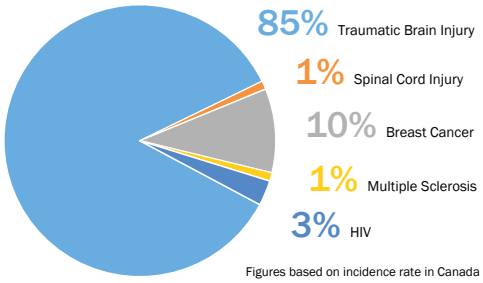
Medicortex Finland is dedicated to improving the diagnostics and treatment of Traumatic Brain Injury (TBI). Current focus is on the development of biomarker diagnostics to evaluate the extent and severity of concussion and traumatic brain injury. Once the development of the diagnostic kit is more advanced, the next goal is to expand the program to the development of an innovative drug to halt the progression of brain injury.

MEDICORTEX Heading Towards a Solution

www.medicortex.fi

Every 15 seconds, someone in the United States suffers a new head injury. Of the 2.5M people treated in hospital emergency rooms each year, 80,000 become permanently disabled because of TBI. The total number is as high as the incidence of Alzheimer's disease, Parkinson's disease, and multiple sclerosis combined. In Finland, it is estimated that about 40,000 people sustain a brain injury every year. In Canada the annual incidence of TBI cases is more than 160,000, and the global numbers are more than 50 million. Brain injuries occur more frequently than breast cancer or AIDS. Currently, there are no reliable diagnostic tests to assess the presence or severity of an injury on-site, nor are there any pharmaceutical therapies that could stop the secondary injury from spreading. Accurate diagnostics would benefit especially mild cases of TBI (concussions), which, if occurring repeatedly, may cause neurodegenerative conditions such as Chronic Traumatic Encephalopathy. Several cytokines and proteins have been studied for the purpose of diagnostics but their applicability and definite correlation with the severity of brain trauma is yet to be demonstrated.

Incidence Rate of TBI in Proportion to Other Major Illnesses



Figures based on incidence rate in Canada

DIAGNOSTIC KIT FOR TBI DETECTION

Medicortex is working towards the identification of brain injury biomarkers and their incorporation into an accurate diagnostic kit, which will give a reliable result rapidly and does not require medical professionals to interpret the result. To date, only one blood test has been approved by regulatory agencies for TBI diagnostics. Medicortex is using non-invasive samples such as urine and saliva and is developing a robust point-of-care test that can be used, for example, in emergency response situations such as traffic accidents, sports injuries and military activity. Furthermore, a new diagnostic kit would also become an end point evaluation of all future clinical trials in TBI, and insurance companies would rely on the test result when processing brain injury related claims.

POTENTIAL MARKET

Every year, millions of people suffer from the effects of TBI. Yet, to this date, the market is lacking a rapid biomarker test to diagnose TBI. Arrowhead Publishers (USA) conservatively estimates that the global potential of TBI diagnostic device (POC) market will exceed €2 billion annually. It can be estimated that the expected US sales alone of a TBI diagnostic kit would be in the range of 400–500 M€ per year. Medicortex Finland's solution ProbTBI™ kit will be extremely desirable for multiple users such as first responders and sport organizations.

PRE-CLINICAL STUDIES

Medicortex has performed preclinical research comparing fluid biopsies from normal and injured lab animals. The results showed some unique biomarkers released as biodegradation products after head injury. The data served as the basis and confirmation for patent applications to protect the novel biomarker idea.

CLINICAL DEVELOPMENT

The first clinical study with Turku University Hospital (Tyks) demonstrated that the new biomarker is applicable for clinical detection of brain injury. Samples collected from 12 TBI patients were compared to 12 healthy volunteers, and the level of biomarker was increased in TBI patients in a statistically significant manner. The result was a significant milestone for Medicortex.

The second clinical trial is underway. The body fluid samples were collected in two Finnish hospitals and currently they are analyzed in research laboratories. Patients with a suspected TBI or orthopedic injury, and healthy controls were recruited in the study (total 68). The study addresses, for example, the specificity and sensitivity of the biomarker and its time-dependent appearance after the injury, the overall objective being to confirm the clinical relevance of the biomarker. The second step with up to additional 100 TBI-patients is pending depending on the outcome of the preceding step. More information about the study is available at ClinicalTrials.gov/NCT03306563.

The next clinical objective is to conduct a multicenter clinical study with children. Children are a big group of brain injury patients yet the adult results achieved so far are not directly applicable to the pediatric patients because of the different stages of growth and development.

ProbTBI™ Three Years R&D Program	2018/ H1	2018/ H2	2019/ H1	2019/ H2	2020/ H1	2020/ H2
Multi-center clinical trial	■	■	■			
Human sample collection	■	■				
Human sample testing:		■	■			
Biomarker structure analysis (LC & MS)		■	■			
Biomarker quantification		■	■			
Development of biochemical detection	■	■	■	■		
* Pediatric Clinical Trial Validation			■	■		
Medical prototype development				■	■	
Prototype testing of samples from hospitals					■	
Initiation of kit production						■
Regulatory application						■
New patent applications		■			■	

REGULATORY STATUS

As diagnostic tests have a relatively short approval process, Medicortex believes that a prototype diagnostic kit can be presented in two years. To further expedite the entry to market, Medicortex may outsource the approval process for the CE-mark acquisition. In parallel, regulatory efforts will be made in the UK and Canada.

