

Developing a test for detection of mild traumatic brain injury

August 2025

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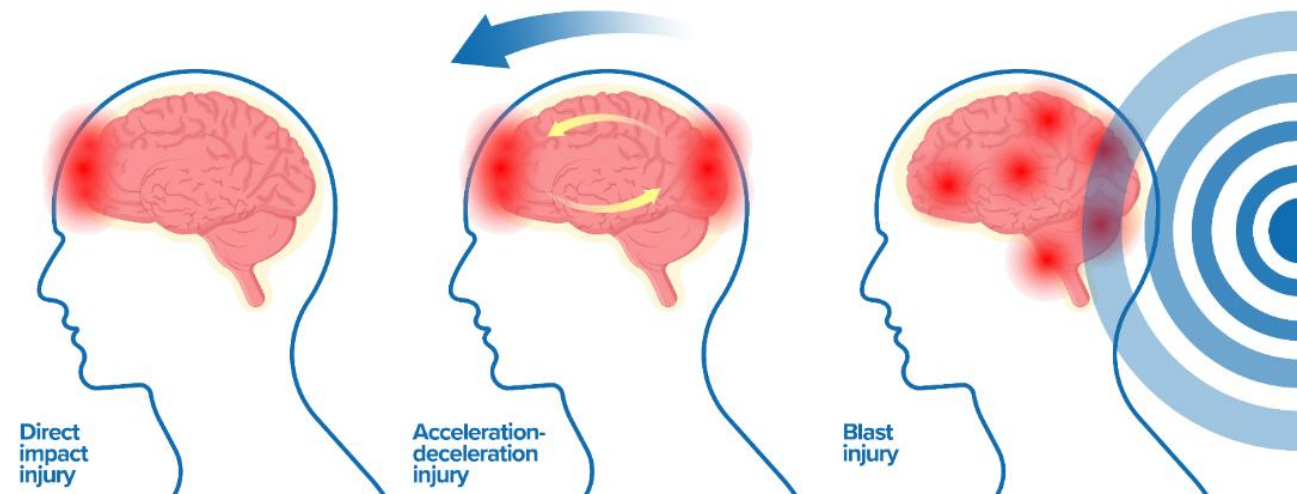
Introduction to the TBI Problem and Our Solution

Traumatic Brain Injury (TBI)



- TBI occurs after a hit to the head
 - For example, in falls, vehicular accidents, contact sports, and blasts
- It causes immediate physical damage to brain tissue
- However, it also exposes the healthy part of the brain to harmful agents such as metal ions, free radicals and inflammation
 - Sets off a cascade of chemical reactions that damages surrounding healthy tissue

Classification System for Traumatic Brain Injury			
Classification	Duration of Unconsciousness	Glasgow Coma Score	Post-Traumatic Amnesia
Mild	<30 mins	13-15	<24 hrs
Moderate	30 mins - 24 hrs	9-12	1-7 days
Severe	>24 hrs	3-8	>7 days



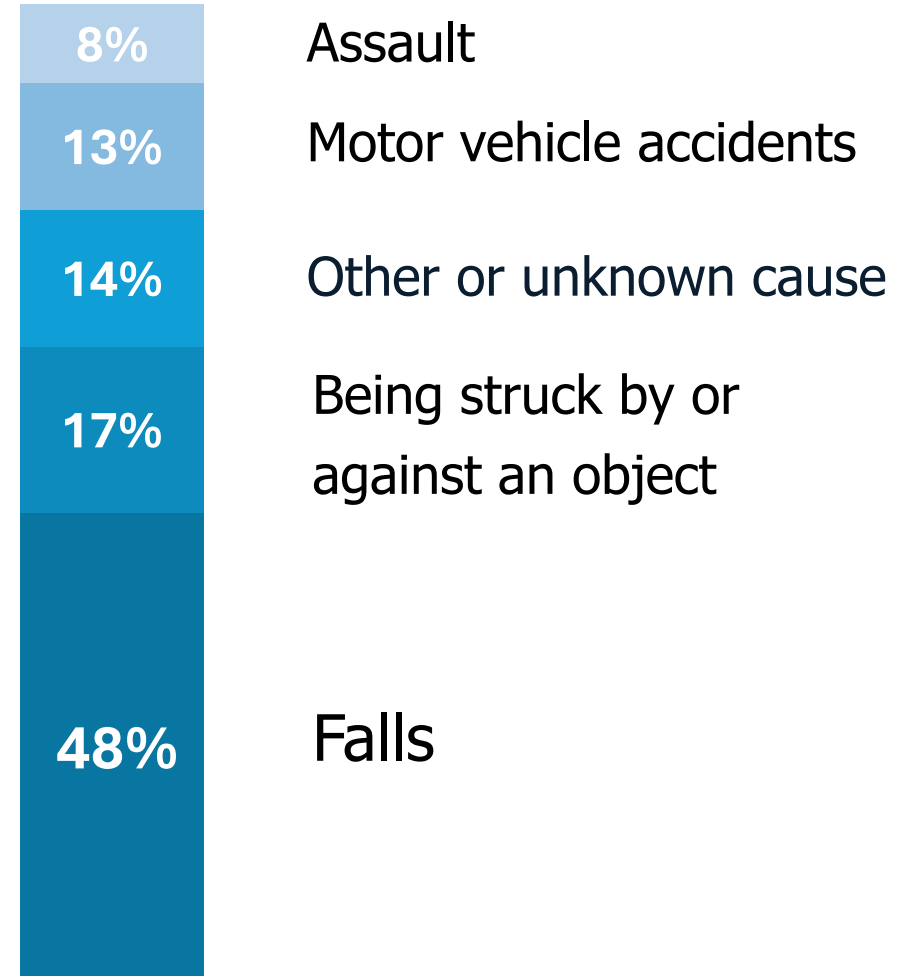
TBI – A Global Problem



New cases each year

- Around 69 million TBI cases globally *
 - 2.8 million in the US **
 - 2.5 million in Europe ***
- Most cases are closed head injuries
 - Difficult to detect, potentially risky situation
 - ~90% of cases are categorized as "mild TBI"

