

**A UNITED STATES MARKET ENTRY ANALYSIS FOR A
NEW MEDICAL DEVICE**

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ABSTRACT

This report provides an analysis of the market opportunities for a medical device developed by io, a New Zealand based company. The device simulates a high altitude, low oxygen environment to encourage the body to develop more red blood cells. Potential medical benefits derived from anecdotal sources have encouraged the company to begin clinical trials to determine efficacy as a medical device. Before committing to a beachhead market, io is interested in understanding the business opportunities in seven different treatment areas. A balanced scorecard was used to weight the different opportunities, aligning them with io's requirements. The results of the market analysis show that chemotherapy induced anemia would be a promising first market followed by the second tier opportunities of insomnia, asthma, obesity and sleep apnea. The lowest scoring treatment areas analyzed were headache and hypertension. This analysis is contingent on io's efficacy data being equal for all treatment areas.

Keywords: high altitude simulation; io; balanced scorecard; medical device; asthma; obesity; sleep apnea; insomnia; hypertension; chemotherapy anemia; headache

Subject Terms: Marketing -- Planning; Altitude, Influence of; Strategic planning; Hyperbaric oxygenation -- Popular works

EXECUTIVE SUMMARY

io is a New Zealand based company that has developed and begun to market a high altitude simulation technology to high performance athletes. While this remains a key part of io's business model, anecdotal accounts from trial users showed the potential for the treatment of various ailments and led io to examine the potential for growth into the medical device market. io is now collaborating with the Mayo Clinic in the United States (US) and beginning early stage trials to determine the potential for further clinical trials with their technology in a number of disease indications. This project is intended to be a US market entry analysis for io by examining the current treatments and market characteristics surrounding the disease indications that io's product could potentially be treating. The focus was narrowed to seven market segments including: asthma, sleep apnea, insomnia, chemotherapy-induced anemia, hypertension, headaches, and obesity. Market data pertaining to each of these segments was collected and presented in a SWOT analysis. The CEO of io, Michael Lodge, was also asked to fill out a balanced scorecard to indicate various criteria he felt were important in determining the market matching for io's product. The final amalgamation of market data, our SWOT analyses and the scorecard conclusions resulted in a ranking model that presented the seven market segments into three tiers with chemotherapy-induced anemia coming out as the leading option. When io receives its efficacy data from the Mayo Clinic they will be able to compare that data with the market information we have provided and use it to make their clinical trial and strategic market entry decisions.

DEDICATION

Dedicated to our long-suffering spouses who have not left us over two painful years of a Management of Biotechnology MBA; also to the makers of Diet Coke & Coke Zero who have kept us awake to write papers, study for tests and complete projects.

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GLOSSARY

Adeno-tonsillar hypertrophy	swollen or enlarged tonsils that block the airways and cause hypoxia during sleep.
Adipose	means fat but is usually used to refer specifically to tissue made up of mainly fat cells such as the yellow layer of fat beneath the skin.
Angiotensin	a family of peptides (smaller than proteins) that act as vasoconstrictors to narrow blood vessels.
Balanced Scorecard	a strategic planning and management system that is used extensively in business and industry, government, and non-profit organizations worldwide to align business activities to the vision and strategy of the organization, improve internal and external communications, and monitor organization performance against strategic goals.
Benzodiazepines	a class of psychoactive drugs with varying hypnotic, sedative, anxiolytic, anticonvulsant, muscle relaxant and amnesic properties, which are mediated by slowing down the central nervous system.
Beta blockers	a group of synthetic drugs used in the treatment of a wide range of diseases and conditions of the sympathetic nervous system.
Blockbuster drug	is a drug generating more than \$1 billion of revenue for its owner each year.
Body Mass Index (BMI)	a simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is defined as the weight in kilograms divided by the square of the height in metres (kg/m ²).
Bronchodilators	a substance that dilates the bronchi and bronchioles, increasing airflow. Bronchodilators may be endogenous (originating naturally within the body), or they may be medications administered for the treatment of breathing difficulties.
Butalbital	a commonly prescribed barbiturate for the treatment of pain.
Cannaboid receptors	molecules found naturally in the body that stimulate appetite
Chronic Obstructive Pulmonary Disease	refers broadly to a group of conditions that cause irreversible respiratory impairment by increasing

Colony stimulating factors	obstruction to airflow through the bronchi of the lungs. secreted glycoproteins which bind to receptor proteins on the surfaces of hemopoietic stem cells and thereby activate intracellular signaling pathways which can cause the cells to proliferate and differentiate into a specific kind of blood cell.
Corticosteroid	an inhaled anti-inflammatory drug that reduces inflammation of the airways
Cytotoxic	Toxic to cells, cell-toxic, cell-killing. Any agent or process that kills cells. Chemotherapy and radiotherapy are forms of cytotoxic therapy.
Diastolic	Referring to the time when the heart is in a period of relaxation and dilatation.
Diuretic	Anything that promotes the formation of urine by the kidney.
Ergotamine	is an ergopeptine and part of the ergot family of alkaloids; as a drug, it constricts the intracranial extracerebral blood vessels to prevent and treat migraines.
Erythropoietin (EPO)	is a glycoprotein synthesized in humans by the kidneys. It regulates erythropoiesis or red blood cell production by stimulating the proliferation and differentiation of immature erythrocytes and growth of erythroid progenitor cells. The release of EPO is triggered by stimuli such as bleeding or exposure to high altitudes.
Erythropoietins	a glycoprotein hormone secreted by the kidney in the adult and by the liver in the fetus, which acts on stem cells of the bone marrow to stimulate red blood cell production
Etiology	that branch of medical science that investigates the causes and origin of diseases; the scientific exposition of the origin of any disease.
Fen-phen	an anti-obesity medication (an anorectic) which consisted of two drugs: fenfluramine and phentermine; the drug's approval was revoked by the FDA in 1997 after it was linked to heart complications
General Practitioner (GP)	a medical doctor who provides medical care, specializes in family medicine, treats acute and chronic illnesses and provides preventive care and health education for all ages and both sexes.
Glycemic index	a measure of the effects of carbohydrates on blood glucose levels.
Heamoglobin	is the oxygen-carrying pigment and predominant protein in the red blood cells.
Homeopathy	a system of medical practice that treats a disease especially by the administration of minute doses of a

Hyperbaric chamber	remedy that would in healthy persons produce symptoms similar to those of the disease sealed chamber in which a high-pressure environment is used primarily to treat decompression sickness, gas embolism, carbon monoxide poisoning, gas gangrene resulting from infection by anaerobic bacteria, tissue injury arising from radiation therapy for cancer and wounds that are difficult to heal.
Immunoglobulin E	a class of antibodies that binds to specialized receptor molecules on mast cells and basophils, causing these cells to release their stores of inflammatory chemicals such as histamine, serotonin, and leukotrienes, which have a number of effects, including constriction of the smooth muscles, which leads to breathing difficulty; dilation of blood vessels, causing skin flush and hives; and an increase in vascular permeability, resulting in swelling and a decrease in blood pressure.
Interleukins	a generic term for a group of multifunctional cytokines that are produced by a variety of lymphoid and nonlymphoid cells and whose effects occur at least partly within the lymphopoietic system.
Long acting B2 agonists	a group of medications called bronchodilators, which open up constricted airways.
Long acting muscarinic agonists	a group of medications that work by inhibiting muscarinic receptors in the bronchial airways which leads to muscle relaxation, bronchodilation and improved lung function.
Mayo Clinic	is a non-profit medical practice based in Rochester, Minnesota. Its headquarters, the Mayo Medical School and its research facilities are in Rochester in addition to hospitals and clinics in Jacksonville, Florida and Phoenix, Arizona. Mayo Clinic partners with a number of smaller clinics and hospitals in Minnesota, Iowa, and Wisconsin, an organization known as the "Mayo Health System".
Medicaid/care	A program in the United States, jointly funded by the states and the federal government, that reimburses hospitals and physicians for providing care to qualifying people who cannot finance their own medical expenses/ A program under the US Social Security Administration that reimburses hospitals and physicians for medical care provided to qualifying people over 65 years old.
Melatonin	a natural hormone that in humans, seems to play an important role in the regulation of sleep cycles.
Metastasized	the spread of cells from the original site of the cancer to other parts of the body where secondary tumors are

	formed.
Monoclonal antibodies	antibodies that are produced by a single clone of cells (hybridoma cells) and therefore are a single type of antibody.
Naturopathy	a system of treatment of disease that avoids drugs and surgery and emphasizes the use of natural agents (as air, water, and herbs) and physical means (as tissue manipulation and electrotherapy)
Oncology	the branch of medicine dealing with the physical, chemical, and biological properties of tumors, including study of their development, diagnosis, treatment, and prevention.
Opiates	analgesic, pain killing drugs, such as heroin and morphine that depress the central nervous system.
pathophysiology	the abnormal physiological processes that cause or are associated with disease or injury; the study of such processes.
pharmoeconomic	the study of cost-benefit ratios of drugs with other therapies or with similar drugs. Pharmacoeconomic studies compare various treatment options in terms of their cost, both financial and quality-of-life.
Pillar Treatment	is a minimally invasive treatment for obstructive sleep apnea (OSA) and snoring that involves placement of three tiny polyester rods in the soft palate. This relatively new treatment is recommended for people with mild to moderate obstructive sleep apnea.
Renin inhibitors	a new group of pharmaceuticals that are used primarily in treatment of hypertension. They act on the juxtaglomerular cells of kidney, which produce renin in response to decreased blood flow
Sleep hygiene	the practice of following simple behavioral guidelines in an attempt to ensure more restful, effective sleep which can promote daytime alertness and help treat or avoid certain kinds of sleep disorders.
Systolic	the maximum arterial pressure during contraction of the left ventricle of the heart.
Tachycardia	a rapid heart rate, usually defined as greater than 100 beats per minute.
Teratogenic	toxic substances that cause fetal abnormalities
Transdermal	entering through the dermis, or skin, as in administration of a drug via ointment or patch.
Triptan	a family of tryptamine based drugs used in the treatment of migraine and cluster headaches. While effective at treating individual headaches, they are neither a preventative nor a cure.
Uvulopalatopharyngoplasty	a surgical procedure used to remove tissue in the throat

Valerian
Vasodilators

to treat or cure sleep apnea.
an herbal medicine used to treat insomnia.
medicines that act directly on muscles in blood vessel
walls to make blood vessels widen.

1: INTRODUCTION

1.1 Introduction to io

io was established in 2005 by CEO Michael Lodge and his brother COO Edward Lodge in Queenstown, New Zealand. The company's product, a high altitude simulator, was initially focused on the high performance athletic market. After successfully expanding their business to six sites across New Zealand and two in Australia, io has recently turned towards the United States and has introduced its high altitude simulators in health care and fitness centres in San Francisco, Santa Clara and Salt Lake City. The company is aiming to grow its US market presence, both by marketing its technology directly to professional sports teams, colleges and the military, and by collaborating with sports centres, gyms, and training centres to attract serious amateur athletes.

io is a family business and the team includes:

- Michael Lodge: Chief Executive Officer
- Alan Lodge (based in the United Kingdom): Chairman
- Edward Lodge (based in the United States): Chief Operating Officer
- James Lodge: Chief Technology Officer

io currently has operations in New Zealand, Australia and the US. They actively pursue partnerships with gyms, fitness centres, chiropractic and physiotherapy clinics to take the process of high altitude training that is practiced by elite athletes and make it accessible to everyone. Manufacturing is outsourced by io and franchise opportunities are available. io has future plans to expand into Canada, South Africa, and Dubai.

1.2 Introduction to the Technology

High altitude simulation encourages the body to increase production of red blood cells that are used to transport oxygen to the muscles and vital organs. This in turn increases the athlete's stamina and performance. The competitive advantage offered by the io system is that it removes the need for hyperbaric chambers or nitrogen tents, both costly and inconvenient methods with little general appeal. In contrast, io has developed a small, sophisticated altitude simulator that provides exposure to high altitude conditions through a mask. The io simulator automatically controls the amount of oxygen delivered and monitors the user's oxygen saturation, changing the output in response to that feedback to deliver a conditioning program unique to each user's specific requirements. io's advanced technology simulates altitudes from 4500 meters to over 8000 meters (Mt. Everest) with oxygen levels of 11 to 7 percent. At sea level, normal oxygen levels in the air are around 20 percent. To gain the benefits of io, users simply sit in a chair and breathe. A typical training program for athletes involves an initial 15-day program consisting of one hour daily sessions, five days a week for three weeks. Conditioning is maintained through a series of five one-hour booster sessions on consecutive days every six to eight weeks.

Figure 1: io Altitude System, Nitrogen Tent, Hyperbaric Chamber



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Based on a series of anecdotal reports from current users of the technology, io believes that high altitude simulation may have important health benefits beyond athletic

performance training. Testing the veracity of these claims clinically is the next step in expanding the market for the device and building io's business. By changing the intended use of the simulator to treat medical problems, io will have to overcome a number of clinical and regulatory hurdles, including the need to prove efficacy to physicians and their patients while satisfying safety and regulatory requirements set out by the Food and Drug Administration (FDA).

1.3 Introduction to the US Medical Device Market

The Food and Drug Administration regulates the pre and post market regulatory controls of medical devices, which are defined as,

“...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.” (“Is The Product A Medical Device?,” 2002)

There are three classes of medical device, General Controls (Class I), Special Controls (Class II) and Premarket Approval (Class III), which have increasingly stringent approval regulations as the device becomes more complicated or invasive. io's altitude simulation device would likely be considered a Class I or Class II device depending on its intended use. If deemed a Class II device, io's product would require special controls such as special labelling requirements, mandatory performance standards, and post market surveillance in addition to the general controls required by Class I ("Device Classes," 2002). A comprehensive outline of the three device classes can be found in Appendix A.

The competitive landscape for medical treatments that io needs to consider are medical devices and pharmaceuticals. The US medical device market was \$90.1 billion in 2006 and is projected to grow to \$110 billion by 2011 (*Health Care Equipment & Supplies Industry Profile: United States*, 2007), and the pharmaceutical market is projected to grow from \$276.4 billion in 2007 to \$343.1 billion in 2012 (*Pharmaceuticals Industry Profile: United States*, 2007). Understanding the incumbents, whether they are medical device manufacturers or drug companies, will allow io to adopt a focused, cost effective strategy to gain market penetration and allow for the successful North American launch of their product. In the United States, 36% of the population have used an alternative therapy to help manage their health in the past year (Barnes, Powell-Griner, McFann, & Nahin, 2004). Adults who have used an alternative therapy do so because they believed that when combined with medical treatments it would help improve their conditions (54%) and/or they thought it would be interesting to try (50%) (Barnes et al., 2004).

1.4 Goal of the Project

The goal of the io market scope project is to determine the market potential and the ease of market entry of this device into several different treatment areas with the ultimate goal of narrowing the field for clinical trials. The level of uncertainty for a company increases as it begins to target multiple markets, especially when it faces the challenges of matching its technological innovation to a market application. io has written several case studies on how the altitude simulation technology has improved not only athletic performance but also several medical conditions such as sleep apnea, insomnia and asthma. It is this improvement in health that has led io to explore using its altitude simulation technology as a medical device. Currently, io is partnered with the Mayo clinic to better understand what affect the altitude simulation is having on sleep disorders, asthma and hypertension. In addition to these indications, io has also expressed an interest in obesity, headache and chemotherapy-induced anemia, and all of the above listed indications will be considered in this report. The co-morbidity of these conditions will also be considered in this market entry analysis, which will be designed so that io will be able to compare these results with the data collected from the Mayo Clinic trials. Beyond efficacy, it is important for io to have confidence that there is a market for their product that offers the opportunity for significant, profitable market penetration. This includes such elements as an achievable marketing program, competitor strength/weakness, channel accessibility and customer or medical insurer's willingness to pay for the product.

1.5 Introduction to the Treatment Areas

Asthma is a chronic lung disease that causes the narrowing or blockage of the airways causing shortness of breath and difficulty breathing. Asthma has two forms – allergic, which is triggered by allergens in the air and non-allergic, which is triggered by anxiety, stress, exercise, cold air, dry air, hyperventilation, smoke, viruses or other irritants. Approximately 20 million Americans suffer from asthma ("Asthma Overview," 2005). In severe cases, asthma can lead to death.

Chemotherapy Anemia is a result of the destruction of red blood cells from treating cancer using cytotoxic chemicals. Anemia is one of the most common and longest lasting side effects of chemotherapy and causes fatigue, compromised immune function and makes it difficult to accomplish day-to-day tasks. Up to seven out of ten chemotherapy patients become anemic during their therapy (Medline, 2008).

Headache is pain or discomfort in the head, scalp, or neck. The three main types of primary headaches are tension, cluster and migraine. Secondary headaches are often attributed to other medical issues including head or neck trauma or vascular disorders. Three percent of doctor visits in the United States are for headaches and 4% of headache cases reported to physicians are for secondary headache (Kernick, 2007).

Hypertension is defined as a consistent high blood pressure of over 140/90mmHg. The measurement for blood pressure is when the heart contracts and forces blood through a person's arteries. High blood pressure causes strain on the blood vessels causing them to weaken, clog or burst and is a risk factor for heart attack, stroke, kidney disease and dementia. Hypertension is categorized into secondary hypertension, when there is a

known cause for high blood pressure, and essential hypertension, where there is no definite cause for high blood pressure (Brookes, 2007).

Obesity is the excessive accumulation of adipose tissue to an extent that health is impaired (Aronne & Segal, 2002) and is usually determined by using body mass index, the weight in kilograms divided by the square of the height in meters ("Defining Overweight and Obesity," 2007). Approximately 33% of American adults meet the criterion for obesity ("Prevalence of Overweight and Obesity Among Adults," 2007). Obesity increases the risk of diabetes, heart disease, stroke, hypertension, cancer, sleep apnea, osteoarthritis and gallbladder disease ("What is Obesity," 2008).

Sleep Disorders: Sleep Apnea is a chronic sleeping disorder in which a person pauses breathing or has shallow breathing during sleep. The pauses can last from seconds to minutes and occur from five to thirty times an hour three or more times a week. The most common form of sleep apnea is obstructive sleep apnea caused when the airway collapses or is blocked during sleep. Sleep apnea can also be caused when the area of the brain that controls breathing does not send signals to the breathing muscles and the patient makes no effort to breathe. Untreated sleep apnea increases the risk for high blood pressure, heart attack, stroke, obesity, diabetes, heart failure and in extreme cases cause death ("What Is Sleep Apnea?," 2008).

Sleep Disorders: Insomnia is a condition where a person has difficulty falling or staying asleep. The majority of insomnia is secondary insomnia that is caused by outside influences such as medication, anxiety or illness. Primary insomnia, a medical condition that effects sleep, is not caused by outside influence, and can last for several months.

Insomnia leads to daytime sleepiness, lack of energy, depression and irritability ("What Is Insomnia?," 2007).

1.6 Introduction to the Criteria

The criteria by which io will make a decision on market entry have been placed in a balanced scorecard and used to rank each treatment area. For a comprehensive explanation of the scorecard, including how each of the metrics was assigned, see Chapter 9 and Appendix B. Each criteria has been given a weighting and target by io. In addition to the balanced scorecard, a position map showing yearly cost vs. efficacy for each treatment has been plotted and appears in each chapter: io will be able to place themselves on the map after completing their initial Mayo Clinic trials. As io does not wish to market their treatment in the same category as alternative therapies such as yoga, acupuncture and homeopathy, this report will focus mainly on conventional treatments.

2: ASTHMA

2.1 Introduction

Asthma is a chronic respiratory disease with episodic symptoms that include reversible inflammation of the airways which manifest in wheezing, coughing, and shortness of breath (Moorman et al., 2007). While medical science is fairly certain of the pathophysiology of asthma, they are not entirely sure of the etiology or causation of the disease (Eder, Ege, & von Mutius, 2006). Some people with asthma will experience symptoms after exposure to certain triggers including smoke, cold air, exercise, animal fur, dust mites, pollen and air pollution. Currently there is no definitive laboratory test for asthma and it is difficult to distinguish asthma from other chronic respiratory diseases (Eder et al., 2006). In fact, estimates of the actual number of cases of asthma come from physician diagnoses and the definitions of the symptoms of the disease vary across countries making it difficult to accurately track the temporal changes in the prevalence of asthma globally (Eder et al., 2006). Therefore, while the prevalence of asthmas overall is increasing, some of that increase is likely related to changes in diagnoses (Eder et al., 2006).

2.1.1 Prevalence

In the latest National Surveillance for Asthma, approximately 20 million people in the United States reported having asthma and just over half of them, 54%, reported having an asthma attack in the last 12 months (Moorman et al., 2007). Adults make up 13.8 million of these cases (2 million of those adults are over 65 years) while 6.2 million cases are

found in children (Moorman et al., 2007). Currently, the prevalence of asthma in the US is higher among children at 8.5% of than that of adults at 6.7% (Moorman et al., 2007). Between the sexes, male children have a higher prevalence (9.6%) compared to females (7.6%) but female adults have a higher prevalence at 8.4% compared with 4.9% for male adults (Moorman et al., 2007). Amongst races, asthma is more prevalent in black children with 12.5% than white children at 7.7%, but the difference amongst adults was smaller with a prevalence of 7.6% in black adults versus 6.7% in whites (Moorman et al., 2007). Hispanics have a lower asthma prevalence than non Hispanics with 5.4% compared to 7.4% (Moorman et al., 2007).

Asthma is the third leading cause of hospitalization among persons under the age of 18 in the United States (Eder et al., 2006). Between 2001 and 2003, there were an average annual 1.3 million hospital outpatient department visits that were asthma related and 1.8 million emergency department visits (Moorman et al., 2007). In this same three year period, there was an average 12.3 million physician visits related to asthma with 7.6 million of those being for adults and 4.7 million being for children (Moorman et al., 2007). This data also showed that on average 61.7 of every 100 people with current asthma made a visit to a physician's office for asthma related reasons (Moorman et al., 2007). During this period there was an annual average of 4210 asthma related deaths with 50% of those deaths occurring in people aged over 65 (Moorman et al., 2007). Very few deaths occurred in persons aged under 18 years and more women died of asthma (2693) than did men (1517) (Moorman et al., 2007).

