# AUTOMATED ANIMAL HIGH THROUGHPUT SCREENING MODEL FOR ANTI EPILEPSY DRUGS

**by**

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# APPROVAL

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# ABSTRACT

This work is a business plan to evaluate an anti-epilepsy drug development technology that has commercial potential to be used as a high throughput screening method. Epilepsy is such a prevalent neurological disorder that it affects over 1% of the general population worldwide. The anti-epilepsy drug (AED) market is in its steady growth along with the high throughput screening (HTS) market, as many biotech and pharmaceutical companies take a disintegrated value chain approach in order to capture more value during the drug development process, which could take over 10 years and cost up to $1 billion. After extensive market research and financial analyses, it is found that the technology could spawn a business that could generate $15 million per year with an outstanding IRR of 72% for the first wave of investors.

**Keywords:** (AED, epilepsy, High Throughput Screening, Technology, Valuation).

**Subject Terms:** Business Plan

# EXECUTIVE SUMMARY

C-Motions' breakthrough anti-epilepsy drug high throughput screening technology is likely to produce rapid growth of shareholder value, leveraging a small amount of equity capital to grow by $15M/year, and the company is likely to become a highly profitable business within six years with an exceptionally high net margin of 32%. C-Motions' business has outstanding characteristics:

- An exclusive $200 million potential world market, currently underpenetrated due to the limitation of existing technologies that C-Motions' Anti Epilepsy Drug (AED) High Throughput Screening (HTS) service overcomes.
- A well fitted, compelling solution to the high cost of the AED development by biotech and pharmaceutical companies worldwide.
- Capable management team combining scientific, engineering and business expertise.
- Easily targeted major customers in the biotech industry with a history of early technology adoption.
- Potential of generating recurring revenues from high-margin sales, and resulting high-volume sales of the consumables from the next generation of product development.
- Small capital requirements relative to market size.
- Potential for profitable exit through sale of company or IPO within seven years.

C-Motions' technology will focus on solving a high cost problem for biotech and pharmaceutical companies during drug development. A rodent model is a gold standard for testing toxicity and efficacy of a potential AED candidate. A rat or a mouse is prepared for up to two weeks to induce epileptic seizure in the animal. In order to test the

candidate drug, a researcher or technician would inject the drug candidate into the prepared animal each time, following extensive monitoring of its behaviours. Due to required person-hours and before/after-cares for the animals used, the model is extensively used only in the later stage of the AED development during the preclinical drug development stage. On the other hand, HTS, a new innovative way to develop potential drug candidates with the least amount of time and resource, is capable of selecting candidate drugs in the early stage of the preclinical drug development. C-Motions' technology exploits the potential gap between the *in vitro* (existing HTS) and *in vivo* (animal model) stages of the AED development, allowing an early stage animal HTS to measure the efficacy and toxicity of AED candidates. C-Motions' management team is bound to bridge the current industry gap between the demands and technology, and build a $15M/year business within six years.

More than 600 million people worldwide have been or will be diagnosed with epilepsy in their lifetimes, which imposes a burden of $25 billion/year on the health care system in the US alone. Each year, biotech and pharmaceutical companies worldwide spend over $77B for new drug R&D in total, with the amount of bringing a new generation of AEDs reaching conservatively $500M/year. C-Motions' technology can expedite these AED discovery efforts by biotech and pharmaceutical companies, providing a fast, reliable and a new golden standard, appropriate for use by both biotech and pharmaceutical companies, as well as by contract research organizations (CROs).

C-Motions' initial strategy will focus on adoption of its technology by taking on a CRO business model, which appeals to potential customers who are actively looking for ways to save the AED development cost while pursuing quality R&D. C-Motions'

business model also allows the potential customers an easier entry to the AED HTS as they can pay for the company's service without purchasing a potentially costly platform for their budgets. Meantime, because C-Motions sells mostly data and information without incurring significant cost-of-goods-sold, the sales of the service will bring the company an exceptionally high net margin of 32%.

C-Motions' marketing will focus on key opinion leaders within the fields of the AED development community in order to gain respected industry referrals. These influences will push other biotech and pharmaceutical companies to use C-Motions' services, while the company's dedicated direct sales force team will target these customers in multiple approaches by visiting and/or calling them as well as attending relevant conferences to promote and facilitate adoption of the technology. Once significant market penetration has been achieved, C-Motions will seek a partnership with a major biotech or pharmaceutical company to provide a tailored AED HTS for the partnered company. That could lead the vertical integration of C-Motions' AED HTS Platform through M&A as an early exit option. Another possible scenario would be development of the AED HTS platform that can be sold to biotech and pharmaceutical companies who wish to operate the AED HTS in-house. In that case, C-Motions will adopt a 'razor-blade' strategy by selling consumables that allows capturing value for both the customers and C-Motions.

Currently C-Motions seeks $500K seed investment to fund product development. Two subsequent venture rounds of $1.5M and $2.5M will fund commercialization and marketing of the technology. C-Motions offers a unique opportunity to the investors, who would like to enjoy an outstanding 72% IRR from a projected service and product

sales with liquidity within six years. The company is looking for sophisticated, experienced investors to join this opportunity.

# DEDICATION

I am dedicating this work to my wife, Keiko, and our daughter, Sujin Sana, who has been motivating me even before she was born.

# ACKNOWLEDGEMENTS

The author would like to thank Mr. Hewapathirane and Mr. Sakaki for their collaboration on this project. Big thanks go to his project supervisors Dr. Pek-Hooi Soh and Dr. Sudheer Gupta for offering the author their advices and guidance to complete this project. Mr. Leo Oppenheimer and Ms. Lisa Werner are also thanked for their kind help and thorough suggestions, despite their busy schedules. In addition, the author would like to acknowledge the BC Innovation Council for awarding the ACE scholarship that has partially provided the basis for this project.

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# GLOSSARY

| | |
|---|---|
| ADME/Tox | Absorption, Distribution, Metabolism, Excretion and Toxicity |
| AED | Anti Epilepsy Drug |
| Anteromesial | A part of the brain where groups of neurons are located in complex vertebrates, including humans; the anteromesial temporal lobe is also known as amygdale |
| CEO | Chief Executive Officer |
| cGLP | Current Good Laboratory Practices |
| COO | Chief Operations Officer |
| Corpus callosotomy | A surgical procedure that disconnects the cerebral hemispheres, which splits the left and right parts of the brain |
| CRO | Contract Research Organization |
| CSO | Chief Scientific Officer |
| CTO | Chief Technology Officer |
| EBITDA | Earnings Before Interest, Taxes, Depreciation and Amortization |
| Efficacy | Ability to bring a desired effect |
| Electrography | A process of using chemically induced electric current to produce images and signals |
| Epileptiform | A stage that resembles epilepsy or its manifestations, such as seizures |
| FDA | The US Food and Drug Administration |
| Gold standard | In medical science, it is a test or a procedure that is considered definitive |

| | |
|---|---|
| Hepatotoxicity | Degree of destructiveness to the liver |
| Hit-to-candidate | Drug development process that uses iterations between chemistry and biology to find a right drug candidate |
| HTS | High Throughput Screening |
| *In silico* | Through computer based calculations or simulations |
| *In vitro* | Through a controlled environment outside of a living organism (e.g. in a test tube) |
| *In vivo* | Through a living organism |
| Intravenous | Within a vein |
| IPO | Initial Public Offering |
| IRR | Internal Rate of Return |
| Lesionectomy | An operation to remove a lesion – a damaged or abnormally functioning area – in the brain |
| Liquidity | Ability to sell/buy an asset with causing a significant change in the price or value |
| Lobotomy | A medical procedure involving incision into a lobe |
| LT | Long Term |
| LTM | Last Twelve Months |
| M&A | Merger and Acquisition |
| Monotherapy | A therapy that consists of only one drug |
| Neonate | A newborn infant (usually less than four weeks old) |
| Neurotherapeutics | Therapeutic treatments for psychological, psychiatric, and nervous disorders |
| NMEs | New Molecular Entities |
| NPV | Net Present Value |

| | |
|---|---|
| Pharmacodynamics | A study of what a drug can do to an organism |
| Pharmacokinetics | A study of what an organism can do to a drug |
| PhRMA | The Pharmaceutical Research and Manufacturers of America |
| Pre-clinical | Before clinical studies in drug development |
| *Pro forma* | Latin: as a matter of form; in business, a *pro forma* document shows actual transactions |
| PTZ | Pentylenetetrazol |
| PV | Present Value |
| R&D | Research and Development |
| ROA | Return On Assets |
| ROE | Return On Equity |
| S&T | Science and Technology |
| SOP | Standard Operating Procedure |
| SR & ED | Scientific Research & Experimental Development |
| Subpial transection | A surgical procedure that involves a series of shallow cuts in the brain tissue in order to control neurological disorders, especially epilepsy |
| SWOT | Strength-Weakness-Opportunity-Threat |
| Temporal | A part of the brain that is involved in speech, memory, and hearing functions |
| Tolerability | A degree to which an exposed organism can resist a drug |
| Toxicity | A degree to which a drug can damage an exposed organism |
| UILO | University Industry Liaison Office |
| Vagus Nerve Stimulation (VNS) | VNS is a treatment for certain types of epilepsy and depression. It uses a stimulator that sends electric impulses to the left vagus nerve n the neck via an implanted electrode under the skin |

| | |
|---|---|
| VP | Vice President |

# 1: THE ANTI EPILEPSY DRUG INDUSTRY

## 1.1 What is Epilepsy?

Epilepsy is a common brain disorder that affects an estimated 1-2% of the general population, and is the second most common serious neurological condition in the United States after stroke. Epilepsy imposes an annual economic burden of approximately $25 billion in the US, mainly due to health care costs and lost productivity. According to the National Institute of Neurological Disorders and Stroke, it is important to begin treatment as soon as possible after diagnosis of epilepsy.[1] With help of modern medicine and surgical techniques, for about 80 percent of the patients, epileptic seizures can be managed. Left untreated, however, the disease can cause significant morbidity and even mortality.

In recent years, epilepsy has become highly treatable with the advent of modern medicines. Epilepsy has received a great deal of attention from the health sector and related industries because:

- Epilepsy is such a common disease
- It is a very misunderstood disease despite its common occurrence
- The social impacts of the disease on its victims are significant.

[1] http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm

As a result, the drug, diagnostics, and surgical operations industries have been rapidly moving forward to treat (and ultimately cure) the affected in order to bring a better quality of life.

## 1.2 Available Epilepsy Treatments

### 1.2.1 Anti Epilepsy Drug Treatment

Epilepsy is not a disease that can be cured solely using pharmacologic approaches at this moment. Therefore, the main objective of drug therapy for epilepsy has been, and is going to be (for a while), to control the frequency and severity of epileptic seizures. Since the critical mechanism of epilepsy has not been fully understood so far, each patient must often undergo extensive period of drug and dose adjustment to find the proper therapeutic regimen.

Table 1-1 shows commonly used anti epilepsy drugs (AEDs) in the market. According to market research[2], *Topamax* was the leading epilepsy drug in 2005 with sales of US$1.7 billion followed by *Lamictal* and *Depakote*. However, all three AEDs became generic as of 2008, which reduced sales revenues drastically (more updated details are in Chapter 4). To date, no large-scale clinical studies have been conducted to establish superiority of the available drugs in the market including older drugs used by the health practitioners. In addition, many commercially available drugs have been introduced since the 90s, indicating there are unmet needs for advanced treatment for the epilepsy patients.

[2] "CNS Market Trends, 2007 to 2010: Key market forecasts and growth opportunities" by The PharmYard

One of the key issues for a new anti epilepsy drug is the use in neonates and younger children, who require extensive pharmacokinetic, tolerability, and efficacy studies because age is a significant factor in determining anti epilepsy drug toxicity and clearance. For example, children will be less tolerant to hepatotoxicity caused by administration of valproic acid.

Another trend for AED is putting new packages on older drugs with improved dosage regime. For example, carbamazepine and divalproex sodium are now available in time-release controlled formulations, which reduce the numbers of daily doses. Valproic acid is now available as an intravenous preparation to increase its efficacy.

**Table 1-1 Commonly Used AEDs in the Market**

| Drug | Brand Name(s) | Company |
|---|---|---|
| Carbamazepine | Carbatrol® | Shire US |
| | Tegretol® | Novartis |
| Divalproex | Depakote® | Abbott |
| Felbamate | Felbatol® | Wallace |
| Gabapentin | Neurontin® | Pfizer |
| Lamotrigine | Lamictal® | GlaxoSmithKline |
| Levetiracetam | Keppra® | USB |
| Oxcarbazepine | Trileptal® | Novartis |
| Phenytoin Sodium | Dilantin® | Pfizer |
| | generics | Elkins-Sinn |
| | | Mylan |
| Pregabalin | Lyrica® | Pfizer |
| Primidone | Mysoline® | Elan |
| Tiagabine | Gabitril® | Abbott |
| Topiramate | Topamax® | Ortho-McNeil |
| Valproic Acid | Depakene® | Abbott |
| | generics | Watson |
| Zonisamide | Zonegran® | Elan |

### 1.2.2 Surgical Treatment

Although many epilepsy patients opt for drug treatment, surgery remains a potential treatment. Many health practitioners, however, agree that surgery should be considered as a treatment of last resort due to its potential risks involved. In general, a patient must have disabling seizures after being treated with two or more serial monotherapy AEDs, which did not show any improved efficacy after maximum dosages. The probability of monotherapy or combination therapy being effective to this patient group is usually lower than 10% ("Collaborative Group for the Study of Epilepsy", 1992; Kwan & Brodie, 2000).

