as their product is derived from the skin of the cod fish. India has one of the highest Muslim populations in the world as seen in the table below.

Table 7: Countries with the Largest Muslim Populations (2009) (Huda, 2009)

Country	Number of Muslims
Indonesia	203 million
Pakistan	174 million
India	161 million
Bangladesh	145 million
Egypt	79 million

A study was conducted in Australia to determine whether there was significant influence regarding medical decision and the use of porcine and bovine products despite religious beliefs. It is understood that people of Jewish, Muslim and Hindu beliefs don't ingest products from pig and cow. So the question remained as to whether these religious groups would consider medical treatments if need be from these animals. Whilst Jewish and Muslim faiths consider the pig as unclean followers of Hinduism avoid slaughtering cattle because of cultural and agricultural reasons, as cows are considered sacred, auspicious and important laborers (Hoesli & Smith, 2011).

Surgeons are often conflicted by these religious beliefs and whilst there is limited research in regards to this it is understood that if there are no alternatives in medicine then patients will turn to animal derived medicine (like pig and cows) as it is the only way to conserve life (Hoesli & Smith, 2011).

Though biological products have significantly improved the outcome of patients with burns and chronic wounds, patients in these countries are clearly informed of the constituents of the biological products they use (Enoch, Shaaban, & Dunn, 2005).

In this table we see the attributes and advantages Kerecis has over its competitors.

Table 8: Key attributes (Kerecis, 2011)

Attribute	Advantage
Religious barriers	Absence of any cultural or religious barriers to clinician/patient acceptance.

Usability and Ease of Use	Ability to create thicker and larger matrix sheets. Current products are very thin and difficult to apply.
Absorbability	The rate of absorption of the marine-derived matrix can be adjusted by varying the amount of cross-links in the material top layers. Materials created from porcine intestines don't allow for this mechanism.
Bio-compatibility	Indications show that marine-derived scaffolds are at least as bio-compatible as porcine-derived materials.
Vascularization	Fish tissue contains fewer cells per cubic unit than, for example, pig tissue. This suggests that it would be easier for cells to maneuver and proliferate in fish-skin tissue than in porcine tissue.
Anti-inflammation	Long-chain polyunsaturated fatty acids (Omega oils) have been connected to anti-inflammatory effects.
Other	Diseases are less common in fish than in pigs. Scaffolds extracted from marine sources are more likely to appeal to people than slaughterhouse-waste-originated porcine products. Certain religious groups that don't use porcine-derived products.

The table below shows the current competitors. All of these products contain either human, porcine, or bovine materials. We can see a comparison of product, source of product, the cost and application. Kerecis has a cost advantage holding the lowest cost amongst its competitors. With its main competitor Oasis Wound Matrix who comes closest to the Kericis Marigen wound, Kerecis, comes in at \$20 cheaper. An affordable product in India comes in handy as there is a wider exchange rate difference and income levels are lower than the average western patient.

Table 9: Competitors in Wound Care (Kerecis, 2011)

Company	Product	Source of Product	Cost	Cost per cm ²	Application

Oasis Wound Matrix	Scaffold (ECM)	Porcine	\$130 (10.5sq.cm)	\$12.30	Intended for single use (no. of applications depends on the patient)
Regranex Gel	Gel containing growth factors (PDGF)	Human	\$520 (15gram tube)	\$34.66 per gram	Normally 6 tubes per ulcer
Integra Flowable Wound Matrix	Gel containing collagen	Bovine	\$1,200 (25sq.cm)	\$48	Intended for single use (no. of applications depends on the patient)
Primatrix	Scaffold	Bovine	\$664 (16sq.cm)	\$41.50	Intended for single use (no. of applications depends on the patient)
Apligraf	Scaffold	Human	\$1,155 (diameter 7.5cm disk)	\$26.16	Intended for single use (no. of applications depends on the patient)
Dermagraft	Scaffold	Human	\$500 (37.5sq.cm)	\$13.3	Intended for single use (no. of applications depends on the patient)
Graft Jacket	Scaffold	Human	\$1,100 (16sq.cm)	\$68.75	Intended for single use (no. of applications

					depends on the patient)
OrCel	Scaffold	Human cells in Bovine	\$995 (36sq.cm)	\$27.60	Intended for single use (no. of applications depends on the patient)
Kerecis Marigen™ Wound Matrix	Scaffold	Fish	\$110 (10.5sq.cm)	\$10.50	Intended for single use (no. of applications depends on the patient)

Chapter 6: Suggestion and Conclusion

The author wished to use the Tows matrix to evaluate strengths and weaknesses, opportunities and threats of Kerecis and the diabetic wound industry market and India. This is a matrix used in Born Global literature.