Leading causes of TBI:



* [Dewan et al. \(2019\) J Neurosurg 130: 1080-1097](#)

** Centers for Disease Control and Prevention (CDC)

*** CENTER-TBI EU

Limitations of Current Diagnostics

- Neurological examination of patient's responses:
Glasgow Coma Score (3 - 15)
 - Vulnerable to confusion, paralysis, intubation, intoxication
- Computer tomography (CT) and Magnetic resonance imaging (MRI)
 - Require hospital environment
 - Expensive procedures
 - Exposure to irradiation (CT)
 - Potential anaesthesia/sedation, especially for children
 - Cannot detect mild injuries
- FDA-approved blood protein tests
 - Require hospital environment and equipment
 - Invasive





Medicortex's Solution for Diagnostics

- Medicortex is developing a non-invasive, point-of-injury test based on saliva or urine samples
- Our biomarkers are *glycans* – carbohydrate structures
 - Degradation products released to the circulation after the brain cell damage

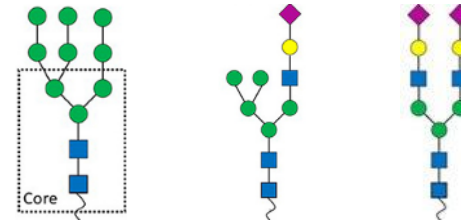
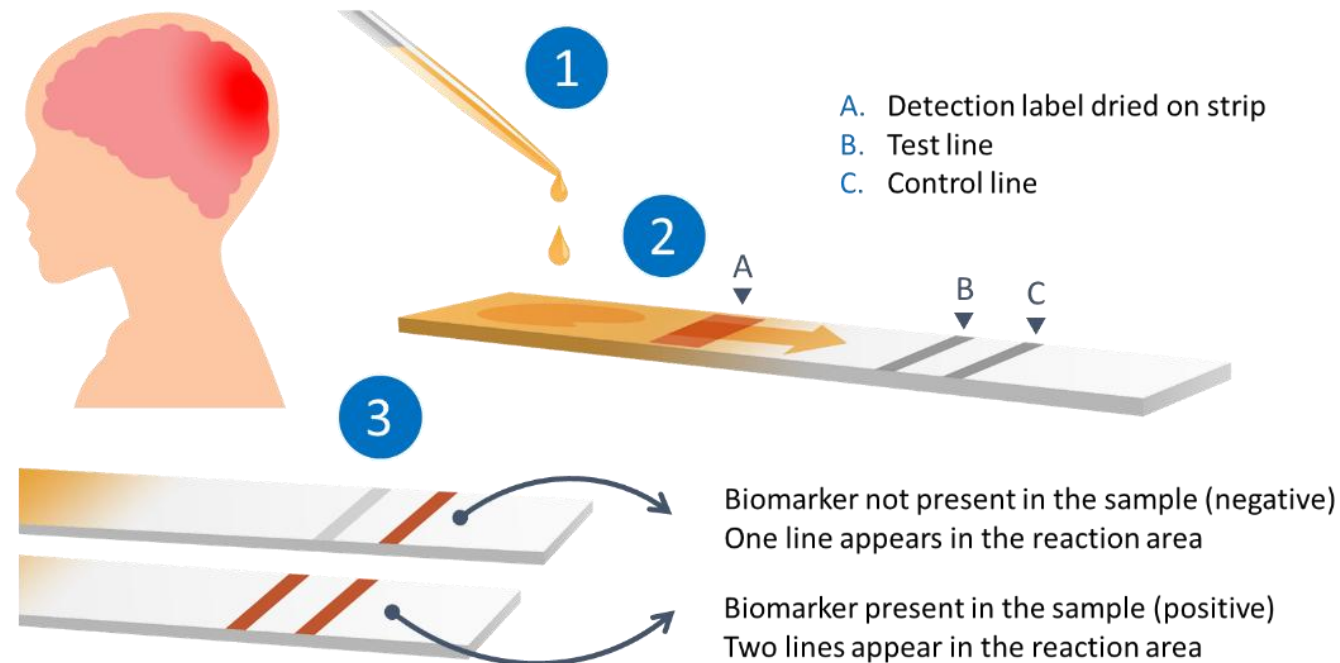


Illustration. Different glycan structures.

Medicortex's Diagnostic Test



1. A **urine** (ProbTBI™) or **saliva** (IndicateTBI) sample is applied on a test strip
2. The sample migrates along the strip
3. The result is readable on the strip