2.1.2 Social and Economic Costs

The annual cost of asthma is estimated to be approximately \$18 billion ("The Costs of Asthma 1992 and 1998 Study, 2000 Update," 2000). Hospitalizations and other direct costs account for \$10 billion of this total while the remaining \$8 billion are derived from indirect costs including \$3 billion alone from lost earnings due to illness or death ("The Costs of Asthma 1992 and 1998 Study, 2000 Update," 2000). Asthma is also the leading cause of hospitalization and of school absenteeism related to chronic illnesses amongst children aged 5 to 17. More than 14 million school days (8 days for each student with asthma) are lost per year ("The Costs of Asthma 1992 and 1998 Study, 2000 Update," 2000).

2.2 Market

The two main conditions focused on by the respiratory drug market, asthma and chronic obstructive pulmonary disease (COPD) are both generally treated with the same drugs but their differentiation is based on etiology (Oversteegen, Rovini, & Belsey, 2007). Asthma is characterized by reversible airway obstruction caused by inflammation, while COPD is a continuous decline in lung function as the disease progresses. There are approximately 45 million people that suffer from asthma in the seven major pharmaceutical markets (US, Japan, and EU-France, Germany, Spain, Italy, UK), 20 million of which reside in the United States (Moorman et al., 2007; Oversteegen et al., 2007). Diagnosis rates in these markets are currently high, approximately 80%, which means that this population is well diagnosed and understood and the market size is stable (Oversteegen et al., 2007). Rates of COPD are expected to decline as smoking trends continue to decline (Oversteegen et al., 2007).

The top five selling brands of asthma drugs accounted for approximately two thirds of the total asthma drug market in 2006 (Oversteegen et al., 2007). These drugs are mature blockbuster products that are highly prescribed by primary care physicians. The majority of sales are driven by direct to consumer spending as opposed to being covered by Medicare/Medicaid or private insurance (Oversteegen et al., 2007). The leading product in asthma drugs is a combination of inhaled corticosteroid and long acting β 2-agonists (ICS/LABA) that is expected to remain the leading class of drugs until 2016 (Oversteegen et al., 2007). Within this category, the top product is Glaxo Smith Kline's Advair/Seretide that accounts for one third of all asthma drug sales at \$6.3 billion in 2006, making it the third best selling drug globally (Oversteegen et al., 2007). Based on a pharmacoeconomics study in 2007, the direct medical costs per patient of annual asthma medication use ranged between \$570 and \$838 (\$US 2005 values) depending on the type of medication used (Oversteegen et al., 2007).

As the current population of diagnosed asthmatics is beginning to plateau and the asthma drug market is becoming saturated, the pharmaceutical companies are looking to find high value sub-populations. New high priced therapies are being introduced such as Novartis' monoclonal antibody drug, Xolair which targets patients with allergic asthma and high immunoglobulin E levels (Oversteegen et al., 2007). Total sales in 2006 for respiratory drugs were \$18.5 billion across the seven markets listed above with the United States accounting for 60% of those sales; 42% of all sales were related to treating asthma (Oversteegen et al., 2007). By 2010, the global respiratory drug market is expected to reach \$44 billion (Klapecki, 2007).

2.2.1 Treatments

There are a number of drug treatments for asthma that are commonly prescribed on their own or in combination with other drugs, including inhaled corticosteroids (ICS), long acting muscarinic agonists (LAMA), long acting β 2-agonists (LABA) and monoclonal antibodies. The combinations that are most commonly seen are ICS/LABA and LABA/LAMA (Oversteegen et al., 2007). A new surgical treatment, bronchial thermoplasty, uses a thin wire that burns off some of the muscle tissue in the lungs that swells during an asthma attack and closes off the airways (Cox, 2008). The treatment takes three outpatient visits of a half-hour each, to thread the wire throughout the lungs, reaching main airways, at a cost of greater than \$2000 US.

There are also various complimentary non-medicinal treatments for asthma such as; breathing exercises, physical exercise, Yoga, acupuncture, relaxation therapy, homeopathy, massage and chiropractic therapy, herbal remedies, fish oil, and magnesium sulphate ("Asthma treatment: Do complementary and alternative approaches work?," 2007). One of the better-known breathing exercises includes the Buteyko breathing technique, which was developed in the Soviet Union in the 1950s to assist those with asthma. Essentially it teaches one to breathe less thus counter-acting the impulse to breathe too much (hyperventilate) when exposed to an asthmatic trigger. Another common breathing technique is the Papworth method, which is a combination of relaxation and deep diaphragmic breathing, nose breathing and breathing in general to suit your level of activity. The learned control of breathing helps to limit the effects of asthma symptoms. Finally, breathing exercises associated with yoga such as pranayama have also been listed as possible complimentary treatments.

Acupuncture has also been proposed as an alternative therapy treatment for asthma. By stimulating the nervous system with an acupuncture needle, signals are sent from the spinal cord to the pituitary gland. The pituitary gland releases endorphins and anti-inflammatories that travel through the blood stream to relieve the inflammation in the lungs (Abraham, C., 2001). The Cochrane Review has compiled the results of several randomized double-blind clinical trials looking at acupuncture for the treatment of asthma. In these trials, 324 patients in 11 randomized control trials, it was determined that acupuncture was not effective for treatment of asthma or asthma like symptoms when looking at lung function (McCarney, Brinkhaus, Lasserson, & Linde, 2004). However, two trials reported significant improvements in subjective quality of life measures (McCarney et al., 2004).

According to an Australian population based survey there is a 42% adoption rate for alternative therapies among adults with asthma and 52% of children with asthma had used at least one complimentary medicine, including vitamins and minerals and herbal preparations (Shaw, Thompson, & Sharp, 2006). Additionally, 24.7% of the children had been taken to a complimentary therapy at a cost of \$A25-\$A400 (median \$A40) per month (Shaw, Thompson, & Sharp, 2006). Only 48% of parents had told their doctors about their use of alternative therapies (Shaw, Thompson, & Sharp, 2006).

2.3 Distribution channels

Asthma treatment is delivered through general practitioners and respiratory clinics. Respiratory clinics are often found in hospitals and patients receive education, medication and treatment from nurses or other trained practitioners. There are two types of chemical asthma treatments, controllers that are taken regularly to prevent asthma

attacks and relievers that are taken when necessary by the patients to stop an asthma attack, both treatments are prescribed by doctors and distributed by pharmacists ("Asthma: Treatment," 2006). Emergency treatments for asthma include mechanical treatments such as oxygen, intubation and a helium/oxygen mixture (Rodrigo, Rodrigo, & Hall, 2004). Patients are only treated with these mechanical treatments when regular medication fails to stop an attack and are delivered by doctors in a hospital setting. Surgeons in a hospital perform bronchial thermoplasty.

Delivery of alternative therapies is through nutritional supplement and naturopathic stores, or through practitioners trained in alternative treatment methods such as acupuncture, breathing, yoga and relaxation. These are privately owned and operated businesses. Some of these treatments may be covered by private insurance but are unlikely to be covered by Medicaid or Medicare.

2.4 SWOT Analysis

2.4.1 Strengths

There is no reason that io's therapy cannot be used in conjunction with traditional chemical therapies. Based on the willingness of asthma sufferers to seek out alternative treatments, this may prove to be an effective market entry strategy. If efficacious, io's product may reduce the need for the use of rescue medications, lowering yearly costs for asthma treatment. The attraction of io's technology may be the reduced incidence rates of serious asthma attacks and thus lowered need for hospitalization or expensive emergency medical intervention: however, this still has to be proven through clinical trials which require an investment in time and money. Customer's willingness to try alternative

therapies is a strength for io. A 2004 study showed that 36% of the US population had tried an alternative therapy (for various medical conditions including asthma) during the previous year (Barnes et al., 2004)

If io chooses respiratory clinics in hospitals as channel partners, the addition of a low risk, value added alternative treatment may induce physicians to help market the device as an ongoing service that could be connected to the regularly scheduled patient visits. Alternatively, io could partner with a large pharmaceutical company that has a strong presence in the asthma market, as a complimentary therapy that will broaden the pharmaceutical company's offering and give them a non-chemical alternative for patients. Ethics will not allow patients to stop taking their standard medications while in an io efficacy trial for treatment of asthma, so any increase in lung function will be complimentary therapy to the standard maintenance regiment.

2.4.2 Weaknesses

This treatment will only be seen by patients and doctors as an alternative therapy for preventative maintenance asthma drugs and will not compete against the emergency brochiodialators. Additionally, there is already a broad selection of alternative therapies for asthma patients and io will have to develop a strong marketing plan in order to stand out. The time commitment required for the initial treatment phase may be difficult to sell to patients; however, the need to come back for booster treatments only every six weeks could balance this factor. Making the system available outside of major urban centres may be difficult, and travel cost and time may be factors in customer adoption. Marketing io will be expensive if io decides to inform all physicians or all asthma

patients, because it will not be a focused or targeted sales strategy. Selling equipment and training for physicians or clinics may be difficult before market data is available showing that patient acceptance is high and ROI is favourable. If the Mayo clinic trial shows that there is drop in use of relief medication while on io's treatment, then the pharmaceutical companies change from being potential partners to being direct competitors.

2.4.3 Opportunities

The high prevalence of asthma in the population and significant ongoing health care cost for treatment helps make this an attractive market for io. It may be possible to focus the initial product launch and marketing strategy on respiratory clinics in large urban centres to get a beachhead market among experts in the field. This would also allow io to start with a smaller, more focused market, reducing the needs for a large sales force. If the device can be used in combination with existing therapies, io may be able to find channel allies looking for alternative treatment options. If the process is efficacious, presenting the findings at scientific conferences of asthma specialists may provide new, influential channel partners in specialty clinics or hospitals.

2.4.4 Threats

The pharmaceutical companies have extremely effective products in the market, powerful channel connections and almost all patients will be familiar with the products. This has created a status quo that may be difficult to overcome. There is always a risk that a new pharmaceutical product will come on to the market that will overcome the limitations of today's drugs, making io's product redundant. There are three constituencies whose

perceptions io needs to consider; physicians, pharmaceutical companies and patients. The threat from physicians is if they do not believe in the efficacy of the product, in which case they will not buy or recommend the product. This risk is mitigated by good efficacy results. However, high efficacy resulting in a decrease of rescue and maintenance medications will cause pharmaceutical companies to view io as a competitor which can result in lack of partnerships, potential intellectual property (IP) infringement and new competition from medical device companies. To get traction in the marketplace and not be dismissed as a quack nostrum, io will need to prove the efficacy of the device to leading respiratory specialists and get their endorsement to make it part of the standard of care. This will allow them to achieve higher market penetration and reduce the burden on sales and marketing. However, getting physicians to change their current patient practice is a difficult task, particularly when it requires them to purchase equipment to do so.

2.5 Summary and Recommendations

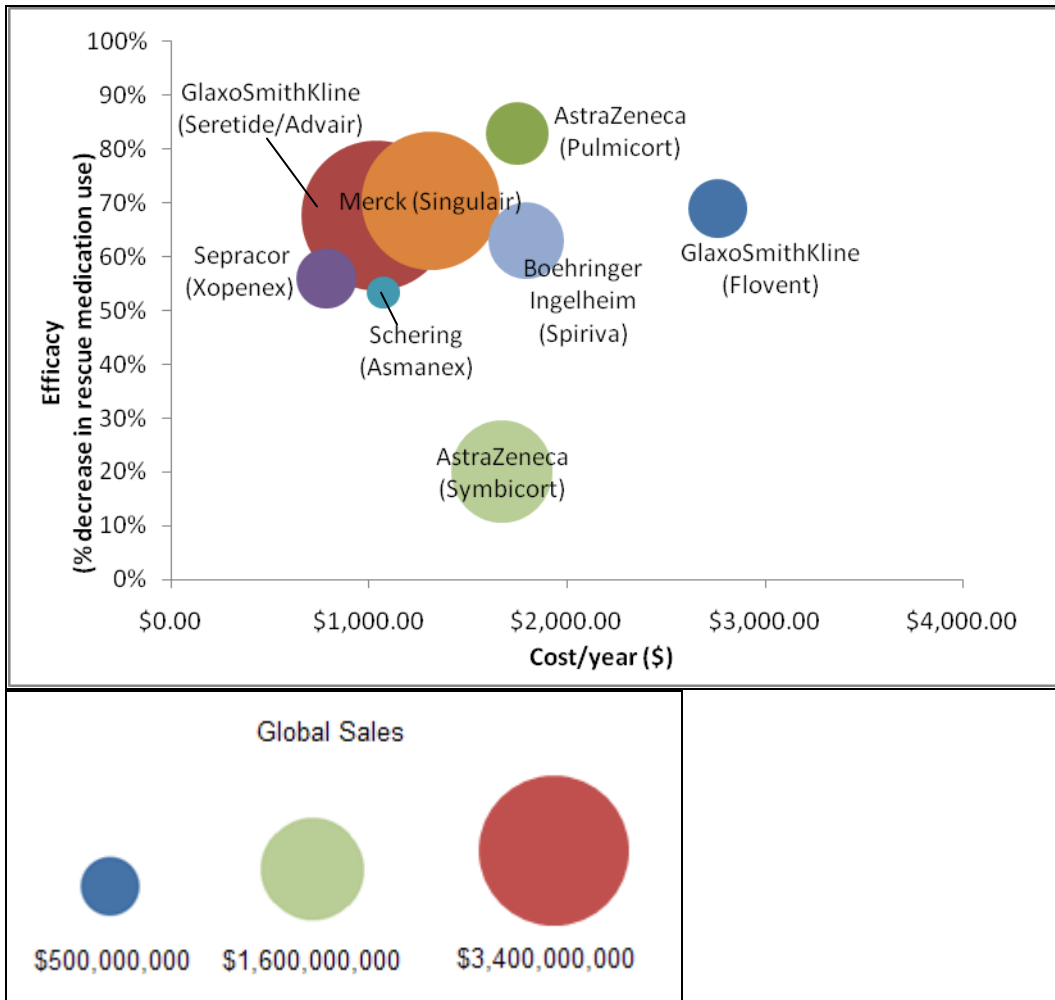
From a business strategy perspective, it is unlikely that io will be able to displace any of the commonly prescribed drugs. There are well-established and reliable pharmaceutical treatments for the prevention and emergency treatment of asthma symptoms. If io is to enter this market, they should market their altitude simulation technology as a complimentary product to existing drug therapies.

If physicians will be the primary source of information to the patient on possible treatments, it will be expensive and time consuming to target doctors who are already bombarded by highly trained and organized pharmaceutical sales and marketing groups. Thus, io should consider a strategic partnership with one or more drug companies to

compliment their existing drug treatments in order to take advantage of these highly effective marketing teams. In addition to this, io should consider partnering with respiratory clinics where they can offer their machines to people who are already going to the clinic for treatment and education. This decision to partner with respiratory clinics should be based on how much control io management wishes to maintain over the value chain.

As a complimentary product, io and their partner can market the device as a maintenance measure to reduce the number and severity of asthma attacks and reduce the need for drugs and hospitalization. This marketing strategy will appeal greatly to people who are wary of the continuous use of steroid drugs. As mentioned previously there is a high willingness to pay for complimentary therapies in Australia and a high adoption rate for alternative therapies in the US. However, the patient pays significant portions of health care costs in America and this may affect the ability for patients to pay in the United States.

Figure 2: Cost vs. Efficacy for Asthma Treatment



Compiled by the authors from the following sources: ("Asmanex," 2008; Asthma Market Size," 2007; AstraZeneca and our year in brief: PRODUCT PERFORMANCE SUMMARY \$M," 2007; CONSUMER INFORMATION SYMBICORT® TURBUHALER®," 2008; Durham, 2004; Evans, 2006; Flovent," 2008; Holmes, 2008; Hatcher, 2008; Monson & Schoenstadt, 2007; Pharmacy," 2008; Pulmicort," 2008; Sepracor 2007 Annual Report," 2007; Seretide, Advair Accuhaler," 2006; Soler et al., 2001; Spiriva Dosage Instructions," 2007; Symbicort," 2008; Xolair: Historical Sales," n.d.; Xopenex," 2006)

3: CHEMOTHERAPY-INDUCED ANEMIA

3.1 Introduction

Cancer is a disease whereby the normal processes of cellular division becomes corrupted, causing uncontrolled cell growth that can lead to illness or death (What is Cancer?," 2008). In order to treat cancer, a number of common therapies are used including; chemotherapy, radiation, surgical intervention and biological therapies ("How is Cancer Treated?," 2008). Chemotherapy uses a number of toxic substances to chemically destroy cancerous cells in the human body while attempting to limit damage to healthy cells and tissue. This treatment is implemented when cancer has metastasized and has spread throughout the body ("Chemotherapy," 2008). Although efficacious, one of the side effects of chemotherapy includes the destruction of red blood cells resulting in anemia.

“The World Health Organization (WHO) classifies anemia according to its severity and haemoglobin levels in five grades, where 0 corresponds to a normal state (Hb > 11 g/dL) and 4 to a life-threatening condition (Hb <6.5 g/dL). The mild (Hb 9.5–10.9 g/dL), moderate (Hb 8–9.4 g/dL) and severe (Hb 6.5–7.9 g/dL) conditions are classified into grades 1, 2 and 3, respectively.” (Ossa et al., 2007)

The effects of anemia include; weakness, feeling cold, dizziness and irritability, impaired concentration, decreased cognition, respiratory distress and tachycardia

(Medline, 2008; New Advancements in the Total Care of Anemia in the Oncology Patient," 2002). Another risk associated with anemia is an increased risk of bacterial infection and thrombocytopenia (risk of bleeding, particularly dangerous when it occurs in the brain or other vital organs) (*Blood Growth Factors Market*, 2003). The primary way of dealing with this type of anemia is through drugs containing blood growth factors, which bolster haemoglobin production to offset the collateral damage caused by treating cancer with chemotherapy. It has been shown that reducing the effects of anemia and fatigue in patients improves both their quality of life and overall productivity (Berndt et al., 2005). This chapter focuses on anemia because, as of the time of writing, there is no evidence that io's product is effective for treating the other side effects of chemotherapy, such as; bone demineralization or cytotoxicity. The concept behind io's technology, of increasing red blood cell counts through high altitude simulation, makes for an excellent match for this market.

3.1.1 Prevalence

When considering the prevalence of this condition, this analysis will only include the subset of patients who receive chemotherapy for treatment for new cases of cancer in the US population. In cases where patients receive other therapies, such as radiation or surgical treatment, anemia is not as significant a problem and these patients are less likely to require io's product. In the United States, about 1,437,180 new cancer cases are projected to be diagnosed in 2008 ("Cancer Facts and Figures 2008," 2008). Anemia occurs in approximately two-thirds of chemotherapy patients; an estimated 837,500 Americans developed chemotherapy-induced anemia in 2002 ("Cancer Facts and Figures 2008," 2008). The number of new cases is expected to increase by 11% to affect 929,495

people in 2009 ("Cancer Facts and Figures 2008," 2008). Other studies substantiate this finding, showing 50-60% of patients suffer from anemia related to the administration of chemotherapy ("New Advancements in the Total Care of Anemia in the Oncology Patient," 2002).

3.1.2 Social and Economic Costs

The National Institutes of Health estimate overall costs of cancer in 2007 at \$219.2 billion: \$89.0 billion for direct medical costs (total of all health expenditures); \$18.2 billion for indirect morbidity costs (cost of lost productivity due to illness); and \$112.0 billion for indirect mortality costs (cost of lost productivity due to premature death). The health care expenditures for treating anemia in this population add approximately \$568 per day per patient (*Blood Growth Factors Market*, 2003). The average cost per year for treating anemia, including health care costs, medical professional and hospital stays, ranges from \$18,000 to \$69,000 USD per patient depending on the type of cancer (*Blood Growth Factors Market*, 2003). However, excluding the associated health care costs and only looking at the cost of drugs, the cost to treat anemia ranges from \$210 to \$1091 per episode (*Blood Growth Factors Market*, 2003). In most chemotherapy cases anemia results in bacterial infection or thrombocytopenia, and hospitalization occurs (*Blood Growth Factors Market*, 2003). The average stay for a patient with these conditions can cost between \$15,000 and \$20,000 (*Blood Growth Factors Market*, 2003).

3.2 Market

The U.S. blood growth factors market for the treatment of complications from cancer therapy generated revenues of approximately \$3.32 billion in 2002. This market is

projected to grow to \$7.71 billion in 2009 at a CAGR of 12.8 percent (*Blood Growth Factors Market*, 2003).

“Procrit sales in the treatment of chemotherapy-induced anemia are projected to increase to \$3.58 billion in 2009, representing 75.6 percent of the total U.S. erythropoietin market in 2009. Aranesp sales in cancer-related anemia are expected to grow to \$1.15 billion in 2009, accounting for 24.4 percent of the market in 2009.” (*Blood Growth Factors Market*, 2003)

3.2.1 Treatment

The current mainstream treatments for chemotherapy-induced anemia are those that mimic the glycoprotein erythropoietin, which stimulates red blood cell growth (*Blood Growth Factors Market*, 2003). The current drug treatments available to combat chemotherapy related anemia include:

Erythropoietins

Epoetin alpha: Procrit (Ortho Biotech)

Darbepoetin alpha: Aranesp (Amgen)

Colony Stimulating Factors

Filgrastim: Neupogen (Amgen)

Pegylated filgrastim: Neulasta (Amgen)

Sargramostim: Leukine (Berlex Laboratories)

Interleukins

Oprelvekin (IL-11): Neumega (Wyeth Pharmaceuticals)

People with cancer are generally willing to try alternative therapies, with an average adoption rate of 31.4% (Ernst & Cassileth, 1998). Alternative therapies used to treat anemia include; "...mind-body approaches (meditation, relaxation, hypnotherapy, visualization, and other imagery techniques), reflexology, dietary approaches and food supplements, Chinese medications, botanical preparations, homeopathy, and spiritual healing." (Ernst & Cassileth, 1998)

3.3 Distribution Channels

All the pharmaceutical treatments for anemia are provided through hospitals, physicians and pharmacists. The alternative treatments used by patients are not necessarily for direct treatment of anemia, but often serve to address its symptoms. The alternative therapy services and products can be found in health food stores, through naturopaths and specialized practitioners. Iron supplements can also be obtained over the counter in grocery stores and pharmacies.