Table 10: The TOWS Matrix

<div> <div>Internal Factors</div> <div>External Factors</div> </div>	Strengths <ul style="list-style-type: none"> • Strong defined niche product • Knowledgeable Staff • Quick and cheap production • Networking Skills 	Weaknesses <ul style="list-style-type: none"> • Lack of financial funding • Not enough sales and marketing staff • Promotion of company and product is weak • Low sales
Opportunities <ul style="list-style-type: none"> • Increased Diabetes • GDP Growth • More opportunity for market entry • Education in this market • More government involvement 	SO Strategies <ul style="list-style-type: none"> • Use knowledgeable staff and networking to form bonds. • More high technology products 	WO Strategies <ul style="list-style-type: none"> • Seek out more financial avenues • Hire More staff • Use promotional tools
Threats <ul style="list-style-type: none"> • Corruption • Legal red tape • Weak Distribution channels • Skilled and educated workforce 	ST Strategies <ul style="list-style-type: none"> • Use higher ups to make the right connection • Seek out organizations that are help the market • Find solid 	WF Strategies <ul style="list-style-type: none"> • Choose stable markets

	distribution channels <ul style="list-style-type: none"> • Hire good agent/consulting firms 	
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6.1 Corporate Readiness

Looking at the TOWS Matrix the author can get a better picture of the internal and external strengths and weakness. Using this and the primary and secondary data, the author will analyze and finally make a decision on the best entry mode.

Current Status of Kerecis

Kerecis is well known in the domestic market with their first product Marigen Footguard. This is a cosmetic cream for acute chronic wounds on the feet. They continue networking at conferences, symposiums and trade shows. They have received the CE marking but are still waiting for FDA approval. Currently they are working with a distributor for the U.K market. Since doing the internship they have downsized, closing their office in the city of Reykjavik in Iceland. This has resulted in fewer staff members. They are currently working on a new product which is made from algae. This product will have the same matrix structure and be used like Marigen wound to help heal chronic diabetic wounds.

Age and International Experience

Kerecis has been in business for five years but their first product didn't hit the domestic market until 2011. The CEO's and senior management come with many years of international and medical expertise. The company's intention was to sell products overseas before production started. They continue to educate themselves in this market with extensive research knowledge and networking with those in the chronic diabetic wound industry. The business development manager is constantly searching out New Venture Fund teams to keep R&D going.

Size and uniqueness

Kerecis is a very small company that is now based in Isafjorður Iceland. Isafjorður is a fishing village in the north western part of Iceland. This is where production takes place. They currently have five full-time employees and five part-time. The uniqueness is in their product that is derived from the skin of the cod fish, there are no other products like this in the market.

Resources and the environment

Kerecis has a large supply of natural resources. Iceland provides plenty of cold and hot water, geothermal energy and a pure farming ground for the fish Kerecis use.

Firm Infrastructure

Kerecis has six senior managers presently but they don't have one that is dealing with marketing. There are a low number of employees and therefore contact with outside customers is low bringing risk to Kerecis. There is some financial ambiguity as they depend on New Venture funding.

Human Resources

Cost of labor in Iceland is high compared to other emerging economies. Iceland is very competitive due to the weak Icelandic currency. With all their resources here in Iceland, Kerecis has no plans to have their production abroad. Iceland has a talented pool of workforce in Biochemistry and the universities are churning out more students able to work in this field.

Technology Developments

Fishing is Iceland's main industry and many companies are experimenting with fish to make a wide range of products. Currently on the market are fish leather goods for clothes, shoes and accessories. Fish oil is constantly being investigated for both animal and human consumption. Kerecis is working on another product which is based on the same product elements as Marigen but will be for internal hernia use. The Marigen Surgical are sheets of marine matrix that contain collagen scaffold materials and lipids, including Omega fatty acids. The matrix is inserted under the abdominal wall and

sutured in place. The suture line goes through the abdominal wall and the matrix then used to close the hernia (Kerecis, 2011)

Product

Products that are made of the Marigen lipid matrix technology will address significant unmet needs in several medical markets. It will improve the rate of tissue repair and outcome quality, while reducing treatment costs. The initial market to be treated is the diabetic market.

Competitive Edge

Marigen wound can successfully compete in the market space. Marigen technology is expected to deliver.