Research and Development: Performed and Planned

Clinical Studies



Three clinical studies conducted

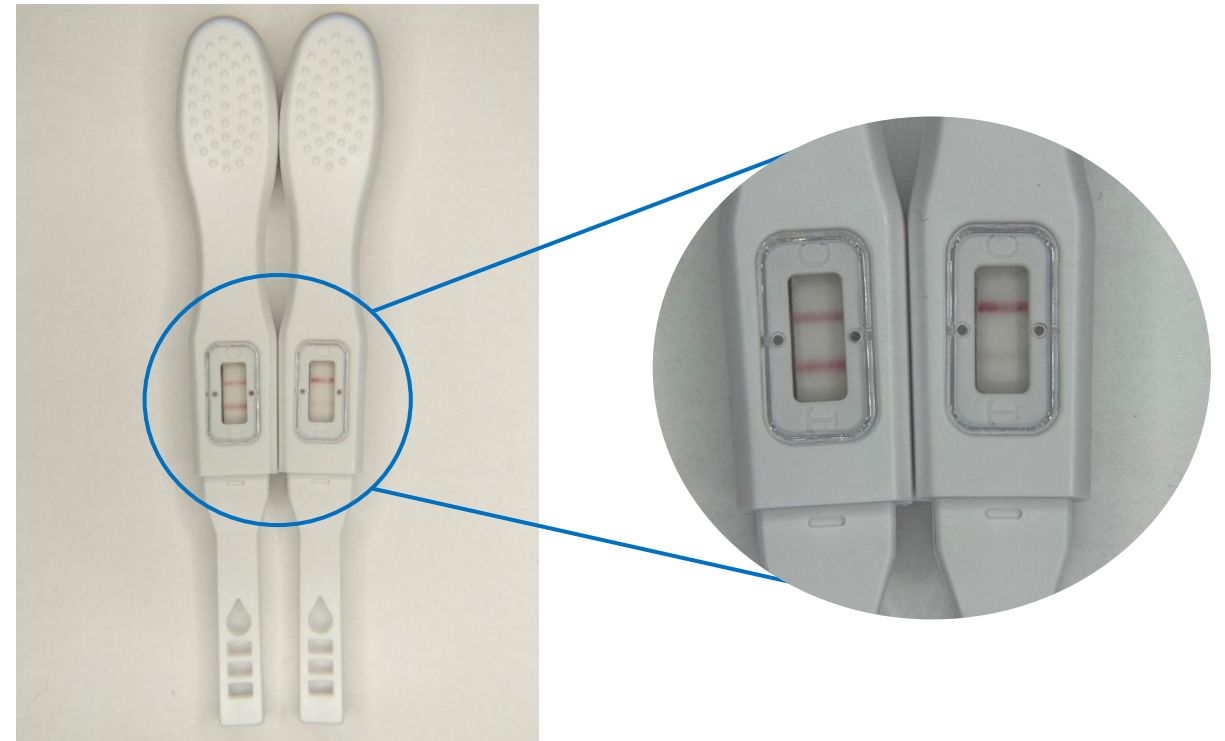
- Collection of plasma, urine and saliva samples
- Profiling of glycan changes related to mTBI
- Characterization of glycan structures associated with mTBI

Combined patient cohort

- 64 patients with suspected concussion or mild TBI
- 16 patients with orthopaedic injuries
- 71 healthy controls

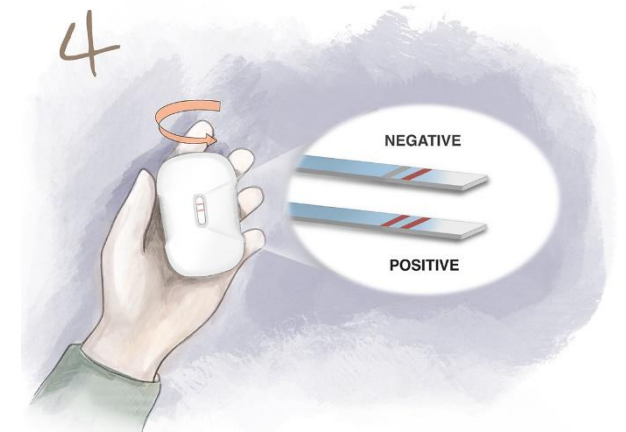
Urine Test Prototype

- **ProbTBITM** - a prototype **glycan detection method** for **urine** samples, in a lateral flow immunoassay cassette is ready for further development
- Fully assembled prototype tests were shipped to the DoD Q1 2025



Saliva Test Development

The objective of the project is to develop a **prototype strip test** for mild TBI based on the detection of unique glycan biomarkers in **saliva** – with an ultimate goal of early assessment and diagnosis of soldiers suffering head injury.