3.4 SWOT Analysis

3.4.1 Strengths

The unique nature of io's product as a non-pharmaceutical solution for anemia allows for significant differentiation from their competitors. The cost of pharmaceuticals for treating anemia may allow io to service a population of patients who cannot afford expensive biologics or for those who want a more natural way of combating their illness. io may be able to market the product for use in conjunction with drug therapies as this may prove to boost drug efficacy. In addition to treatment after chemotherapy, io could explore the

possibility of pre-chemotherapy treatment to help mitigate the effects of post treatment anemia.

3.4.2 Weaknesses

There are already highly effective drugs available for treating chemotherapy-induced anemia. The incumbents are all well entrenched in the system and have proven their value to physicians over many years. It may be difficult to get doctors to recommend using io's product or attract them as channel partners for chemotherapy clinics or hospitals.

3.4.3 Opportunities

The use of io's product prior to chemotherapy makes it a unique offering in the marketplace. Cancer patients are actively looking for alternative and complimentary treatments and are willing to pay for them without support from insurers or federal aid (Ernst & Cassileth, 1998). If io's product works well in conjunction with the current blood growth pharmaceuticals (and does not reduce the need for drugs), there may be opportunities to partner with drug companies to take advantage of their channels and marketing dominance. Chemotherapy-induced anemia has a very large market size and io has the opportunity to offer a less costly treatment than the incumbents. Additionally, the FDA has been looking at limiting the use of anemia drugs because over prescription and over use has lead to heart problems ("FDA panel recommends limits on Amgen's drugs," 2008).

3.4.4 Threats

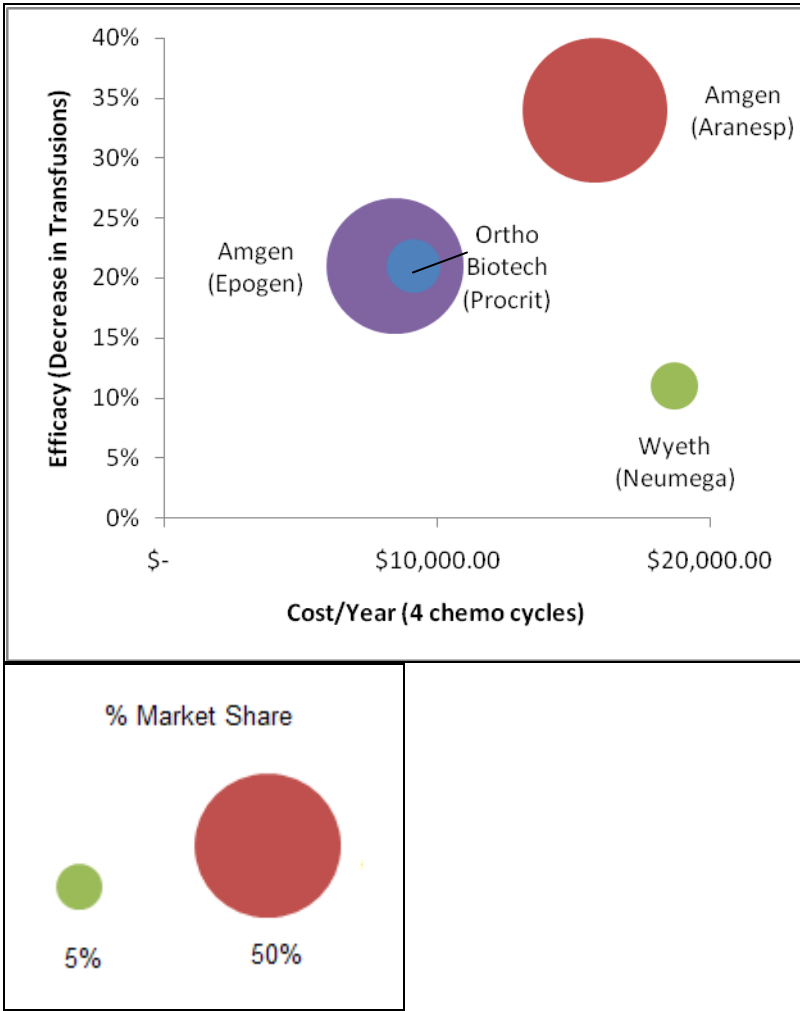
The key threat comes from the incumbent competition. The big pharmaceutical companies have effective products and strong brand awareness with physicians and insurers. Direct competition may be difficult in this market. If io's product is seen as competition (i.e. reduced need for drugs) then they will be up against the marketing machine and proven efficacy of pharmaceutical products.

3.5 Summary and Recommendations

This market is a good fit with io's technology, as it already has been shown to help increase red blood cell counts in athletes. io may also be able to take advantage of the current treatment channels and provide their service through hospitals and clinics. As patients already travel for treatment, this would reduce their burden to adopt io's therapy. The underinsured market in the US may provide an excellent beachhead into chemotherapy-induced anemia treatment, as the willingness to pay is high but the current options are all costly.

The chemotherapy-induced anemia market is large but is well served by the drug companies. It will be difficult to make headway against well established incumbents with strong track records and physician brand awareness and support. However, if io's treatment improves the efficacy of the current pharmaceutical solutions, a strategic alliance between io and a pharmaceutical company may be the fastest way to enter the market.

Figure 3: Cost vs. Efficacy for Chemotherapy Related Anemia Treatment



Compiled by the authors from the following sources: ("Aranesp Product Insert," 2007; EPOGEN Product Insert," 2005; *Managing the Side Effects of Chemotherapy*, 2005; Neulasta Product Insert," 2004; NEUMEGA Product Insert," 2004; Ogg, 2007; Procrit Product Insert," 2005; St.Onge & Lawrence, 2007)

4: HEADACHE

4.1 Introduction

Researchers classify headaches as primary or secondary depending on the ability of a physician to determine an underlying cause (Kernick, 2007). The three main types of primary headaches are tension, cluster and migraine. Secondary headaches are often attributed to other medical issues including head or neck trauma or vascular disorders. Three percent of doctor visits in the United States are for headaches and 4% of headache cases reported to physicians are for secondary headache (Kernick, 2007). Grouped together, headaches are in the World Health Organization's top 10 diseases in disability-adjusted life years (the length of time and degree of disability) (Kernick, 2007).

4.1.1 Prevalence

Headaches affect over 90% of the United States population at some point over their lifetime. Chronic headaches affect 25% of Americans and 4% of the population suffer headaches daily (Kaniecki, 2003). As many as 45 million Americans get chronic, recurring headaches every year, making headaches a more common occurrence than asthma, diabetes, and coronary heart disease combined (Devine, Farley, & Hadsall, 2005). In the 2002 American Productivity Audit, headaches were identified as the most frequent cause of productivity loss; ahead of back pain, arthritis pain, and other musculoskeletal conditions (Stewart, Ricci, Chee, Morganstein, & Lipton, 2003).

Tension headaches affect 38% of adults in the United States each year but are generally not reported to physicians because they usually do not lead to high levels of disability or dysfunction (Kaniecki, 2003). Tension headaches are often the result of stress, anxiety or fatigue and treatment of tension headaches is usually with over-the-counter medications like acetaminophen or ibuprofen ("The Complete Guide to Headache," n.d.). Tension headaches can be chronic or episodic and affect women more than men ("The Complete Guide to Headache," n.d.). Cluster headaches are very uncommon, affecting less than 0.1% of the population (Kaniecki, 2003) and affect men more than women (5:1) ("The Complete Guide to Headache," n.d.). The pain associated with cluster headaches is considered the most severe and can last from 30 minutes to several hours up to four times a day ("The Complete Guide to Headache," n.d.). Migraine headache affects 18% of women and 6% of men in the United States but is considered the most highly unreported and misdiagnosed type of headache (Kaniecki, 2003). Migraines often begin as a dull ache and then develop into a constant, throbbing and pulsating pain at one or both temples, front or back of one or both sides of the head. The pain is usually accompanied by nausea and vomiting, and sensitivity to light and noise ("The Complete Guide to Headache," n.d.).

4.1.2 Social and Economic Costs

Between \$13 billion to \$17 billion is spent yearly on migraine treatment in the United States (Goldberg, 2005). This cost is primarily on medication, emergency room treatment, hospitalization, primary and specialty care, laboratory service and management of side effects. There are also the indirect costs of lost productivity in the workplace that total more than \$60 billion dollars a year through lack of performance, absenteeism and

medical expenses (Stewart et al., 2003). Migraines alone costs employers in excess of \$14.5 billion; \$7.9 billion from absenteeism, \$5.4 billion from impaired work function and \$1.2 billion on medical costs (Hu, Markson, Lipton, Stewart, & Berger, 1999). Approximately \$1.5 billion of the total cost of headache treatment are associated with medication; \$1.18 billion is spend on triptans (the primary migraine drug) alone (Goldberg, 2005). In 2000, patient complaints of headache at US emergency departments reached approximately 3 million (McCaig & Burt, 2003). At one emergency room, over a six month period, of a total of 518 patient visits, 54 patients made 50% of the visits and among the repeating patients 79.6% of visits were headache related (Maizels, 2002).

4.2 Market

In 2002, the US over-the-counter pain medication market was 1.76 billion dollars and the prescription market was 13.9 billion dollars (Devine et al., 2005). Forty-six percent of the people who reported suffering from headache used at least one medication for its treatment (Devine et al., 2005). The highest used class of medication was migraine-specific relief medication, used by 36% of people (Devine et al., 2005). Opiates and butalbital products were used by 22% and 17% of the headache suffering population respectively (Devine et al., 2005). A wide variation in the use of prescription medication was observed across socio-demographic characteristics including age, ethnicity, and insurance status. The highest usage of prescription medication for headaches is seen in the adult population ranging from ages 25-64. Black and Hispanic patients are less likely to report use of prescription medications to treat headaches than are Caucasians. Individuals who report migraine headaches are more likely to use prescription medication than those who suffer from other headaches. Sufferers who have health insurance report a

higher use of prescription headache medication than those without insurance. Finally, those who have a reported good health status are less likely to rely on prescription drugs. (Devine et al., 2005).

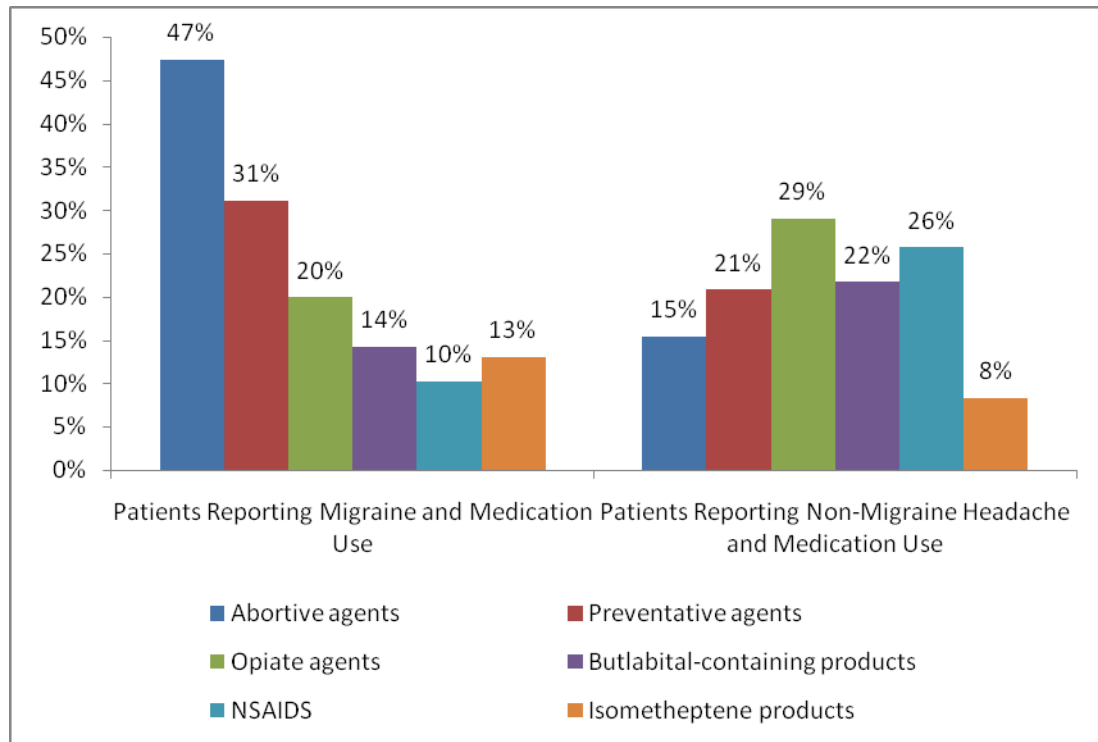
4.2.1 Treatment

Headache treatment is primarily chemical for both prevention and pain relief. Medications such as beta blockers, tricyclic antidepressants, anti-seizure medication, cyproheptadine (antihistamine) and botulinum toxin type A (botox) are used as preventative medications for cluster, migraine and tension headaches but researchers are uncertain of the mechanism of action ("Headache," 2007). Pain relief medications include nonsteroidal anti-inflammatory (NSAID), triptans, ergotamine, anti-nausea medications, butalbital combinations and opiates ("Headache," 2007). Oral tablets, nasal sprays and injections deliver both preventative and pain relieving medication. Many migraine sufferers have nausea or vomiting as part of their symptoms and for 30 to 40% of those patients it interferes with their oral drug delivery (Pierce, 2008). A form of transdermal drug delivery is currently in phase 3 testing that will be completed by late 2009 (Pierce, 2008).

The current preventative treatments for headaches are prescribed on a case by case basis depending on severity and may take up to three months to significantly alter headache severity and frequency (Loder & Martin, 2004). Preventative medications are only 50% effective at best at reducing frequency of migraines and no medication completely stops headache attacks (Loder & Martin, 2004). A common side effect for preventative headache medication is weight gain and prescription to obese patients is an issue, a second side effect is teratogenicity in pregnant woman (Loder & Martin, 2004).

Alternative treatments for headaches include acupuncture, chiropractics, stress management, and aromatherapy ("Headache Topic Sheets," 2007). Oxygen therapy has been explored for the treatment of cluster headaches; studies have shown that oxygen is safe and effective but 100% oxygen must be used at a high rate of flow (10-12L/min) (Kernick, 2007).

Figure 4: Medication Use by Headache Patients



Source: (Devine et al., 2005)

4.3 Distribution Channels

Chemical headache treatment is either over-the-counter or prescribed by doctors and distributed by pharmacists. Delivery of alternative therapies is through nutritional supplement and naturopathic stores, or through people trained in alternative treatment methods. io could collaborate with headache and pain relief treatment centres, such as Chesapeake Neurology Associates in Maryland.

4.4 SWOT Analysis

4.4.1 Strengths

io's therapy would be attractive to chronic headache sufferers who may wish to enhance their current preventative medication with the io therapy or those patients who are not taking preventative medicines who want to reduce their headaches without chemical intervention. io's treatment is not habit forming and has none of the side effects of pharmaceutical treatment. If efficacious, io's treatment could remove the need for costly preventative drugs and reduce hospitalization and emergency room visits. Oxygen treatment has been used as a mainstream therapy for cluster headaches and physicians may be more willing to see io's treatment as mainstream instead of alternative. Currently there are no other mainstream mechanical treatments for headaches and io would be uniquely positioned in the market.

4.4.2 Weaknesses

The population suffering from headache and chronic headache is very widespread and reaching them directly will involve a large and costly marketing plan. There are effective headache treatments for most types of headaches that have a long-term presence in the market so patients feel that these treatments are safe and effective. The cost of io's treatment will affect its adoption in the United States where many patients are already facing the high costs of medication. Similar to other market areas, with so many established pharmaceutical options, it is unlikely that insurance providers will cover this treatment in the short term.

4.4.3 Opportunities

The majority of Americans have suffered from headache at some point and 45 million of them will have chronic headaches, which has a significant cost in both treatment and lost productivity hours. The initial product launch could be focused on migraine management clinics in large urban centres allowing io to focus on patients who are seeking treatment for their chronic condition. To reduce the cost of the marketing plan, io could focus on neurologists and headache clinics for education who in turn can educate their patients. The regulatory path for headache treatment will be easier (Class I) than asthma or sleep apnea, because the headaches are not life threatening and io's treatment could not result in loss of life. The medications for headache are very expensive for the most effective treatments (\$20-35 per pill) (Goldberg, 2005) and io could place the monthly cost of treatment at an equal or lower value than the monthly cost of preventative medications.

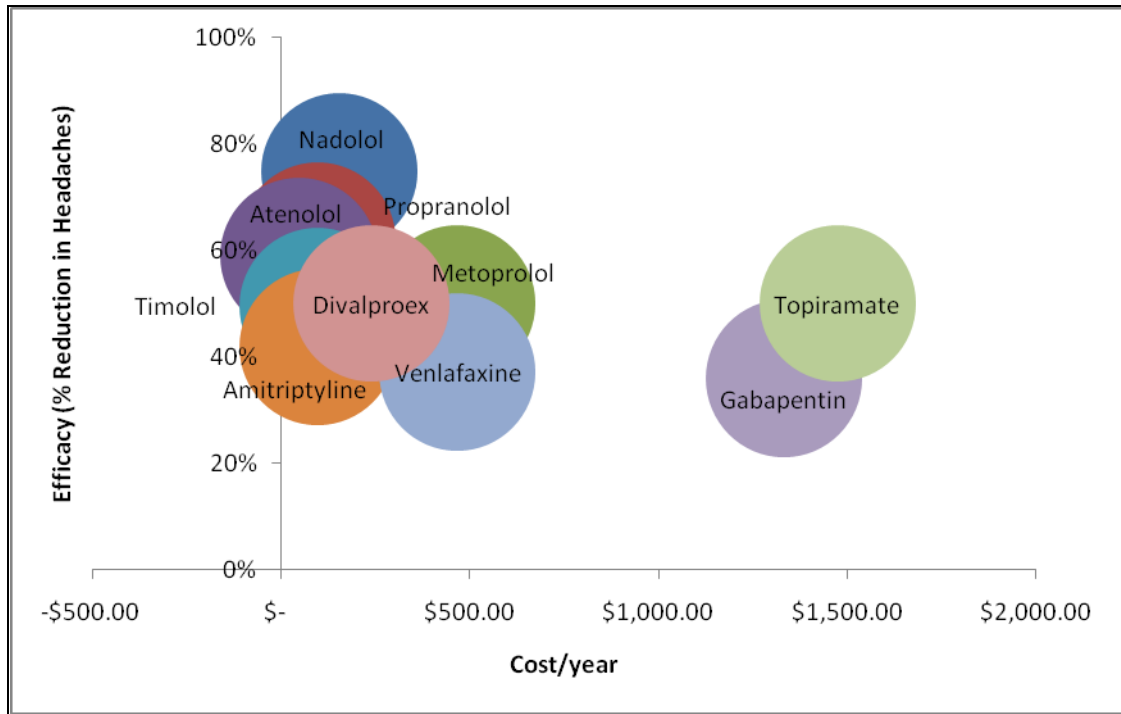
4.4.4 Threats

Oxygen treatment has been used for headache previously and io will have to check for potential patent conflicts in this area. The drug companies have a strong foothold in the headache market and will be very difficult to displace. Additionally, Medicaid, Medicare or private insurance covers some of the medications and io would have to work to have their treatment accepted by these bodies in order to gain market share. As io management wants their therapy to be considered in the mainstream market rather than an alternative therapy it will be necessary to prove efficacy in headache prevention to doctors and clinics that focus in that area.

4.5 Summary and Recommendations

In the headache market, io will be competing with well established pharmaceutical treatments for prevention and relief of headache and chronic headache. However, the prevention drugs can take up to three months to be effective and will only reduce pain or frequency of chronic headache, usually by approximately 50%. If io's treatment is more efficacious or faster acting and has less/no side effects then there is a chance that io will be able to displace some of the current preventative care market. As io management wants their therapy to be considered in the mainstream market rather than an alternative therapy it will be necessary to prove efficacy in headache prevention to doctors and clinics that focus in that area. io should consider a partnership with established headache and neurology clinics in the United States in order to reach a wide patient population without the cost of developing a massive sales force and campaign. The market for headache treatment is so large that there is room for new competitors and, because of io's unique niche as a non-chemical preventative therapy for headaches, it should allow io to gain a foothold in this market. io may be able to establish themselves as a market leader in preventative headache therapy.

Figure 5: Cost vs. Efficacy for Headache Prevention Treatment



Compiled by the authors from the following sources: (Evans, 2006; Freitag, 2003; Gallagher, Stagliano, & Sporazza, 1987; Grottemeyer, Scharafinski, Schlake, & Husstedt, 1990; Johannsson et al., 1987; Lainez et al., 2007; Mathew, 1981; Medina, 1988)

Note: Market share for these preventative treatments is not known as they are also sold for other applications.

Note: These drugs are only effective in a maximum of 50% of the population (ex. Nadolol is 75% effective in 50% of the population) for prevention of chronic headache.

5: HYPERTENSION

5.1 Introduction

Hypertension, also known as high-blood pressure, is defined by the Centre for Disease Control (CDC) as having a systolic pressure of 140mmHg or higher and a diastolic pressure of 90mmHg or higher ("What is High Blood Pressure?," 2005). People who fall into the category of pre-hypertensive have a systolic pressure range of 130-139mmHg and a diastolic pressure range of 80-89mmHg; these people have twice the risk of becoming hypertensive than people with normal blood pressure (Lenfant, Chobanian, Jones, & Roccella, 2003). A non-hypertensive person would have readings of less than 120mmHg systolic pressure and less than 80mmHg diastolic pressure by comparison. Hypertension increases the risk for cardiovascular diseases (CVD) such as heart attack and stroke, leading causes of death in the United States ("High Blood Pressure Fact Sheet," 2006). Approximately 31.7% of Americans with hypertension are not even aware that they have the disease ("High Blood Pressure Fact Sheet," 2006).