- It has high cultural and religious acceptability as well as being derived from the pristine waters of the Atlantic Ocean.
- Identical or better healing rate than competing biologic matrices.
- Unique lipid content.
- Stronger and larger format, providing a platform for a range of specialized applications.
- A favorable price-performance relationship and the ability to compete on differentiating factors other than price.

Price

With efficient process, low labor rates, small freight component in comparison to price, the Kerecis matrix could effectively be produced at a low price.

Promotion

Marketing materials will need to be provided for Marigen Wound as well as product training for representatives. Promotion will be done in journals and magazines as well as targeting nurses and specialists. Encouraging more seminars with top specialists and provide samples and materials. It is important for them to trial the products and publish in scientific papers. The internet can be used to market web based materials and this will help connect to more international customers, build more cases and provide customer support. The author agrees that Kerecis is a highly differentiated firm that creates highly-quality, best designed, and most attractive products. The knowledgeable staff with international back-grounds is also strong for the future of Kerecis. Having said this funding is an issue as firms like this need to have financing for R&D projects and the

running of its production. There are few staff but all are highly skilled needing to be paid. Currently Kerecis is not seeing much in the way of sales with its products so there is very little in the way of money coming into the firm.

6.3. Conclusions and Limitations

The author derived a model that was based on the literature review. India has a large diabetic population and represents a vast and viable market for Kerecis products.

Efforts will be made for Kerecis to enter into low barrier markets. The diabetic market is a low barrier market where products take a relatively short time, at a low cost and with relatively low regulatory requirements. The importance is to find partners that have proven track records in wound care and surgical supplies. The author has made some suggestions about finding the right partners.

International Visits

Technology has advanced so quickly and communication across continents is fast and efficient, however face to face contact is still highly recommended. Contact with new and existing clients can make a huge difference in business relations. Face in the Asian markets takes on a completely different meaning but is such an important element when do business in these markets. The term face in Asia depicts all parts body, soul and spirit. It has a lot to do with the person's honor, reputation, image, and everything else that allows him to appear and look good before his family members, friends, relatives and peers and the community at large (Chow & Combe, 2009).

Trade Exhibition and Mission

Trade exhibitions are places to meet many people all in the same industry. You could find a potential new customer and or business relations that could help with distribution. Here is where you experience the face to face contact with several business persons. The criticism of trade shows is that they can be expensive and there is no guarantee the right contacts will be made. They consume a lot of time and energy. However, these shows can also help business owners to learn what is happening in the market at the time, and could provide a comfortable platform for the launch of a new product. Listed below are some of the most successful trade shows.

The Medical Asian Fair

The largest medical health fair is held in Suntec Singapore. The focus is on equipment and supplies for hospital's diagnostic, pharmaceutical, medical and rehabilitation sectors. It attracts over 500 exhibitors from 35 countries and has around 8000 trade visitors. One of the most successful trade fair companies Messe Duesseldorf GmbH has joined with Singapore subsidiary (Asia, 2012).

WUWHS 2012

The World Union of Wound Healing Societies is a conference that is for all wound care and product companies around the world. This is a great network and educational ground. The main aims are to educate about care and treatment of acute and chronic wounds, develop new treatment models for wounds, develop surgical treatments for wounds, limb salvage and treatment care for diabetic foot, innovation of regenerative medicine in wound treatment, development of wound care materials, nursing care of pressure ulcers and ostomy sites and incontinence, advancement and promotion of wound care in Asian countries and developing countries and new research into wound healing (WUWHS, 2011).

SAWC

The Symposium On Advanced Wound Care focuses on bringing together physicians, podiatrists, nurses, therapists and researchers that focus on advanced wound care. This conference prides itself on the level of education, number of quality sessions, and renowned educators from all over the world (SAWC, 2011)

AWHA

Asian Wound Healing Association's mission is to enhance the lives of persons with wounds. Every two years they bring together wound care professionals from all over Asia to discuss their latest experiences, learn about new products and development in the industry and network with others in the industry. The meeting gives insightful information into the wound care markets and brings prestigious wound care specialists from India, Malaysia, Thailand, Singapore, Philippines, Japan, China and Sri Lanka (AWHA, 2011)

Medical Fair India

The International Exhibition and Conference attracts 261 exhibitors from 46 countries. Over 5000 people visit including traders, businessmen and doctors from all sectors. Every year this trade show attracts more and more people. The top buyers are medical equipment at 50%, Medical consumables at 23%, Preventive health Care 20%, diagnostic, laboratory medicine 16%, hospital and clinical utilities 10%, biomedical

10%, medical furniture and fabrics 7%, physiotherapy/orthopaedic technology 5%, rescue and emergency equipment, medical service 4%, equipment and devices 3%, alternative medicine 2% and management 2% (India M. F., 2011)

Consultancy Companies

Finding the right consultancy company to deliver all the correct information about a new market is another popular way of entering the market. India is a large country, and nowadays consultants are hired to find out all the necessary information (such as political, social and legal) to make entry of foreign companies more successful.