The various surgical treatments for epilepsy include resection (temporal lobotomy), lesionectomy, subpial transection, corpus callosotomy, and vagus nerve stimulation. Among these treatments, anteromesial temporal lobotomy has been the most commonly performed procedure resulting in approximately 70% success rate. As mentioned, however, all the surgical options bear their risks, which can be irreversible, even life threatening in some cases.

## 1.3 Current Unmet Needs for AEDs

It is a fact that the world needs a better AED that reaches a wider range of patients. Despite advances in the AED research in recent years, approximately 20 to 30% of patients still suffer from epileptic seizures due to limitation of AED treatment. In addition, in developed parts of the world, there are increasing number of epilepsy patients among the elderly, for reasons not fully understood (Sander, 2003). The risk of developing epilepsy is estimated to be 1% from birth to age 20 years; however, the risk increases to 3% at age 75 years. With a significant growth of the aging population in

developed countries, the prevalence of epilepsy will be significantly increasing in the near future. The US AED market alone was $3.2 billion in 2006 with a steady growth rate, indicating that biotech and pharmaceutical companies could contribute to bring a better treatment for epilepsy to the world.

In addition, as of January 31st, 2008, the FDA issued a sobering warning that states that the risk of suicide and suicidal behaviour could double for patients taking AEDs.[3] In the current market, many AEDs are also prescribed for pain and psychiatric illnesses. Some of the drugs are blockbusters such as Lyrica (Pfizer), which sells about $1.2 billion US per year. This indicates that the current market could generate even greater demands for the next generation of AEDs.

[3] U.S. Food and Drug Administration, FDA News, January 31, 2008.

# 2: COMPANY, MANAGEMENT TEAM, AND PRODUCT

## 2.1 Company Description

C-Motions (read as See-Motions) is a Vancouver based biotech platform development and related services company that is developing an innovative drug development platform that will expedite drug development process. C-Motions is currently proving the concept of the AED screening animal model, which will serve as a proprietary AED development platform for biotech and pharmaceutical companies who are actively searching for a better epilepsy treatment. Available methods of testing efficacy of AED require extensive preparations of animals in order to induce chronic epilepsy in the animals. In order to facilitate introduction of the platform, C-Motions will commence a service based business model for the biotech and pharmaceutical companies who are into AED Research and Development (R&D).

## 2.2 Management Team

C-Motions' focused strategy will be executed by a management team with diverse backgrounds in science, engineering and business. The followings are the profiles of the co-founders of C-Motions Biotechnology:

**JS Joseph Lee, PhD** is a co-founder of C-Motions and the current Chief Operating Officer (COO). He received his Ph.D. and held postdoctoral fellowship from the University of British Columbia. He has a variety of experience in different industries before he started his higher education and academic career, including sales, and small

business. In his academic career, his research interests were liquid crystals, controlled drug release, cellulose, molecular sieves, fuel cell and polymeric materials for the chemical industry. Dr. Lee is currently an MBA candidate at Simon Fraser University, specializing in Biotechnology within the Management of Technology program.

**Sesath Hewapathirane** is a co-founder of C-Motions and the current Chief Scientific Officer (CSO). He received his MSc from the University of Toronto in the field of Pharmacology, where he gained extensive exposure to drug development research. He has extensive experience in epilepsy research. Mr. Hewapathirane is currently a PhD candidate under the supervision of Dr. Kurt Haas, who is a leading biomedical researcher in the field of brain diseases, in Neuroscience at the Brain Research Centre, University of British Columbia, working on the verification of the albino *Xenopus laevis* tadpole model for AED candidate screening.

**Kelly Sakaki** is a co-founder of C-Motions and the current Chief Technology Officer (CTO) of the company. He received his MSc from the University of Victoria. Kelly Sakaki is a member of the Laboratory of Applied Control and Biorobotic Systems (LACOBS) under the supervision of Dr. Edward Park. He is currently completing a Ph. D. in Biomedical Engineering through the faculty of Mechanical Engineering. He has a Bachelors Degree in Computer Systems Engineering and a Diploma in Telecommunications Engineering Technology. He has been involved in the mechanical and electrical design of biomedical instruments, and robotics for the past four years, and has recently designed and fabricated the Biological Cell Manipulator (BCM) for the autonomous injection of cells. He has a strong understanding and experience in the

design and development of electromechanical systems, computer vision and significant experience working with cells at the discrete level.

C-Motions is currently seeking inspirational, industry-experienced board members who will guide the company to the next phase of the business venture.

## 2.3 Product Description

Figure 2-1 shows rodent models of chronic epilepsy, which are known as the "gold standard" in AED research. The models require the animals to go under proper care and maintenance following current Good Laboratory Practices (cGLP), not to mention the recurring cost of the animals for a larger group study. Cost of burden extends to the research staff who would prepare the animals, which should add significant overhead cost to the already strenuous R&D budget for a small biotech company. In addition, it takes weeks (14 ~ 30 days) to induce epilepsy in rodent models using chemical triggers, which are still manageable periods but not so desirable while testing efficacy in thousands of potential AED candidates.

C-Motions' AED Screening Platform technology, which uses an albino *Xenopus* tadpole (Figure 2-2) model, can screen efficacy of potential AEDs quickly and accurately using a proprietary visual tracking protocol for the following reasons:

- The cost of the tadpole is a fraction to those of rodent animals, not to mention easy breeding and following maintenance regiments of the species. Usually one breeding colony of a pair of *Xenopus* frogs can produce thousands of tadpoles that are ready in a couple of weeks after hatching from the eggs.

- The growth pattern of the tadpole that exhibits weeks of juvenile period is beneficial to study childhood epilepsies in humans, which are related to the still developing brains.
- Easy preparation and low footwork of the tadpole model allow a high throughput platform, which expedites the AED candidate screening process.
- Seizure induction using chemical triggers in the tadpoles occurs within minutes (as short as 10 minutes) as opposed to weeks in the rodent models.

### 2.3.1 Scientific Basis

It is known that the immature brain is exceptionally susceptible to seizures. The current research of the Haas research group in the UBC Neuroscience Department focuses on a novel *in vivo* model system of developmental seizures based on the transparent albino *Xenopus laevis* tadpole, which allows direct examination of seizure activity, and seizure induced effects on neuronal development within the intact unanesthetized brain. The chemical triggers used are *pentylenetetrazol* (PTZ), *kainic acid, bicuculline, picrotoxin, 4-aminopyridine*, and *pilocarpine*, which are known to induce seizure in tadpoles (Baraban, 2007). All six compounds induce convulsive motions in the tadpoles depending on their dosages, which are typical behaviours in epileptic seizures. A further study (Hewapathirane, Dunfield, Yen, Chen, & Haas, 2008) using PTZ has characterized that the convulsive motions (Figure 2-2) are indeed identical to the epileptiform electrographic responses, which can be stopped by valproate, a commonly used AED in human patients. Detailed description of the experimental procedures and results will be published in a reputable journal (currently in press).

### 2.3.2 Proof of Concept

Currently C-Motions is testing proof of concept in the AED Screening Platform for an automated process using a camera system and in-house developed motion detection software. The current apparatus can capture the tadpoles in motion before and after exposure to PTZ and AEDs. The algorithm for the convulsive motion detection in epileptic seizures of tadpoles is currently under development in the Engineering Department at the University of Victoria.

### 2.3.3 Regulatory Compliance

In order for C-Motions' Platform to be used for drug discovery phase, it must follow current Good Laboratory Practices (cGLP) guidelines. CGLP is a basic quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. C-Motions' Platform should be considered as both testing facility and equipment; the platform will have the capability of following Standard Operating Procedures (SOPs) that are approved by the testing facility management team, have a change control system that reflects Quality Assurance of the research, and be able to indicate identity, strength, purity and composition of each experimental batch.

**Figure 2-1 Typical schematic of the rodent models for the study of chronic epilepsy used in many AED research laboratories**

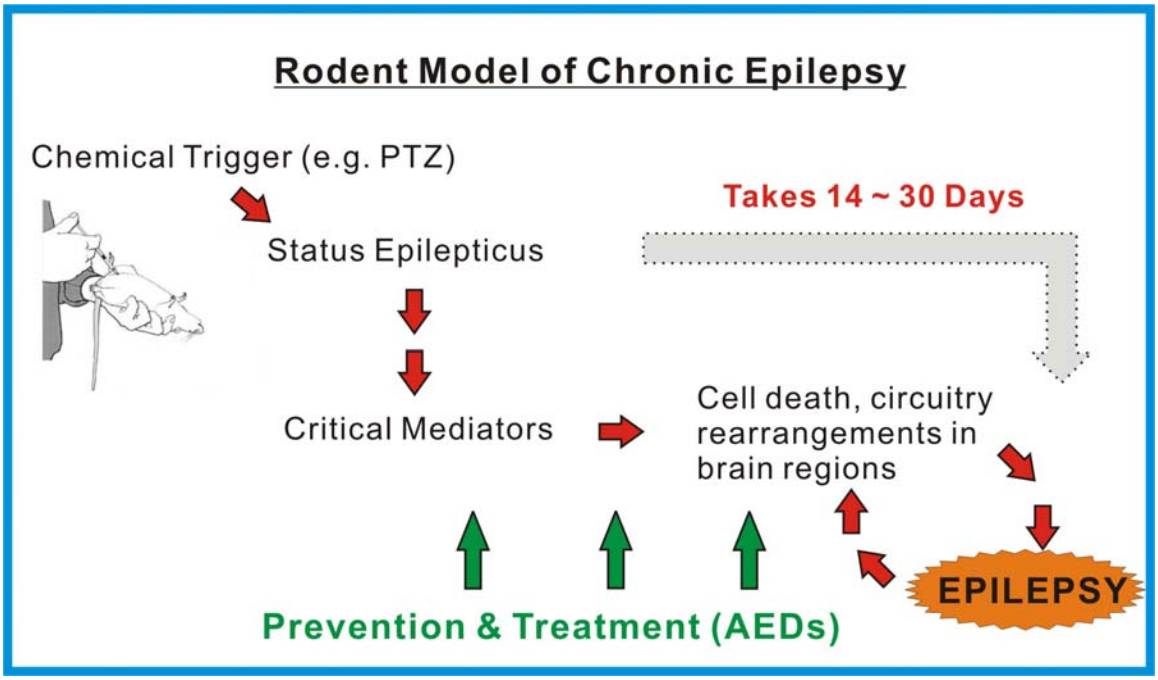
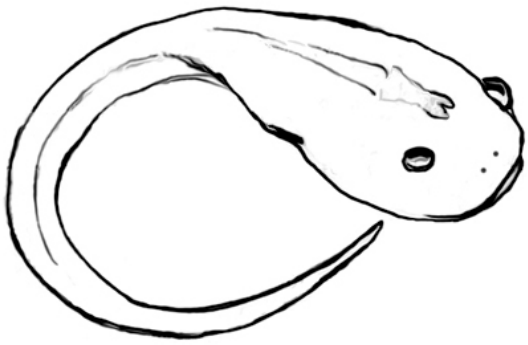



**Figure 2-2 A typical 'C' shaped convulsive motion of albino *Xenopus* tadpole due to epileptic seizure after the PTZ exposure**



# 3: MARKET ANALYSIS AND OPPORTUNITY

## 3.1 World AED Market Overview

According to the National Institute of Health, epilepsy affects 2.5 million people with 200,000 new cases a year in the US alone. Although about 75% of those affected can be treated with existing AEDs to achieve seizure control, the rest are still waiting for better treatments. The world neurotherapeutics market for epilepsy was $3.05 billion in 2002 and is estimated to be $5.21 billion in 2010.[4] The world market potential for AED has been steadily growing at about 7% compounded annually since 2001[5], which is the highest growth among the neurotherapeutic drugs.

### 3.1.1 Notable AED R&D Efforts

Approximately a dozen companies have been or are developing AEDs worldwide (as of August 2008). Notable companies with their developmental AEDs are[6]:

- Abbott (Depakote®, Approved by FDA)
- Cephalon, Inc. (Gabitril®, Approved by FDA as an anti-convulsive medication)
- D-Pharm Ltd. (DP-VPA, In Phase 2)
- Eisai (Rufinamide, Submitted to FDA)
- Elan Corporation plc (Zonegran®, Approved by FDA)

[4] "The World Market for Neurotherapeutic Drugs", August 2002 by MarketResearch.com
[5] Source: Kalorama Information
[6] Sources: Company websites

- NPS Pharmaceuticals, Inc. (NPSP156, Preclinical)
- Neurologix, Inc. (NLX-E201, Preclinical)
- Neuromed (T-type calcium channels blockers, In Discovery)
- Parke-Davis, Now Pfizer (Cerebyx®, Approved by FDA)
- Pfizer (Lyrica®, Approved by FDA)
- Shire Pharmaceuticals Group plc. (Carbatrol®, Approved by FDA)
- UCB SA (Keppra®, Approved by FDA; Brivaracetam, In Phase 3)
- Valeant Pharma (Epilepsy Discovery Program, Discovery/Pre-Clinical; Diastat® NS, In Phase 1; Retigabine, In Phase 3)

### 3.1.2 AED Worldwide Market Shares

There are four popular prescription AEDs in the market as of 2007. Table 3-1 shows the AED market share worldwide for the non-generic drugs. Among those, Depakote® lost its patent protection on January 29, 2008, which will significantly influence its sales by Abbott Laboratories. In addition, all the four drugs are included in the list of the FDA that alerts risk of suicidal thoughts and behaviour with AEDs. An interesting fact to notice would be that all the popular epilepsy drugs have more than single indications, which could bring bigger motivation to develop a new generation of AEDs. For C-Motions, the companies that are actively searching for new AEDs will be the primary target for marketing the AED HTS service.