5.1.1 Prevalence

Hypertension affects approximately 49 million Americans or 17% of the population (Balu & Thomas, 2006). Of those with hypertension, 5.1% are 18-30 years old, 49.6% are 31-60 years old and the final 45.3% are over 61 years of age (Balu & Thomas, 2006). In 2002, there were approximately 49,707 deaths related to high blood pressure in the United States underscoring the need for treatment and early detection ("High Blood

Pressure Fact Sheet," 2006). Low socio-economic status and high obesity are correlated with higher levels of hypertension (Colhoun, Hemingway, & Poulter, 1998).

5.1.2 Social and Economic Costs

The estimated incremental expenditure of treating hypertension in the United States using 2001 data is \$55 billion (Balu & Thomas, 2006). This breaks down to approximately \$1,130.70 per American and 90% of those costs are related to prescription medicine and in/out patient visits (Balu & Thomas, 2006). In 2006, for every 1000 US workers aged 18-64, approximately 4.5 weeks of work were lost due to hypertension (Brookes, 2007). When one considers the cost of presenteeism, which is where people are still at work but not as productive due to illness, the average annual cost due to hypertension is approximately \$247 per suffering worker (Brookes, 2007).

5.2 Market

Market data for hypertension is presented on a global scale based on the information freely accessible. Market data specifically for the US is available but only through the purchase of market reports. The global market size for antihypertensive drugs is currently \$38.5 billion (*Cardiovascular Drug Discoveries 2008: what the future holds*, 2008). The top nine antihypertensive drugs in 2006 combined for a total of approximately \$20 billion dollars (R. Smith & Ashiya, 2007). It should be noted that a number of the top antihypertensive drugs will be coming off patent in the next several years. It appears that the major pharmaceutical companies are switching focus away from cardiovascular drugs and more towards oncology drugs. This means that there is a dwindling pipeline and less chance for the development of new antihypertensive therapeutics ("Antihypertensives:

Generics striking at heart of the market," 2007). Regardless of this, the market is projected to grow to \$50 billion by 2014 within the seven major markets of the US, Japan, Germany, France, Italy, Spain and the UK (*Antihypertensives-Two Years to Shape the Market?*, 2005).

5.2.1 Treatment

The pharmaceutical treatments for hypertension can be broken down into several drug categories, calcium channel blockers, angiotensin converting enzyme inhibitors (ACE inhibitors), angiotensin receptor blockers, angiotensin II receptor blockers, thiazide diuretics, and renin inhibitors ("High Blood Pressure," 2008). The above pharmaceutical treatments are prescribed individually or in combination regimens, and, if there is little or no progress, additional drugs are prescribed including alpha blockers, alpha-beta blockers, central-acting agents, and vasodilators ("High Blood Pressure," 2008). In addition to pharmaceutical treatments, doctors recommend a number of self-care initiatives to achieve or maintain a healthy blood pressure. These include losing weight to have a healthy BMI, reducing the intake of sodium, limiting alcohol consumption, quitting smoking, and managing stress ("High Blood Pressure," 2008). People who are classified as pre-hypertensive do not require medication but do require these lifestyle modifications (Lenfant et al., 2003). The US department of Health and Human Services has published a guide for people with hypertension that includes a recommended diet called DASH (Dietary Approaches to Stop Hypertension) that emphasizes fruits, vegetables, whole grains and low-fat dairy foods (*Your Guide to Lowering Blood Pressure*, 2003). Alternative treatments for hypertension include taking Co-enzyme Q10, garlic, the herb hawthorn, fish oil, folic acid, and supplements of calcium, magnesium

and potassium (Wong, 2008). There are also claims that mind-body intervention therapies such as yoga, biofeedback and autogenic training (relaxation technique) can help reduce blood pressure (Wong, 2008). Finally, traditional Chinese medicine recommends a combination of acupuncture and traditional herbs (Wong, 2008).

5.3 Distribution Channels

Healthcare professionals such as family doctors or hypertension specialists are the primary prescribers of pharmaceutical treatments for hypertension. The lifestyle changes that are recommended alongside medical treatment can be obtained through publications found in medical clinics, from nutritionists, or directly from the US National Institute of Health online and through the various hypertension societies in the United States.

5.4 SWOT Analysis

5.4.1 Strengths

There is no medical device currently mentioned in the literature for treating hypertension. The altitude simulation technology offered by io can be used for all forms of hypertension including cases that are classified as pre-hypertensive. In fact, it might benefit and appeal to those pre-hypertensive person who do not need or want to go onto medications but do require lifestyle modifications. Lifestyle changes are required alongside drug treatment for the successful reduction of high blood pressure and io has already positioned itself as a method to improve the performance of athletes and assist in the treatment of various ailments, something that should appeal to those hoping to improve their health.

5.4.2 Weaknesses

As in asthma, io faces a condition that is successfully treated by pharmaceuticals. In fact, according to the 7th Joint National Committee on Hypertension, most people with hypertension will require a combination of at least two drugs to lower their blood pressure (Lenfant et al., 2003). Currently, patients with high blood pressure obtain their treatments from physicians and by making dietary and lifestyle changes. The treatment from io would require a different distribution channel and a significant change in the routines of patients in order to adopt io's technology as part of their weekly or monthly schedule.

5.4.3 Opportunities

Obesity and sleep apnea are both causes of hypertension (Wolk, Shamsuzzaman, & Somers, 2003). This presents io with an opportunity to approach hypertension through markets in which it might be stronger, such as sleep apnea. Hypertension is often called the "silent killer" as otherwise normal looking person can still have high blood pressure. If so many people are unaware of hypertension, io could combine a blood pressure monitor with their altitude simulation technology to inform users of the system for other conditions that there are benefits for its use against hypertension as well. The medical establishment supports the combination of lifestyle modifications with medical treatments for hypertension. This provides the opportunity for io to introduce their technology into fitness centres as not just a method for higher athletic performance, but also a treatment to enhance the lifestyle changes needed to combat hypertension.

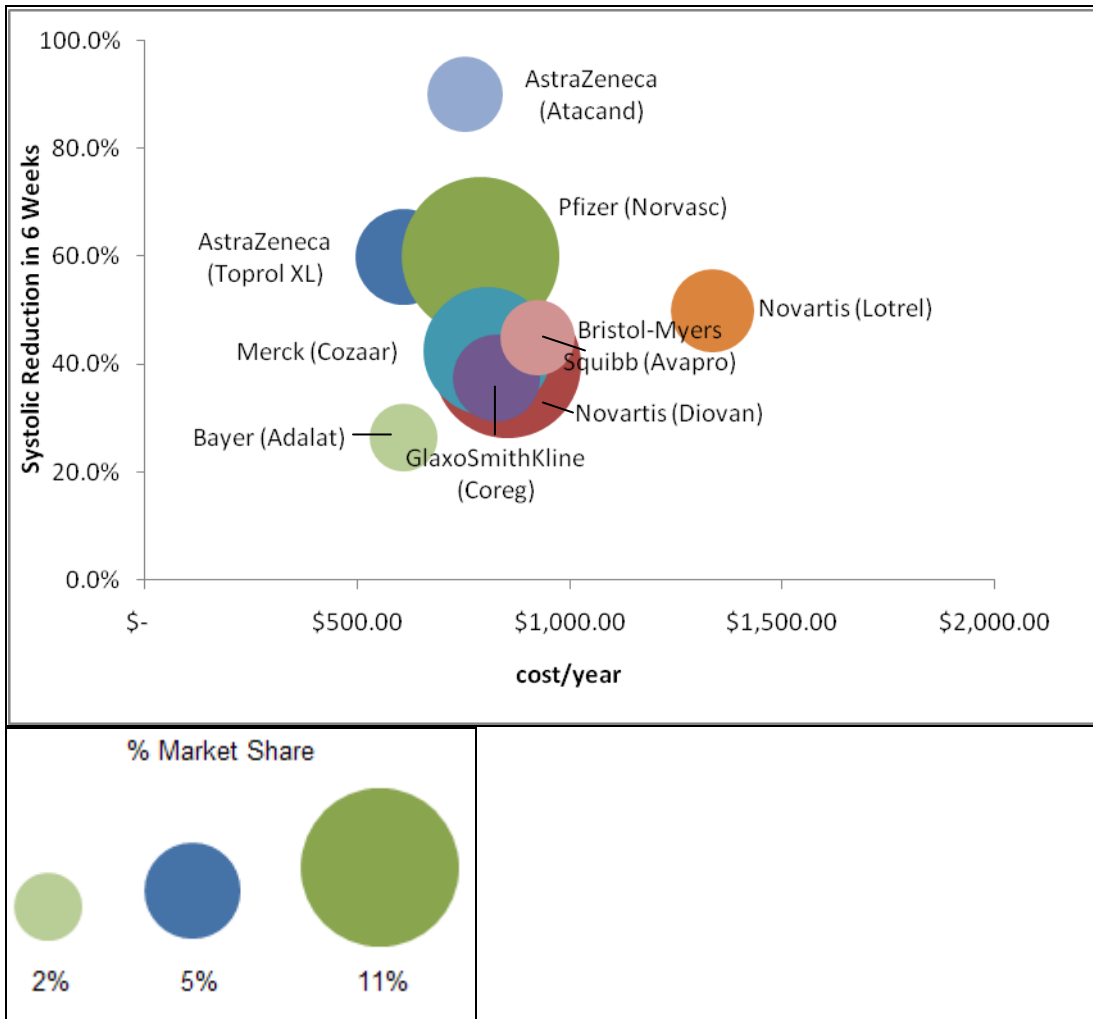
5.4.4 Threats

This market is clearly dominated by the previously mentioned pharmaceutical options. New breakthroughs and new blockbuster drugs could capture most of the market. Hypertension is potentially fatal and weakens the heart. This would mean that io's technology would likely have to undergo the rigorous FDA trials required for a Class II medical device. Careful clinical trials will also have to be performed to in order to ascertain the safety of this technology with various stages of this condition. One risk that io faces is that negative complications such as heart attack or death in patients associated with io's treatment could lead to serious legal challenges.

5.5 Summary and Recommendations

The hypertension market has inherent risks due to the potential for fatality for people with this condition. The causes of the condition are multiple and generally unknown. There are a number of risks associated with clinical trials including adverse events such as death that might be held against io's product. It might also be difficult to run trials on hypertensive patients because of possible interaction effects that might occur with the various pharmaceutical combinations that those patients are currently using. This market has a large population and it might be beneficial for io to consider a less risky population in those people who are considered pre-hypertensive. As mentioned previously, io could market their technology as one that assists people in making the necessary lifestyle modifications needed to achieve a more healthy blood pressure.

Figure 6: Cost vs. Efficacy for Hypertension Treatment



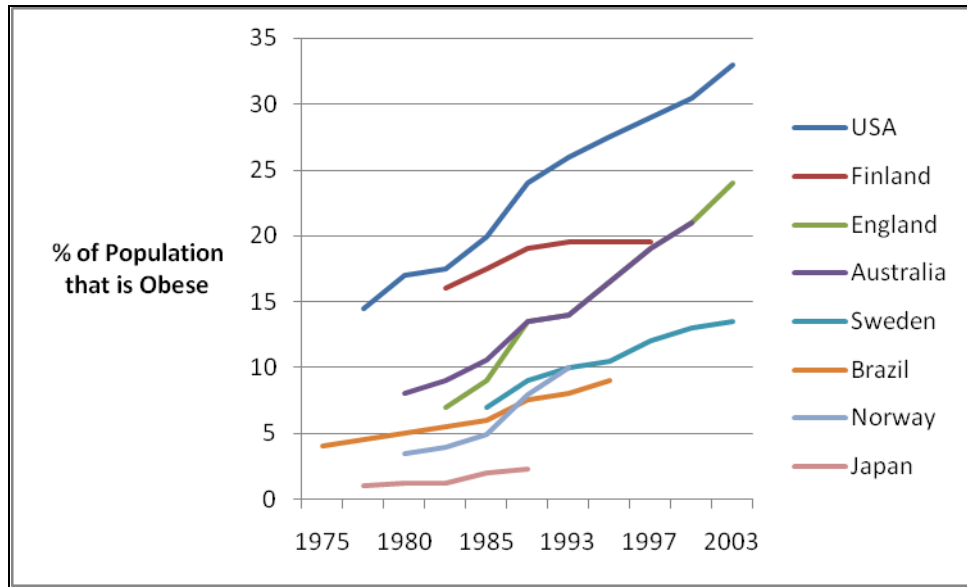
Compiled by the authors from the following sources: ("ADALAT Product Insert," 2004; ATACAND Product Insert," 2005; AVAPRO Product Insert," 2005; COREG Product Insert," 2005; COZAAR Product Insert," n.d.; Diovan Product Insert," 2005; Holmes, 2008; Lotrel Product Insert," 2004; Norvasc Product Insert," 2005; Pharmacy," 2008; TOPROL-XL Product Insert," 2005; What is High Blood Pressure?," 2005)

6: OBESITY

6.1 Introduction

Obesity is defined by the US Center for Disease Control (CDC) as having a Body Mass Index (BMI) greater than 30; while having a BMI greater than 25 places one in the overweight category ("What is Obesity," 2008). The risk factors for obesity include; inactivity, overconsumption of food, poor diet, lower socio-economic status and genetic predisposition ("Childhood Obesity" 2005; James, 2008). Figure 7 depicts this trend for eight industrialized countries. The sudden increase in the weight of the North American population since the 1970's is unprecedented and leads a global obesity trend that has occurred across all industrialized nations (James, 2008). Although many different solutions have been tried and are currently available in the marketplace, (including basic nutritional education and recommendations from physicians) the number of people with this condition is becoming endemic.

Figure 7: Escalating Obesity Rates Worldwide



Source: (James, 2008)

6.1.1 Prevalence

The US government has conducted a series of longitudinal studies called the National Health and Nutrition Examination Survey (NHANES) since the mid 1970's (Beals, 2007). Table 1 has been abstracted from the CDC and shows the prevalence of overweight and obese adults in the population. This translates into approximately 72 million obese people and approximately 136 million overweight people in the American population based on a population estimate of 300 million ("Obesity: Health costs estimated at \$75 billion," 2006).

Table 1: Age-adjusted* prevalence of overweight and obesity among U.S. adults among, age 20-74 years

	<i>Overweight or obese (BMI greater than or equal to 25.0)</i>	<i>Obese (BMI greater than or equal to 30.0)</i>
<i>NHANES III (1988-94)(n=16,679)</i>	56.0%	22.9%
<i>NHANES (1999-2000)(n=4,117)</i>	64.5%	30.5%
<i>NHANES (2001-02) (n=4,413)</i>	65.7%	30.6%
<i>NHANES** (2003-04) (n=4,431)</i>	66.3%	32.2%
<i>NHANES II (1976-80)(n=11,207)</i>	47.0%	15.0%
<i>NHANES III (1988-94)(n=14,468)</i>	64.5%	30.9%
<i>NHANES (2001-02)(n=3,916)</i>	65.7%	31.3%
<i>NHANES (2003-04)(n=3,756)</i>	66.2%	32.9%

*Age-adjusted by the direct method to the year 2000 U.S. Bureau of the Census estimates using the age groups 20-39, 40-59, and 60 years and over.

**Crude estimates (not age-adjusted) for 2003-4 are 66.5% with a BMI \geq 25 and 32.3% with a BMI \geq 30

Source: (Beals, 2007)

For American children between the ages of 2 and 5 years old, the prevalence of being overweight has skyrocketed from 5% in the 1975-80 survey to 13.9% (2003-2004 survey) ("Childhood Obesity", 2005). For those between the ages of 6 and 11, the number of children classified as being overweight changed from 6.5% to 18.5% and for teens between the ages 12 and 19 a similar trend was observed with an increase from 5% to 17.4% of the population affected ("Childhood Obesity," 2005). This translates into over 9 million obese children over the age of six ("Childhood Obesity," 2005). Although the increase in obesity has skyrocketed, the most recent data from the CDC has shown that obesity incidence rates are stabilizing and that the population prevalence has not increased in recent years ("Prevalence of Overweight and Obesity Among Adults," 2007). One consequence of the obesity epidemic in the United States is the explosive growth in

medical conditions associated with high bodyweight, particularly amongst children. These include type II diabetes, orthopedic problems, sleep apnea and hypertension ("Prevalence of Overweight and Obesity Among Adults," 2004). Treating obesity rather than the resulting health problems is beginning to be seen as the most effective way to improve quality of life and reduce medical costs.

6.1.2 Social and Economic Costs

The costs for being overweight have moved beyond simply being a personal problem to one that is beginning to affect society as a whole and, more specifically, has become a cost issue for employers who provide medical insurance, insurance companies and Medicare (Finkelstein, Fiebelkorn, & Guijing, 2003). The annual cost of obesity and obesity related illnesses is estimated to be between \$74 and \$93 billion USD (Finkelstein et al., 2003). To put this in perspective, \$93 billion represents approximately 9% of US medical expenditures per year (Finkelstein et al., 2003). Based on an analysis of obesity and drug costs, the authors determined that 8% of the increased spending on prescription drugs between 1990-1999 was a result of increasing obesity in the population (Vandegrift & Datta, 2006). Medicaid and Medicare carry a significant proportion of the costs of treating obese patients; 8.8% and 11.1% respectively (Finkelstein et al., 2003). Between 1979 and 1999 the hospital costs for treating obese children (ages 6-17) for obesity related illnesses rose from \$35 million to \$127 million (2001 USD) (Wang & Dietz, 2002).

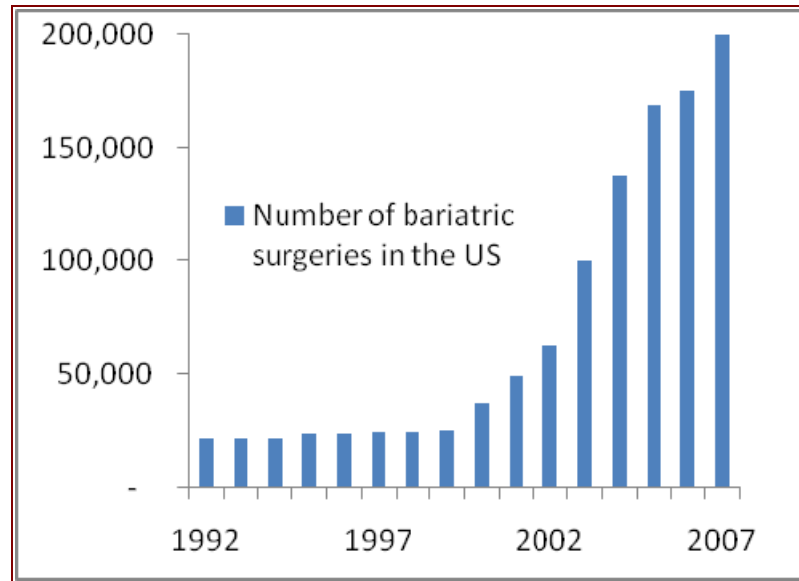
6.2 Market

The weight loss market consists of three major categories; prescription drugs, surgical intervention and weight loss/diet programs and systems. The World Health Organization expects the number of overweight adults worldwide to grow from 1.6 billion to 2.3 billion by 2015 ("The Business Week," 2008). Total US sales in 2006 for weight loss remedies is estimated to be \$33 billion (Rundle, 2008).

Prescription Drugs: The global market for prescription drugs to combat obesity and related diseases is estimated to be \$70 billion and is expected to double by 2020 ("The Business Week," 2008). In the United States, prescription drug sales account for an estimated \$200 million of the global market ("The Business Week," 2008; Vandegrift & Datta, 2006).

Surgical Intervention: The two key surgical techniques used to combat obesity include bariatric surgery and gastric banding (Rundle, 2008). Bariatric surgery involves surgically reducing the size of the patient's stomach to prevent them from overeating. A similar result occurs with gastric banding where a device is tightened around a portion of the stomach to reduce its size (Rundle, 2008). Gastric banding costs \$15,000-40,000 and is rarely covered by insurance. However, as of February 2007, Tricare (which covers retired US military personnel and their families) has begun to cover gastric banding. The total sales for surgical treatment of obesity in 2006 was \$270 million – a 50% increase over 2005 sales (Rundle, 2008).

Figure 8: Number of Bariatric Surgeries in the US



Source: (Rundle, 2008)

Weight Loss/Diet Programs: There are many different weight loss programs available. One of the largest is Weight Watchers, which has a presence in 28 countries and had revenues of \$1,233 million in 2006 up from \$624 million in 2001 (*SWOT Analysis, 2007*). Weight Watchers generates this revenue from a number of sources including; weight management services, partnering with food manufacturers and publishing weight loss materials such as diet books. Every week, 1.5 million people attend 50,000 Weight Watchers meetings globally (*SWOT Analysis, 2007*). The North American market makes up 65% of Weight Watchers revenues (\$801 million) (*SWOT Analysis, 2007*).

6.2.1 Treatments

There are a number of different prescription drug options available to combat obesity and all the major pharmaceutical companies have products or a developing products for this market. However, prescription drugs have not been particularly effective for treating

obesity and most products have limited effectiveness, typically reducing bodyweight by only 5 to 10% ("Pharmaceutical companies set," 2004). Due to a history of serious side effects from these drugs and the fact that obesity is considered by many to be a lifestyle problem rather than a disease, the FDA has increased the standards for bringing new weight loss drugs to market (Toelke & Horkova, 2008). Two significant players include Roche's Xenical and Abbot Laboratories Meridia ("Pharmaceutical companies set," 2004). There are three major classes of drugs on the market; those that target cannabinoid receptors, seizure and diabetes drugs that have a weight loss side effect and "fen-phen" which was effective but was also responsible for heart valve defects in patients ("Pharmaceutical companies set," 2004). Gastric bypass surgery and gastric banding are considered major surgeries and are not recommended except in cases of morbid obesity where other treatments have failed. The invasive nature of surgical intervention makes this a last resort treatment that will be unlikely to service the vast majority of people who are overweight but not obese. There are a number of major weight loss systems and programs available, including innumerable books. Most recommend reducing the amount of calories and dietary fat, although there are diets that focus on the glycemic index or reducing carbohydrate intake (Wadden, Butryn, & Wilson, 2007). The common element to all these solutions is that they require significant behavioral change on the part of the participant and are rarely effective in the long term (Wadden et al., 2007).