Whilst distribution and licensing is important, having the middle man seems to be an important part of finding the right partnerships within India.

Emergo Group is a leading consultancy company that provides a wide range of quality assurance, regulatory, and distribution to medical device and In Vitro Diagnostics (INV) companies.

Pacific Bridge Medical has many consultants with years of experience within the medical device industry.

PricewaterhouseCooper is the largest multinational firm with offices in 771 cities across 158 countries. The total revenues in 2012 were \$31.5 billion.

Limitations

The author selected International Business literature on market entry to investigate this study. The information regarding India and Iceland and their trade prospects was limited due to the lack of publications and expert advice. The evaluation of the market was limited to electronic and personal communication, which were all subject to time and cost.

Appendix

Recommendation Report to Kerecis

The following are a set of recommendations made for Kerecis and their Marigen wound care product. After reviewing market literature and business models, the management of Kerecis should consider the following:

India is an emerging market and has potential, the negatives to consider:

- Large population
- Poor Infrastructure
- Legal issues
- Corruption
- Distribution problems

The business network model and Born Global research model give recommendations into networking strategies. The management of Kerecis should continue in:

- Train and educate staff in the field of chronic wound care.
- Connect with those skilled and informed in the industry.
- Involve owners and staff in current activities related to the wound care market. Such as symposiums, trade shows, conferences etc.

Kerecis should commit to the diabetic wound niche market. Suggestions are

- Who are Kerecis? Build more brand awareness.
- Work closely with diabetic experts.
- Keep working on new R&D and product development.
- Promote your products through diabetic avenues.

Market entry: Distribution or Agents would be the best in entry as they bridge the gap between countries that are psychically distant. Whilst some distribution channels are ambiguous, connecting with the right ones can create business success.

The conclusions were derived from a series of primary and secondary data. In the literature review the author reviewed old and new strategies for entry modes into international markets. Literature was found through articles on the diabetic wound market, health report and general website information on this topic. The author had a series of interviews with other medical device companies as well as Indian officials in the related field.

The author recommended agents and distributors as entry modes into India. The alternative is not to enter into India and chose other markets like Scandinavia, United Kingdom and The United States of America. They are closer in culture and distance and have less bureaucratic issues.

Interviews

An individual in depth interview was held at Kerecis on April 5th 2012 with Medical Director and co-founder **Dr. Baldur Tumi Baldursson M.D., Ph.D.**

The purpose of the interview was to see what aims Baldur had for the company and whether they had the man power and resources to take on a market like India. Kerecis has just recently received the CE mark and will be entering first into the European markets.

- What are your interests as a company? Would you like to be market leaders in this field or are you just focusing on particular markets in Europe and the Unites States?
- Is there a difference between farmed cod and regular cod?
- Do you think it best to have specific distributors or agents per region if you want to enter into emerging economies due to cultural distance, or would you just rather have one global distributor?
- Do you have the man power and technology to take on a large market like India?
- Will Kerecis be in charge of its own marketing, or will that be taken care of by the distributors?
- How will Kerecis promote its products?
- As a biochemical medical device company, what avenues for funding have you looked into for R&D?
- How do you feel about your competitors?
- Are you worried about properties right and the duplication of your products?

The conclusion from the interview overall was that Kerecis was positive that is could have a long standing in the diabetic wound market. They have plenty of resources, however licensing and distribution were their main choices in entry modes due to the fact they did not see themselves setting up production abroad. They didn't feel they needed to establish production overseas because the fish that they farm is the purest off the east coast of Iceland. Farming the fish also adds a quality to the fish that is vital to

the product. The difference is found in the thickness and it is so important that the skin of the cod is thin in order to be beneficial. R&D and funding remains to be very important part of the development of Kerecis, so working with government, new Venture fund groups and diabetic organizations would continue the growth of this company. Dr.Baldur did not see an issue with entering the Indian market, but was more looking for a global distributor.

Kine, Nox, Össur and ORF Genteics Ltd.

