



Imagine: Harnessing the power of the molecule that can do this, for the benefit of humans and animals!



Sir Charles Bell, Painting of a soldier with tetanus. Circa 1809.

### **Executive Summary**

Patented unique, World First therapeutic product of modified tetanus toxins to pioneer treatment in the Global low tone muscle weakness market, which has <u>no current drug options</u>

### **Target Markets:**

Cosmetic muscle tightening: eyelid, facial, chin..... Sleep disordered breathing: Snoring, Sleep Apnoea. Sphincters: Anal, oesophageal, bladder, pelvic floor. Neurological: MS, MND, Myopathy. Veterinary: BOAS disorders, "Roaring" larynx...

## **Provenance of Technology**

Where did the idea come from? An intersection of 3 factors:

- 1. Treating Tetanus in India
- 2. realizing that sleep apnoea is muscle hypotonia (low tone in sleep),
- 3. and the success of Botox.....

*Botulinum toxin* decreases muscle tone by reducing neuronal impulse rates and is one of the most successful drugs discovered.

Tonetox/Snoretox (*Modified Tetanus Toxin*) does exactly the opposite to Botox, instead of relaxing muscles it tightens them, by increasing neuronal impulse rates.

It acts similarly to Botox, but at a different site, on the upper motor neuron, not the lower.

We have successfully modified tetanus toxins to by-pass antibodies, enabling use in humans and animals, unlocking the therapeutic potential.

### **Snoretox Pty Ltd**



#### **Current Device-based treatments**



### Solution to a Problem



There are many diseases that can be treated by the control of muscle tone.

Tetanus toxin increases local muscle tone for an extended period.

The problem is people are vaccinated against tetanus, resulting in anti-tetanus antibodies, rendering tetanus toxin useless for therapeutic applications.

**Tetanus Toxin Molecule** 

The solution is to develop a molecule that is effective in the vaccinated population.

### Scope of Opportunity Examples of Low-Tone Muscle disorders

#### **SLEEP APNOEA & SNORING**

1 billion sufferers globally (18.6% of population). <50% compliance with CPAP.

### OTHER LOW-TONE DISORDERS

Lax sphincters, pelvic floor weakness, weak limb and core muscles. <u>MND</u>, muscular dystrophy, myopathies, multiple sclerosis.



#### **EYELIDS & COSMETIC**

Ectropion incidence is 2.9% in the elderly. Eyelid lifting & Facial muscle toning. Potential use as complementary treatment to Botox as well as unique cosmetic treatment option.

#### VETERINARY

Over 5 million brachycephalic dogs worldwide - disordered breathing a significant and untreated problem. "Roaring" Laryngeal Disorders, a large veterinarian problem.

### **Intellectual Property**

#### Snoretox Pty Ltd owns all intellectual property

Royalty deal with RMIT – 10% of profits (after expenses). 1<sup>st</sup> Patent: lodged 1 July 2018: all 36 claims passed Examination (International Phase) March 2020. 2<sup>nd</sup> Patent lodged 2 Feb 2020. Future IP will be similarly protected as product development and trials proceed.

Griffith Hack engaged to write and file patent Griffith Hack is part of IPH limited with considerable experience protecting IP and extensive international networks

#### Claims

Modified neurotoxins to be effective in vaccinated individuals

#### Claims

Novel methods for evading the immune response

#### Claims

**IP** Amplified

griffith

Methods for treating lowtone muscle disorders with modified neurotoxins



### **Tetanus toxin mode of action**

- Tetanus toxin enters motor-neurons at the injection point
- Transported up to the spinal cord synapse and enters the inhibitory neuron (upper motor neuron).
- Cleaves the SNARE proteins responsible for synaptic firing, for up to 6 months (like Botox).
- Reduces the off signal to the muscle increasing resting tone in the muscle, in a dose dependent way.
- Does not spread in the CNS localised response
- Similar action to Botox; except Botox reduces the excitatory neuron firing of the peripheral nerve, but Tetanus Toxin <u>lowers</u> <u>the inhibitory neuron firing</u> in the CNS, thereby <u>increasing the</u> <u>peripheral nerve firing rate</u>.

### **Critical data**

# **Treatment of OSA in a Bulldog**



Successful trial of Tetanus Toxin in a bulldog resolving its sleep apnoea. Treatment with 10 IU of tetanus toxin significantly reduced the respiratory disturbance index of the dog by over 50%, the effect lasting over 4 months. (Sasse *et. al.* 2005)

## **Snoretox functions in vaccinated model**

![](_page_12_Picture_1.jpeg)

![](_page_12_Picture_2.jpeg)

Two vaccinated mice injected with the same units of tetanus toxin (left) and Snoretox (right).

Right Mouse showing stiff right hind leg indicating muscle response to Snoretox, indicating effective drug, with avoidance of antibodies.

![](_page_12_Figure_5.jpeg)

Superiority of Snoretox (red) and Tetanus toxin (blue) upon injection int o the hind limb of mice vaccinated with tetanus toxoid (manuscript und er review, McLean *et. al.*)

![](_page_13_Picture_0.jpeg)

Legal and regulatory engagement

**IP** protection

Funding and Industry partnerships

#### **Research and Development**

Veterinary trials

![](_page_13_Picture_6.jpeg)

![](_page_13_Picture_7.jpeg)

Human clinical trials Establish collaborations Identify therapeutic targets

#### **KEY MEDICAL INNOVATIONS & HIGHLIGHTS**

A Quick Breakdown

![](_page_14_Picture_2.jpeg)

### **Snoring and Sleep Apnoea Mass Market Opportunities**

![](_page_15_Picture_1.jpeg)

A major cause or aggravator of a wide range of disorders such as tiredness, stroke, cardiac diseases, depression, macula disease and glaucoma.