6.3 Distribution channels

The distribution channels for weight loss greatly depend on the type of treatment. Surgical interventions are usually performed in major hospitals, but a recent trend has been to encourage plastic surgeons to take up gastric banding as part of their practice and

perform the operation as day surgery or outpatient surgery. In these cases, the patient goes home directly after the operation. The profitability and increased safety of the gastric banding solution has attracted the backing of venture capitalists to help open new clinics across the US (Rundle, 2008). Prescription drugs are most commonly prescribed by family doctors and are filled by pharmacists at local drug stores. Weight loss programs operate in every urban and suburban community. The low cost to set up provides low barriers to enter the market and there are many different options available. Some health clinics and municipal or state health and wellness programs also provide nutritional counselling.

6.4 SWOT Analysis

6.4.1 Strengths

The side effects and long-term health risks associated with drug intervention makes a non-medicinal alternative attractive to people trying to lose weight. The vast number of people with BMI's over 25 and the constant societal pressure for thinness means that there is a large, motivated market. io's product has the potential to be seen as an easy way to lose weight – considering the more demanding alternatives of diet and exercise or the risks associated with prescription drugs. The market is massive and has shown a willingness to try and pay for alternative treatments (Narbro & Sjostrom, 2000; Roux, Ubach, Donaldson, & Ryan, 2004). Due to the low efficacy of current solutions, even a marginal efficacy on io's part could allow for strong market adoption.

6.4.2 Weaknesses

The sheer number of established weight loss therapies, whether drug, weight loss programs, supplements or surgical options makes entering this market challenging. Although io's product is significantly different from the competition, its newness may require significant education for the customer before they are comfortable that the program is efficacious and worth the money. The sheer number of ineffective products on the market makes this a potential problem; if io enters the obesity market with low efficacy, it may impair their ability to gain credibility in other markets. This is partially to do with the perception of weight loss medical devices as fraudulent attempts to separate the desperate from their money.

6.4.3 Opportunities

People prefer not to use drugs when alternative methods are available but they also do not want to suffer discomfort or struggle unduly to achieve their weight loss goals. The willingness to pay for successful weight loss alternatives is high and the potential market is very large (Narbro & Sjoström, 2000). The long history of serious side effects from using pharmaceuticals to combat obesity has sensitized the community to the dangers of overreliance on pharmaceutical solutions. The high prevalence of obesity and overweight people means there are large numbers of potential customers.

6.4.4 Threats

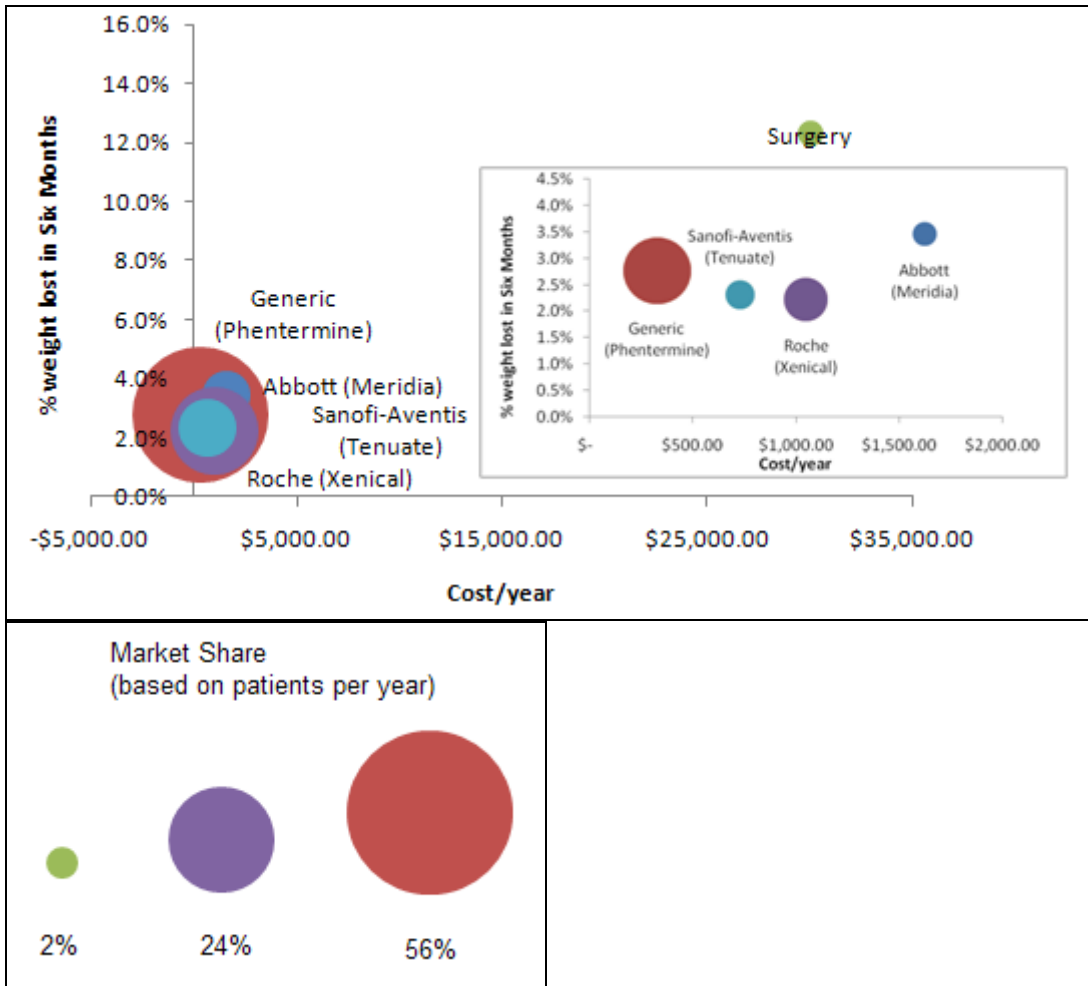
The advent of a new blockbuster drug with moderate to high efficacy has the potential to capture the lion's share of the market. The sheer number of companies working on

weight loss drugs and treatments increases the chance of this occurring. The efficacy and backing of gastric banding may lock io out of the morbidly obese market. The sheer number of alternative options will make it difficult for io to stand out and will require a serious commitment to marketing and sales.

6.5 Summary and Recommendations

The immense size of the obesity market in the US makes it an attractive place to begin expanding io's sales. The prescription drug competition is largely ineffective at treating obesity and the invasiveness of the surgical options will discourage adoption by most of the overweight and obese population. The morbidly obese may be more attracted to surgical options but the high cost may be a barrier from which io can take advantage. Weight loss programs and systems will be the most challenging competitors as they have low barriers to entry and have well established brand identities. However, io could partner with these centres and take advantage of their distribution systems as they already have market penetration across the US. io's greatest advantage is that it can be used as a complimentary therapy with any of the leading weight loss treatments. The fact that the market is full of weight loss alternatives makes io's marketing job much more difficult. The fact that most weight loss treatments are largely ineffective over the long term means that the size of the market is unlikely to change unless there is a significant, unpredictable scientific breakthrough.

Figure 9: Cost vs. Efficacy for Obesity Treatment



Compiled by the authors from the following sources: (Henderson, 2006; Hatcher, 2008; "A Review of Three Weight Loss Medications," 1999; SAUL, 2005; Sramek et al., 2002; TENUATE Product Insert," 2003; Weber et al., 2004)

7: SLEEP DISORDERS

7.1 Sleep Apnea

7.1.1 Introduction

Obstructive sleep apnea syndrome (OSAS) is a condition characterized by a blockage or closing of the respiratory tract resulting in interference in normal breathing and a drop in blood oxygen levels. Sufferers of this condition experience a number of negative health outcomes including poor quality sleep, increased risk of heart attack, stroke, daytime drowsiness (a risk factor for motor vehicle accidents), mood disorders and irritability ("What Is Sleep Apnea?," 2008). Obesity is a major risk factor for developing obstructive sleep apnea due to an increase in fat lining the throat. Doctors recommend that all patients with sleep apnea lose weight and reduce their BMI to under 25 ("How Is Sleep Apnea Treated?," 2008).

7.1.1.1 Prevalence

There are currently 12 million cases of OSAS in the U.S. which represents approximately 5% of the US adult population (Caples, Gami, & Somers, 2005). Of the 12 million cases, approximately 4 million were adults between the ages of 30 and 64 (*US Sleep Apnea Diagnostic and Therapeutic Market*, 2001). In the total population of American senior citizens, the prevalence of sleep apnea is 30% in women and 80% in men compared to 2% and 4% in middle aged adults respectively (Tarasiuk, Greenberg-Dotan, Simon-Tuval, Oksenberg, & Reuveni, 2008). Obstructive sleep apnea is estimated to occur in 0.7

to 3% of children and has been linked to developmental problems and cognitive disorders related to low oxygen saturation during sleep (Wildhaber & Moeller, 2007).

7.1.1.2 Social and Economic Costs

The economic cost of sleep apnea can be partially correlated with congestive heart failure, as untreated sleep apnea significantly increases the risks of heart failure (Lopez-Jimenez, Kuniyoshi, Gami, & Somers, 2008). The average cost of hospitalization and treatment for patients with heart failure in 1997 was \$20,000 to \$30,000 within a few years of a patient's first heart failure. Lifetime cost of treatment would be even higher. Treatment of sleep apnea over 45 years using Continuous Positive Airway Pressure masks (CPAP) would cost approximately \$14,000 (*U.S. Positive Airway Pressure Therapy Devices Market*, 2006). Motor vehicle accidents that involve sufferers of OSAS can have profound economic costs. In the year 2000, more than 800,000 vehicle accidents in the United States were OSAS related and cost \$15.9 billion and 1,400 lives (Sassani et al., 2004). It is estimated that treating all OSAS sufferers in the United States with CPAP would cost \$3.18 billion but save \$11.1 billion in collision costs and 980 lives (Sassani et al., 2004).

7.1.2 Market

Currently, there is no approved pharmaceutical treatment for sleep apnea. Mechanical treatments include the CPAP mask, oral appliances and surgical treatments, which include the Pillar Treatment and Uvulopalatopharyngoplasty (UPPP). Childhood OSAS is most commonly caused by adeno-tonsillar hypertrophy, and is treated by tonsil removal (Wildhaber & Moeller, 2007). Finally, patient weight loss will reduce the amount of fat

in the neck thus enlarging the size of the airway and lowering the need for other interventions (Nasaw, 2004).

CPAP is a device that has a close fitting mask worn over the mouth and/or nose during sleep and forces air into the breathing pathways. The addition of pressurized air while sleeping prevents the airways from closing. In addition to improving sleep apnea symptoms, the CPAP mask also reduces snoring in patients. This is the most common treatment because it works regardless of the etiology of the patient's sleep apnea; however, there are some issues with the device. The mask can be uncomfortable during sleep; it can take a considerable amount of time for patients to get used to wearing it and some never do and discontinue its use. The CPAP machine is also noisy and can keep a sleeping partner awake at night ("CPAP Devices for Sleep Apnea," 2007). CPAP machines range from ~\$200 - \$5000 US for the device depending on the model and options; some CPAP machines are eligible for insurance coverage but this varies according to the patient's plan ("CPAP Devices for Sleep Apnea," 2007).

Oral appliances and dental splints are similar to mouth guards and move the jaw forward during sleep in order to prevent a patient's tongue from blocking his/her airway during sleep (S. D. Smith, 2007). Oral appliances can put pressure on the jaw and cause additional discomfort and this treatment will only work with patients whose sleep apnea is the result of jaw and tongue movement during sleep (S. D. Smith, 2007). There are several different models of oral appliances that can be covered by insurance if prescribed by a doctor and the patient is eligible for insurance coverage.

Figure 10: Oral Appliances for Sleep Apnea



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The FDA approved the Pillar Treatment in 2004 for the treatment of sleep apnea caused by the collapse of the upper palate across the airway. In this procedure, three polyester bars are implanted surgically into the soft palate after which tissue grows around the implants and keeps the palate from closing the airway. The procedure costs approximately \$2500 US and is performed under local anaesthesia at a doctor's office in about 30 minutes ("New treatment for sleep apnea," 2006). According to Restore Medical, the developer of Pillar; "more than 30,000 people worldwide have been treated with the Pillar Procedure" since 2004.

Figure 11: The Pillar Treatment for Sleep Apnea



© 2007, Restore Medical, Inc., from Media Package

Uvulopalatopharyngoplasty (UPPP) is a surgical procedure that removes excess tissue from the back of the throat. Unlike the Pillar surgery, it may require general anaesthesia, an overnight hospital stay and may take up to two weeks to heal. Laser assisted UPPP is a newer option that has a faster healing time and does not require

anaesthetic or a hospital stay; however, it is not currently an approved procedure with the American Academy of Sleep Medicine for the treatment of sleep apnea (Littner, 2001). If the treatment is not covered by insurance, the cost would be approximately \$2000 US. It may still be necessary for a patient to use a mechanical device after surgery if it does not completely cure the sleep apnea. There is currently no good evidence on how well UPPP will work with obstructive sleep apnea (Sundaram, 2006), but limited research shows that about 40% to 60% of people who have UPPP see an improvement in their symptoms (Guilleminault & Abad, 2004).

7.1.3 Distribution Channels

Obstructive Sleep Apnea can be treated by any of the therapies described above, but the first recommendation by any medical professional for overweight patients is to begin a weight loss program. The obesity chapter discusses distribution channels for weight loss aids, medications, and surgery. Of the OSAS specific devices and surgical options, nasal Continuous Positive Airway Pressure (CPAP) devices are ordered from medical device suppliers and used in the home while sleeping. Oral appliances have to be fitted at a dentist or orthodontist's office while surgical options such as UPPP are performed at hospitals. And laser UPPP has the convenience advantage of being able to be performed at any GP's office (Littner, 2001).

OSAS is exacerbated by sleeping on the back and an effective low tech method includes shirts with uncomfortable items sewn onto the back (such as tennis balls). These can be ordered from medical supply stores or made at home. Patients can also buy position alarms that sound if a patient remains on their back for more than 15 seconds and these are typically available from medical supply stores.

7.1.4 SWOT Analysis

7.1.4.1 Strengths

In terms of advantages over mechanical therapies such as sleep masks, io's altitude simulation technology does not need to be worn while sleeping, nor does it need nightly treatments. Instead, patients can schedule their treatments when they are most convenient and do not need to worry about the apparatus disturbing their sleeping partners. Damage to teeth and jaws has been caused by mechanical therapies, while the io treatment has no such risk. When comparing io's technology to surgical techniques, the altitude simulation technology fares well as it is non-invasive, it does not require the presence of a doctor or surgeon, there is no recovery time required and the treatments can be administered in many locations including local sleep clinics, GP offices, medical clinics and hospitals.

7.1.4.2 Weaknesses

The current mechanical therapies such as CPAP are widely available worldwide on the internet while io's technology will likely be too expensive for single families to purchase and will have to be used in clinics. Efficacy data is still required for io and therefore there is no information available about insurance coverage and overall cost. Weaknesses in terms of competition with surgical techniques lie in the fact that io's technology is not a permanent solution and it remain to be determined if the technology is effective in this indication and whether medical insurance will cover it.

7.1.4.3 Opportunities

It is estimated that approximately 50% of patients stop using their CPAP machines in the first year of use and patients who make it past one year will usually only use the CPAP

machine 3 to 5 hours per night (Stepnowsky, Palau, Marler, & Gifford, 2007). Only 6% of patients use the machine for more than 7 hours a night (Stepnowsky et al., 2007). This suggests that although the treatment is effective, CPAP machines are simply not a popular treatment method with almost half of current users. This presents a huge opportunity for io should their altitude simulation technology prove to be effective in this treatment area. CPAP machines are acknowledged to help to decrease the number of motor vehicle accidents related to OSAS but the high misuse of these machines would make io's more convenient technology an attractive option for endorsement by auto insurance companies. Due to a growing rate of obesity, there will be increased cases of OSAS and possibly other diseases linked to obesity on which io might be able to focus in the future. The existence of sleep clinics provides an established client base for io to target and as of yet there is no similar technology in use for treating sleep apnea.

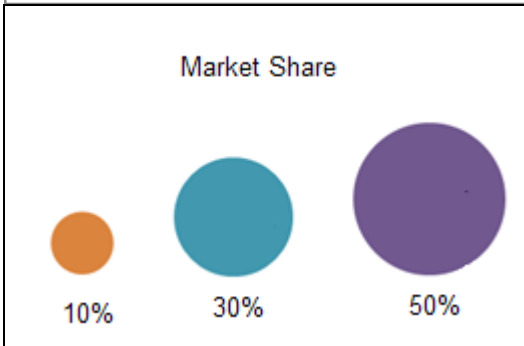
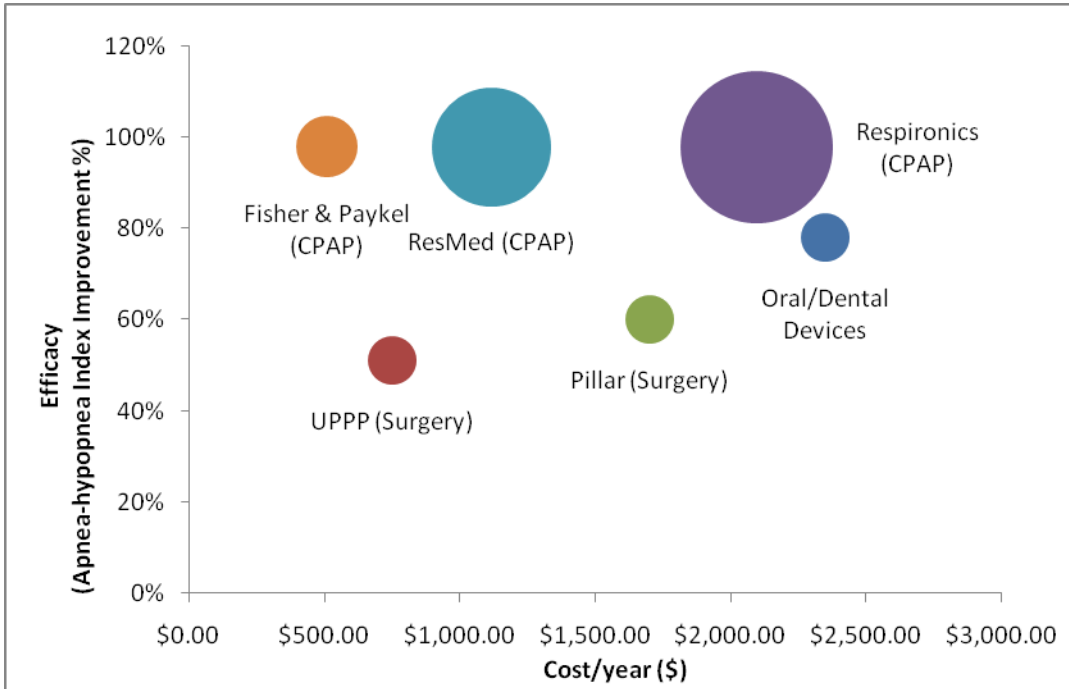
7.1.4.4 Threats

Sleep Apnea affects only 4% of the US population so io will have to balance this fact with the three major challenges facing them. First, FDA approval will be required to market a medical device and this will require time and resources. CPAP machines are considered a Class II medical device and io's device will likely face the same FDA approval requirements ("Is The Product A Medical Device?," 2002). Second, the efficacy of this technology to treat sleep apnea will have to be proven to doctors to receive their endorsement or recommendation. Finally, health insurance companies may not be interested in covering the costs for treatment with this technology. A potential threat is improvement in surgical interventions that may reduce the population of patients that would use io's device.

7.1.5 Summary and Recommendations

Sleep Apnea is an ideal beachhead market for io to enter should their Mayo clinic data prove an effective in this treatment area. This market is already accustomed to medical devices such as the CPAP machine. The staggering statistic that approximately 50% of CPAP users decrease their use of this treatment after one year suggests a large market looking for an alternative and more convenient treatment method -- which io would be well positioned to offer. Another attractive characteristic of this market is that pharmaceutical treatments are nonexistent, making medical devices the major player. Surgery for treatment of sleep apnea is not widely used as it is an invasive treatment with associated surgical risks and complications and does not guarantee that a patient will not have to continue to use a device for treatment. As well, there is a clear link between OSAS and obesity, providing a link between two treatment areas in which io is interested. To enter this market, io could partner with sleep clinics who already have access to the patient population or io could license their technology to a medical device company that is already in this space and will be able to sell to the major players in this market. Since CPAP devices are sold for home use, the marketing strategy will have to motivate significant behavioural change to ensure patients will come in for their regular maintenance therapy.

Figure 12: Cost vs. Efficacy for Sleep Apnea Treatment



Note: Market share for UPPP, Pillar and Dental Devices is not known.

Note: While efficacy is high for CPAP machines there is only a 50% compliance rate for these devices.

Compiled by the authors from the following sources: ("All About Sleep Apnea: The Patient Guide to Diagnosis and Treatment," 2005; Hoffstein, 2007; Jones, n.d.; Joshi, 2007; *US Sleep Apnea Diagnostic and Therapeutic Market*, 2001)

7.2 Insomnia

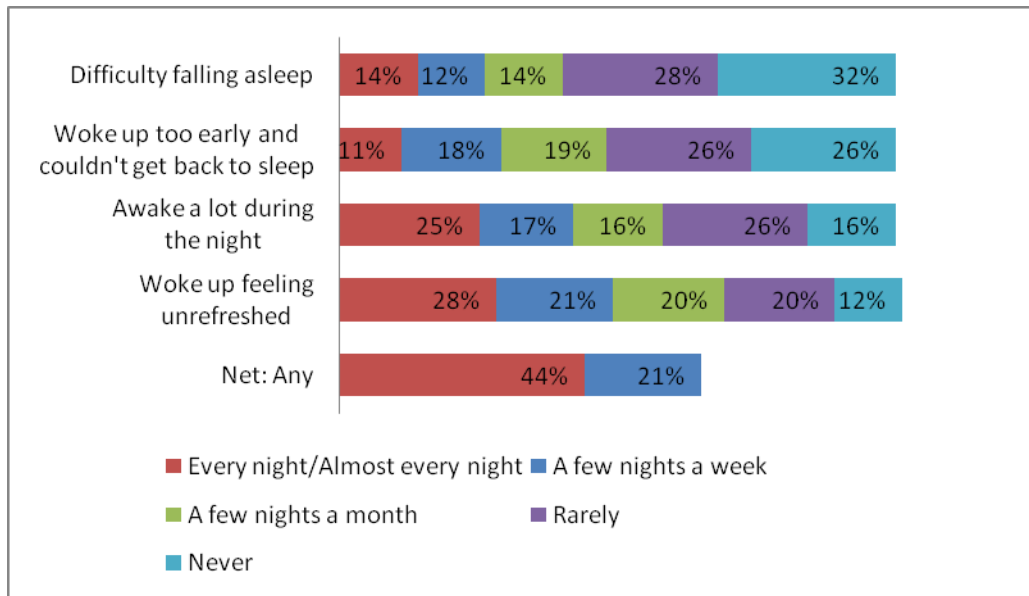
7.2.1 Introduction

Insomnia, characterized by difficulty falling asleep or maintaining sleep throughout the night, is classified into two forms, primary and secondary. Primary insomnia has no apparent cause while secondary insomnia is a result of another medical condition for example, pain from arthritis, gastrointestinal problems such as heartburn, stress and depression ("What Causes Insomnia?," n.d.). Primary insomnia is not usually diagnosed unless a person has experienced it for at least three nights a week over a one-month period ("What Causes Insomnia?," n.d.).