At the beginning of April 2012, the management of seven medical device companies were approached, via telephone to determine whether they were in the Indian market. Out of the seven four said they were. A questionnaire was sent to this four companies. The Questionnaire was eleven open ended questions. The main purpose was to see if these companies were in the Indian market and if so how they entered and were there any challenges. Whilst 3 out of the 4 are SME's, Össur the larger firm, is the most well known global firm in Iceland's medical device market. Many of Kerecis staff have worked there and the author was keen to know how they entered into India's market

The Research Findings

Table 11: The following results are from the data collected from the research questions.

Company	Employees	Classification	Entry Mode
Kine	10	Medical Device	Agent
Nox Medical	15	Medical Device	Partnership/Medical Supplier
Össur	1600	Medical Device	Partnership/Distribution Some Consultancy
ORF	35	Biotech	Consulting/Distribution

Whilst the responses were different they all used entry modes that were expected from SME medical device/biotechnology companies. Agents, distributors and licensing contracts are more popular modes of entry. Trade shows seemed to be a overtly expensive and energy consuming and an ORF's representative concluded, having a good networking base is the most successful way to find the right contacts.

Emailed Questionnaires

Reykjavik University

April 7th 2012

To whom it may concern:

My name is Kristjana Welch and I am a MSc International Business student doing a thesis on the Medical Device industry. Would you please take the time to answer these questions?

- Is your company considered a small to medium enterprise?
- How many are currently employed within your company?
- Is your company currently in the Indian market?
- If you answered yes to the previous question, which entry mode did the company use to enter the Indian market?
- Were there any difficulties entering this market?
- Did the company use any consulting firms to gain information about this market?
- Did the company use different strategies to enter into India?
- Did the company do much networking prior to entering the Indian market, for example, trade shows, conferences etc?
- Does the firm have outside R&D facilities, or only in Iceland?
- In regards to marketing which promotional tools does the company use the most?

I thank you for taking the time to answer these questions.

Yours Sincerely

Kristjana Welch

Attention: Manjula Seresh
S.L.Raheja Hospital Road,
Mahim, Mumbai -400016

From: Kristjana Ingrid Welch (MSc International Business student at Reykjavik University, Iceland)

Date: September 27th 2012

We spoke via the phone and I asked if you could assist me with questions in regards to diabetes and healthcare in India. Below I have written questions and would really appreciate a response so that I can get a better understanding of this disease in India and the healthcare system. My thesis is about an Icelandic company Kerecis that makes a product from the skin of farmed codfish to assist in the healing of chronic diabetic wounds. The market that I have been looking into is India which currently as understood has one of the highest diabetic populations.

1. Are there many products on the market for chronic diabetic wounds?
2. Has the government been able to assist to provide affordable healthcare to treat diabetic patients?
3. How is access and distribution of healthcare products?
4. Is healthcare different in certain parts of India; if so which area provide better healthcare?
5. Are there strict laws involving medical device products?
6. In your opinion what is the best way to enter India with a product like this? (i.e. distribution, agent)
7. With most patients do they have religious views on the products that are used? For instance many competitors today are making products from Pigs and cows.
8. Is the Indian population using more commercial healthcare products or are many still using traditional remedies?

If there is any further relevant information that you would like me to know it would be very much appreciated.

If there are other contact names or websites where you think I can obtain other information regarding this that would also be helpful.

I look forward to hearing from you.

Best Regards

Kristjana Ingrid Welch

December 7th 2012

Dear Mr. Kumar

Second Secretary

Embassy of India

Reykjavik,Iceland

Thank you for seeing me yesterday and for offering to help in my search for information. I have attached a document which gives a brief description about the company Kerecis and its product. I have also listed questions that I am seeking answers to.

Questions

1. What is the best way into the medical device market in India? Do they use specific agents or distributors? What are the names of the largest, most successful agents/distributors that can handle a product like MarigenWound. Do different agents and distributors work for different regions, or do they operate the whole of India?
2. What is the best way in India to access medical products? Hospitals, physicians, clinics, retail stores?
3. Are there specific laws involving medical device products especially with imports?
4. I mentioned agents and distributors earlier. In your opinion is there a more effective way to enter the diabetic market? I was looking at government initiated programs as well as the diabetic associations of India.
5. Is there a difference between private and government distribution of medical device products?
6. Are more Indians using commercial medicines and are they more affordable?
7. I see they are implementing more insurance policies. What is the state with reimbursements on medical devices?

Kind Regards

Kristjana Welch

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