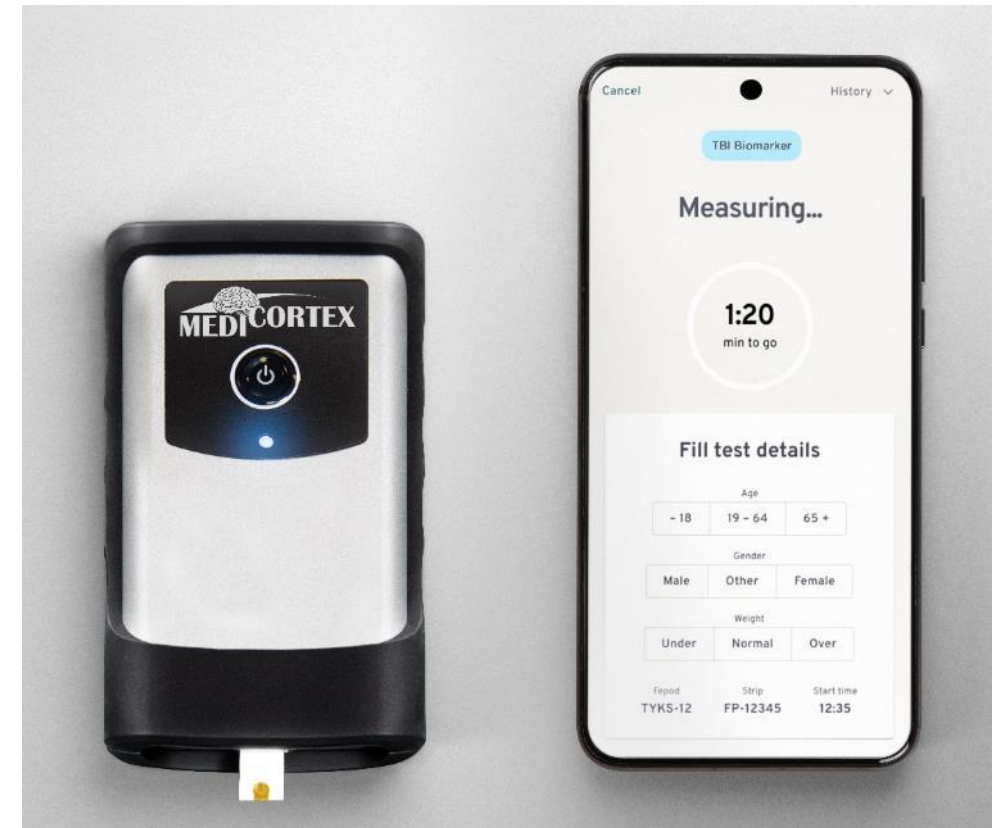


2nd Generation Test: Additional Benefits



Enables **quantitative** and **repeated** measurement beneficial for patient monitoring

- Electrochemical sensor and device (TesTBI)
- Recognition of the biomarker in sample by highly specific synthetic binding molecules (aptamers)
- Biomarker in sample triggers an electric signal on sensor which is translated to quantitative value through unique software
- Collaboration with Fepod Oy Ltd (www.fepod.fi)
- Funding is searched for expanding the project