7.2.1.1 Prevalence

A 2008 survey of 1000 randomly selected participants conducted by the National Sleep Foundation (US) found that 4% of those surveyed reported a diagnosis of insomnia (*2008 Sleep in America Poll - Summary Findings*, 2008). However, the number of unreported cases is suspected to be much higher. In Figure 13, many subjects reported symptoms associated with an insomnia diagnosis almost every night or a few nights a week. It is extremely hard to determine an accurate population statistic for the prevalence of insomnia due to the number of cases that go undiagnosed and untreated. From various sources, an estimated 10-33% of the population have insomnia and a further 9-12% of adult sufferers have chronic insomnia (Morin, 2006; "National Institutes of Health," 2005). For many people, insomnia is transitory, lasting only a few nights, even though it may occur again many times throughout their lifetime. For others however, insomnia may last for months or even years ("National Institutes of Health," 2005).

Figure 13: 2008 Sleep on America Poll for Insomnia



Source: (2008 Sleep in America Poll - Summary Findings, 2008)

7.2.1.2 Social and Economic Costs

The direct and indirect costs for insomnia sufferers in the United States was estimated to be \$1,253 per person, per year for those between the ages of 18 and 64 (Ozminkowski, Wang, & Walsh, 2007). For the elderly, the authors estimated the cost to be \$1,143 per person per year (Ozminkowski et al., 2007). The direct economic costs come from pharmacy costs, inpatient, outpatient and emergency room visits. Indirect costs come primarily from absenteeism from work. The overall costs from sleep disorders was examined in an Australian study which found that for a population of 20.1 million, the yearly cost was \$7494 million AU (Hillman, Murphy, & Pezzullo, 2006). The direct costs were \$143 million; the indirect economic costs came from motor vehicle accidents (\$808 million AU), work related injuries (\$1956 million AU), other productivity losses (\$1201 million AU) and the cost of suffering (\$2970 million AU) (Hillman et al., 2006).

7.2.2 Market

In 2003, the insomnia market was estimated to be \$1.65 billion in the United States and is expected to grow to \$3.36 billion by 2010 (*U.S. Insomnia Therapies Markets*, 2004). Pharmaceuticals are the primary treatment for insomnia and include short term use sedative-hypnotic benzodiazepines and non-benzodiazepine sleeping pills such as zolpidem (Ambien), eszopiclone (Lunesta), zaleplon (Sonata), ramelteon (Rozerem) and the anti-depressant trazodone (Desyrel) (Harms, 2007). Doctors do not recommend sleeping pills be used regularly because they are habit forming and have been linked to depression (Gibbons et al., 1999). Herbal medicines such as valerian and melatonin are often used as alternative therapies for insomnia (Ramakrishnan, 2007). However, 70% of the people who had used melatonin said that it did not help their sleep issues ("Which alternative treatments work?," 2005). This is consistent with a study by the U.S. Agency for Healthcare Research and Quality that found that, while melatonin helps insomniacs fall asleep, it does not help to keep them asleep or have restful sleep ("Melatonin for Treatment of Sleep Disorders, Structured Abstract," 2004).

In addition to pharmaceutical treatments, there are also behavioral therapies that are used in combination with drugs or on their own and are usually taught to patients by health care professionals such as psychologists, psychiatrists, or doctors, for use in their own homes. These behavioral therapies are reviewed in the publication *2008 Sleep in America Poll - Summary Findings*, 2008 and are summarized here with information from that source. Stimulus control is a behavioral therapy that trains people to practice good sleep hygiene by treating their beds and bedrooms as areas for sleeping and sex only. This is taught by a professional but practiced in the home. Cognitive Therapy is conducted with a health professional, usually in the professional's office, to address the

patient's attitudes and beliefs that might contribute to lack of sleep. Relaxation training is practiced in the home but taught by professionals to reduce tension and stress in the muscles and body. Chronotherapy is a technique used by therapists to re-set a person's biological clock by strict regulation of waking hours and sleep times. Light Therapy involves a technique where people are exposed to bright light from special light boxes for two hours in the morning and then required to avoid bright light for several hours before bedtime. These light boxes can be purchased from medical supply stores and treatments are done in the home.

7.2.3 Distribution Channels

Pharmaceutical treatments are prescribed by physicians and dispensed by a pharmacist; herbal remedies can be found over-the-counter at most pharmacies or through naturopaths and homeopathies. Physicians, psychologists, psychiatrists, clinicians and sleep therapists deliver behavioural therapies. While training is done in their offices, the actual therapies are done by the patient at home.

7.2.4 SWOT Analysis

7.2.4.1 Strengths

Chronic insomnia is debilitating and sufferers want something that can help them. Io offers a non-pharmaceutical option to a chronic condition that has an extremely desperate population. The io treatment does not conflict with any of the other treatment options and may be able to be used as an alternative therapy in populations that don't tolerate sleep drugs well. Since io's treatment has none of the dangerous side effects or addictive properties associated with the pharmaceutical treatments, if proven efficacious, it is likely

to be widely adopted by people with chronic insomnia. There are no commonly used mechanical aids for the treatment of insomnia and therefore io would be in a unique position in this market.

7.2.4.2 Weaknesses

In this market, it would be very unlikely that, in the short term, insurance companies or Medicaid/Medicare would cover the treatment. Additionally, there are many established pharmaceutical solutions that hold the entire market and potential customers may not even consider non-pharmaceutical solutions without a large marketing campaign or recommendations from their current health provider.

7.2.4.3 Opportunities

The pharmacological treatments for insomnia all have unpleasant side effects such as addictive, depression, habituation, nausea, grogginess and daytime sleepiness. The herbal-based treatments do not have a good efficacy. People need sleep and an effective non chemical/herbal based treatment would appeal to a large number of people. If the sleep market is chosen, io could use the same distribution channels as for sleep apnea and may be able to capture both markets. The aging population has increased sleep problems and therefore, there may be an increased market size as time goes on. Since insomnia is not a life threatening condition, it is likely that the FDA would allow a Class I device designation.

7.2.4.4 Threats

Because of the market size and the long history of pharmaceutical treatment, there is the potential for the release of a new drug that has less side effects and higher efficacy. Drugs

of this type will have the power of a large pharmaceutical company behind it for marketing and distribution.

7.2.5 Summary and Recommendations

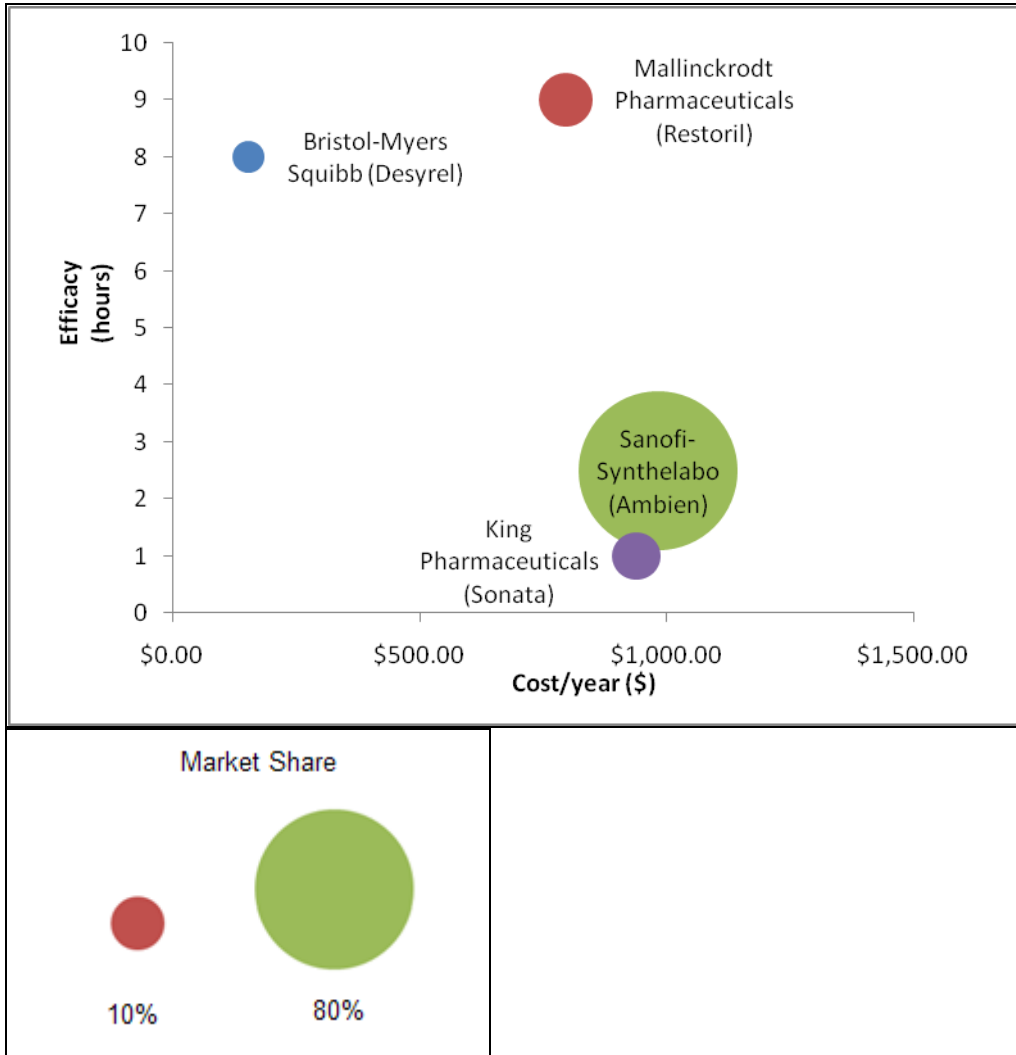
While there are more the 50 million adults in the United States that are affected by insomnia, only 14% of those report the use of prescription or over the counter drugs for this condition (Gershell, 2006). Penetration by various treatments are limited due to a lack of understanding of current treatments, poorly tested remedies (such as alcohol or herbal remedies), and a low level of the appreciation of the importance of chronic insomnia to the general community (Gershell, 2006). There are over 200 sleep disorder centers in the United States but it is estimated that 95% of people suffering from sleep disorders go undiagnosed (*2008 Sleep in America Poll - Summary Findings*, 2008). This suggests a large untapped market and probably a large portion that is looking for alternative therapies.

Secondary insomnia is a transient condition, affecting people occasionally and most people with secondary insomnia do not seek treatment. As it often goes undiagnosed in people, the actual market size is debatable. Since the secondary insomnia population is likely to have a low willingness to pay for an insomnia treatment, it will significantly restrict the market size. It would be better for io to focus on people with chronic insomnia.

Any significant penetration in to the sleep disorder market would require a marketing campaign involving awareness of the large number of people who silently suffer from these conditions. io's technology would appeal especially to those who are wary of the side effects of drugs such as amnesia, tolerance/withdrawal,

dependence/abuse potential, next-day residual sedation, and mental and behavioral changes. In this market, io is positioned to take advantage of patients who are unwilling to take pharmaceutical treatments and for whom behavioral therapies are not working, as io's treatment would be the only clinically validated mechanical sleep aid for insomnia.

Figure 14: Cost vs. Efficacy for Insomnia Treatment



Compiled by the authors from the following source: (*U.S. Insomnia Therapies Markets*, 2004)

8: RELATED DISEASE STATES AND CO-MORBIDITIES

8.1 Introduction

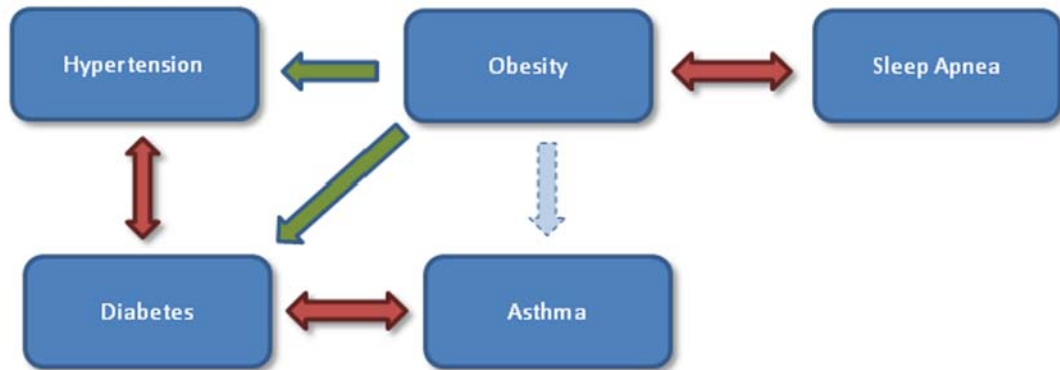
When researching the previous sections, it became apparent that a number of the different diseases io is interested in providing solutions for have causal or co-morbid relationships. These relationships add additional complications and opportunities for marketing io's product. This section of the report will examine these relationships and provide suggestions on how to leverage these relationships for maximum effectiveness and market penetration.

8.2 Relationships

Figure 15 shows the relationships between the different diseases states discussed in the previous chapters. The chart does not include chemotherapy, headache or insomnia, as these conditions have not been shown to have any significant relationship with the other conditions of interest. The arrows in the graphic represent the direction of the relationship and the strength of the relationship. The green arrows show that one disease, in this case obesity, is linked causally to hypertension and diabetes. However, obesity and sleep apnea have a self-reinforcing relationship – as a person gains weight, it increases the severity of the sleep apnea (Simon, 2006). The result is that the patients become tired and may try to maintain wakefulness by consuming food to boost their energy levels. This in turn increases their weight and exacerbates the sleep apnea. Obesity has also been shown

to increase problems associated with night-time asthma symptoms ("Obesity Worsens Impact Of Asthma, Study Shows," 2008).

Figure 15: Co-Morbidities



Diabetes has been added to the graphic because it is related to three of the conditions of interest. Obesity can cause type II diabetes in adults and children ("Prevalence of Overweight and Obesity," 2004). Diabetes is also associated with increased severity of symptoms in patients with hypertension and asthma (Adams et al., 2006; Jong, White, Sica, & Gerber, 2005). The use of io's system to indirectly address diabetes may provide io with an opportunity to work with insurance and health care providers in an industry that costs the United States an estimated \$174 billion yearly in direct and indirect medical costs ("Direct and Indirect Costs of Diabetes in the United States," n.d.). As outlined in the obesity chapter (see Section 6.1.2), insurance companies have begun to fund treatments for obesity in the hopes of driving down medical costs resulting from diabetes.

8.3 SWOT Analysis

8.3.1 Strengths

The overlap in patient populations makes for a natural experiment beyond the beachhead market. For example, if io chooses to tackle sleep apnea first, they could also choose to track patients' weight. If the patients lose weight, this data can be used by marketing to expand into the obesity market directly. These results can also be added to the FDA aftermarket (Phase IV) follow up to help justify validity in the secondary disease population.

8.3.2 Weaknesses

The overlap between conditions may add to the complications in clinical trials. Teasing out why io's product is effective may be more difficult or may be open to different interpretations. The claim that io's product can be a panacea for multiple medical problems may strain the credulity of consumers who have been bombarded with overhyped claims of efficacy in other products, particularly related to obesity and weight loss.

8.3.3 Opportunities

Obesity, as a key risk factor for a number of diseases, has been a hot topic of interest for government agencies, health care providers and insurance companies. As discussed in the obesity chapter, insurance companies are looking at the cost benefit ratios of dealing with obesity rather than the costs of the subsequent health complications. If insurance companies can be convinced that io can provide a cost effective way of reducing obesity,

thus bringing down overall health care costs for their clients, this may provide an opportunity for payment opportunities through medical insurance coverage.

8.3.4 Threats

Obesity seems to be the key link between most of the conditions. Any major advance, whether pharmaceutical or social, that impacts the levels of obesity on the population will dramatically change the number of patients with the co-morbid conditions. The size of this market and the huge potential profit that a highly effective solution will provide mean that there are many companies that are trying to exploit this market. This increases the chance that someone else will discover an effective treatment.

8.4 Summary and Recommendations

Obesity, as a key variable in many of the conditions of interest, should be considered important regardless of the beachhead market selected. If efficacy can be shown for obesity, io may be able to market the process through channels associated with co-morbid conditions. The reverse can also be valuable, if io chooses another beachhead market and can show efficacy for weight loss, the demand from the marketplace may provide opportunities for growth.

9: COMPARATIVE ANALYSIS

9.1 Building the Balanced Scorecard

The balanced scorecard approach was used to allow us to quantify a large amount of data from disparate sources into a single comparative metric. The initial framework was adapted from Robert S. Kaplan and David P. Norton's balanced scorecard which encompasses the major considerations (Financial, Customer, Internal Processes and Learning and Growth) that a company should look for in a market analysis (Kaplan & Norton, 1992). From this framework we chose 8 metrics that we determined appropriate to develop a scorecard with, namely; potential profitability, adoption risk, approval risk, competition level, io's values, customer perception, customer convenience and efficacy (Table 2). These metrics were further broken down into sub-metrics that had quantifiable measurements available (Table 3). The scorecard, along with nine additional questions (Appendix C), was presented to io to ensure the metrics made sense to their management. After approval of the metrics, the CEO, Michael Lodge, assigned weightings to the importance of each metric and sub-metric to io, based on his understanding of the business model and overall strategy.

The goal of the layered metric/sub-metric system is to prevent obvious bias from coloring the analysis. It is not inherently intuitive for the company or the analyst to predict the outcome using this system. It does work better if there are 2-5 sub-metrics per metric; however, data was not available for all of the measurement areas. We strongly discourage changing the weighting of the metrics after the data has been entered or the

analyst risks biasing the results. Included in the metrics was io's efficacy which is not available at this time. When efficacy data becomes available io management can enter the data into the scorecard to reassess the ranking of the different treatment areas.

9.2 Scoring System

The balanced scorecard in this report uses a scoring system that gives each sub-metric a score between 0 and 10, so that each value can be equally weighted amongst the others. A summary of this information can be found in Appendix E. Several assumptions were made in each of the treatment areas based on their unique challenges; these assumptions can be found in Appendix F. The quantifiable sub-metrics for potential profitability, adoption risk, approval risk, competition level, io's values, customer perception, customer convenience and efficacy are discussed below.

9.2.1 Potential Profitability

To quantify potential profitability, we assessed the three sub-metrics of market size, market growth and disease prevalence. Market size values were reported in billions of dollars per year and the highest value was assigned a score of 10. All other values were then weighted as a percentage of the highest value and converted to the 10 point scale; for example, a score of 63% would become 6.3. Market growth was reported as a percentage based on population increase per year. All the percentages were converted into a 10 point scale; for example, a score of 15% became 1.5. Finally, the prevalence of the diseases in the US population was reported as percentage which was then converted to fit our 10 point scale; for example, a score of 50% became a 5.

9.2.2 Adoption Risk

To quantify adoption risk, we assessed the adoption rate of alternative, complimentary or new therapies for each disease indication. The adoption rate was reported as a percentage and these scores were converted into a 10 point scale. As all our scores were found to be under 10%, we converted each score to a decimal and multiplied it by 100. Therefore, a score of 5% became a score of 5 on our scale.

9.2.3 Approval Risk

To quantify approval risk, we assigned a risk level to obtaining various FDA classifications and we compared demographics between each disease population. For the FDA classifications, a Class I medical device received a score of 10, a Class II medical device received a score of 5, and a Class III medical device received a score of 0. This was meant to show that there are greater risks for entry into a market where a medical device requires a Class II classification. Adults are usually the first group that participates in clinical trials and therefore we considered the percentage of adults that existed in total disease populations. We chose to use the percentage of adults 18-64 when comparing treatment areas because approval risk is higher for children and the likelihood of adverse events in clinical trial is higher for the elderly and FDA approval for those two age groups requires more strenuous testing. Scores were converted from percentages into our 10 point scale; for example, a score of 45% became a 4.5.

9.2.4 Competition

To quantify the metric of competition, we assigned four sub-metrics: number of mainstream competitors, number of alternative competitors, market share held by largest

competitor, yearly cost of competitive treatment and efficacy or perceived efficacy of competitive treatment. First, the number of significant mainstream competitors and the total number of alternative competitors were considered. We selected mainstream competitors that had market shares of greater than 10% and scored them in reverse order as we defined the fewest number of competitors as being better for io. All numbers were under 10, so we simply took 10 and subtracted each value to arrive at our final score. For example, if there were 8 competitors we would give a score of 2 because this was worse than a score of 7 which meant there were only 3 competitors. The same system was applied to the alternative competitors.

We also looked at the market share of the largest competitor and the average yearly cost of the competitive treatment. For market share, the highest value was given a score of 10 and all others were given a weighted percentage of the highest value and converted from a percentage to a 10 point scale. For example a score of 53% became 5.3. The yearly cost of competitive treatments was based on our cost efficacy graphs seen at the end of Sections 2 through 7. The highest value was assigned a score of 10 and all other scores received a weighted percentage of the highest value and were converted from a percentage to our 10 point scale.

