

# NeuraGap

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NeuraGap offers services and consultations for pre-clinical validations with a focus in brain diseases. We strive to provide industrial standard with academic knowledge.

## Team members

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## 1. Executive Summary

NeuraGap is a company that offers services and consultations for pre-clinical validations. Drawing from our extensive research experience with various rodent models of brain diseases, we seek to be the partner for start-ups and academic laboratories who have compounds that they wish to quickly and accurately validate in an animal model.

With an aging population, caring for patients with brain diseases is projected to be the big ticket item for personal and government spending. The common theme in all brain diseases such as stroke, brain injury and Alzheimer's diseases is the death of brain cells called neurons. Therefore, there is an urgent need and a big market for any drug candidates that will reverse or maintain the health of neurons (i.e. neuroprotection). A survey of recent publications reveals that there are many potential neuroprotective candidates that are not validated in a brain disease model. In addition, conclusions can be misleading if the validation is not carried out correctly and reproducibly in an animal model. We understand the difficulty to acquire trained personnel and to obtain quick approval for animal protocols. Following years of surgical experience in mice, we have generated a reproducible baseline to assess neuron health due to stroke. As a company, we are able to focus on delivering the results on time. We expect to generate revenue by providing validation services in rodent models and consultations in experimental design. Our extensive academic network and proven track record in high-impact academic journals will distinguish us from our competitors.

We are also optimizing a validation platform that is based on a 3-dimensional (3D) model system that mimics the native environment of brain tissue. The platform will allow us to offer an additional validation service to quickly assess potential therapeutic compounds for dosage and efficacy in human cells. To bring this platform into service, we will collaborate with academic laboratories in grant competitions that promote academic-industry liaison. We hope to use NeuraGap to enter a niche market that demands a highly specialized skill set and in-depth knowledge in brain science. By offering our services to early start-ups with limited capital in exchange for options, we hope to form partnerships that will lead to the development of promising drug candidates.

## 2. Market Analysis

The combined direct and indirect costs including hospital care, physician care and drug expenditures for stroke is \$4.3 billion and accounts for close to 50% of all brain diseases costing \$8.9 billion (report generated in 2007 by Canadian Brain and Nerve Health Coalition, partnered with the Canadian Institute for Health Information and the Public Health Agency of Canada based on 2001 data. Furthermore, over 400,000 Canadians are living with long-term disabilities caused by stroke, which imposes a large financial burden on the healthcare system,

### 2.1. Problem

Accordingly, there are many incentives for academic researchers and biotechnology companies to generate therapeutic compounds to protect brain cells from insults. However, many investigators and small companies may not be able to access expertise and resources to conduct proper in vitro and in vivo pre-clinical validations.

### 2.2. Market Need

In an academic setting, the validation of an isolated compound in neuroprotection can take years and is not cost-effective; it involves generating the paperwork for animal protocols and hiring or training new personnel. Often the findings may still be misleading due to insufficient understanding of brain complexities, if for example, an academic investigator with a medicinal chemistry expertise. We provide a cost-effective alternative for small to mid-sized pharmaceutical or biotechnology companies to quickly test their existing compounds or biomarkers in a collaborative academic-like environment without the bureaucracy encountered when dealing with a university administration.

### 2.3. Market Size

It is hard to predict the market size. Based on the renewed interest in brain diseases due to an aging population in Canada and other developed countries, we expect there will be a need for highly-skilled experimentalists and knowledge experts to offer validation services for researchers and companies wishing to explore the possibility of entering the neuroprotection market.

## 3. Competition

Our competitors will be other academic laboratories with the same research expertise, and contract research organizations (CROs) that offer pre-clinical validations.

### 3.1. How are Customer Needs Addressed Today

To set up the validation program, an academic investigator will hire an experienced researcher, either a postdoctoral fellow or a research associate. Even if the hired personnel is a perfect fit, it is often a long process due to demanding ethics protocols for animal studies. Small companies will find it cost prohibitive for a 'one-off' project. Thus, they often 'collaborate' with academic laboratories. However, the schedule and focus of an academic laboratory is not geared towards efficient output. The personnel are often trainees working towards a graduate degree, or undergraduates doing an internship, and there is no mechanism set in place to ensure that the experimental protocol will not be affected by high turnover of personnel.

### 3.2. Environmental Scan

A survey on the website (<http://www.contractresearchmap.com/places/canada>) revealed 10 companies or public institutions that offer similar services in Canada. Our list does not include companies or institutions that are part of the Northeast Preclinical Network (<http://www.nepn.net/>) offering comprehensive services; our target customers are different. We identified 2 companies that specifically work with brain diseases and offer stroke model in their portfolio. There are CNS|CRO preclinical neurological diseases services and NeuroInvestigations. A third company, Biospective does not offer stroke in their brain disease models.