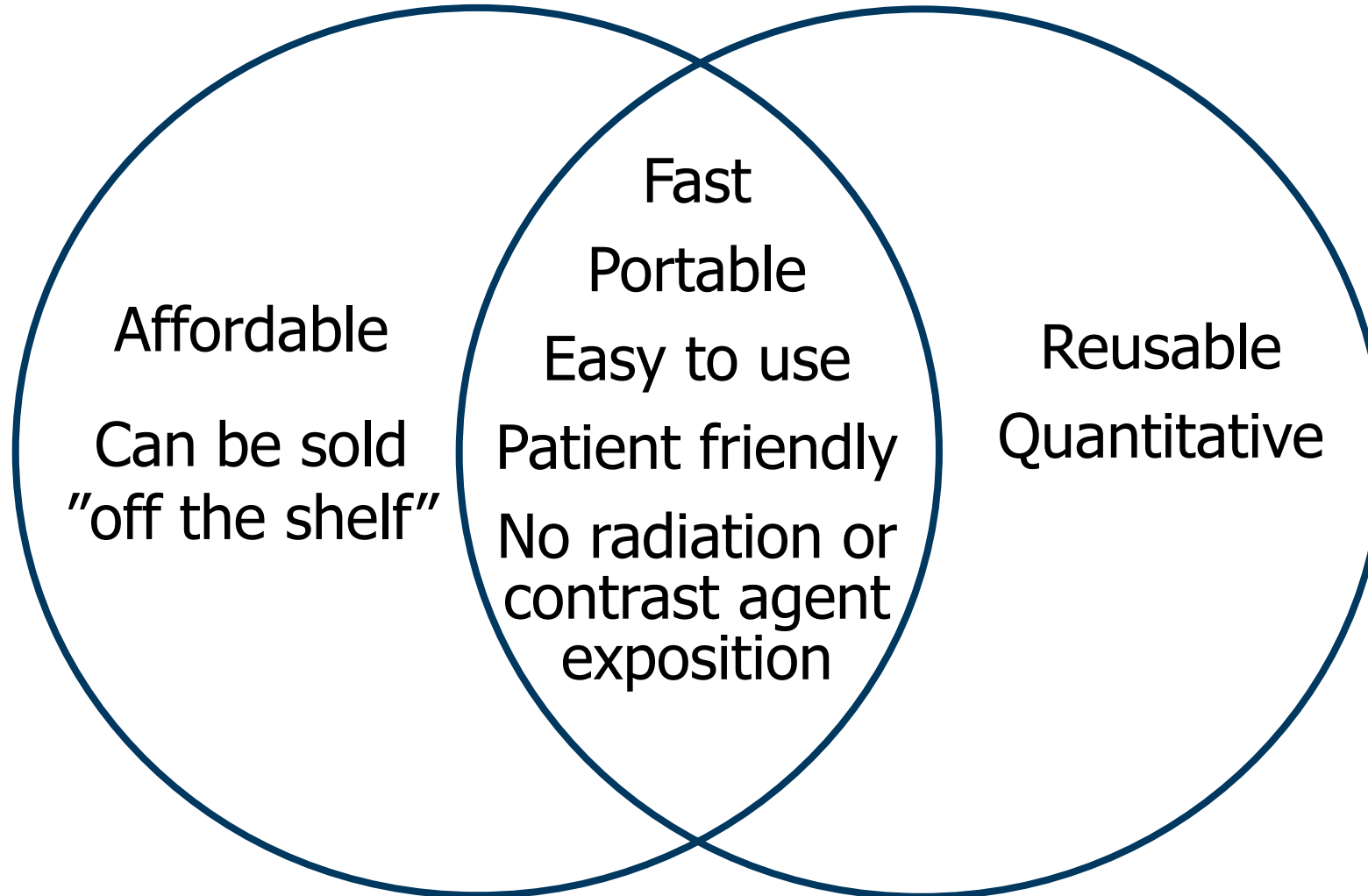
Illustration

Medicortex Test Advantages



ProbTBI™ Kit

TesTBI Device



Our Potential Clients



Medicortex is targeting **B2B institutional customers**



Military



**Paramedics &
first responders**



**Schools & nursing
homes**

**Sports
organizations**

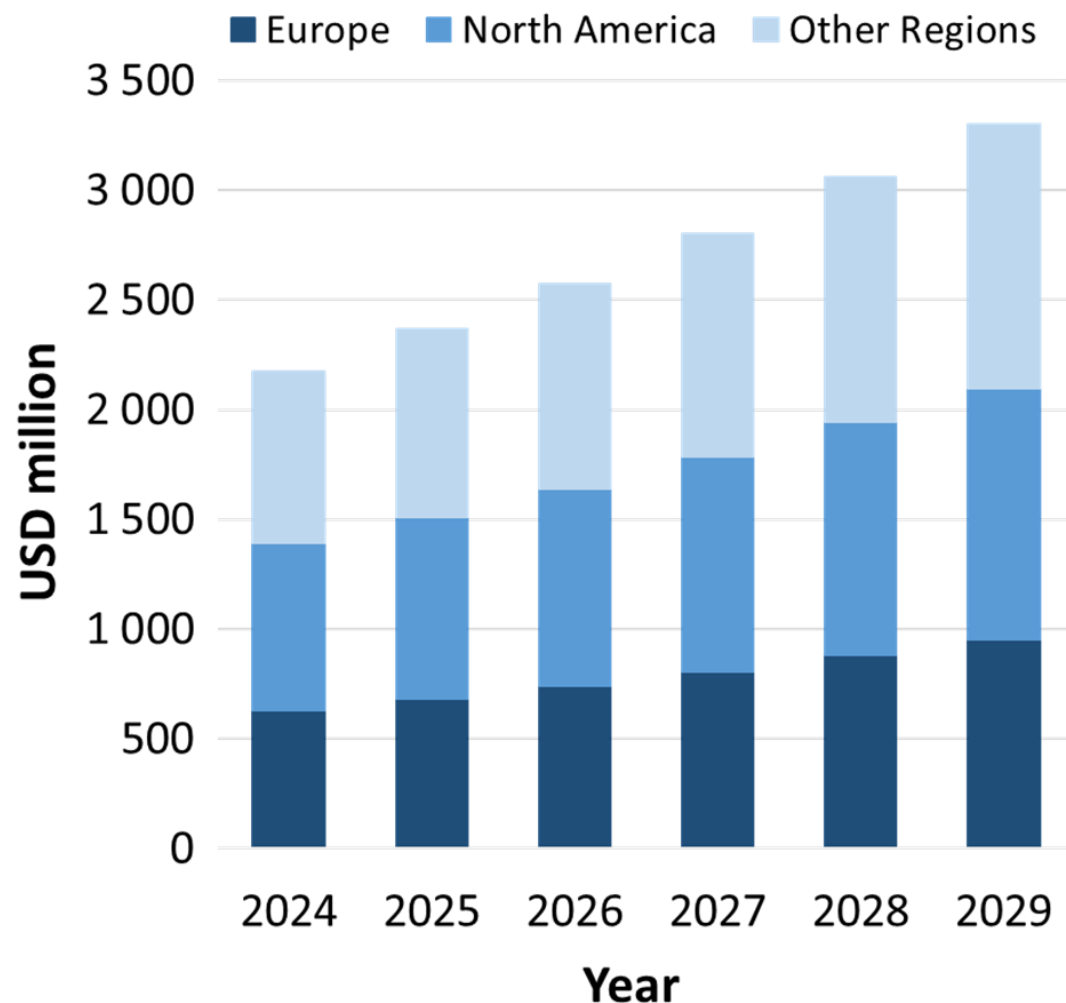
**Hospitals and
emergency rooms**

**Pharma
companies**

**Insurance
companies**

TBI Market

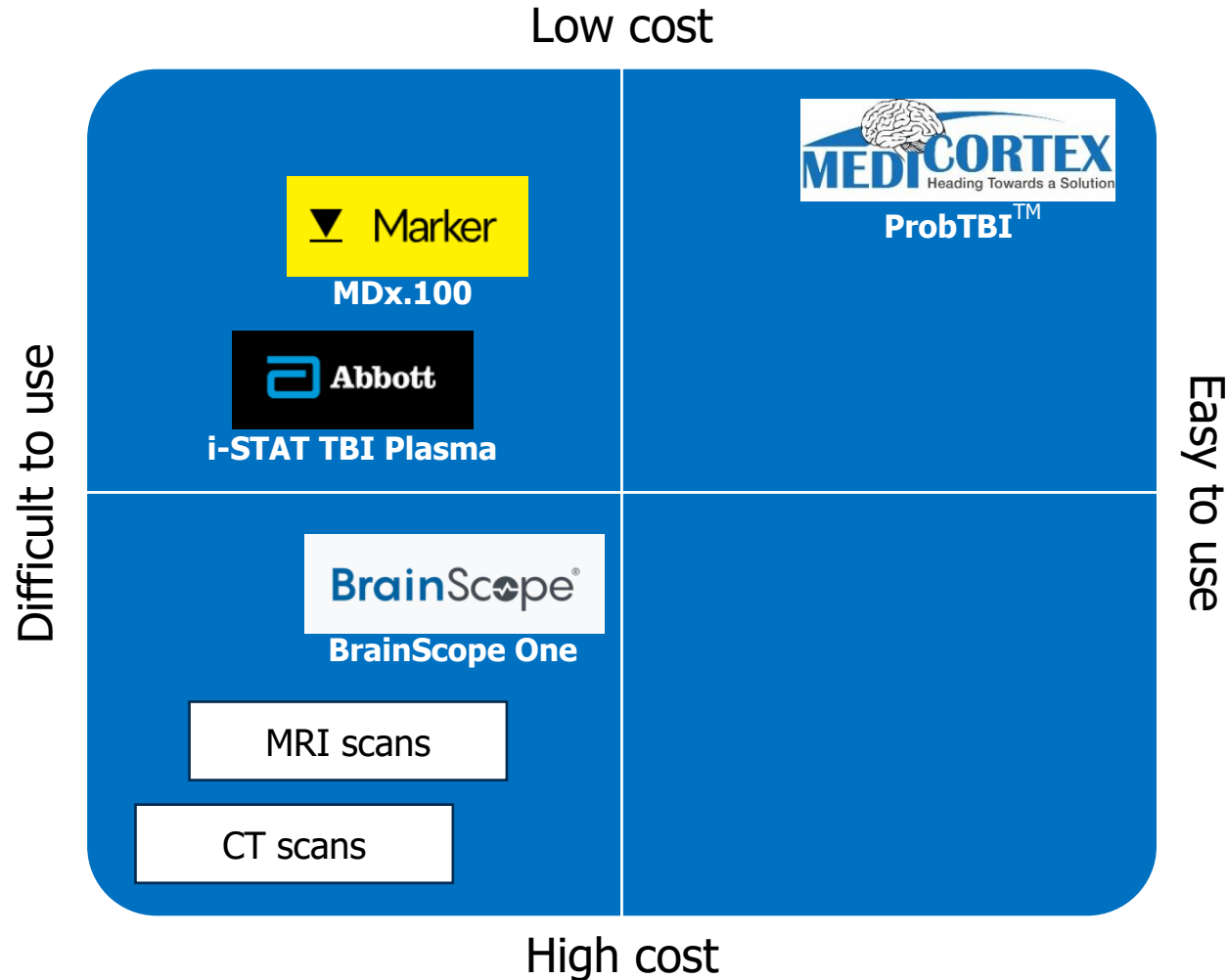
Global TBI diagnostic market expected to reach **\$3.3 billion** by 2029