Finally, we considered the efficacy of all the competitive treatments. Once again, values were based on our cost-efficacy graphs and all scores were arrived at by taking the values which are reported as a percentage and converting them to fit our 10 point scale. For example, a score of 15% became 1.5.

9.2.5 Values

To quantify the fit of each indication with io's values, we considered the sub-metrics of potential sales revenue, saving lives, and the quality of life. Potential sales revenue considered the total market size divided by the number of competitors. The highest value was given a score of 10 and each subsequent value received a weighted percentage of the highest value. Each percentage was then converted to our 10 point scale.

The sub-metric for saving lives was based on two questions, "Is the condition life threatening" and "Could io's treatment save lives". A yes answer was worth five points and a no was worth 0.

The Quality of life sub-metric had four yes/no questions with a yes being worth 2.5 points and a no worth 0 points. The questions were "Is this disease affecting day to day quality of life," "Do people who are using the treatments have a low quality of life," "Does this reduce the number of treatments that a patients need (burden of disease)," and "Are there a high number of side effects of current treatment."

9.2.6 Customer Perception

To quantify customer perception, we considered the two sub-metrics of mainstream therapies versus alternative therapies and whether or not io would be perceived as a competitive or complimentary therapy in this section. For mainstream versus alternative, we asked three yes/no questions "Are other mainstream treatments mechanical," "Is the distribution channel the same," and "Is io's treatment regime similar or better than incumbent treatments." Each "yes" received a score of 3.33 for possible scores of 0, 3.33, 6.66 or 10 (9.99).

In the competitive versus complimentary sub-metric we asked the following yes/no questions “Would a customer stop using other treatments,” and “Would customers reduce their use of other treatments.” For each “yes” a score of 5 was given for possible scores of 0, 5 or 10.

9.2.7 Customer Convenience

To quantify customer convenience, we compared io’s treatment to the available alternatives in each indication, and asked four questions about relative convenience. The scorecard included only chronic treatments in this section and permanent solutions were not considered. This is because customers who choose permanent solutions such as UPPP for sleep apnea will no longer require treatment including io’s altitude simulation technology. For this section we asked the following four questions, “Does io have an advantage over the incumbent on the number of treatments required,” “Does io have an advantage over the incumbent regarding the amount of travel required to receive treatment,” “Is the incumbent treatment uncomfortable,” and “Does the incumbent treatment have side effects.” For scoring this we considered who had the advantage; io, the incumbent, or neither. If the answer to question was io, a score of 10 was given. Following this rationale, 5 points were given if the answer was neutral and 0 points were given if the incumbent was the answer.

9.3 Blank Scorecard

Below is a blank scorecard that was sent to io in a spreadsheet which auto-calculated the scores to ensure that all totals equalled 100%. Table 2 depicts the 8 metrics used to rank the disease indications as potential markets for io’s technology according to weightings

supplied by io. Table 3 depicts the sub-metrics which are used to quantify each metric, again, according to weightings supplied by io.

Table 2: Scorecard Metrics

Number	Item	Value (%)
1	Potential profitability	
2	Adoption risk	
3	Approval risk	
4	Competition level	
5	Fit with io's values	
6	Customer Perception (Alternative or Mainstream)	
7	Customer Convenience	
8	Efficacy of io's treatment	
		100.00%

Table 3: Scorecard Sub-metrics

1. Potential Profitability will be based on:	Weighting (%)
Market Size (\$/year)	
Market Growth (%/year)	
Prevalence (% of population)	
Cost to Enter	
	100.00%
2. Adoption Risk will be based on:	Weighting (%)
Alternative, Complimentary or new therapy adoption (%)	
	100.00%
3. Approval Risk will be based on:	Weighting (%)
If the device will be required to be Class I or Class II device	
Demographic (age ranges of population that will be receiving treatment)	
	100.00%
4. Competition Level will be based on:	Weighting (%)
Number of mainstream competitors	
Number of alternative competitors	
Market share held by the largest competitor	
Yearly cost of competitive treatment	
Efficacy (or perceived efficacy) of competitive treatment	
	100.00%
5. Io's values: Does io value	Weighting (%)
Potential Sales Revenue	
Saving lives	
Improving quality of life	
	100.00%
6. Customer Perception: will customers view io's treatment as,	Weighting (%)
Mainstream vs. Alternative	
Compete vs. Compliment	
	100.00%
7. Customer Convenience will be based on:	Weighting (%)
How often does a customer have to take a treatment	
Travel to receive a treatment	
How uncomfortable is the treatment	
What are the side effects of a treatment	
	100.00%

9.4 io's Scorecard

Below are the weighting that were given to each metric and sub-metric by Mr. Lodge.

Table 4 shows the relative weights assigned to each metric by Mr. Lodge. Table 5 shows how Mr. Lodge rated each of the sub-metrics. Each sub-metric was weighted by io (Table 5) and then combined to create a value (Table 7). That value was weighted using the values that were given in Table 4 and a value was recorded (Table 6). Finally, each treatment area was given a value (Table 8).

Table 4: io's Metric Values

Number	Item	Value (%)
1	Potential profitability	20.00%
2	Adoption risk	10.00%
3	Approval risk	15.00%
4	Competition level	5.00%
5	Fit with io's values	15.00%
6	Customer Perception (Alternative or Mainstream)	10.00%
7	Customer Convenience	5.00%
8	Efficacy of io's treatment	20.00%
		100.00%

Table 5: io's Sub-metric Values

1. Potential Profitability will be based on:	Weighting (%)
Market Size (\$/year)	45.00%
Market Growth (%/year)	30.00%
Prevalence (% of population)	20.00%
Cost to Enter	5.00%
	100.00%
2. Adoption Risk will be based on:	Weighting (%)
Alternative, Complimentary or new therapy adoption (%)	100.00%
	100.00%
3. Approval Risk will be based on:	Weighting (%)
If the device will be required to be Class I or Class II device	60.00%
Demographic (age ranges of population that will be receiving treatment)	40.00%
	100.00%
4. Competition Level will be based on:	Weighting (%)
Number of mainstream competitors	35.00%
Number of alternative competitors	10.00%
Market share held by the largest competitor	20.00%
Yearly cost of competitive treatment	25.00%
Efficacy (or perceived efficacy) of competitive treatment	10.00%
	100.00%
5. Io's values: Does io value	Weighting (%)
Potential Sales Revenue	45.00%
Saving lives	10.00%
Improving quality of life	45.00%
	100.00%
6. Customer Perception: will customers view io's treatment as,	Weighting (%)
Mainstream vs. Alternative	55.00%
Compete vs. Compliment	45.00%
	100.00%
7. Customer Convenience will be based on:	Weighting (%)
How often does a customer have to take a treatment	40.00%
Travel to receive a treatment	25.00%
How uncomfortable is the treatment	15.00%
What are the side effects of a treatment	20.00%
	100.00%

9.5 Scorecard Results

Below is a summary of the scorecard results. The raw data for these results can be found in Appendix B. Figure 16 is a comparison of the metrics across treatment areas that show that in certain metrics, i.e. competition level, there is not a large amount of variability. However, in potential profitability, adoption risk and approval risk there is large variability between treatment areas showing the differentiation in each market.

Table 6: Scorecard Metric Results

	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Potential profitability	1.12	0.77	0.48	0.49	0.64	1.19	1.22
Adoption risk	0.70	0.40	0.70	0.31	0.52	0.90	0.10
Approval risk	0.80	0.65	1.28	0.99	1.10	1.28	0.78
Competition level	0.28	0.34	0.32	0.09	0.30	0.35	0.26
Fit with io's values	0.96	1.16	1.01	0.95	1.15	1.13	0.99
Customer Perception	0.41	0.82	0.45	0.45	0.45	0.45	0.23
Customer Convenience	0.29	0.38	0.38	0.38	0.44	0.38	0.30

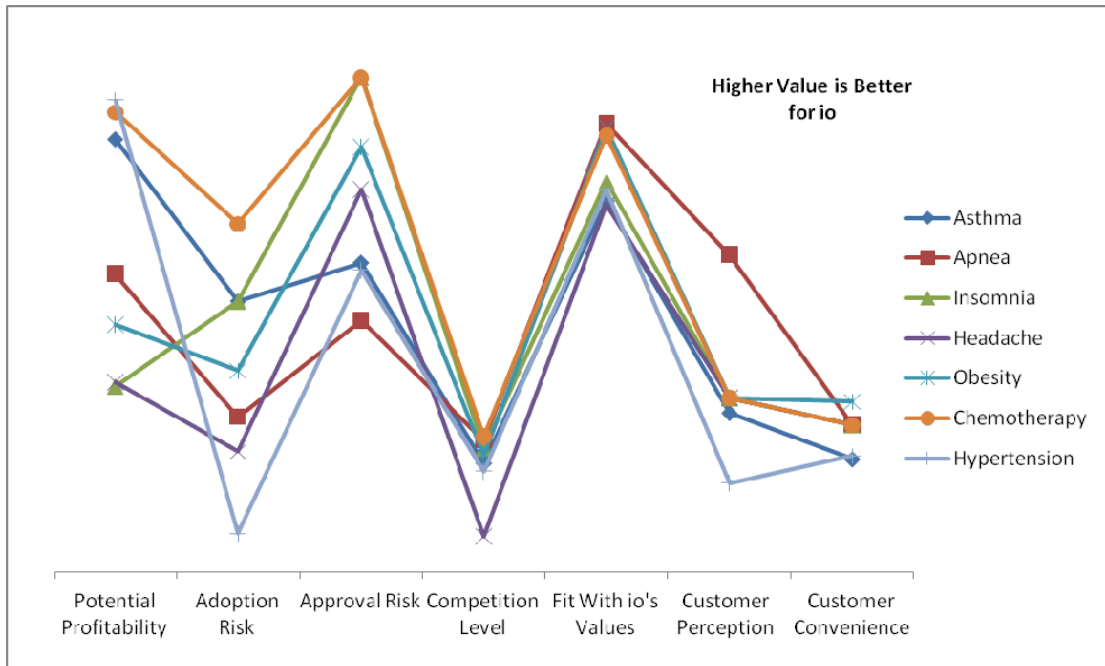
Table 7: Scorecard Sub-metric Results Summary

	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Potential profitability	5.59	3.85	2.39	2.45	3.20	5.95	6.12
Adoption risk	7.00	4.00	7.00	3.10	5.20	9.00	1.00
Approval risk	5.36	4.35	8.52	6.60	7.32	8.52	5.20
Competition level	5.66	6.79	6.39	1.88	5.91	6.92	5.23
Fit with io's values	6.40	7.75	6.75	6.30	7.65	7.53	6.63
Customer Perception	4.08	8.16	4.50	4.50	4.50	4.50	2.25
Customer Convenience	5.75	7.50	7.50	7.50	8.75	7.50	6.00

Table 8: Scorecard Summary Results

	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Summary	4.56	4.51	4.61	3.65	4.59	5.67	3.88

Figure 16: Comparison of Metrics by Treatment Area

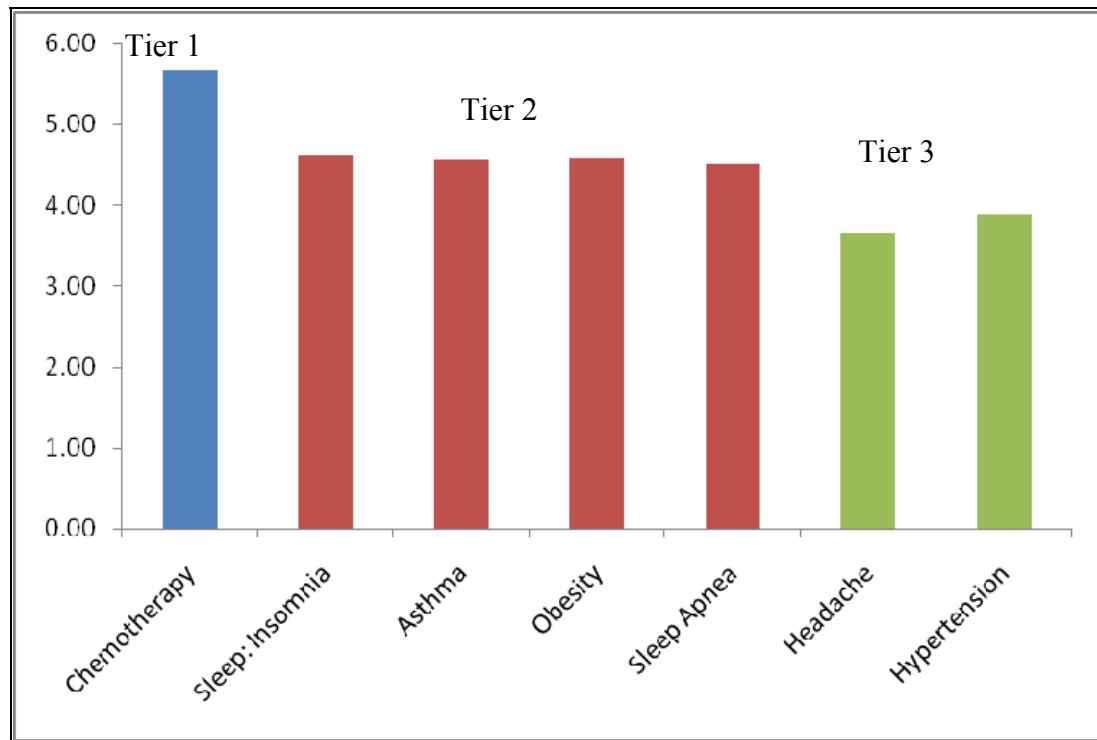


10: DISCUSSION AND RECOMMENDATIONS

10.1 Scorecard

The balanced scorecard was designed and used to compare the different treatment areas of interest to io in one comprehensive analysis. The analysis results indicate which treatment areas offer the highest potential for successful market penetration and adoption for io's technology. Although the exact method is outlined in Chapter 9 and Appendix B, the basic concept was to create a weighting system that reflected io's key concerns and important metrics. By placing values on the metrics and sub-metrics, we were able to create a tiered system that is not inherently intuitive and subsequently is resistant to bias and preconceived beliefs. As an electronic resource, the scorecard can be modified easily if new information becomes available – in this case, as efficacy data becomes available, it can be incorporated into the scorecard. The new results can then be examined and used to inform strategic decision making. The scorecard exercise created three tiers for the disease indications that io is interested in for their altitude simulation technology. The first tier solely belongs to chemotherapy-induced anemia. The second tier includes four indications: insomnia, asthma, obesity and sleep apnea. Finally, the third and bottom tier includes headache and hypertension. Figure 17 shows the results of the balanced scorecard.

Figure 17: Results from Balanced Scorecard



10.2 Tier 1

10.2.1 Chemotherapy-Induced Anemia

After considering all the criteria in the scorecard and weighting them against the criteria considered important by io CEO Michael Lodge, our ranking system has placed chemotherapy-induced anemia into the top tier of disease indications that io might consider when determining the best initial medical target market for their altitude simulation technology. io's altitude simulation technology promotes the growth of red blood cells, a clear treatment for anemia. In addition to this, there is no current medical device being used in this market and this provides a huge advantage to io to market a non-pharmaceutical treatment. Currently, in chemotherapy-induced anemia, there is a large market size that is dominated by pharmaceutical therapies. The costs of these drugs are high and, while there is efficacy, there is still room for improvement. In addition to

this, the FDA has been looking at the safety of anemia drugs due to their possible over-prescription and use ("FDA panel recommends limits on Amgen's drugs," 2008).

The willingness of cancer patients to adopt alternative therapies is high, and io stands to benefit from this if they can show that their technology is an efficacious complimentary therapy to the use of anemia drugs in the following ways. First, there is a large potential market for io if they can complete studies proving that io's technology can be used in a pre-chemotherapy market to increase a patient's red blood cell count before receiving their chemotherapy treatments. The hope for this would be that patients who receive treatment exhibit less anemia symptoms after chemotherapy and/or require less anemia medication. If io's process requires patients to use less medication post chemotherapy this will put them in direct competition with pharmaceutical companies who they may wish to partner with. If the patients take the same medications post chemotherapy but exhibit less severe symptoms, a partnership is a promising avenue for entering the pre-chemotherapy anemia treatment market. Secondly, studies will need to be done to see if there is any benefit in using io's technology as a complimentary treatment along with anemia drugs in a post-chemotherapy treatment regime. Two-thirds of all chemotherapy patients currently develop chemotherapy-induced anemia and an efficacious io therapy would make entry into this market a good choice.

10.3 Tier 2

10.3.1 Insomnia

Insomnia, and especially chronic insomnia, presents a condition that has a huge quality of life impact. People require sleep, and, as noted in our sleep chapters, there are significant social and economic costs related to lack of sleep. Insomnia is a condition that goes

largely undiagnosed, and, when it is, the most common treatment involves pharmaceutical drugs that are only recommended for short term use and have ugly side effects such as addiction, habituation, and depression. This benefits an effective io treatment because it has none of these side effects and it would be the only medical device in this market. Insomnia becomes more prevalent in an older population, and, with most countries facing aging demographics, this market will continue to grow. Acute insomnia is hard to quantify as a market because most people with insomnia go undiagnosed. Therefore, io would be better to initially consider the chronic insomnia market as their beachhead as it is better defined and hence easier to target.

10.3.2 Asthma

Asthma is a potentially life threatening condition and has a highly diagnosed and relatively stabilized population in the United States. Asthma patients have a high willingness to try alternative therapies due to a concern about the effects of continued use of inhaled steroids. io's technology would easily be perceived by the public as a breathing device for a breathing problem. The asthma market is dominated by highly effective pharmaceutical treatments that have had a long presence. As io's technology will not treat emergencies such as asthma attacks, people will not be giving up their relief inhalers. io's treatment will most likely focus on asthma maintenance and, again, faces a highly effective regiment of inhaled medications.

10.3.3 Obesity

Obesity has a large market size with no efficacious alternative therapies. Thirty-three percent of the US population is obese. Drugs are not effective on this condition and have

a large number of side effects while behavioural and lifestyle changes such as diets and exercise are difficult. As pointed out in the co-morbidity chapter, obesity is linked to a number of other conditions of interest, and being in obesity may help io bridge into other markets. There are a large number of competitors in this market who are mostly ineffective. The public is wary of new miracle claims and it might be risky to place io in a market known for vibrating belts and fat dissolving creams unless its clinical trial data is strong.

10.3.4 Sleep Apnea

Medical specialists and sleep therapists would be receptive to an effective io treatment because medical devices have already been widely used in this market (i.e. CPAP machine). However, io would have an advantage as there is only a 50% compliance rate by users of the CPAP machine due to user discomfort and sleep disruption of sleep partners. The rate of diagnoses of this condition is growing and there is a larger potential untapped market. There is a chance that car insurance companies would be interested in io's technology due to the large costs related to vehicle accidents tracked back to sleep apnea. io's technology is not a cure for this condition as it is an ongoing physical problem: io can treat the symptoms but ultimately their cure lies in surgery and weight loss.

10.4 Tier 3

10.4.1 Headache

Headaches are difficult to diagnose as to cause and type and there are many misdiagnoses. There is a low prevalence of chronic headaches thus making an accurate

and stable market difficult to determine. There are a number of good relief drugs for both chronic and acute headaches that are available for a low cost, and switching from pills taken during the headache to regular scheduled treatments on io's technology would be a huge behavioural change that would only be made by the more serious and smaller population of headache sufferers. There are not many reasons for io to target this market, but among them are poor preventative medications. People with chronic headaches have severe quality of life issues and would gratefully try any therapy that would help them.

10.4.2 Hypertension

There are highly effective drug therapies in the antihypertensive market and in fact many patients are prescribed combinations of drugs. The treatments are not greatly expensive averaging approximately \$800 year for a potentially lifesaving and life extending treatment. Hypertension is life threatening and often called a silent killer. If io markets its technology as a treatment for hypertension it should consider that people will die regardless of the efficacy of io's product due to direct link of hypertension to heart attack and stroke and the multiple other factors required for treatment such as behavioural and lifestyle changes. This may create legal and regulatory costs for io.

10.5 Recommendations

Upon completion of the Mayo Clinic trials, io should rank their efficacy data on a 1-10 point scale and enter it into the balanced scorecard spreadsheet that will be provided with this market analysis. This may affect the rankings of the current treatment areas. In the cases of extreme efficacy (high or low) io may wish to re-evaluate the scorecard. The

scorecard was designed to differentiate between markets where the efficacy for different treatment areas is relatively similar.

Currently, chemotherapy-induced anemia appears to be the most attractive beachhead market for io. If the efficacy data is good for chemotherapy-induced anemia, io should begin to consider their strategic position in this area. Due to the entrenchment of large pharmaceutical companies, such as Amgen, in this market, io management may wish to consider a partnership with one of these companies, if io's treatment will be complimentary to the pharmaceutical treatment. However, if the treatment will be a competitive therapy with the current pharmaceutical treatments, io can look to partner with hospitals, physicians and cancer treatment centres. Currently, pre-chemotherapy treatment is an underserved/unserved market and io may be able to create a niche.

As shown in Section 8, obesity has a major effect on a number of different disease states. During clinical trials, io should gather data on any impact on patient obesity and/or BMI. Before entering a treatment area, io should conduct another, more focused, analysis on potential partnerships, market entry strategy, financial requirements, FDA approval, in-depth competitor analysis, and human resource requirements needed to help a successful product launch. io has a number of excellent options for a beachhead market with a number of viable secondary markets into which they can expand.

APPENDICES

- A. Medical Device Classification
- B. Scorecard Results
- C. Additional Scorecard Questions
- D. Scorecard Raw Data
- E. Scorecard Scoring System
- F. Scorecard Assumptions

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APPENDIX A: MEDICAL DEVICE CLASSIFICATION

Taken directly from the FDA website – ("Is The Product A Medical Device?," 2002)

Medical Device Definition

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers. If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and postmarketing regulatory controls. A device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Class I - General Controls

Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Class I devices are subject to "General Controls" as are Class II and Class III devices.

General controls include:

1. Establishment Registration (use FDA Form 2891) of companies which are required to register under 21 CFR Part 807.20, such as manufacturers,

distributors, repackages and relabelers. Foreign establishments, however, are not required to register their establishments with FDA.