**Table 3-1 Four Popular Non-generic AEDs: Their Market Shares and Indications**[7]

| Non-generic Drugs | Company | 2007 Sales Worldwide (million) | Prescribed for |
|---|---|---|---|
| Depakote®* | Abbott | $1,580 | Epilepsy, chronic pain, migraine headaches |
| Lyrica® | Pfizer | $1,580 | Partial seizures, neuropathic pain |
| Keppra® | UCB | $1,500 | Epilepsy, occasionally neuropathic pain |
| Lamictal®** | GlaxoSmithKline | $588 | Epilepsy, bipolar disorder |

* Depakote® became generic in 2008

** Since 2005, Lamictal® has been sold as generic in the US and Canada only for low dosage tablets (5 mg and 25 mg)

### 3.1.3 Global AED Market Analysis

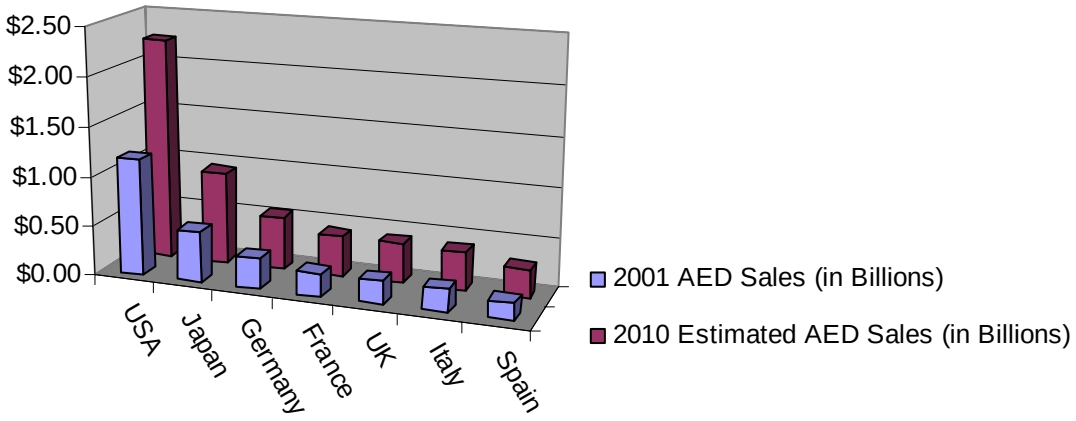
Most of the profit from AED sales comes from the seven major world healthcare markets, which are the USA, Japan, Germany, France, Spain, the UK and Italy. Table 3-2 and Figure 3-1 show the market potential for the seven countries, showing that the USA has the highest market potential followed by Japan by 2010. Thus, it is also imperative for C-Motions to recognize the motivation behind the new AED development worldwide, and the company's strategy will be focused according to the geographical presence of the biotech and pharmaceutical companies that develop AEDs.

[7] Sales figures compiled with the companies' financial data from CoreReference and the US Securities and Exchange Commission.

**Table 3-2 Market Potential for the Seven Major World Healthcare Markets[8]**

| Country | 2001 AED Sales (in Billions) | 2010 Estimated AED Sales (in Billions) |
|---|---|---|
| **USA** | $1.17 | $2.24 |
| **Japan** | $0.51 | $0.94 |
| **Germany** | $0.31 | $0.54 |
| **France** | $0.23 | $0.41 |
| **UK** | $0.23 | $0.41 |
| **Italy** | $0.23 | $0.39 |
| **Spain** | $0.17 | $0.29 |

**Figure 3-1 Market Potential Comparison between 2001 and 2010 for the Seven Major Markets[9]**




## 3.2 Today's Drug Development Process in General

Drug development process is long and costly (Figure 3-2). In any given year, the FDA approves about 90 drugs, among which only few reach the blockbuster stage, where the drug has sales over $1 billion. A typical drug development cost reaches hundreds of millions and is steadily rising. Many pharmaceutical companies are spending about 20% of the revenue for R&D to look for a next blockbuster, with global R&D spending estimated to be over $77 billion in 2007 (See Table 3-3). A recent trend is that

[8] Table created by author with data from "The World Market for Neurotherapeutic Drugs", August 2002 by MarketResearch.com

[9] Chart created by author from Table 3-2.

pharmaceutical companies get involved in the later stages of drug development process whereas the early stages are carried by biotech companies. Transferring the drug development process from one company to another can cause various degrees of disruptions and risks, which could be an opportunity for some. Recently, many companies are exploring possibilities to maximize values of the drug development process by positioning themselves in different parts of the value chain. A typical example is the case of Xenon Pharmaceuticals, a Burnaby-based biotech company that focuses on capturing value in the clinical data of drug development.[10]

**Table 3-3 Global R&D Spending by Biotech and Pharmaceutical Companies in 1996 – 2007[11]**

| Year | Global R&D Spending (in billions) | Growth Rate |
|---|---|---|
| **1996** | $35.3 | |
| **1997** | $36.8 | 4% |
| **1998** | $38.9 | 6% |
| **1999** | $40.2 | 3% |
| **2000** | $41.8 | 4% |
| **2001** | $44.8 | 7% |
| **2002** | $48.4 | 8% |
| **2003** | $52.3 | 8% |
| **2004** | $57.3 | 10% |
| **2005** | $63.4 | 11% |
| **2006 (Estimated)** | $70.0 | 10% |
| **2007 (Estimated)** | $77.3 | 10% |

### 3.2.1 Drug Discovery Process

In drug development, the drug discovery process is typically the most lengthy and costly period (Figure 3-2; Figure 3-3), which requires many iterative cycles between

[10] Simon Pimstone, CEO and founder of Xenon Pharmaceuticals commented that many biotech companies are moving from genomics to human (clinical) data, during the lecture of BUS776 SFU MOT in Summer 2008.

[11] Table created by author, with data source: CMR International and Kalorama Information

chemistry and biology. Nowadays, drug discovery requires both target-based and chemistry-based technologies, which calls for many different types of technical expertise in the areas of molecular biology, high throughput screening, molecular and behavioural pharmacology, and combinatorial, medicinal and analytical chemistry. Therefore, carrying over the entire drug discovery process would be a major challenge, especially, for a small biotech company, which typically has a limited amount of budget, and, hence, needs focused operations.

**Figure 3-2 Stages of Drug Development with Numbers of Drug Candidates Tested at Each Stage**

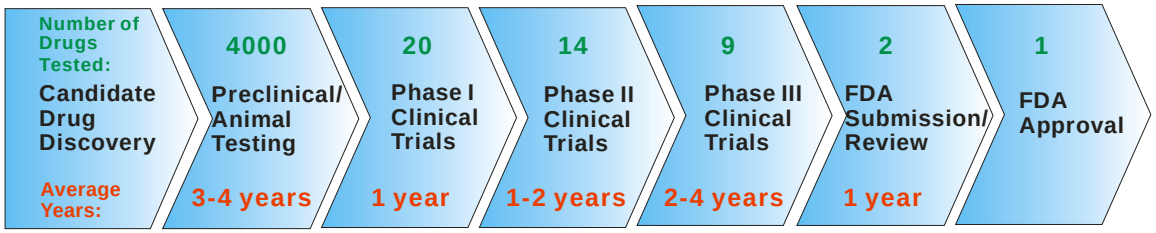
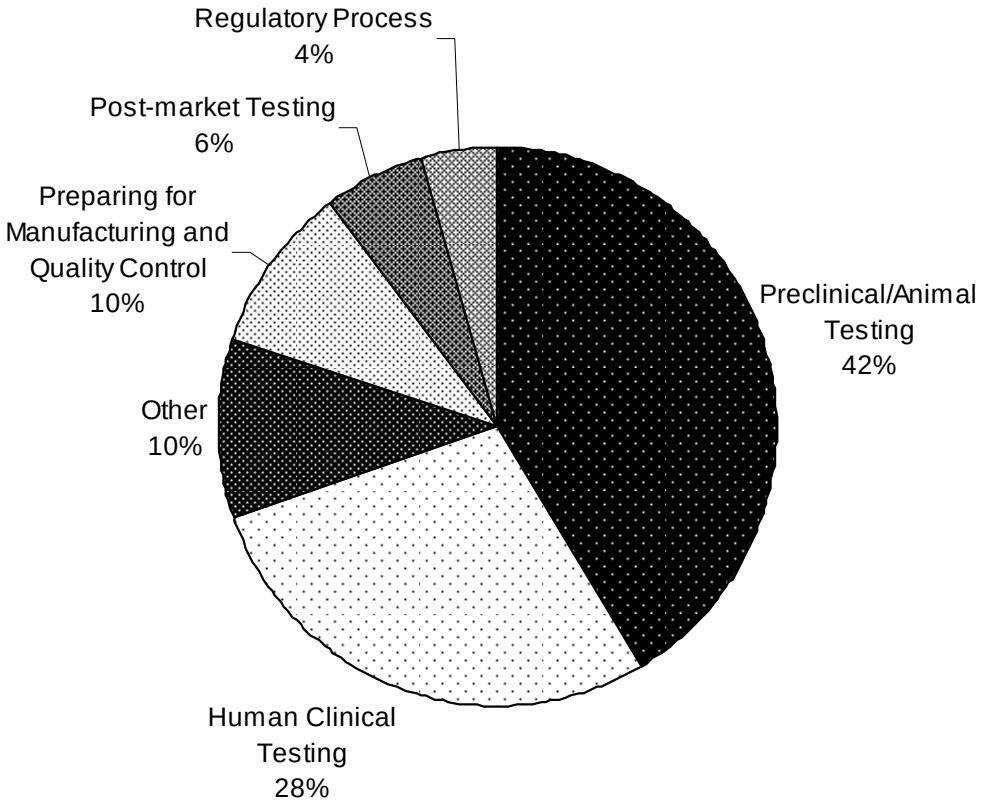



**Figure 3-3 A Typical Budget Allocation in R&D**[12]




[12] Chart created by author with data from "Health's Price Tag," *The Boston Globe*, March 28, 2001, p. D4. The diagram shows the allocation of $26 billion in research and development by the US drug companies in 2000.

### 3.2.2 What Speeds the Drug Discovery Process?

The Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that approximately $0.8 ~ $1 billion is required to bring one successful product to market[13]. The most crucial element to accelerate costly and lengthy drug development process is the early prediction of the candidate drug's behaviour for its absorption, distribution, metabolism, excretion and toxicity (ADME/Tox) as well as improvement on target identification and validation. In order to comply with these demands, the drug R&D has been focusing on new areas of science using various *in vitro*, *in vivo*, and *in silico* methods and models.

### 3.2.3 Potential Bottlenecks during the Drug Discovery Process

One of the most critical bottlenecks during the drug discovery process is the hit-to-candidate stage, which is an iterative process between chemistry and biology to find the drug candidate for later stages of drug development (Anon, 2002; Clark, 2003). Over the last decade, due to advancement in the genomic and proteomic research, we know much more about types of the drug targets, but not their biological functions or pathways. In order to eliminate the bottleneck, the interaction between the drug and its potential targets must be established, and anti-targets must be eliminated to speed up the drug candidate selection process.

Another possible bottleneck is establishing the ADME/Tox of new drug candidates on the established drug targets. This has become increasingly crucial for the success of later drug development stages, especially during clinical trials. Since failures

[13] *Drug Discovery and Development*, PhRMA Publication, February 2007

in clinical trials are much more expensive and damaging, biotech and pharmaceutical companies are willing to spend extra to sort out early failures.

The bottlenecks above can be eliminated by implementing combinatorial chemistry and high throughput screening for biological targets and drug leads. However, most biotech and pharmaceutical companies do not have the expertise or in-house programs to fully utilize these innovative technologies. Therefore, to keep up with these novel technologies and to identify potential drug compounds more efficiently, companies often turn to outsourcing, which also saves on the over all drug development cost. As one of the senior scientists from Bristol Myers Squibb mentioned[14], "Outsourcing has become so paramount in a pharmaceutical's infrastructure and drug discovery strategy that it can no longer be considered an option."

## 3.3 Outsourcing the Drug Development Process

More biotech and pharmaceutical companies are moving in the direction of outsourcing their preclinical and clinical research during drug development. The worldwide drug discovery outsourcing market reached $5.4 billion in 2007, which increased 15% from $4.1 billion in 2006. It is expected that the market will grow to exceed $8 billion in 2010 based on market research[15]. The compound annual rate of the market is 16%, reaching almost $14 billion in 2013[16].

[14] Quoted from Dr. Arvind Mathur's speech at PABORD 06: The Pharmaceutical & Biotech Outsourcing, Research & Development Expo & Conference, London, UK (September 13 – 14, 2006)
[15] Source: *Outsourcing in Drug Discovery, 3rd Edition*, MarketResearch.com
[16] *Ibid*.

### 3.3.1 Why Outsource?

The number of new molecular entities (NMEs) filed has been dropping precipitously over recent years (See Figure 3-4) despite steady and significant increases in R&D spending of biotech and pharmaceutical companies (Table 3-3). The number of NMEs was 53 in 1996, which was an historical high, and dropped to 17 in 2007 while global R&D spending has doubled within the period (from $35 billion in 1996 to $77 billion in 2007). The general view of the industry is that the pharmaceutical industry must find ways to cut the drug discovery time by prioritising projects that are more promising in order to improve the efficiency and productivity of the R&D programs. Of many business models to accomplish these goals, such as M&A, in-licensing, and strategic partnerships, the outsourcing model has been the most successful option to improve R&D productivity and reduce the costs.