Source: Cognitive Market Research

Market growth can be related to increase in population, aging population, increased number of vehicles on the road, and extra leisure time to get engaged with risky activities, as well as enhanced clinical classification and diagnostics

Competitors Landscape



Medicortex's solution for diagnostics is unique:

Our test combines **affordability** with **ease of use**

Blood-based tests:

- **Abbott: i-STAT TBI Plasma** & Alinity i TBI
- Roche: Elecsys® S100
- Quanterix: Simoa™ N4PA Advantage Kit

Saliva-based tests:

- **Marker: MDx.100** (laboratory environment required)

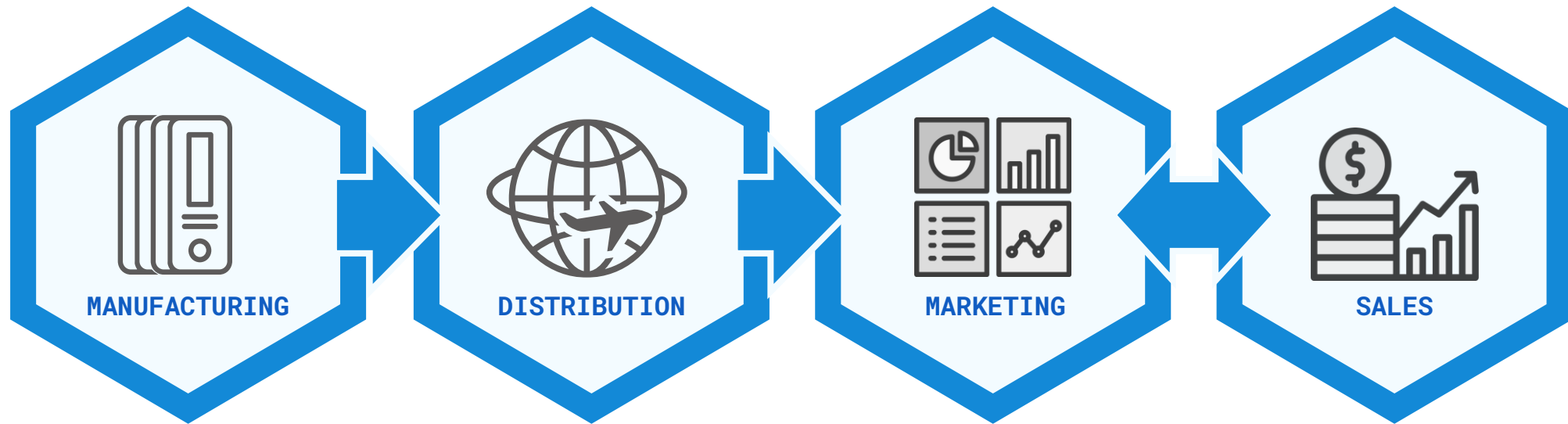
EEG methods:

- **BrainScope: BrainScope One**
- Firefly Neuroscience: BNA™
- Neurovigil: iBrain™