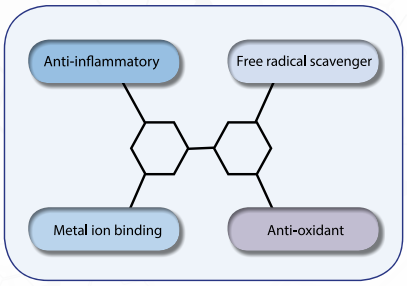
INTELLECTUAL PROPERTY STATUS

Medicortex holds the following pending patents for the biomarker development:

1. "Prognostic and diagnostic glycan-based biomarkers of brain damage"; WO/2016/166,419.
2. "Non-invasive brain injury diagnostic device" WO/2018/154,401.
3. "Portable device and methods for continuous diagnosis of brain injuries" US application 62/720,936.

DRUG FOR BRAIN INJURY TREATMENT

Medicortex has designed several chemically verified proprietary NCE's (new chemical entities), each with at least two of the following neuro-protective functions: free metal ion binding, anti-oxidation, anti-inflammation and free radical scavenger action. The unique chemical composition of these compounds inhibit the neurodegenerative cascade after the brain injury and they will be developed into multifunctional, synergistic treatment.



Since secondary brain injury is caused by multiple cascades of biochemical reactions, previous attempts using a single biochemical mechanism have all failed. Medicortex has developed and synthesized a formulation for its first compound TBI-466 which was found to be safe in the first preclinical studies.

INTELLECTUAL PROPERTY STATUS

Medicortex has the patent and applications for the drug development:

1. "Multivalent Compounds for Use in the Treatment and Prevention of Brain Damage" granted US 9,975,846, granted FI 127 024.
2. "Conjugates for TBI and Neurodegenerative diseases" US 62/680,610.
3. "Compounds for the prevention or treatment of TBI and neurodegenerative diseases" US 62/698,156.

POTENTIAL MARKET

TBI is one of the leading causes of death and disability in young adults. Yet, to this date, there are no approved pharmaceutical therapies for TBI or the cascades that exacerbate the injury. Arrowhead Publishers (USA) conservatively estimates the global potential therapeutic TBI market to exceed €10 billion per year. The US market alone is estimated to range €4–6 billion annually.

REGULATORY STATUS

Medicortex will initiate clinical trials and regulatory applications after completion of its pre-clinical data acquisition. This will take place once the funding and adequate resources of clinical trials are guaranteed. Intention of the company is to use an EMA agency and hospitals in the EU region for its Phase I clinical trials.

MEDICORTEX'S SOLUTION TO BRAIN INJURY TREATMENT

- Synthesis of New Chemical Entities (NCE)
- Physico-chemical characterization
- In-vitro functionality testing
- Ex-vivo efficacy testing
- In-vivo efficacy and pharmacology testing
- Toxicology
- Regulatory application

BOARD OF DIRECTORS

- Chairman of the Board **Adrian Harel**, PhD, MBA.
- Member **Mårten Kvist**, MD, PhD, Associate Professor, Medical Director.
- Member **Tom Palenius**, MSc, Director, Services for Startup Companies at Turku Science Park Oy.

SCIENTIFIC AND CLINICAL ADVISORY BOARD

- **Heikki Rauvala**, Chairman of the SAB, Professor, Neuroscience Center, University of Helsinki, Finland.
- **Antti Kaipia**, MD, PhD, Associate professor. Chief, Department of Urology, Tampere University Hospital, Finland.
- **Lauri Kangas**, PhD, Associate Professor, Pharma Scientific Adviser, Chief Scientific Officer, Finland.
- **Timo Kurki**, MD, PhD, Associate Professor. Neuroradiologist, Chief of Medical Imaging, Terveystalo Oy, Finland.
- **Risto O. Roine**, Professor and Chairman, Division of Clinical Neurosciences, Turku University Hospital and University of Turku, Finland.
- **Markku Tuominen**, MD, PhD, Chief Physician. CEO, Medisport Oy, Tampere, Finland.

USE OF FUNDS

Medicortex intends to raise 500 K€ in this financing round for a comprehensive clinical sample analysis and summing up the final report as well as for launching the new pediatric study. This investment could be partially matched by Business Finland (former Tekes), the Finnish Government's agency for innovation, in the form of a grant or a low-interest loan that Medicortex will apply.

The biomarker development program consists of the following phases:

1. Identification of a biomarker in human brain-injured patients.
2. Analytical and biochemical testing of the biomarker.
3. Building of a prototype diagnostic device/kit to identify brain injury.
4. Clinical validation of the biomarker and approval for CE-mark acquisition.

Total investment needed for the entire project in 2019–2021 is 4–5 M€.

Medicortex believes that its investors should have the opportunity to exit and secure their profit at every successful milestone, at the investor's sole discretion.

Medicortex offers investors a clear path towards value creation. While the risk is initially relatively high, it will be reduced as each milestone is achieved, simultaneously increasing the company's value. Given the immense market potential, the risk-benefit ratio is looking extremely favorable.

Established	June 2014
Name	Medicortex Finland Oy (ID 2625992-6)
Founder and CEO	Adrian Harel (PhD, MBA)
CFO	Marjukka Iitti
Medical Director	Mårten Kvist (MD, PhD, Associate Professor)
Head of R&D	Lasse Välimaa (PhD)
Head of Regulatory Affairs	Michael Evelegh (PhD, RAC)
Head of Marketing	Tomi Virkki (BA Honors)
Research Coordinator	Oskar Haavisto (BSc)
Facilities	Bio-incubator in Turku, Finland
Company's Activity	Diagnostics for TBI
Current valuation	7.6 M€
Post-Money Valuation	8.1 M€

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