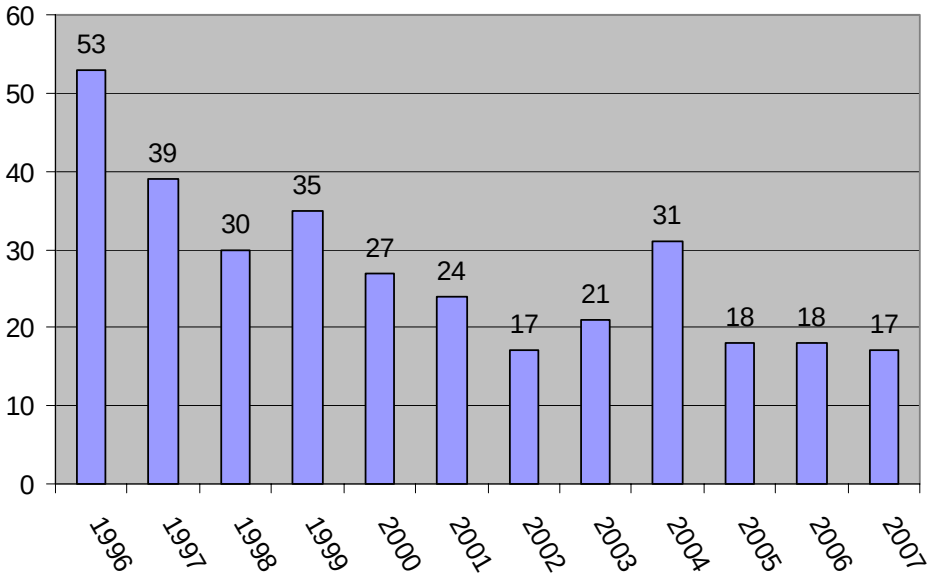
There are several benefits to outsource, especially for a small size biotech company. Those benefits are:

- Cost savings
- Access to talent and new emerging technology
- Compressed timelines
- Increased production
- Flexible resource planning

Flexible resource planning due to outsourcing is a result of the other benefits, which allows biotech and pharmaceutical companies to allocate their resources more efficiently. This is the most important aspect of outsourcing, as outsourcing can provide a flexible

pool of resource, allowing the company to reduce wide swings between uptime and downtime of their resources, and thus, to maintain a steady-level of resource.

**Figure 3-4 Number of NMEs Filed Worldwide from 1996 to 2007**[17]




### 3.3.2 What Not to Outsource?

There are several things to be considered before outsourcing any drug development activities. Those are:

- Intellectual property protection
- Confidential information and trade secrets
- Fraud and corruption
- Meeting regulatory compliance demands

[17] Chart created by author, with data from: *Ibid*.

- Geographical distance

All the factors above are preventable by applying a good work ethics and an unambiguous company policy. Thus, it is vital for a CRO to recognize these factors and proactively manage the company's reputation and relationships to minimize any negative perception to the customers.

### 3.3.3 Contract Research Organizations

The main goal of CROs is to provide flexible capacity or complementary capabilities for the sponsoring company. Pharmaceutical and biopharmaceutical companies of all sizes have been hiring contract research organizations (CROs) to outsource their drug development process[18]. Nowadays, it is possible for biotech and pharmaceutical companies to hire CROs to carry out any stage of the drug development process, as the CRO market has become a one-stop shop full of expertise from diverse fields.

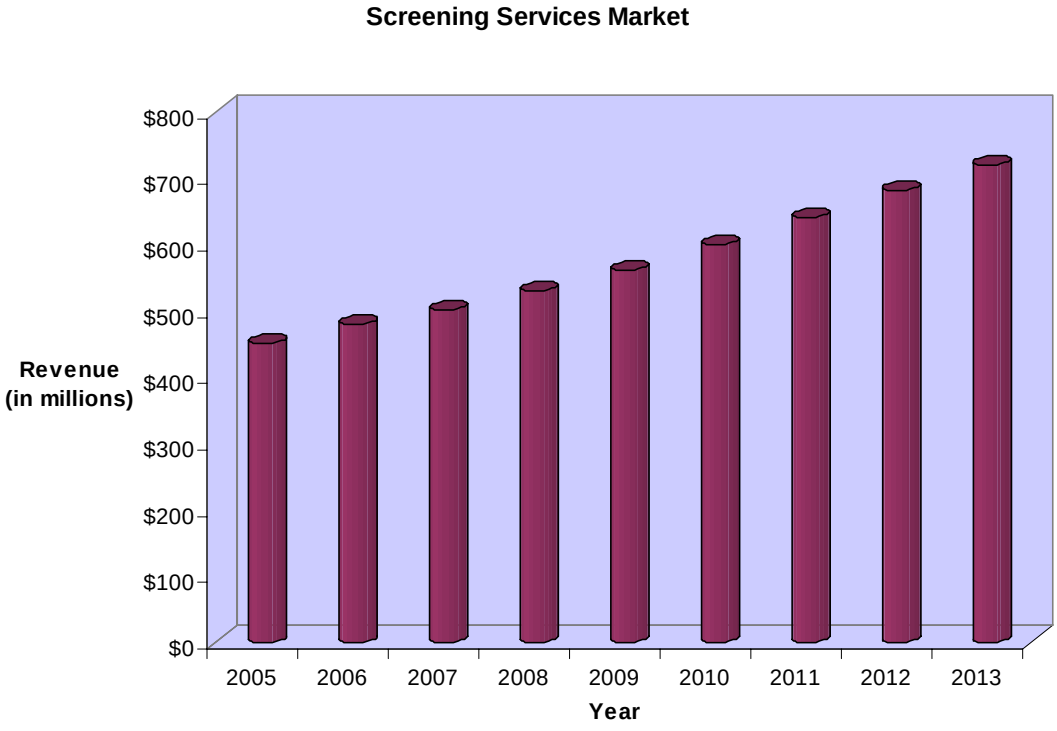
### 3.3.4 Outsourcing Trend of High-throughput Screening

High-throughput screening (HTS) is the automated, simultaneous testing of thousands of distinct chemical compounds in models of biological mechanisms. Active compounds identified through HTS can provide the starting point in the design of powerful research tools that allow pharmacological probing of basic biological mechanisms, and which can be used to establish the role of a molecular target in a disease process, or, its ability to alter the metabolism or toxicity of a therapeutic agent. Of the $5.4 billion spent on outsourcing the drug discovery process, outsourcing of high-

[18] For drug discovery phase, there are four phases: 1) Target identification, 2) target validation, 3) high-throughput screening and 4) lead optimization.

throughput screening took 9% of the total market, about $500 million in 2007.[19] Increasing at a steady annual compound growth rate of 6%, the overall HTS market will grow to $720 million in 2013 (See Figure 3-5).

**Figure 3-5 Worldwide Screening Services Market growth in Revenues (2005 – 2013)[20]**




## 3.4 Estimated AED HTS Market Potential

Based on the market analysis of the overall HTS outsourcing of pharmaceutical companies, it can be concluded that approximately 10% of the drug sales for AEDs will

[19] Source: Kalorama Information

[20] Chart created by author, with source: *ibid*.

be allocated to the AED drug discovery[21]. Since the preclinical/animal testing of drug candidates takes upto 42% of the overall drug discovery effort, it is concluded that C-Motions' potential AED HTS market size can be optimistically estimated to be $200M worldwide based on the total AED sales of $5.21B in 2010.

[21] Overall worldwide pharmaceutical sale is estimated to be $900B in 2008 while the R&D budget is $77B with 10% annual increase. Thus, approximate budget allocation for the drug discovery would be 10% with a conservative estimation. (source: http://www.medicalnewstoday.com/articles/8875.php)

# 4: COMPETING TECHNOLOGIES

There are several different technologies on the market to measure efficacy and toxicity of AED candidates during the discovery/preclinical stage of drug development. Each technology has its own advantages and weaknesses. C-Motions recognizes these factors for the technologies, which will potentially compete with C-Motions' AED HTS technology. The technologies that might be the contenders against C-Motions' are 1) rodent models, 2) fruit fly models, 3) zebra fish models, and 4) *in vitro* models.

## 4.1 Rodent Models

A rodent model for the AED efficacy testing has been a gold standard for the biotech and pharmaceutical companies who actively look for a potential compound for treating epilepsy. The model is somewhat advantageous and one of the closest comparables to the human brain. There have been several approaches in recent years so that rodents could mimic human brains as closely as possible with help of genetic modifications (e.g. EpiMouse™[22]). Rodent models in general, however, require individual preparation of the lab animals for testing AEDs, which incurs high R&D costs, and are not suitable for high throughput screening of multiple potential AED compounds.

[22] Neurofit Preclinical Research, www.neurofit.com

## 4.2 Fruit Fly Models

A patent[23] has been granted for a fruit fly model to screen potential AEDs. The detail of the invention relates to a method for screening AEDs using a common fruit fly (*Drosophila melanogaster*) by generating mutations in the genes to induce epileptic seizures in male flies, which show leg-shaking motions. By measuring a reduced intensity of leg shaking, efficacy of a potential AED can be tested under stereomicroscope. The model has a potential merit to be used as a high throughput screening method. However, fruit flies have limitation when human AEDs are tested on them because their ADME/Tox studies cannot reveal comparable results to humans. In addition, other types of disorders, not exclusively due to epileptic seizures, can potentially cause their leg shaking movements, which could cause false negative results.

## 4.3 Zebra Fish Models

Zebra fish (*Danio rerio*) has been touted as a well-characterized model organism for potential AED screening, which provides invaluable whole organism in vivo data that is relatively close to humans. The model was developed by a group of scientists (Baraban, Taylor, Castro, & Baier, 2005; Berghmans, Hunt, Roach, & Goldsmith, 2007) using a commercial motion detection video monitoring system by Noldus[24]. DanioLabs, a UK based zebra fish drug discovery company, was the pioneer of the technology to use the zebra fish model for searching active ingredients to treat human neurological disorders. On March 22nd, 2007, VASTox plc, a UK biotech company, acquired DanioLabs for £15 million. VASTox (now Summit plc) is a medium sized drug

[23] US Patent 6291739

[24] Noldus EthoVision XT *Zebrafish larvae activity monitoring system* http://www.noldus.com/site/doc200711027

discovery company, which has a broad set of clinical, pre-clinical, and discovery programmes for the treatments of serious disease areas with highly unmet medical needs. The zebra fish AED screening platform is amenable to high throughput analysis using an automated tracking system to measure the amount of movement induced by exposure to PTZ. The company is currently testing the possibility of using the system to screen the library for potential AEDs[25].

## 4.4 *In Vitro* Models

There are several *in vitro* methods available to screen AED candidates such as measuring cell-swelling response[26], molecular targets and genetic mark-up testing. *In vitro* testing, however, is not likely to replace screening in animal models because *in vitro* systems cannot model the specific pharmacodynamic actions required for seizure protection, and do not assess bioavailability and brain accessibility.

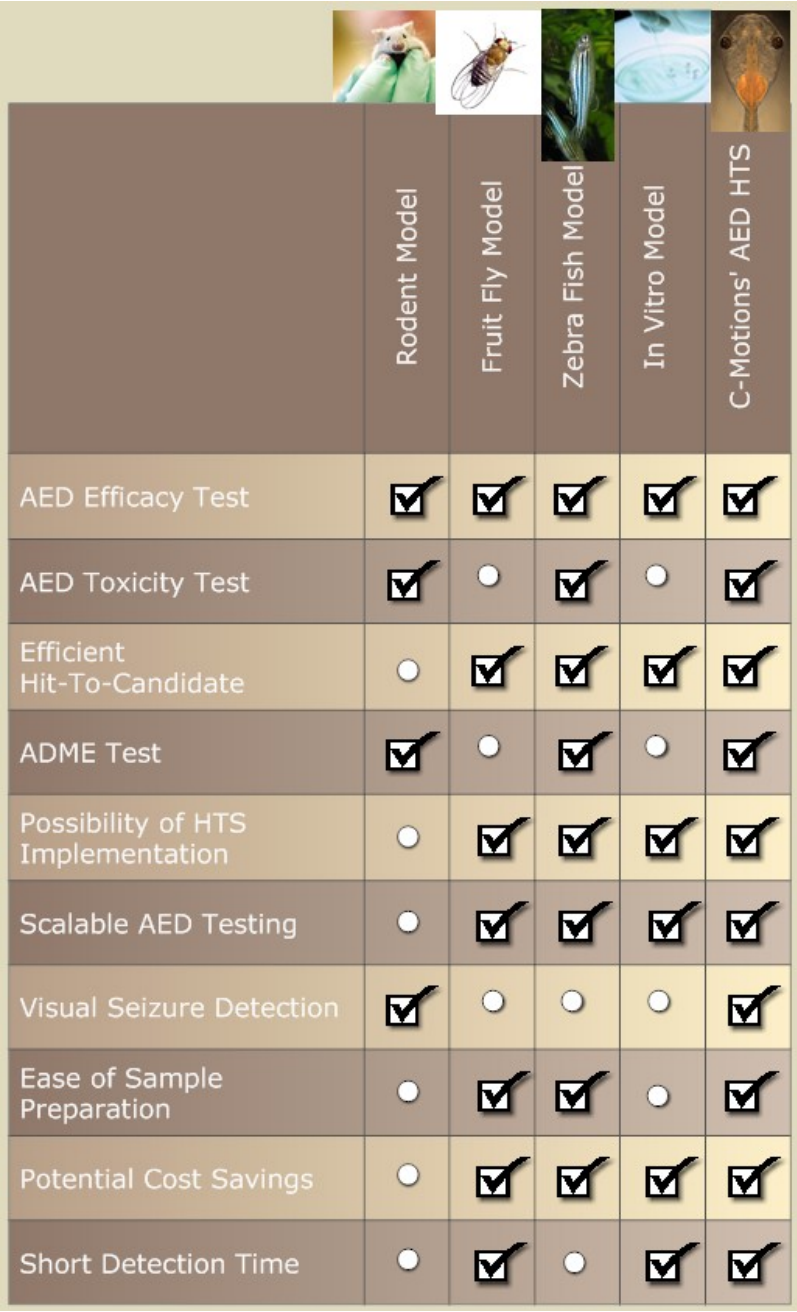
## 4.5 C-Motions' Technology versus Others

All the technologies mentioned above show their unique attributes that are valuable during the drug development process since they are comparably effective to detect efficacy of AED candidates with their own usefulness. However, when it comes down to scalable, hit-to-candidate, or ADME/Tox testing with a possibility of HTS implementation, C-Motions' technology stands out as it covers the widest spectrum of the capabilities during the AED research (See Figure 4-1). In addition, it could cover the longest timeframe during the drug discovery/preclinical period because of its HTS and animal-based screening aspects. It is also superior to zebra fish, which could be capable

[25] Zebrafish Screening by Summit plc http://www.summitplc.com/Zebrafish%20screening.htm
[26] US Patent 5902732

of HTS implementation, as *Xenopus laevis* shows a much more distinctive seizure pattern than *Danio rerio*, and thus, reduces potential errors or false positive results.