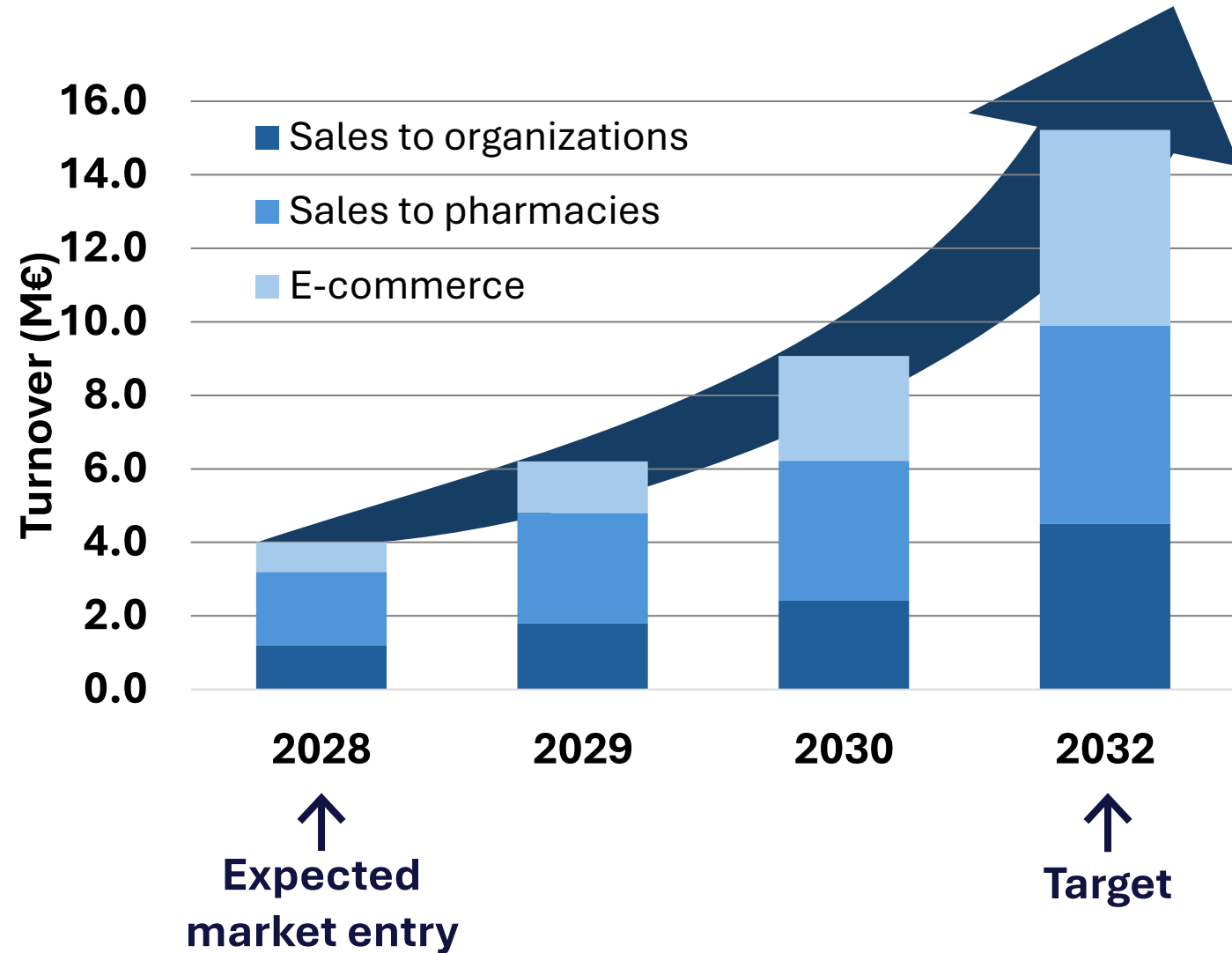
Marketing Strategy for ProbTBI™



- The preferred option – subcontracting manufacturing and using professional distribution companies, as well as contracting professional marketing and sales service providers
- The main focus of marketing and sales will be B2B



Sales Forecast ProbTBI™



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Intellectual Property Position

Patents for the Biomarker and Diagnostics



1. Prognostic and Diagnostic Glycan-based Biomarkers of Brain Damage

- European patent No. 3283880
- US patent No. 10,739,335
- Canadian patent No. 2,982,503
- Israeli patent No. 254 980

2. Non-invasive Brain Injury Diagnostic Device

- South African patent (number pending)
- Israeli patent No. 268 793
- Utility model granted in China and Australia

3. Device and Method for Detecting of Brain Injury in a Subject

- Australian innovation patent No. 2020104474
- Finnish utility model No. 13179

Patents for the Biomarker and Diagnostics

(continues)



4. A Method for Determining a Lectin-binding Glycan Indicative to Traumatic Brain Injury

- European patent No. 4133279

5. A Method for Diagnosis of Traumatic Brain Injury

- Finnish patent No. 130340
- PCT-application WO 2023/161557

6. Method of Detecting Tissue Damage

- Finnish patent No. 130428
- Divisional Finnish patent No. 130798
- PCT-application WO 2023/161553

7. A Hand-held Liquid Sample Collection and Testing Device

- Finnish utility model No. 13331
- German utility model No. 20 2023 100 246



Patents for the Drug Development



1. Multivalent Compounds for Use in the Treatment and Prevention of Brain Damage
 - US patent No. 9,975,846
 - Finnish patent No. 127024
 - Israeli patent No. 251407
 - European patent No. 3201173
2. Conjugates and Conjugates for Use in Preventing or Treating of Brain Damage and Neurodegenerative Diseases
 - Finnish patent No. 130262

Patent for COVID-19 Diagnostics

1. Method for Determining Coronavirus and Kit for the Same
 - European patent No. 3911956

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Public and Private Financing

Equity up to Now

- About 3.4 M€ from the founder and 299 private investors
- Total number of shares issued about 22.1 million
- Current price per share 1.00 € and total valuation 22.1 M€

Subsidies in the Past / Ongoing

- Total of 5.2 M€ in grants
 - Including 4.6 M dollars from the US Department of Defense
- 70 k€ in awards
- **Medicortex is looking for investors:**
 - <https://www.medicortex.fi/eng/investors/>