![](_page_15_Picture_3.jpeg)

Affects 1 billion people world-wide (18.6% of population). 30 million CPAP users (est.).

![](_page_15_Picture_5.jpeg)

We have performed a successful trial of Tetanus Toxin in a Bulldog resolving its sleep apnoea.

![](_page_15_Picture_7.jpeg)

![](_page_15_Picture_8.jpeg)

![](_page_15_Picture_9.jpeg)

### Sphincters and Cosmetics Market Opportunities

![](_page_16_Picture_1.jpeg)

![](_page_16_Picture_2.jpeg)

![](_page_16_Picture_3.jpeg)

#### Ectropion: 2.9% of elderly patients

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Anal Incontinence: 1.2% of the population = 84 million

![](_page_16_Picture_7.jpeg)

Pelvic Floor Weakness

![](_page_16_Picture_9.jpeg)

Eyelid elevation, Floppy eyelids, Facelift, muscle toning

![](_page_16_Picture_11.jpeg)

![](_page_16_Picture_12.jpeg)

![](_page_17_Picture_0.jpeg)

![](_page_17_Picture_1.jpeg)

![](_page_17_Picture_2.jpeg)

Myopathy

Forms of Motor Neuron Disease

**Multiple Sclerosis** 

> Not a cure, but a symptom alleviator

event (no compliance needed), Snoretox: \$500 annually, single event studies to - date show ability to (no recovery needed), the only drug CPAP or Machine, used completely offset musculature failure solution on market, same cosmetic nightly, inconvenient, breakthrough level as Botox. causing concern. annual cost of \$1190. Surgery: (eyelid: \$2400+ High non - compliance USD, facelifts : \$2800) numbers. invasive treatment, long recovery period, timely and **SLEEP APNEA** Throat Surgery, costs of **COSMETICS** costly. / SNORING \$10,000, painful, low success rates (long term) TREATMENT COMPARISONS LOW TONE Pad Usage LAX **NEUROLOGICAL** Uncomfortable, , band -**SPHINCTER DISEASES** aid solution, socially NO DRUG SOLUTION inconvenient. **Sphincter Surgery:** Snoretox: \$500 6 months lasting Costly, weeks of recovery, **Snoretox:** \$500 6 months lasting \*Indicative prices effect, no recovery needed, the only invasive treatment. effect, no recovery needed, the only drug solution on market, ability to drug solution on market, ability to tighten/tone targeted muscle groups. tighten/tone targeted muscle groups.

Snoretox: \$1000 annually, single

### **Veterinary Health**

Snoretox also has the potential to be used to treat a range of orphan veterinary conditions, including:

- Disordered Breathing in Brachycephalic Dogs
- Floppy Larygneal "Roaring" Disorders (particularly in horses).
- Faecal Incontinence
- Other uses such as hemiplegia, muscle weakness, spinal cord injury etc.

![](_page_20_Picture_0.jpeg)

There are over 5 million brachycephalic class dogs in the world. Breathing problems are common and a significant health and welfare issue.

Snoretox successfully treated a bulldog with sleep apnoea.

![](_page_20_Picture_3.jpeg)

### **Early Commercial Opportunity**

Disordered breathing and sleep problems in short-nosed (brachycephalic) dogs is a significant problem and the need for a simple treatment is unmet. Snoretox offers the next generation of treatment for the global veterinary market.

### Manufacturing and scale-up plan

![](_page_21_Figure_1.jpeg)

Currently in talks with accredited Australian laboratory for GMP production.

Scale up is straight forward. All procedures scale linearly with batch size. Only tiny amounts required per dose.

## **Risk & Mitigation**

Risk	Mitigation
Unforeseen adverse event profile of the drug	Botox is safe in humans; Tetanus toxin is essentially identical. Strict dose control
Standard Commercial risks – failure to secure funding	Use experts in Business and the Pharmaceutical industry. Control costs tightly.
Patent Risk – defeat or circumvention of patent portfolio	Use Griffith Hack Patent Attorney
Failure of drug to achieve expected therapeutic results despite having achieved excellent results in mice	Considered very unlikely by experts at RMIT. Tetanus toxin & Snoretox are powerful molecules.
Unforeseen new significant medical breakthroughs in therapeutics in low tone muscle disorders	Medical breakthroughs are difficult to achieve
Sovereign risks	Hopefully Australia continues good relations with both the USA and China.
Competition from Big Pharma once they realize the size of this market, with research to develop new but similar molecules, and various efforts to thwart our own progress, such as any legal or scientific loopholes.	We have a large head-start, will keep key data secret, diligently work for patent security, patent all new relevant ideas, use experienced legal and patent attorneys, and try to stay ahead of the market.

## Regulatory pathway

![](_page_23_Picture_1.jpeg)

Complete pre-clinical trials for toxicology, efficacy and safety studies in animal models

First regulatory application – treatment of breathing disorders in dogs

Manufacturing & Control protocols

Human application for treatment of ectropion repair and possibly sleep apnoea

Complete Phase I, II & III clinical trials

#### Reimbursement

Subsequent human FDA/TGA/EMA approval applications

## **Human Timeline**

![](_page_24_Figure_1.jpeg)

![](_page_24_Figure_2.jpeg)

Approx. \$2.5M for efficacy in phase 1; \$8M for completing phase 2.

## **Vet Timeline**

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![](_page_25_Figure_2.jpeg)

#### Trials for market ready product approx. \$1M over 3 years

## **Business timeline**

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### **Investment Highlights**

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# Thank you

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