**Figure 4-1 Comparison of the Competing Technologies with C-Motions' AED HTS**



# 5: C-MOTIONS' STRATEGY

## 5.1 SWOT Analysis of C-Motions

C-Motions acknowledges the currently competitive HTS market in the drug development process. The SWOT (Strength-Weakness-Opportunity-Threat) analysis of C-Motions is to identify the key internal and external variables to evaluate the strategic objectives. The internal variables are divided into the strengths and weaknesses of C-Motions to determine the impacts of those variables to the company. The external variables are evaluated for the opportunities and threats from the outside of the company to establish a basic understanding of the business environment. Based on the analysis, C-Motions will strategize its business and product development, as well as its exit path.

### 5.1.1 Internal Environment

C-Motions is uniquely positioning itself in the value chain of the drug development process as its technology covers a wide range during drug discovery/preclinical process. While there are many opportunities, the company also expects to see many different challenges. First, the notable strengths of C-Motions that have been identified are:

- Strong science and technology
- Knowledge and capability of the founders in science and technology
- Well-established network within the epilepsy research in North America

However, the weaknesses of C-Motions have been also recognized in tackling the challenges ahead. Those are:

- Uncertain financial backing
- Still in-progress IP process
- Lack of geographical presence other than Vancouver
- Inexperience of the management team

The identified weaknesses are incorporated into the business development and sales, risk management, exit strategies of C-Motions with corresponding action plans.

### 5.1.2 External Environment

The external environment will always be a mixture of diverse opportunities and threats. It is a task for C-Motions' management team to understand the external environment and to identify current and potential opportunities and threats. The identified opportunities for C-Motions are:

- Emerging HTS market
- Public awareness of epilepsy
- Value chain approaches of biotech companies
- Fast growth in the CRO market
- Growing trends in Preclinical studies[27]

[27] One of the most notable current trends in the biotech sector is trading data from pre-clinical and clinical studies. One of the examples of data trading is hiring a CRO during any stage of drug development. C-Motions will fully exploit the current trend by serving specialized segment of the AED discovery process for biotech and pharmaceutical companies.

There are major threats that C-Motions will encounter during the business launch. The imminent threats from the external environment to C-Motions are:

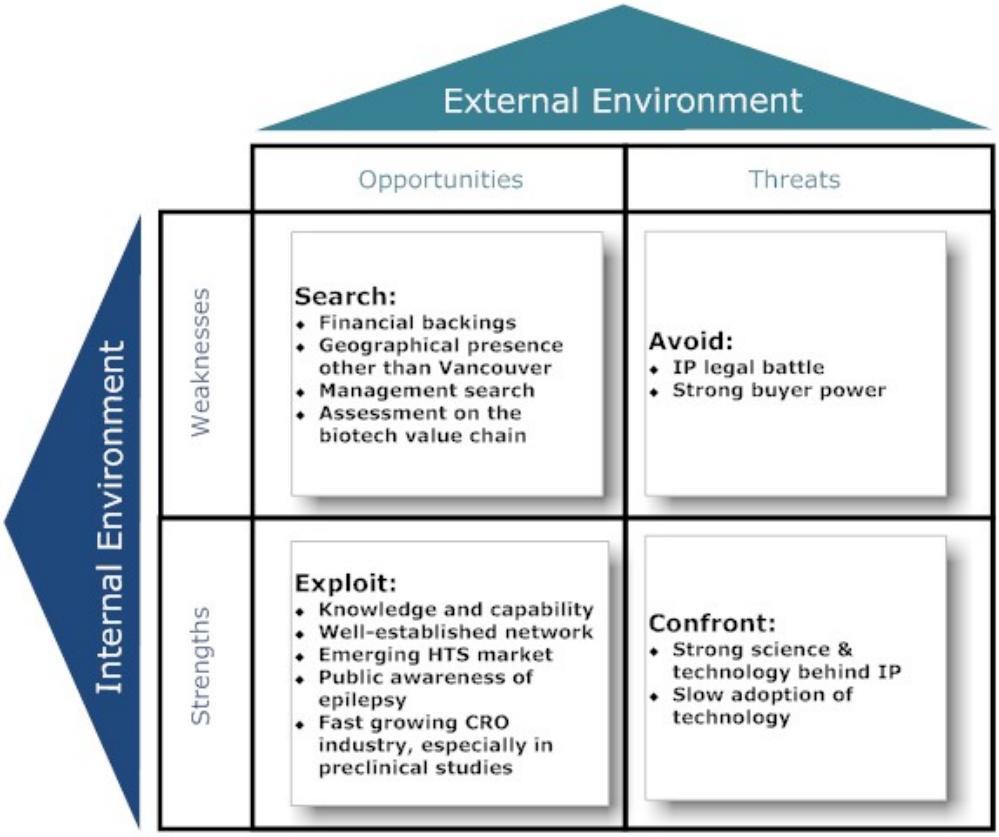
- Other comparable or alternative technologies
- Strong buyer power by biotech and pharmaceutical companies
- Slow adoption of its concept and technology.

Among these threats, the slow adoption of the technology can be seen as the most significant issue to deal with to create the AED HTS market in the biotech industry due to the newness of the technology. In order to facilitate adoption of the technology, C-Motions will use a push strategy that involves strong sales and marketing effort.

### 5.1.3 SWOT Analysis

Based on the internal and external environments identified, the SWOT analysis of C-Motions has been formulated (Figure 5-1). From the SWOT of C-Motions, it is possible to strategize the company's direction using the Search, Avoid, Exploit, and Confront action plans. As a small startup, C-Motions' strongest assets are its technology, academic network, and the people involved, on which the company should focus with maximum effort. On the other hand, at this stage, it would be wise to avoid any activity that may cause extensive cash expenditure, such as any legal battle with a competitor.

**Figure 5-1 SWOT Analysis of C-Motions**



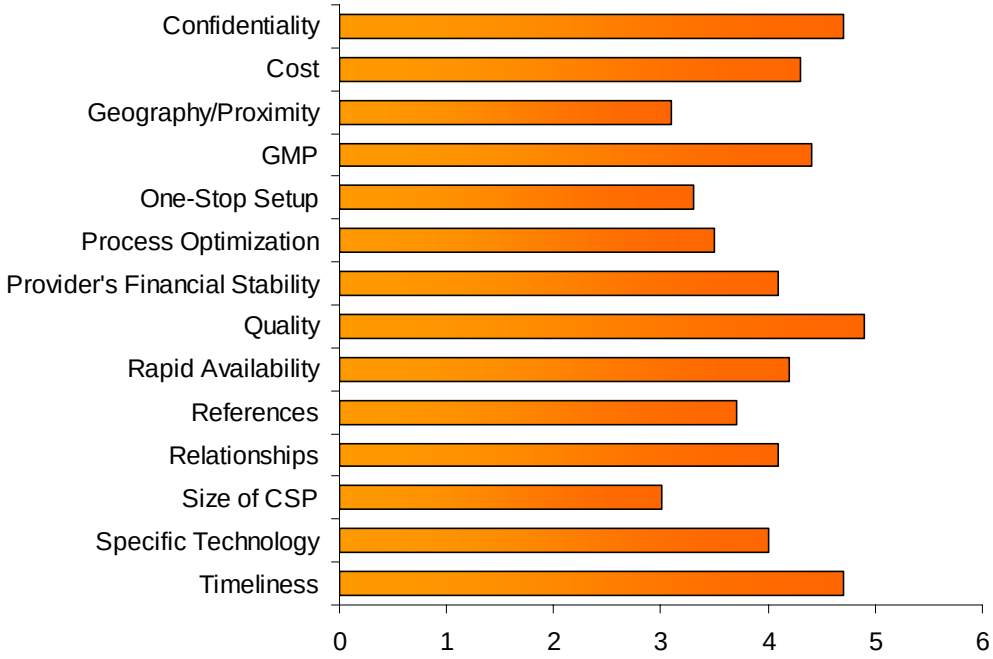

### 5.1.4 Success Factors

In order for C-Motions' business to be successful, it must satisfy the overall needs of an effective HTS Screening assay for its core services and products. These needs are to establish:

- Stability and reliability of the HTS screening assay
- Biological relevance of the assay, which is capable of detecting novel molecular interactions
- Kinetically valid assay that can predict how the compound and target will interact

The objectives above can be primarily obtained by having biochemical expertise, assay development professionals, ability to produce relevant biological models, access to reagents and support services, and own robotic systems that are in-house and validated for drug screening. In addition, in conducting its business as a CRO, C-Motions must focus on achieving excellence in confidentiality, quality and timeliness among many factors (Figure 5-2), which have been identified as the leading decision making points by the biotech and pharmaceutical companies who wish to outsource their drug development process. (Roth, 2007).

**Figure 5-2 Factors Involved in Making Outsourcing Decisions**[28]




[28] Chart created by author, with data from: Contract Pharma: 2007 Annual Outsourcing Survey, May 2007

## 5.2 Business Development and Sales Strategy

The following business model has been devised based on the SWOT analysis of C-Motions. It focuses on speed to market for early revenue generation with positive cash flow, establishment of market presence, and refinement/expansion of the core technology.

### 5.2.1 Business Model

C-Motions will start out its business by offering services to biotech and pharmaceutical companies for AED screening of candidate compounds. The biotech and pharmaceutical companies will physically send their AED candidates to C-Motions laboratory, which screens potential AEDs for toxicity and efficacy. The resulting data will be sent to the biotech or pharmaceutical company for further analysis by an encrypted online packet or by registered mail. Following service contracts, C-Motions will move toward establishing a relationship with a strategic service partner of the neurotherapeutic areas, such as J&J, Shire Pharmaceuticals, or Neurochem, Inc, which have well-established presence in the related area. The initial aim for the business model is to expedite the adoption of C-Motions' technology as well as to generate a positive revenue growth in the early stage of the business establishment.

### 5.2.2 Customer Profiles

In the biotech service industry, successful products and services enter the market through a similar pattern to a new technology product. Influential "early adopters" who are the voices of the industry first use a new innovative service. For this reason, C-Motions' first line of customers will be the biotech and pharmaceutical companies who are actively pursuing AED development, such as Johnson & Johnson and Shire

Pharmaceuticals Group plc. In addition, there are number of small academic laboratories that are actively searching for potential AEDs, on which C-Motions can concentrate its early sales efforts.

### 5.2.3 Sales Channels

The recommendation of C-Motions' services will be commenced by a talented group of direct sales force, whom C-Motions will begin hiring in 2010. A competitive salary has been budgeted for direct sales personnel to attract experienced individuals with well-established neurotherapeutic networks. The early sales team will consist of a small team of highly qualified sales representatives and service education specialists managed by the VP of Sales. While sales representatives target biotech and pharmaceutical companies' decision makers to use C-Motions' AED Screening service, service education specialists provide necessary training and correct interpretation of the data after a service contract has been made. This bilateral sales team approach has been adopted by many successful service based companies to increase service frequency and utilization, which will ensure ongoing sales of C-Motions' services. In the beginning, C-Motions is likely to focus on the North American market, as it has the highest market potential for the AED related sales (See Figure 3-1). In the long term, however, the company has plans to establish a global presence of its sales effort since the CRO business model is less bound to its geographical location or proximity (See Figure 5-2).

### 5.2.4 Pricing

Since the HTS for AED candidate drugs is still in the proof of concept stage, it is challenging to determine proper pricing at this point. However, there are several

comparable services (See Table 5-1 and Table 5-2) in the outsourcing market, which can be referenced to decide the initial price point of C-Motions' HTS. The prices of the screening services may be different depending on the types of services and regions; however, it is certain that the *in vitro* HTS is an order of magnitude less expensive than the *in vivo* service for similar experiments in general. The pricing strategy of C-Motions' HTS will be based on adding-on options as the technology becomes more refined. The service will start at $100 per compound for its first basic efficacy test on potential AED compounds with cGLP complying data and standard. The service will offer more biological assays options depending on capability of the HTS platform at higher prices.