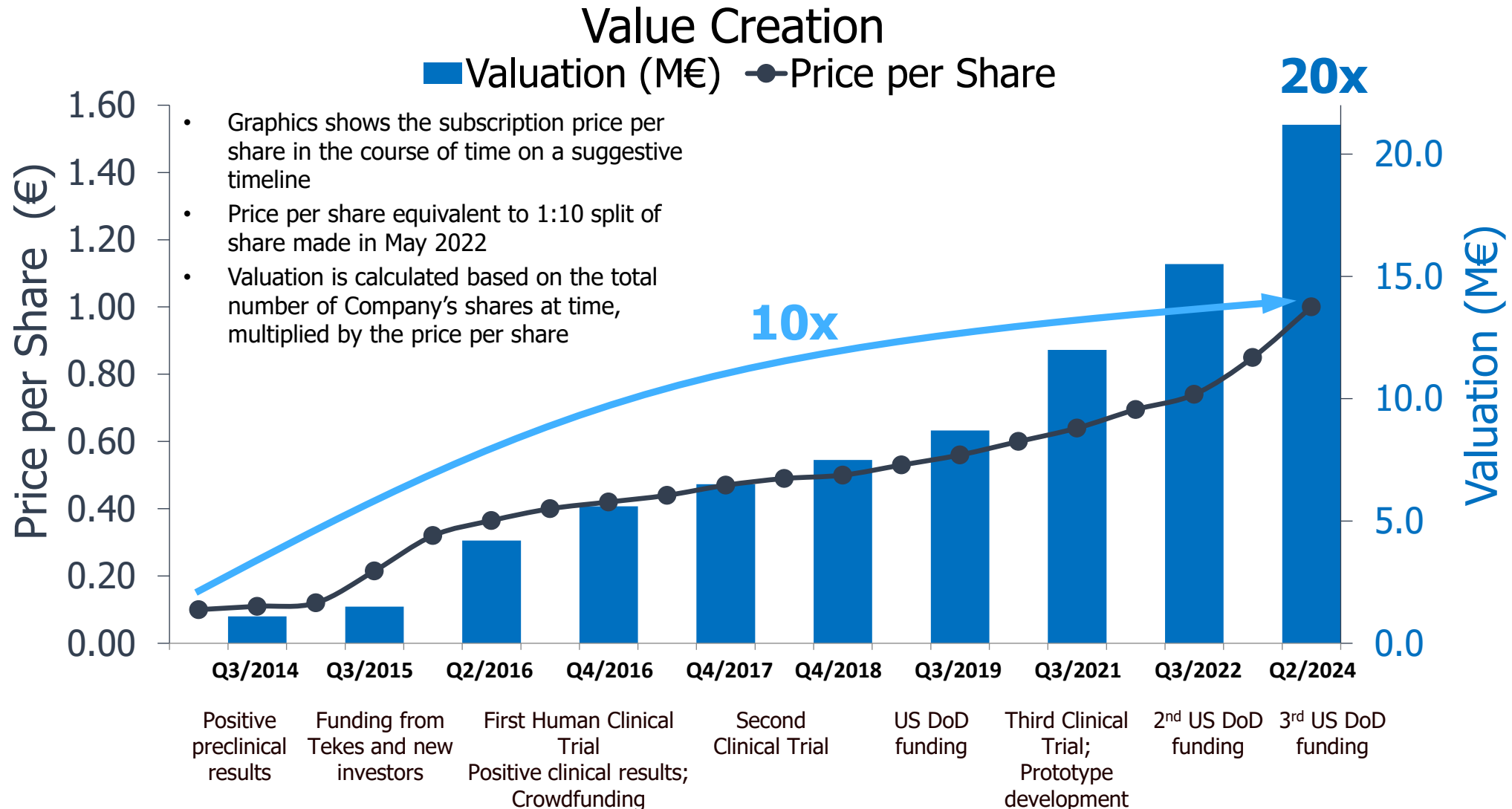
Funded by the
European Union



ELY Centre



From 2014–2024 Increase in Value



Use of Funds 2025-forward



www.medicortex.fi

The company is looking for 5M€ that will be used for:

- Further development/improvement of diagnostic assay chemistry
- Prototype test development and assembly
- Prototype manufacturing
- Validation in clinical experiments
- Initiation of the regulatory process

Board of Directors



- Chairman of the Board - [Anna Tenstam](#), MSc, MBA, served as a manager and board member in several companies
- Dependent Member – [Adrian Harel](#), PhD, MBA, Founder and CEO of Medicortex
- Independent Member - [Nils Grönberg](#), experienced Executive in many companies and foundations
- Independent Member - [Ville Ranta-Panula](#), MSc, MBA, experienced drug development and business development professional



The Team



CEO, Founder
Adrian Harel
PhD, MBA



CSO
Lasse Välimaa
PhD



COO
Pihla Miettinen
MSc



Research Scientist
Leonardo Lara-
Valderrábano
PhD



Product Manager
Begüm Utz
PhD



Senior Scientist
Ivette Bañuelos-Cabrera
PhD



Development Engineer
Kaisa Leppä
MSc tech.

YouTube videos

- [How repeated concussions affect your brain](#)
- [Concussion in sports and Medicortex test](#)
- [Concussion in army personnel and Medicortex test](#)

LinkedInTM group

- [The Science Behind TBI](#)
 - Posts and discussion about science and research on TBI
 - >3,000 members

www.medicortex.fi



Contact:
Dr Adrian Harel, CEO
adrian.harel@medicortex.fi



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M&A and Deals



Examples:

- Teladoc Health to acquire Catapult Health for \$65M to enhance preventive care and at-home testing (USA, 2025)
- Aditxt Subsidiary Pearsanta Acquires MDNA Life Sciences Cancer Testing Platform for Over \$25M (USA, 2024)
- Biosynex completes acquisition of Chembio Diagnostics for \$17.2M to expand rapid diagnostic test offerings (USA, 2023)