### 3.3. Competitive Advantage

NeuraGap will be the first service company that is based in Western Canada as most of the CROs are mainly located in Quebec and Ontario. Therefore, we can offer the option to carry out the rodent surgery on-site if the customers wish to induce stroke in their transgenic rodent models, for example, the susceptibility of stroke damage in mice with Alzheimer's genes. Another competition may come from scientific outsourcing companies but they are weighted towards remote computing and do not appear to offer similar services. It should be noted that some CROs who offer brain disease models may be only providing drug dosage and efficacy studies in rodents bearing the disease genes; the drug delivery process usually does not involve challenging brain surgery. We have a highly experienced rodent surgeon (>20 years) with numerous peer-reviewed publications using the rodent stroke model since 2000. We have a SOP (standard operating protocol) that has virtually eliminated animal morbidity and minimized inflammation, 2 possible results from surgery performed by inexperienced personnel. We can offer additional services such as characterizing brain pathologies with protein biomarkers and measuring the dosage and efficacy of the customer's compounds in cultured brain cells in order to determine the possible therapeutic range in rodents. If necessary, we have experienced and successful grant writers that will help the academic researchers to apply for funding. As a start-up, we will have more flexibility in contract negotiations with small companies. Although we do not have in-house animal facility, we have access to various facilities in Vancouver. In summary, we aim to provide a 'concierge' service by providing valuable knowledge about the field. Our scientific advisor, Professor Christian Naus is recognized in Neuroscience and Cancer and holds a Tier 1 CRC (Canada Research Chair) since 2003. Finally, it has become clear for a while that numerous positive clinical findings gained from rodent studies are not replicated in humans; accordingly, 3D human tissue engineering (bioprinting or organoid) is gaining more attention. However, the 3D technology is still a maturing field and has yet to completely capture a native living environment; therefore, we expect our business model will still be relevant for at least 5 years.

## 4. Commercialization Plan

We will mainly pursue a 'fee-for-service' research contracts as our main revenue generating source. As such, we will make use of our extensive academic connections and advertise our services by presenting at scientific conferences. Tapping into existing contract out-sourcing network is another option to increase our client base.

### 4.1. Science / Technology Overview

We offer several MCAO (middle cerebral artery occlusion) rodent stroke models. Permanent MCAO is conducted with electrical coagulation of the artery, a technique that is well tested and widely published in scientific literature. It produces local damage that is highly reproducible and predictable. Permanent MCAO is quick to perform and a pilot report can be delivered in 3 months. Reperfusion MCAO is carried out with artery clips or iron chloride ion coagulation followed by tissue plasminogen activator (tPA) that opens the blood vessels, allowing the return of blood flow. The reperfusion model mimics the secondary damages to the brain in stroke patients due to the mixing of oxygen in the blood with materials generated by the dying cells during the initial blockage. Post-stroke recovery can be assessed by basic behavior testing paradigms such as tape test, cylinder rearing test and mesh walking test, and can be combined with processing of brain tissues for histology analysis.

## 4.2. Growth Strategy

By offering our rodent services to start-ups with promising drug candidates, we seek to establish a portfolio of strategic partners. Initially, we will focus on offering a stroke model. However, we also have experience in brain tumor rodent model. There will be options later for customers to supply their own mice for the project. We will also be available to work on the customer's site if necessary. As part of our commitment to develop a suite of validation tools that allow drug validations with human cells, we are optimizing a 3D culture platform.

## 4.3. Milestones

Months	Milestones
3	Set up company and complete paperwork, website, domain name
6	First research contract through existing academic and industrial contacts
12	Expand market base in scientific conferences, new hires to expand business
18	Expand offer of animal models such as a traumatic brain injury model
24	Set up partnerships with early start ups with promising candidates
36	Offer 3-dimensional human brain cells validation platform

## 5. Financial Plan

As our service is labor intensive, we are initially targeting a niche market and aim to sign on a few contracts and projects depending on the scope of the client's request.

### 5.1. Financial Needs and Justification

We have acquired relevant experience in academic collaborations where we contributed our expertise in rodent stroke. We have successfully performed a stroke surgery off-site (Seattle, USA) and we recently completed a service contract with Zealand Pharma. Depending on the size of the experimental cohort, a basic package can vary from CAD \$20,000 to \$50,000 for a pilot validation contract. The sum covers everything including consumables and salaries. We will have increased financial needs after 1 year due to traveling costs and new hires in anticipation of increased workload. Conference costs can vary from \$1000 to \$3000. We anticipate the new hires will mainly be UBC undergraduates in the co-op program that usually last for 8 months, costing about \$20,000 per hire. When we are ready to expand our services, we will need to hire experienced employees on short term contracts. Additional investment will also be needed if we seek to form partnership by acquiring options from small start-ups that do not have enough capital. Already, we have one enquiry from an American start-up that is interested to test their drugs in our rodent model.

### 5.2. Fundraising plan

Year 1: Line of credit or bank loans or personal funds to cover the costs of marketing and attending conferences.

Year 2: MITACS to subsidize hiring of employees, government grants and SR&ED credits for developing 3D human cell validation platform.

Year 3: Consider approaching angel investors for equipment acquisition if we are ready to expand into 3D validation platform.

### 5.3. Exit

The company will be privately held with cash flow from customer-paid services and non-diluting funding sources to develop the 3D platform. We expect that pre-clinical validation using animal models is still the golden standard for the next 5 years.

## 6. Team

Our founders not only have years of research experience and laboratory management, they also have complementary skill sets. As the CEO of the company, Dr. Wun Chey Sin is an accomplished scientist with high impact publications and successful academic grant applications. As the chief operating manager, John Bechberger has extensive mouse surgical experience and contacts with the animal facilities in Vancouver. In addition, John also has prior small business experience in Ontario as an independent contractor. We are also privileged to have Prof. Christian Naus as the scientific advisor of the company. Prof. Naus is part of the Canadian Stroke Network, holds a Tier 1 CRC in Gap Junctions & Disease since 2003 and is an elected member of the Canadian Academy of Health Sciences since 2012.