**Table 5-1 *in vitro* HTS Assay Kits in the Market[29]**

| Company | Service | Price |
|---|---|---|
| Biocompare | TACE HTS Assays | $442 for 96 Tests |
| McGill Life Science | Automated acquisition and analysis imaging system | $15 per screen of plate of 80 compounds |
| Rockefeller University | Library Screen with Post Screen Assistance | $12,150 for External Users |
| Invitrogen | Ion Channel Biology Assay kits | $270 - $5,600 for 100 plates |

**Table 5-2 Price Comparison between *in vitro* and *in vivo* Anti-Cancer Drug Screenings[30]**

| Service | Price |
|---|---|
| In vitro anti-cancer drug screening and evaluation | One drug (five different doses) using one cancer cell line costs $600 |
| In vivo anti-cancer drug screening and evaluation | One drug (three different doses) using one cancer cell nude mice xenograft model costs $12,000 |
| Acute toxicity evaluation | One drug costs $3,000. |

[29] http://www.biocompare.com/matrix/17989/TACE-Assays-(High-Throughput-Screening).html; http://www.lifesciencescomplex.mcgill.ca/hts-hcs/fees; http://www.rockefeller.edu/highthroughput/pricing.php; http://www.invitrogen.com/site/us/en/home/Products-and-Services/Applications/Drug-Discovery/Target-and-Lead-Identification-and-Validation/Ion-Channel-Biology.html

[30] http://www.keygentec.com/service.aspx (Nanjing KeyGen Biotech. Co. Ltd)

## 5.3 Product Development Strategy

C-Motions' service based launch strategy focuses on maximum exploitation of the current technology in the early part of the business launch. In addition, C-Motions will develop different models of the platforms that use the same core technology in order to satisfy the unmet needs for whom would like to pursue the screening process independently. Main target customers are the biotech and pharmaceutical companies that value confidentiality of information and are capable of integrating C-Motions' technology to their unique research platforms.

### 5.3.1 Engineering R&D/Prototyping

C-Motions Biotechnology has a connection to Dr. Edward Park, the director of the newly established Lab for Applied Control and Bio-Robotic Systems (LACOBS) in Victoria, Canada. Dr. Park's research is inherently multidisciplinary, encompassing a number of fields in engineering and science. Focuses in his biomedical research are the invention and development of new biomedical research tools or techniques, or the improvement on existing tools/techniques. This connection will allow C-Motions to develop a research platform that can automatically screen potentially efficacious AED candidates that can be forwarded to further non-clinical or clinical studies.

### 5.3.2 Additional Product Development

In the beginning, the platform will be aimed for the in-house operation for HTS. Thus, the platform will suffice to have more complex features and sophisticated functions with less explicit instructions for the in-house engineers. As the adoption of the HTS technology progresses, however, C-Motions will seek for opportunities to sell the

platform as a product. That shall require the platform to be adequately 'packaged' for its marketing and sales as an independent unit. The initial targets for the product will be biotech and pharmaceutical companies, who would prefer their own in-house HTS to outsourcing HTS operations for the reasons to achieve economy in operations and/or, more importantly, to protect their confidential drug development process. C-Motions AED HTS Platform will be refit to be robust and easy to operate with basic instructions and manuals. The platform will also be coupled with consumables for the convenience of HTS by a third party.

## 5.4 Intellectual Property

The C-Motions team is currently under provisional patent filing process through the UBC UILO. The cost of the patent filing process and related work will be covered by UBC once the UILO decides to proceed to file the patent. The final agreement between C-Motions and other related institutions has not been established at this point. In any case, a broad US patent filing with international extension coverage is expected, which will protect the company for its methods of conducting the AED HTS process, image generation and computer pattern recognition, and the company's proprietary algorithm that manages the overall HTS process and data handling. The company also understands that the patent is only the first step to protect C-Motions' IP, not the last.

Having the UBC UILO is advantageous in many aspects, as it has been known to be successful at facilitating the exchange of knowledge between the institution and the wider community. The company will use this opportunity to create a strong network of potential collaborators from the industry, which will promote its IP and related

technologies.  In addition, the relationship will enable the company to leverage its IP to execute its business strategy.

Once the UBC UILO agrees to participate in this venture, it can further help the company to promote the service and product to a wider range of customers.  The institution can also help us to negotiate with other biotech or pharmaceutical companies as well as to design patent strategies that ensure quality product delivery to those most in need, while securing a sustainable local infrastructure.

# 6: RISK AND EXIT STRATEGY

## 6.1 Key Risks

**Patent Approval:** Since C-Motions' platform technology is still under review for the provisional patent, there is a possibility that the patent process could be delayed. Although not innovative or effective as C-Motions' AED HTS technology, there are competing technologies in the market. Since the HTS market is expanding rapidly, C-Motions is to position itself as the first mover to establish its reputation and brand by entering the market as quickly as possible.

Risk management – In order to mitigate the risk, C-Motions' management team has been working with the UBC UILO personnel to follow the ongoing patent filing efforts. In addition, it is important to note that a patent is to exclude competitors from using the idea. Therefore, it is extremely important for the C-Motions' management team and the UBC UILO to identify the gist behind C-Motion's technology that differentiates its innovation from other technologies.

**Management Risk:** C-Motions recognizes that, in the future, the company needs to bring on additional management. For example, an industry seasoned CEO will be required to coordinate the intricacies of the product development of the technology and a final go-to-market strategy.

Risk Management – All members of the management team are willing to work with C-Motions' investors to find suitable management candidates for key roles when the company grows to a level of sophistication beyond the scope of current management.

## 6.2 Exit Strategy

There are three main exit scenarios for C-Motions based on the internal and external environment. The scenarios that the C-Motions Management Team is investigating are:

- Out-licensing the proprietary technology
- Selling the company, joint venture or M&A
- Early IPO

At this moment, out-licensing the technology is the least feasible option. To be evaluated fairly, C-Motions should be viewed as a synergistic entity that is capable of conducting business, not only with its technology, but also with a strong management team and a sound business strategy. In addition, the amount of royalties from licensing the technology is usually a small fraction of the company's value, not to mention losing control over its core technology, which is one of the most important assets.

The current ideal exit path is an early IPO (in Year 7) of the company in order to capture the full value of the company. The company's revenue is predicted to be $15M in year 7, which is not adequate for NASDAQ, which requires a higher revenue range (over $75M) to be a successful IPO (Rosenberg, 2007). Hence, C-Motions will look for an opportunity to be listed on the TSX, which is a relatively small capital market, but is closer to the Canadian investors. In any case, C-Motions will prepare its IPO by focusing on generating strong revenue and maintaining positive cash flow with the company's solid IP portfolio.

In case of selling the business or doing a joint venture, C-Motions will look for major pharmaceutical companies as potential buyers or partners so that the AED HTS platform technology can be further developed into a larger commercial scale that can bring economies of operation through the resources of a large pharmaceutical company. Ideal candidates for the purchasers in the pharmaceutical companies would be J&J, P&G, Shire Pharmaceuticals, and Neurochem, Inc who have had the dominant presence in the AED development. These companies have their own brands of AEDs that became generic or will become generic in the near future, which will make C-Motions' technology attractive to their AED and related neurological R&D programs.

# 7: FINANCIALS

## 7.1 Assumptions

There are several financial assumptions recognized for C-Motions' business:

**1) Sales Volume:** Conventional rodent model drug screening can be time-consuming and labour intensive; however, due to its value to the AED research, the market for conventional rodent model drug screening will sustain as is. C-Motions conservatively estimates its innovative AED Screening Platform to capture 0.25% of the total market for the potential AED screening market worldwide in 2011 upon its introduction. The worldwide market penetration of C-Motions' AED Screening Platform technology is estimated to grow to approximately 2% by 2013 by adding more sales channels and finding reputable R&D partners for drug discovery worldwide.

**2) Median yearly incomes used[31]:** A 35% markup is applied to salaries to cover taxes, benefits (25% of the incomes), profit sharing and stock options for the employees of C-Motions.

**3) Revenue and Pricing:** C-Motions' service is priced at $100 CAD per compound for basic toxicity and efficacy testing. The premium service will be priced at $500 CAD per compound, which will provide more details of information with options of tailoring to customers' needs including toxicity and efficacy checks.

[31] Source: Canada Revenue Agency

**4) Rates:** The Canadian inflation rate is 2% per year, the discount rate is 30%, the long-term growth rate is 5%, and the overall corporate tax rate is 30%[32] with tax paid at the beginning of the next fiscal year.

**5) Market Growth:** The world HTS market is estimated to grow at 6% through 2013. The customer adoption rate of C-Motions' service assumes the sales revenue reaching 50% a year after introduction, growing at the same rate for 2 years and then growing at a slower 25% in 4 years.

**6) Other factors:** In Canada, many government incentives are offered to a R&D based company for business development. Besides the SR & ED tax credits that function similarly to grants, other grants are also offered by the National Research Council of Canada through the industrial Research Assistance Program, Technology Partnerships Canada and Government Assistance Programs for S&T Research. C-Motions is aware of these unique opportunities and intends to seek them for extended funding.

**7) Investor IRR and Exit Value:** Exit value is calculated based on a 10x EBITDA multiplier, on the conservative side of recent available comparable data in the biotech industry[33].

## 7.2 Start-up Investment and Equity Structure

C-Motions' start-up costs are estimated at $550,000 CAD in total. The initial fifty thousand will be paid for the patent and administrative fees by the founders, while the remaining $500,000 CAD for the first-wave of the product development will be funded by seed round funding. In 2010, a Series A offering of $1,500,000 will allow the

[32] Source: KPMG in Canada, Canadian Corporate Income Tax Rates

[33] Biotech industry average LTM Sales Multiple = 28.5 (Source: FactSet and Public Company Filings)

completion of C-Motions' initial marketing and sales for the AED HTS services. In order to fund the second-wave of the product development and marketing, C-Motions will seek a Series B round of $2,500,000 CAD in 2012 from different sources or series A investors as part of the Series A round.

## 7.3 Investment Requirements and Return Potential

C-Motions is currently raising a $500,000 Seed investment. This investment offers Seed investors an outstanding 77% IRR with a 30% final equity stake (after Seed conversion of a one year, 120% yield note). In 2010, C-Motions will offer Series A shares for additional $1.5M. Series A investors will enjoy a 54% IRR with a 25% equity stake. An employee option pool of 5% equity (final dilution) is available for incentive stock options. The co-founders will own a 24% equity stake after all financing rounds. Liquidity will be realized by year 7 of operations (2015).

## 7.4 *Pro Forma* Financials

C-Motions will begin formal marketing efforts in early 2010 after academia and local reviews for the basic service and related data analysis. The forecasted numbers of new customers is 25 by direct sales in 2010. The numbers will grow to 50 in 2011. Projected gross margin for C-Motions service is over 30% including its maintenance and related labour. The physical parts of the C-Motions platform construction will be built in house. Initially the company will offer 2% sales commission for the direct sales, which is subject to increase later depending on the scale of sales. In the beginning of the sales, marketing will be targeted at major biotech companies allowing the company to focus on efficient advertising in scientific journals and academic conferences. Accounts

receivable is estimated to be 30% of the total goods sold and anticipated not to be realized at 30 days from delivery to reimbursement. The net income of C-Motions will reach over $7M by year 8 with the previous assumptions (See Figure 7-1).

As an investment opportunity, C-Motions offers outstanding opportunity to potential investors. As one of the examples displaying its potential, by the third year of sales, 2013, C-Motions will achieve a ROA of 37% and ROE of 44%, which will be close to double in the following year. The company expects to be cash flow positive by 2013 with significant cash generation and market penetration leading to an exit in 2015 (See Figure 7-2).