2. Medical Device Listing (use FDA Form 2892) with FDA of devices to be marketed.
3. Manufacturing devices in accordance with Good Manufacturing Practices (GMP) in 21 CFR Part 820.
4. Labeling devices in accordance with labeling regulations in 21 CFR Part 801 or 809.
5. Submission of a *premarket notification [510(k)]* before marketing a device.

Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Most Class I devices are exempt from the premarket notification and/or good manufacturing practices regulation. Information on Class I exempt devices is located under the heading

Class II - Special Controls

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls.

A few Class II devices are exempt from the premarket notification.

Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance.

Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

Class III - Premarket Approval

Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls.

Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Premarket approval is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Not all Class III devices require an approved premarket approval application to be marketed. Class III devices which are equivalent to devices legally marketed before May 28, 1976 may be marketed through the premarket

notification [510(k)] process until FDA has published a requirement for manufacturers of that generic type of device to submit premarket approval data.

Class III devices which require an approved premarket approval application to be marketed are those:

1. regulated as new drugs prior to May 28, 1976, also called transitional devices.
2. devices found not substantially equivalent to devices marketed prior to May 28, 1976.
3. Class III preamendment devices which, by regulation in 21 CFR, require a premarket approval application.

Examples of Class III devices which require a premarket approval include replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

Class III devices which can be marketed with a premarket notification 510(k) are those:

- postamendment (i.e., introduced to the U.S. market *after* May 28, 1976) Class III devices which are substantially equivalent to preamendment (i.e., introduced to the U.S. market *before* May 28, 1976) Class III devices and for which the regulation calling for the premarket approval application has not been published in 21 CFR.

Examples of Class III devices which currently require a premarket notification include implantable pacemaker pulse generators and endosseous implants.

Classifications of Medical Devices Similar to io's Treatment

PART 868 -- ANESTHESIOLOGY DEVICES

Subpart C--Monitoring Devices

Sec. 868.2377 Apnea monitor.

(a) *Identification.* An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor also includes indirect methods of apnea detection such as monitoring of heart rate and other physiological parameters linked to the presence or absence of adequate respiration.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA."

[67 FR 46852, July 17, 2002]

PART 868 -- ANESTHESIOLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 868.5570 Nonrebreathing mask.

(a) *Identification.* A nonrebreathing mask is a device fitting over a patient's face to administer oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38795, July 25, 2001]

PART 868 -- ANESTHESIOLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 868.5470 Hyperbaric chamber.

(a) *Identification.* A hyperbaric chamber is a device that is intended to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure. This device does not include topical oxygen chambers for extremities (878.5650).

(b) *Classification.* Class II (performance standards).

APPENDIX B: SCORECARD RESULTS

Scorecard Summary

Number	Item	Value (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
1	Potential profitability	20.00%	1.12	0.77	0.48	0.49	0.64	1.19	1.22
2	Adoption risk	10.00%	0.70	0.40	0.70	0.31	0.52	0.90	0.10
3	Approval risk	15.00%	0.80	0.65	1.28	0.99	1.10	1.28	0.78
4	Competition level	5.00%	0.28	0.34	0.32	0.09	0.30	0.35	0.26
5	Fit with io's values	15.00%	0.96	1.16	1.01	0.95	1.15	1.13	0.99
6	Customer Perception (Alternative or Mainstream)	10.00%	0.41	0.82	0.45	0.45	0.45	0.45	0.23
7	Customer Convenience	5.00%	0.29	0.38	0.38	0.38	0.44	0.38	0.30
8	Efficacy of io's treatment*	20.00%	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		100.00%	4.56	4.51	4.61	3.65	4.59	5.67	3.88

* to be added by io upon completion of trials

Scorecard Sub-metrics

Potential Profitability will be based on:	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Market Size (\$/year)	45.00%	4.50	0.34	0.53	0.48	0.64	2.48	4.44
Market Growth (%/year)	30.00%	0.30	3.00	0.90	0.30	0.30	3.00	0.60
Prevalence (% of population)	20.00%	0.44	0.30	0.61	1.52	2.00	0.02	1.03
Cost to Enter	5.00%	0.35	0.20	0.35	0.16	0.26	0.45	0.05
	100.00%	5.59	3.85	2.39	2.45	3.20	5.95	6.12
Adoption Risk will be based on:	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Alternative, Complimentary or new therapy adoption (%)	100.00%	7.00	4.00	7.00	3.10	5.20	9.00	1.00
Approval Risk will be based on:	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
If the device will be required to be Class I or Class II device	60.00%	3.00	3.00	6.00	6.00	6.00	6.00	3.00
Demographic (age ranges of population that will be receiving treatment)	40.00%	2.36	1.35	2.52	0.60	1.32	2.52	2.20
	100.00%	5.36	4.35	8.52	6.60	7.32	8.52	5.20
Competition Level will be based on:	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Number of mainstream competitors	35.00%	2.10	2.45	2.45	0.00	2.10	2.10	2.80
Number of alternative competitors	10.00%	0.00	0.60	0.70	0.50	0.70	0.00	0.30
Market share held by the largest competitor	20.00%	0.66	0.98	1.60	0.20	0.58	1.76	0.26
Yearly cost of competitive treatment	25.00%	2.50	2.33	1.18	0.69	1.53	2.18	1.37
Efficacy (or perceived efficacy) of competitive treatment	10.00%	0.40	0.43	0.46	0.49	1.00	0.88	0.50
	100.00%	5.66	6.79	6.39	1.88	5.91	6.92	5.23

Io's values: How does io value	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Potential Sales Revenue	45.00%	3.15	2.25	2.25	1.80	3.15	3.15	4.50
Saving lives	10.00%	1.00	1.00	0.00	0.00	0.00	1.00	1.00
Improving quality of life	45.00%	2.25	4.50	4.50	4.50	4.50	3.38	1.13
	100.00%	6.40	7.75	6.75	6.30	7.65	7.53	6.63
Customer Perception: will customers view io's treatment as:	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
Mainstream vs Alternative	55.00%	1.83	3.66	0.00	0.00	0.00	0.00	0.00
Compete vs Compliment	45.00%	2.25	4.50	4.50	4.50	4.50	4.50	2.25
	100.00%	4.08	8.16	4.50	4.50	4.50	4.50	2.25
Customer Convenience will be based on:	Weighting (%)	Asthma	Apnea	Insomnia	Headache	Obesity	Chemotherapy	Hypertension
How often does a customer have to take a treatment	40.00%	4.00	4.00	4.00	4.00	4.00	4.00	4.00
Travel to receive a treatment	25.00%	0.00	0.00	0.00	0.00	1.25	0.00	0.00
How uncomfortable is the treatment	15.00%	0.75	1.50	1.50	1.50	1.50	1.50	0.00
What are the side effects of a treatment	20.00%	1.00	2.00	2.00	2.00	2.00	2.00	2.00
	100.00%	5.75	7.50	7.50	7.50	8.75	7.50	6.00

APPENDIX C: ADDITIONAL SCORECARD QUESTIONS AND ANSWERS

Other Questions:

1. Is there a market size that would be too small or too large to enter? (Y/N)
 - a. If yes, please provide values/range
2. Will io want to enter the market with a large partner or partner on a case to case basis?
3. Does age range of treatment population matter to you? (Y/N)
4. Are you interested in treating children? (Y/N)
5. Are you interested in treating elderly? (Y/N)
6. Do you want your treatment to be viewed as mainstream (similar to the doctor prescribed treatments)? (Y/N)
7. Do you want your treatment to be viewed as alternative (similar to yoga or acupuncture)? (Y/N)
8. Has io explored patent protection in any of these treatment areas? (Y/N)
9. Are there other items that you would base your decision to enter a treatment area on? (Y/N)

If yes, please suggest a metric

io Answers:

1. Is there a market size that would be too small or too large to enter? (N)
2. Will io want to enter the market with a large partner or partner on a case to case basis? (This will depend on the market)
3. Does age range of treatment population matter to you? (Y)
4. Are you interested in treating children? (Y)
5. Are you interested in treating elderly? (Y/N)
6. Do you want your treatment to be viewed as mainstream (similar to the doctor prescribed treatments)? (Y/)
7. Do you want your treatment to be viewed as alternative (similar to yoga or acupuncture)? (N)
8. Has io explored patent protection in any of these treatment areas? (N)
9. Are there other items that you would base your decision to enter a treatment area on? (Y)

If yes, please suggest a metric – Are there treatment areas that the government is focusing special programs on to help treat (ex. Obesity)

APPENDIX D: SCORECARD RAW DATA

Area	Sub-metrics	Asthma Score	Asthma Raw Data	Apnea Score	Apnea Raw Data
Potential Profitability	Market Size (\$ million/year)	10	\$14,153	0.76	\$1,066
	Market Growth (% pop/year)	1	1%	10	15%
	Prevalence (% of US population)	2.2	7.33%	1.5	5%
Adoption Risk	Alternative, Complimentary or new therapy adoption (%)	7.0	7%	4	4%
Approval Risk :	If the device will be required to be Class I or Class II device	5	Class II	5	Class II
	Demographic (% adults * 10)	5.9	11.8 million/20	3.375	4.05/12
Competition Level	Number of mainstream competitors (~10% market share or greater)	6	4	7	3
	Number of alternative competitors	0	11	6	4
	Market share held by the largest competitor	3.3	33%	4.9	49%
	Yearly cost of competitive treatment	10	\$1,522	9.3	\$1,419.51
	Efficacy (or perceived efficacy) of competitive treatment	4	60%	4.3	81% but only 50% compliance (CPAP) = 57%
Io's values	Potential Sales Revenue - total market size/# comp	7	3538	5	355.33
	Saving lives	10		10	
	Is it a life threatening condition (y/n)		Y		Y
	Could io treatment save lives in this (y/n)		Y		Y

	Improving quality of life	5		10	
	Is this disease affecting day to day quality of life (y/n)		Y		Y
	Do people who are using the treatments have a low quality of life (y/n)		N		Y
	Does this reduce the number of treatments that a patients need (burden of disease) (y/n)		Y		Y
	There are high number of side effects of current treatment (y/n)		N		Y
Customer Perception	Mainstream vs.. Alternative	3.33		6.66	
	Are other mainstream mechanical (y/n)		N		Y
	Is channel the same (y/n)		Y		N
	Similar number of treatments (y/n)		N		N - io better
	Competative vs. Complimentary	5		10	
	Would a customer stop using the other treatments (y/n)		N		Y
	Would customer reduce their use of other treatments (y/n)		Y		Y
Customer Convenience	How often does a customer have to take a treatment (advantage to -)	10	io	10	io
	Travel to receive a treatment (advantage to -)	0	Incumbent	0	Incumbent
	How uncomfortable is the treatment	5	neutral	10	io
	What are the side effects of a treatment (advantage to -)	5	neutral	10	io
Area	Sub-metrics	Insomnia Score	Insomnia Raw Data	Headache Score	Headache Raw Data
Potential Profitability	Market Size (\$ million/year)	1.18	1.65 billion	1.07	1.5 billion
	Market Growth (% pop/year)	3	2.70%	1	0.89%
	Prevalence (% of US population)	3	10%	7.6	25%
Adoption Risk	Alternative, Complimentary or new therapy adoption (%)	7	7%	3.1	3.08%
Approval Risk :	If the device will be required to be Class I or Class II device	10	Class I	10	Class I
	Demographic (% adults * 10)	6.3	6.30%	1.5	15.75%

Competition Level	Number of mainstream competitors (~10% market share or greater)	7	3	0	11
	Number of alternative competitors	7	3	5	5
	Market share held by the largest competitor	8	80%	1	10%
	Yearly cost of competitive treatment	4.7	\$717.23	2.7	\$417.82
	Efficacy (or perceived efficacy) of competitive treatment	4.6	64%	4.9	51%
Io's values	Potential Sales Revenue - total market size/# comp	5	550	4	136.36
	Saving lives	0		0	
	Is it a life threatening condition (y/n)		N		N
	Could io treatment save lives in this (y/n)		N		N
	Improving quality of life	10		10	
	Is this disease affecting day to day quality of life (y/n)		Y		Y
	Do people who are using the treatments have a low quality of life (y/n)		Y		Y
	Does this reduce the number of treatments that a patients need (burden of disease) (y/n)		Y		Y
	There are high number of side effects of current treatment (y/n)		Y		Y
Customer Perception	Mainstream vs.. Alternative	0		0	
	Are other mainstream mechanical (y/n)		N		N
	Is channel the same (y/n)		N		N
	Similar number of treatments (y/n)		N		N
	Competative vs. Complimentary	10		10	
	Would a customer stop using the other treatments (y/n)		Y		Y
	Would customer reduce their use of other treatments (y/n)		Y		Y
Customer Convenience	How often does a customer have to take a treatment (advantage to -)	10	io	10	io
	Travel to receive a treatment (advantage to -)	0	Incumbent	0	Incumbent
	How uncomfortable is the treatment	10	io	10	io
	What are the side effects of a treatment (advantage to -)	10	io	10	io

Area	Sub-metrics	Obesity Score	Obesity Raw Data	Anemia Score	Anemia Raw Data
Potential Profitability	Market Size (\$ million/year)	1.43	~2 billion (drugs, surgery, WW)	5.51	7.71 billion
	Market Growth (% pop/year)	1	0.89%	10	12.80%
	Prevalence (% of US population)	10	33%	0.1	0.3098%
Adoption Risk	Alternative, Complimentary or new therapy adoption (%)	5.2	took avg. of all other scores	9	9.00%
Approval Risk :	If the device will be required to be Class I or Class II device	10	Class I	10	Class I
	Demographic (% adults * 10)	3.3	33%	6.3	63%
Competition Level	Number of mainstream competitors (~10% market share or greater)	6	4	6	4
	Number of alternative competitors	7	3	0	12
	Market share held by the largest competitor	2.9	29%	8.8	88%
	Yearly cost of competitive treatment	6.1	\$932.61	8.7	\$1,324.59
	Efficacy (or perceived efficacy) of competitive treatment	9.97	2.80%	8.8	22%
Io's values	Potential Sales Revenue - total market size/# comp	7	2087.5	7	1927.5
	Saving lives	0		10	
	Is it a life threatening condition (y/n)		N		Y
	Could io treatment save lives in this (y/n)		N		Y
	Improving quality of life	10		7.5	
	Is this disease affecting day to day quality of life (y/n)		Y		Y
	Do people who are using the treatments have a low quality of life (y/n)		Y		Y
	Does this reduce the number of treatments that a patients need (burden of disease) (y/n)		Y		Y

	There are high number of side effects of current treatment (y/n)		Y		N
Customer Perception	Mainstream vs.. Alternative	0		0	
	Are other mainstream mechanical (y/n)		N		N
	Is channel the same (y/n)		N		N
	Similar number of treatments (y/n)		N		N
	Competative vs. Complimentary	10		10	
	Would a customer stop using the other treatments (y/n)		Y		Y
	Would customer reduce their use of other treatments (y/n)		Y		Y
Customer Convenience	How often does a customer have to take a treatment (advantage to -)	10	io	10	io
	Travel to receive a treatment (advantage to -)	5	neutral	0	incumbent
	How uncomfortable is the treatment	10	io	10	io
	What are the side effects of a treatment (advantage to -)	10	io	10	io
Area	Sub-metrics		Hypertension Score		Hypertension Raw Data
Potential Profitability	Market Size (\$ million/year)		9.86		13.8 billion (60% of global market=US)
	Market Growth (% pop/year)		2		1.90%
	Prevalence (% of US population)		5.2		17%
Adoption Risk	Alternative, Complimentary or new therapy adoption (%)		1		1%
Approval Risk :	If the device will be required to be Class I or Class II device		5		Class II
	Demographic (% adults * 10)		5.5		54.70%
Competition Level	Number of mainstream competitors (~10% market share or greater)		8		2
	Number of alternative competitors		3		7
	Market share held by the largest competitor		1.3		13%
	Yearly cost of competitive treatment		5.5		\$834.54
	Efficacy (or perceived efficacy) of competitive treatment		5		50.20%

Io's values	Potential Sales Revenue - total market size/# comp	10	115500
	Saving lives	10	
	Is it a life threatening condition (y/n)		Y
	Could io treatment save lives in this (y/n)		Y
	Improving quality of life	2.5	
	Is this disease affecting day to day quality of life (y/n)		N
	Do people who are using the treatments have a low quality of life (y/n)		N
	Does this reduce the number of treatments that a patients need (burden of disease) (y/n)		N
	There are high number of side effects of current treatment (y/n)		Y
Customer Perception	Mainstream vs.. Alternative	0	
	Are other mainstream mechanical (y/n)		N
	Is channel the same (y/n)		N
	Similar number of treatments (y/n)		N
	Competative vs. Complimentary	5	
	Would a customer stop using the other treatments (y/n)		N
	Would customer reduce their use of other treatments (y/n)		Y
Customer Convenience	How often does a customer have to take a treatment (advantage to -)	10	io
	Travel to receive a treatment (advantage to -)	0	incumbent
	How uncomfortable is the treatment	0	incumbent
	What are the side effects of a treatment (advantage to -)	10	io

APPENDIX E: SCORECARD SCORING SYSTEM

- All scores will be based 1-10 so that they can be equally weighted amongst sub metrics.
- All raw data and references in appendix
- **Potential Profitability**
 - Market size in billions of dollars per year
 - Highest value = 10, all others scored as a % of the highest value and converted to 10 point scale (e.g. 50% = 5)
 - Market growth in % population increase per year
 - All % transformed into raw score and multiplied by 10 (e.g. 15% = .15 = 1.5)
 - Prevalence (% of US population with disease)
 - Highest value = 10, all others scored as a % of the highest value and converted to 10 point scale (e.g. 50% = 5)
- **Adoption Risk**
 - Alternative, Complimentary or new therapy adoption
 - % adoption rate converted into 10 point scale directly as all scores were under 10% (e.g. 5% = 5)
- **Approval Risk**
 - Class 1 or 2
 - (Class 1 gets 10 points, Class 2 gets 5) because class II requires more FDA oversight
 - Demographic
 - % of adults out of the total disease population who have the disease is the score out of 10
- **Competition**
 - Competitors
 - Number of significant mainstream competitors (>10% market share)
 - # of competitors, reverse scored because fewer competitors are better
 - Total number of alternative competitors across all treatment areas
 - # of competitors, reverse scored because fewer competitors are better
 - Market share of largest competitor
 - Highest value = 10, all others scored as a % of the highest value and converted to 10 point scale (e.g. 50% = 5)
 - Yearly cost of competitive treatment
 - Based on cost efficacy graphs – see appendices
 - Average yearly treatment cost
 - Highest value = 10, all others scored as a % of the highest value and converted to 10 point scale (e.g. 50% = 5)

- Efficacy of competitive treatment
 - Based off of cost efficacy graphs – see appendices
 - All % transformed into raw score and multiplied by 10 (e.g. 15% = .15 = 1.5)
- **Values**
 - Potential Sales Revenue
 - Total market size/number of competitors
 - Highest value = 10, all others scored as a % of the highest value and converted to 10 point scale (e.g. 50% = 5)
 - Saving lives (0Y = 0, 1Y = 5, 2Y = 10)
 - Is it a life threatening condition (y/n)
 - Could io treatment save lives in this (y/n)
 - Quality of life (yes is good for io) (1 Y = 2.5 – 4 Y = 10)
 - Is this disease affecting day to day quality of life (y/n)
 - Do people who are using the treatments have a low quality of life (y/n)
 - Does this reduce the number of treatments that a patients need (burden of disease) (y/n)
 - There are high number of side effects of current treatment (y/n)
- **Customer perception**
 - Mainstream therapy vs. Alternative – prescribed by doctors, high score is more mainstream (1 Y = 3.33, 2 Y = 6.66, 3 Y = 10)
 - Are other mainstream mechanical (y/n)
 - Is channel the same (y/n)
 - Similar number of treatments (y/n) – to be coded Y if io is perceived to be better value than the currently available options
 - Competitive vs. Complimentary - high score is more competitive (0Y = 0, 1Y = 5, 2Y = 10)
 - Would a customer stop using the other treatments (y/n)
 - Would customer reduce their use of other treatments (y/n)
- **Customer Convenience*** (who has advantage? Io = 10, neutral = 5, Incumbent = 10)
 - How often does someone have to use the treatment
 - Travel is it required (y/n) high score if also have to travel to treatment
 - Discomfort (is the treatment uncomfortable) y/n
 - Side effects y/n

* Scorecard includes only chronic treatments, permanent solutions are not being considered because customers who choose this route will no longer need any treatment including io's (ex UPPP for sleep apnea)

APPENDIX F: SCORECARD ASSUMPTIONS

- Asthma
 - Yearly cost of competitive treatment (average) excludes Zolar. The cost of Zolar is significantly higher than all other treatments. Despite its small market share, it increased the average cost of treatment beyond what the average user would expect to pay.
- Apnea
 - Growth in the sleep apnea market is based on new cases being diagnosed. The prevalence in the population may be rising due to age and obesity, but most of this increase comes from new awareness of the disease.
 - UPPP and Pillar were included in the average cost analysis as well as CPAP. The surgical interventions are not significantly more expensive than high end CPAP machines, but may be considered a “cure” for many patients.
 - For effectiveness of competitor treatment, CPAP effectiveness was reduced by 50% to account for the individual who abandon the device or use it sporadically.
- Insomnia
 - The cost for insomnia drugs assumes 7 day usage, 365 days a year. This may overestimate the actual cost for most users. This better represents the chronic insomnia market
- Headache
 - The number of competitors in the market is difficult to determine. There are many generic manufacturers producing the same drugs. The number of competitor only includes preventative treatment providers. Acute treatments were excluded from the analysis.
- Obesity
 - Obesity market size excludes costs associated with co-morbid conditions. The analysis only considered the pharmaceutical, surgical and diet market. The diet market was estimated using Weight Watchers, as the market leader. This may underestimate the total size of the market if it were to include all diet programs, books and exercise equipment.
- Chemotherapy
 - Only chemotherapy induced anemia was considered in the analysis.
 - The adoption rate for alternative therapies only included herbal supplements. Other alternative therapies were related specifically to cancer, and not anemia.
- Hypertension
 - US hypertension market size was unavailable. The number used was calculated based on 60% of the global hypertension market. The choice of 60% was based on the global distribution of drug sales for asthma drugs.