**Figure 7-1 C-Motions' Net Income Grows to Over $7 Million by Year 8**

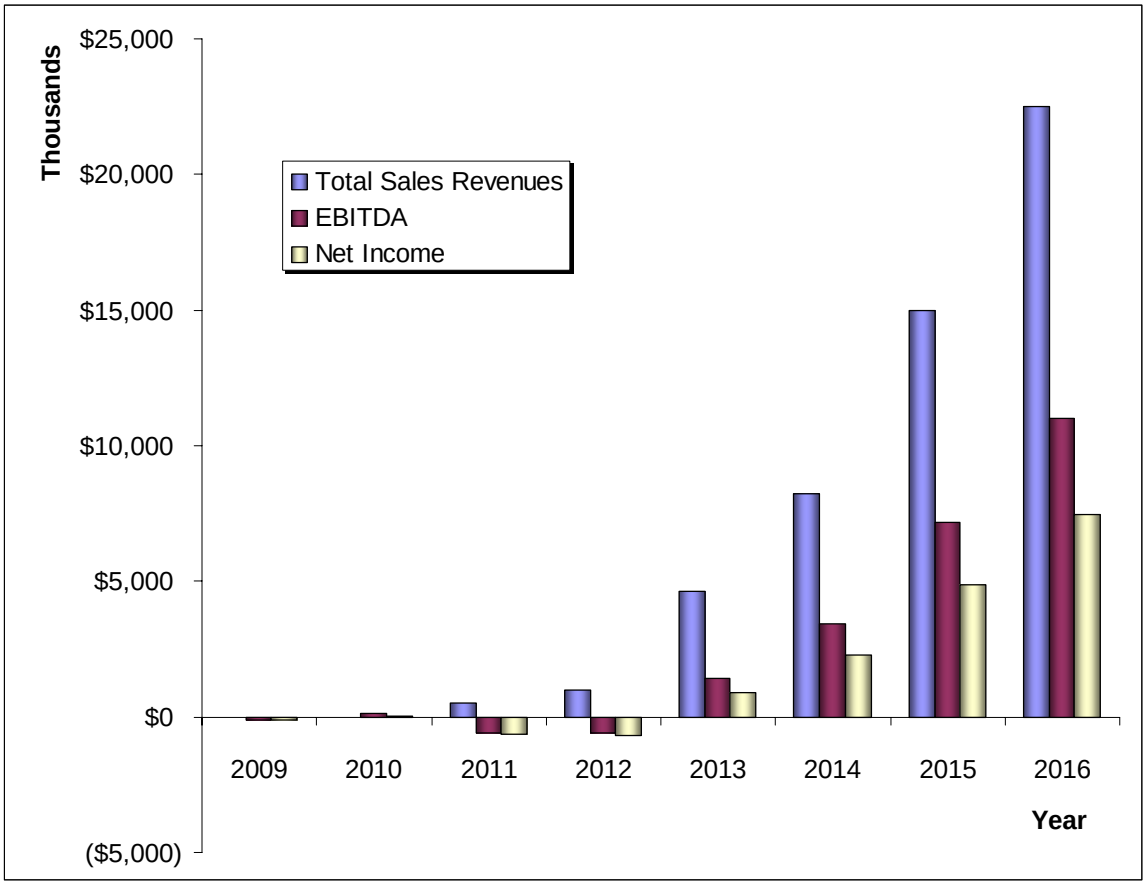
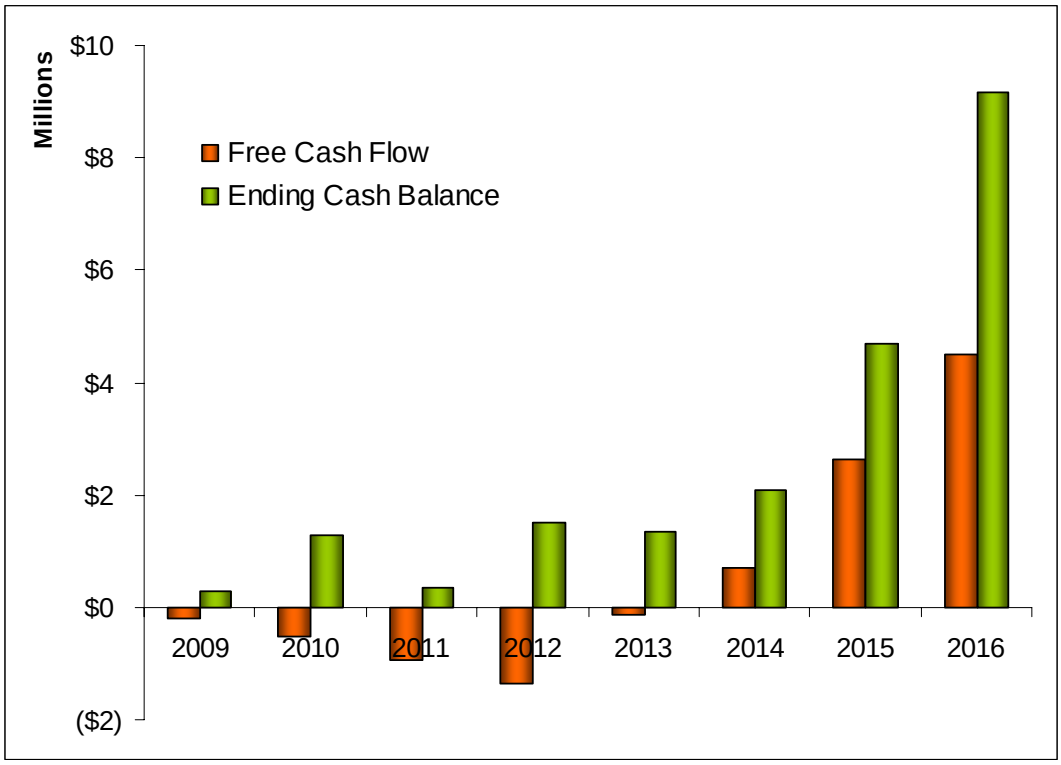


**Figure 7-2 C-Motions' Free Cash Flow and Year End Cash Position**



# 8: CONCLUSION

C-Motions' breakthrough anti-epilepsy drug high throughput screening technology is likely to produce rapid growth of shareholder value, leveraging a small amount of equity capital to grow by $15M/year, and the company is likely to become a highly profitable business within six years with an exceptionally high net margin of 32%. C-Motions' business has outstanding characteristics:

- An exclusive $200 million potential world market, currently underpenetrated due to the limitation of existing technologies that C-Motions' Anti Epilepsy Drug (AED) High Throughput Screening (HTS) service overcomes
- A well fitted, compelling solution to the high cost of the AED development by biotech and pharmaceutical companies worldwide
- Capable management team combining scientific, engineering and business expertise
- Easily targeted major customers in the biotech industry with a history of early technology adoption
- Potential of generating recurring revenues from exceptionally high-margin, and high volume sales of consumables for the next generation of product development
- Small capital requirements relative to market size
- Potential for profitable exit through sale of company or IPO within seven years
- C-Motions solves a high cost problem for biotech and pharmaceutical companies.

Currently C-Motions seeks $500K seed investment to fund product development. Two subsequent venture rounds of $1.5M and $2.5M will fund the commercialization and marketing of the technology. C-Motions offers a unique opportunity to the investors

who would like to enjoy  great financial returns, as well as a chance to contribute to C-Motion’s commitment to find cures for the incurables.

# APPENDICES

## Appendix I: Forecasted Income Statement, Cash Flow, Balance Sheet

**Projected Yearly Income Statement (2009 to 2016)**

| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|---|---|
| **Sales Volumes** | | | | | | | | |
| **Direct Sales** | | | | | | | | |
| C-Motions AED HTS Basic Service | - | - | 2500 | 5000 | 10000 | 15000 | 22500 | 33750 |
| C-Motions AED HTS Premium Service | - | - | 500 | 1000 | 2000 | 3000 | 4500 | 6750 |
| C-Motions AED HTS Platform | - | - | 0 | 0 | 5 | 10 | 20 | 30 |
| C-Motions AED HTS Consumables | - | - | 0 | 0 | 5000 | 10000 | 20000 | 30000 |
| | | | | | | | | |
| **Total Sales Revenues** | - | - | $500,000 | $1,000,000 | $4,625,000 | $8,250,000 | $15,000,000 | $22,500,000 |
| | | | | | | | | |
| **Total Cost of Goods Sold** | - | - | $50,000 | $100,000 | $462,500 | $825,000 | $1,500,000 | $2,250,000 |
| **Contribution Margin** | - | - | $450,000 | $900,000 | $4,162,500 | $7,425,000 | $13,500,000 | $20,250,000 |
| *Contribution Margin %* | 0% | 0% | 90% | 90% | 90% | 90% | 90% | 90% |
| **Operating Expenses** | | | | | | | | |
| Salary Expenses | ($112,500) | ($325,000) | ($762,500) | ($993,750) | ($1,353,125) | ($1,525,000) | ($2,287,500) | ($3,431,250) |
| Commission Expenses (Total) | $0 | $0 | ($10,000) | ($20,000) | ($92,500) | ($165,000) | ($300,000) | ($450,000) |
| **Total Employee Expenses** | ($112,500) | ($325,000) | ($772,500) | ($1,013,750) | ($1,445,625) | ($1,690,000) | ($2,587,500) | ($3,881,250) |
| Facilities Rent | ($5,000) | ($25,000) | ($75,000) | $500,000 | $625,000 | $781,250 | $976,563 | $1,220,703 |
| Administrative Expenses | ($11,250) | ($32,500) | ($77,250) | ($101,375) | ($144,563) | ($169,000) | ($258,750) | ($388,125) |
| Marketing Expenses | $50,000 | $500,000 | ($75,000) | ($150,000) | ($693,750) | ($1,237,500) | ($2,250,000) | ($3,375,000) |
| R&D Expenses | ($20,000) | ($50,000) | ($120,000) | ($250,000) | ($475,000) | ($1,250,000) | ($1,500,000) | ($2,250,000) |
| Insurance | ($5,000) | ($10,000) | ($35,000) | ($120,000) | ($180,000) | ($200,000) | ($250,000) | ($312,500) |
| SR & ED Tax Credits (provincial) | $2,000 | $5,000 | $12,000 | $25,000 | $47,500 | $125,000 | $150,000 | $225,000 |
| SR & ED Tax Credits (federal) | $7,000 | $17,500 | $42,000 | $87,500 | $166,250 | $437,500 | $525,000 | $787,500 |
| **Total Operating Expenses** | ($94,750) | $80,000 | ($1,100,750) | ($1,022,625) | ($2,100,188) | ($3,202,750) | ($5,194,688) | ($7,973,672) |
| **EBITDA** | **(94,750)** | **80,000** | **(650,750)** | **(122,625)** | **2,062,313** | **4,222,250** | **8,305,313** | **12,276,328** |
| Depreciation | ($10,000) | ($70,000) | ($80,000) | ($100,000) | ($125,000) | ($175,000) | ($245,000) | ($350,000) |
| **EBIT** | ($104,750) | $10,000 | ($730,750) | ($222,625) | $1,937,313 | $4,047,250 | $8,060,313 | $11,926,328 |
| Operating Margin | - | - | - | - | - | - | - | - |
| Interest Income (Expense) | - | - | - | - | - | - | - | - |
| **EBT** | ($104,750) | $10,000 | ($730,750) | ($222,625) | $1,937,313 | $4,047,250 | $8,060,313 | $11,926,328 |
| Less loss carry forward | - | - | ($94,750) | ($825,500) | - | - | - | - |
| Provision for Income Tax | ($31,425) | $3,000 | ($247,650) | ($314,438) | $581,194 | $1,214,175 | $2,418,094 | $3,577,898 |
| **Net Income** | **($104,750)** | **$7,000** | **($730,750)** | **($222,625)** | **$1,356,119** | **$2,833,075** | **$5,642,219** | **$8,348,430** |
| Net Margins | 0.00% | 0.00% | 0.00% | -22.26% | 29.32% | 34.34% | 37.61% | 37.10% |

**Projected Yearly Cash Flow Statement (2009 to 2016)**

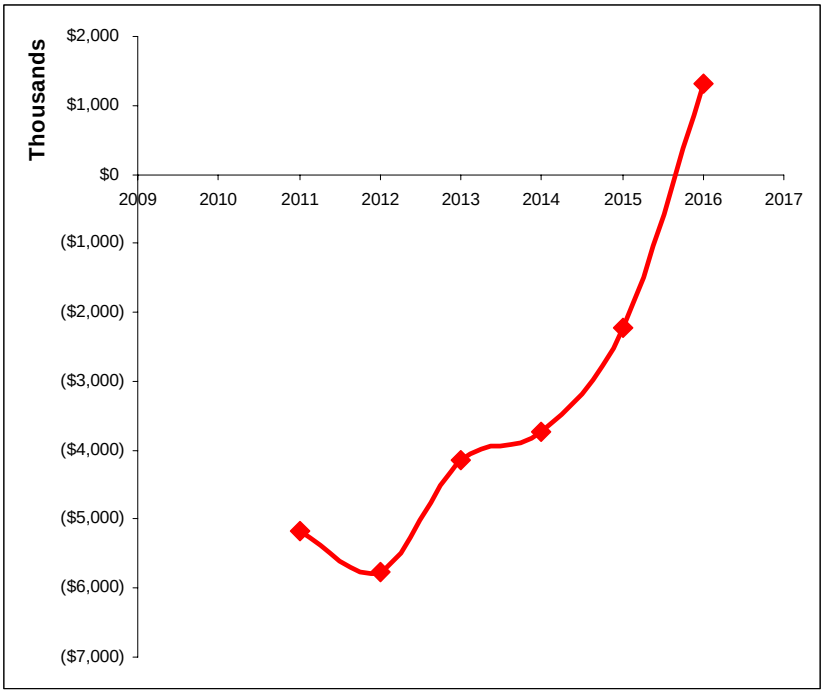
| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|---|---|
| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 | Year 7 | Year 8 |
| **Month** | **Total** | **Total** | **Total** | **Total** | **Total** | **Total** | **Total** | **Total** |
| **Cash Flows From Operations** | | | | | | | | |
| Net Income (Loss) | ($104,750) | $7,000 | ($730,750) | ($222,625) | $1,356,119 | $2,833,075 | $5,642,219 | $8,348,430 |
| + Depreciation | $10,000 | $70,000 | $80,000 | $100,000 | $125,000 | $175,000 | $245,000 | $350,000 |
| (Inc.)/Dec. of Accounts Receivable | - | - | ($150,000) | ($300,000) | ($925,000) | ($1,650,000) | ($3,000,000) | ($4,500,000) |
| (Inc.)/Dec. of Prepaid Expenses | ($833) | ($2,917) | ($13,333) | $23,333 | ($1,458) | ($20,313) | ($64,453) | ($111,816) |
| (Inc.)/Dec. of Inventory | - | (16,667) | (33,333) | (115,625) | (206,250) | (375,000) | (562,500) | (562,500) |
| Inc./(Dec.) of Current Liabilities | ($8,646) | $4,792 | ($81,229) | ($64,594) | $527,116 | $1,147,904 | $2,378,953 | $3,504,051 |
| Total Cash Flows From Operating | ($104,229) | $62,208 | ($928,646) | ($579,510) | $875,526 | $2,110,667 | $4,639,219 | $7,028,164 |
| **Cash Flows From Investing Activities** | | | | | | | | |
| Capital Expenditures | ($50,000) | ($300,000) | ($50,000) | ($100,000) | ($125,000) | ($250,000) | ($350,000) | ($525,000) |
| **Total Cash Flows From Investing** | **($50,000)** | **($300,000)** | **($50,000)** | **($100,000)** | **($125,000)** | **($250,000)** | **($350,000)** | **($525,000)** |
| Free Cash Flows | ($204,229) | ($537,792) | ($1,028,646) | ($779,510) | $625,526 | $1,610,667 | $3,939,219 | $5,978,164 |
| **Cash Flows From Financing Activities** | | | | | | | | |
| Angel Round, Convertible note | $500,000 | - | - | - | - | - | - | - |
| Venture Round A | | 1,500,000 | - | - | - | - | - | - |
| Venture Round B | - | - | - | 2,500,000 | - | - | - | - |
| Long Term Debt | - | - | - | - | - | - | - | - |
| Government Grants | - | - | - | - | - | - | - | - |
| **Total Cash Flows From Financing** | **$500,000** | **1,500,000** | **$0** | **2,500,000** | **-** | **-** | **-** | **-** |
| **Total Cash Flow** | **$295,771** | **$962,208** | **($1,028,646)** | **$1,720,490** | **$625,526** | **$1,610,667** | **$3,939,219** | **$5,978,164** |
| Beginning Cash Balance | $0 | $295,771 | $1,257,979 | $229,333 | $1,949,823 | $2,575,349 | $4,186,016 | $8,125,234 |
| **Ending Cash Balance** | **$295,771** | **$1,257,979** | **$229,333** | **$1,949,823** | **$2,575,349** | **$4,186,016** | **$8,125,234** | **$14,103,398** |

**Projected Yearly Balance Sheet (2009 to 2016)**

| | Fiscal Year Ending in December of | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
| Cash & Cash Equivalents | $500,000 | $295,771 | $1,257,979 | $229,333 | $1,949,823 | $2,575,349 | $4,186,016 | $8,125,234 |
| Accounts Receivable | - | - | $150,000 | $300,000 | $925,000 | $1,650,000 | $3,000,000 | $4,500,000 |
| Prepaid Expenses | $833 | $2,917 | $13,333 | ($23,333) | $1,458 | $20,313 | $64,453 | $111,816 |
| Stock/Inventory | - | $16,667 | $33,333 | $115,625 | $206,250 | $375,000 | $562,500 | $562,500 |
| Total Current Assets | $500,833 | $315,354 | $1,454,646 | $621,625 | $3,082,531 | $4,620,661 | $7,812,969 | $13,299,551 |
| Net Fixed Assets | $50,000 | $350,000 | $400,000 | $500,000 | $625,000 | $875,000 | $1,225,000 | $1,750,000 |
| Accumulated Depreciation | ($10,000) | ($70,000) | ($80,000) | ($100,000) | ($125,000) | ($175,000) | ($245,000) | ($350,000) |
| Total Non-Current Assets | $40,000 | $280,000 | $320,000 | $400,000 | $500,000 | $700,000 | $980,000 | $1,400,000 |
| **Total Assets** | **$540,833** | **$595,354** | **$1,774,646** | **$1,021,625** | **$3,582,531** | **$5,320,661** | **$8,792,969** | **$14,699,551** |
| Accounts Payable | ($8,646) | $4,792 | ($81,229) | ($64,594) | ($54,078) | ($66,271) | ($39,141) | ($73,848) |
| Income Taxes Payable | - | - | - | $0 | $581,194 | $1,214,175 | $2,418,094 | $3,577,898 |
| Total Current Liabilities | ($8,646) | $4,792 | ($81,229) | ($64,594) | $527,116 | $1,147,904 | $2,378,953 | $3,504,051 |
| Long Term Liabilities | - | - | - | - | - | - | - | - |
| **Total Liabilities** | **($8,646)** | **$4,792** | **($81,229)** | **($64,594)** | **$527,116** | **$1,147,904** | **$2,378,953** | **$3,504,051** |
| Paid In Capital | $2,050,000 | $2,050,000 | $7,050,000 | $7,050,000 | $7,050,000 | $7,050,000 | $7,050,000 | $7,050,000 |
| Retained Earnings | ($1,500,521) | ($1,459,438) | ($5,194,125) | ($5,963,781) | ($3,994,584) | ($2,877,243) | ($635,984) | $4,145,500 |
| **Total Liabilities & Common Equity** | **$540,833** | **$595,354** | **$1,774,646** | **$1,021,625** | **$3,582,531** | **$5,320,661** | **$8,792,969** | **$14,699,551** |

# Appendix II: Profitability Ratios and Break Even Ratios

| Profitability Ratios & Break Even Ratios | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|
| Contribution Margin | 90.00% | 90.00% | 90.00% | 90.00% |
| Return of Assets | 37.85% | 53.25% | 64.17% | 56.79% |
| Return on Equity | 44.38% | 67.89% | 87.97% | 74.57% |
| **Liquidity Ratios** | **2013** | **2014** | **2015** | **2016** |
| Current Ratio | 679.65% | 463.51% | 369.62% | 419.50% |
| Quick Ratio | 640.52% | 430.84% | 345.97% | 403.45% |
| Cash Ratio | 369.90% | 224.35% | 175.96% | 231.88% |




C-Motions will break even in 2015.

## Appendix III: Proposed Capitalization Structure

| Category | Paid In Capital | # of Shares | Ownership% (Fully Diluted) |
|---|---|---|---|
| Founders | $50,000 | 5000000 | 24% |
| Employee/Option Holders | $0 | 1000000 | 5% |
| Seed Investors | $500,000 | 6333333 | 30% |
| Series A Investors | $1,500,000 | 5333333 | 25% |
| Series B Investors | $2,500,000 | 3333333 | 16% |
| Total | $4,550,000 | 20999999 | 100% |

## Appendix IV: Valuation Table after Funding

| Valuation | First Round Funding (2009) | Second Round Funding (2010) | Third Round Funding (2012) |
|---|---|---|---|
| Total Shares | 6333333 | 5333333 | 3333333 |
| Price Per Share | $0.12 | $0.37 | $0.87 |
| Pre Money Value* | $973,684 | $4,968,750 | $15,750,001 |
| Post-Money Value | $1,473,684 | $6,468,750 | $18,250,001 |

## Appendix V: Internal Rate of Return

| | Exit Year 2015 | | |
|---|---|---|---|
| Year | Seed | Series A | Series B |
| 2009 | ($500,000) | $0 | $0 |
| 2010 | $0 | ($1,500,000) | $0 |
| 2011 | $0 | $0 | $0 |
| 2012 | $0 | $0 | ($2,500,000) |
| 2013 | $0 | $0 | $0 |
| 2014 | $0 | $0 | $0 |
| 2015 | $15,314,594 | $12,896,500 | $8,060,312 |
| **IRR** | **77%** | **54%** | **48%** |

# Appendix VI: Employee Hiring Plan

| MONTH | | | YEAR 1 | | | | Y1 | YEAR 2 | | | | Y2 | YEAR 3 | | | | Y3 | YEAR 4 | | | | Y4 | YEAR 5 | | | | Y5 | YEAR 6 | | | | Y6 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| X 1.25 | | | Q1 | Q2 | Q3 | Q4 | | Q1 | Q2 | Q3 | Q4 | | Q1 | Q2 | Q3 | Q4 | | Q1 | Q2 | Q3 | Q4 | | Q1 | Q2 | Q3 | Q4 | | Q1 | Q2 | Q3 | Q4 | |
| **G&A** | **Salary** | **w/ benefits** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CEO (founder) | $50,000 | $62,500 | - | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Accountant | $45,000 | $56,250 | - | - | - | 0 | **0** | - | - | - | 0 | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Secretaries | $30,000 | $37,500 | - | - | - | 0 | **0** | - | - | - | - | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| **Marketing & Sales** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| VP Sales & Bus. Dev. | $60,000 | $75,000 | - | - | - | 0 | **0** | - | - | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Account & Product Manager | $55,000 | $68,750 | - | - | - | 0 | **0** | - | - | - | - | **0** | - | - | - | - | **0** | - | - | - | 0 | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Product Ed. Specialists | $55,000 | $68,750 | - | - | - | 0 | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Direct Sales | $70,000 | $87,500 | - | - | - | 0 | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 2 | 2 | **2** | 2 | 2 | 3 | 3 | **3** | 3 | 3 | 4 | 4 | **4** |
| **Customer Service** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Field Engineers | $45,000 | $56,250 | - | - | - | 0 | **0** | - | - | - | 0 | **0** | - | - | - | - | **0** | - | - | - | 0 | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 2 | 2 | **2** |
| **R&D** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Chief Scientific Officer (founder) | $65,000 | $81,250 | - | - | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Software Developers | $50,000 | $62,500 | - | - | - | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 2 | 2 | **2** | 2 | 2 | 3 | 3 | **3** | 3 | 3 | 3 | 3 | **3** | 3 | 3 | 3 | 3 | **3** |
| Research Scientists | $40,000 | $50,000 | - | - | - | 0 | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| **Productions and Operations** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| COO (founder) | $65,000 | $81,250 | - | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Engineering | $45,000 | $56,250 | - | - | - | 1 | **1** | - | - | - | - | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 2 | 2 | **2** | 2 | 2 | 3 | 3 | **3** | 3 | 3 | 4 | 4 | **4** |
| Director of MFG. | $55,000 | $68,750 | - | - | - | 0 | **0** | - | - | - | - | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| QA/QC | $40,000 | $50,000 | - | - | - | 0 | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| Purchasing | $40,000 | $50,000 | - | - | - | 0 | **0** | - | - | - | 0 | **0** | - | - | - | - | **0** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** | 1 | 1 | 1 | 1 | **1** |
| **Total Employees** | | | - | - | 3 | 3 | **1.5** | 4 | 4 | 5 | 5 | **4.5** | 11 | 11 | 12 | 12 | **12** | 13 | 13 | 18 | 18 | **16** | 20 | 20 | 22 | 22 | **21** | 22 | 22 | 25 | 25 | **24** |

# Appendix VII: Proposed Pre-Money Valuation and Methodology

| | |
|---|---|
| Disc factor | **70.00%** |
| LT Growth Rate | **5.00%** |
| Year to exit | **7** |

| **Conventional VC Valuation Model:** | Per Plan | VC |
|---|---|---|
| *(Multiple of after-tax earnings)* | | *25% Discount* |
| After-tax Income (2015) | $5,642,219 | $4,231,664 |
| Price/Earnings Multiple (a) | 20 | 20 |
| | $112,844,375 | $84,633,281 |
| Private Co. Discount (40%) | ($45,137,750) | ($33,853,313) |
| Estimated Value (2015) | $67,706,625 | $50,779,969 |
| Estimated Value Today | **$1,650,018** | **$1,237,514** |

| **First Chicago Method:** | **Home Run** | **Double** | **Single** |
|---|---|---|---|
| *(Multiple of after-tax earnings)* | | | |
| Revenue (2015) | $15,000,000 | $7,500,000 | $1,250,000 |
| After-tax Profits | $5,642,219 | $2,821,109 | $470,185 |
| Price/Earning Ratio | 20 | 15 | 10 |
| Estimated Value (2015) | $112,844,375 | $42,316,641 | $4,701,849 |
| Private Co. Discount (40%) | ($45,137,750) | ($16,926,656) | ($1,880,740) |
| Estimated Value (2015) | $67,706,625 | $25,389,984 | $2,821,109 |
| PV Discount Factor | 41.0338673 | 41.0338673 | 41.0338673 |
| Estimated Value Today | $1,650,018 | $618,757 | $68,751 |
| Probability Factor | 10% | 50% | 40% |
| Expected Present Value | $165,002 | $309,378 | $27,500 |
| Sum of Expected Values | **$501,881** | =Estimated Present Value | |

| **Present Value of Future Net Income (NI) Streams:** | | | | |
|---|---|---|---|---|
| Year | After-tax Income | PV Factor | PV of Earnings | 25% VC Discount |
| 2009 | ($104,750) | 1.7 | ($61,618) | ($46,213) |
| 2010 | $7,000 | 2.89 | $2,422 | $1,817 |
| 2011 | ($730,750) | 4.913 | ($148,738) | ($111,554) |
| 2012 | ($222,625) | 8.3521 | ($26,655) | ($19,991) |
| 2013 | $1,356,119 | 14.19857 | $95,511 | $71,633 |
| 2014 | $2,833,075 | 24.137569 | $117,372 | $88,029 |
| 2015 | $5,642,219 | 41.0338673 | $137,502 | $103,126 |
| 2016 | $8,348,430 | 69.75757441 | $119,678 | $89,758 |
| | | | $235,474 | $176,605 |
| | | PV of NI >2016 | $1,584,383 | $1,188,287 |
| | | Estimated PV | **$1,819,857** | **$1,364,893** |

| **Multiple of Revenues** | Per Plan | 25% VC Discount |
|---|---|---|
| 2015 Sales | $15,000,000 | $11,250,000 |
| Multiple of Revenues (a) | 2 | 2 |
| | $30,000,000 | $22,500,000 |
| Private Co. Discount (40%) | ($12,000,000) | ($9,000,000) |
| Est. Value (2014 dollars) | $18,000,000 | $13,500,000 |
| PV Discount Factor (70%) | 41.0338673 | 41.0338673 |
| Estimated Value Today | **$438,662** | **$328,997** |

| **Summary of Valuation Methods Listed Above:** | Per Plan | 25% VC Discount |
|---|---|---|
| Conventional VC Valuation Model | $1,650,018 | $1,237,514 |
| First Chicago Method | $501,881 | $376,410 |
| Present Value of Future Net Income (NI) Streams | $1,819,857 | $1,364,893 |
| Multiple of Revenues | $438,662 | $328,997 |
| Maximum Valuation | $1,819,857 | |
| Minimum Valuation | $328,997 | |
| Average of 8 Values | **$964,779** | |

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