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Age-related Diseases: A Global Crisis

Sovereign Wealth
Hevolution Foundation: $1 billion annually to fight aging and age-related diseases
"There is not a bigger medical problem on the planet than this one."
(Mehmood Khan, Fund Manager)

Most Successful Entrepreneurs
Jeff Bezos and Yuri Milner: $3 billion to Altos Labs for cell rejuvenation and fight aging
Larry Page: $1.5 billion for Google’s anti-aging California Life Company
Larry Ellison and Peter Thiel: $1 billion for age-related disease and sustainability

Governments
“Public health expenditure in EU may grow to 7.7 % of GDP in 2070 only on accounts of demographic ageing”
(European Commission, 2021 Ageing Report)

2https://www.technologyreview.com/2022/06/07/1053132/saudi-arabia-slow-aging-metformin/
5https://www.breakoutlabs.org/
An age-related disease with no cure

A leading cause of death in adults, about 500,000 per year¹

Affects 10% over 65 and 50% over 85 in the US²

The global numbers have more than doubled from 1990 to 2016²

The costliest disease for adults, averaging over $52k/year/adult²

¹https://www.usagainstalzheimers.org/alzheimers-disease-get-facts
²https://curealz.org/the-disease/stats-and-costs/
Biogen $28 billion drug debacle

Biogen’s disregard of FDA’s decision NOT to endorse the company’s Alzheimer’s drug Aduhelm in 2021 compelled the FDA to call for an investigation.

“We have spent more than $28 billion in R&D since 2003” (Biogen CEO, 2021)

99.6% failure rate

A graveyard for drugs: 1 out of 244 drugs for Alzheimer's disease was approved in 2002-2012, a 99.6% failure rate

$42.5B since ‘95

Over 2,200 clinical trials, with no cure and no effective therapeutic solution

NIH: $16 billion

NIH spend over $16 billion on Alzheimer’s drug solutions since 2008. All have failed

Merck’s drug failures

No significant new drug for Alzheimer’s has been approved in the past 20 years, despite massively expensive trials

Roche Group drug failure

A decade-long clinical trial of a potential Alzheimer’s drug failed to prevent or slow cognitive decline, another disappointment in the effort to find solutions for the disease

2 https://www.science.org/content/article/another-alzheimers-drug-flops-pivotal-clinical-trial
4 https://www.nytimes.com/2022/06/16/health/alzheimers-drug-crenezumab.html
Progress? Not so fast.

Biogen & Eisai recently announced\(^1\) that their drug Lecanemab appeared to slow down Alzheimer’s

- Results come after the failure of the companies’ drug Aducanumab
- Clinical trials based on outdated small molecule drugs strategy and too short a time frame
- Lecanemab is unlikely to produce a different disease outcome from the fatal one we see 100%
- Drug effect is to help suppress the symptoms, equivalent to using a cough suppressant to treat a virus infection such as the recent pandemic
- Alzheimer’s and CNS is addressed by Telocyte with
  - next generation biologic clinical methods
  - superior gene therapy techniques with faster routes for clinical evaluation
  - reduced program cost and much shorter development timescales

Regrettably, Eisai recently published that Lecanemab has likely contributed to a patient’s death\(^2\)

\(^1\)https://apnews.com/article/health-2e51397597577d49dd5f83bc0042871
\(^2\)https://www.fiercebiotech.com/biotech/lecanemab-may-have-contributed-patient-death-report
Telocyte Mission

Disrupt
global healthcare and the pharmaceutical industry with telomerase therapy

Reverse
age-related diseases starting with Alzheimer’s

Deliver
preventative and therapeutic healthcare via AI and Big Data driven Virtual Diagnostic Clinics
Telocyte Disruption

Only biotech company addressing Alzheimer’s and age-related diseases using the Telomerase protocol & AI Therapeutics

TELOMERASE INNOVATION

The first and only Human Telomerase Protocol to cure human age-related diseases

EXPERTISE

Telocyte is founded by Dr. Michael Fossel, the world’s leading expert on cellular aging and age-related diseases

AI THERAPEUTICS

Ethical AI+VR: deliver a holistic therapeutic precision preventative care, and substantially reduce clinical costs

KNOWLEDGE PLATFORM

Telocyte’s innovative knowledge strategy ensures effective, secure, and compliant clinical execution, as well as enabling the advent of digital similars in life sciences
Telomerase Origins

1974

Alexey Olovnikov
First prediction of telomerase existence and link to aging and cancer

1981

Elizabeth Blackburn
Isolates and describes the telomerase enzyme

1997

Calvin Harley
Telomerase resets aging in human cells and tissues

1998

Calvin Harley
CSO, GERON
Telomerase protocol with Calvin Harley

2004

Blackburn, Greider, Szostak
2009 Nobel Prize for the discovery of telomerase

2009

Michael Fossel
Founder of Telocyte
Telomerase protocol for age-related diseases

2012

Maria Blasco
Telomerase delays aging in mice

2020

Michael Fossel
Clinical Medicine Expert, GERON
Telomerase resets aging in human cells and tissues

1https://en.wikipedia.org/wiki/Alexey_Olovnikov
2https://en.wikipedia.org/wiki/Elizabeth_Blackburn
3https://doi.org/10.1001/jama.1997.0355016006504
7https://jamanetwork.com/journals/jama/article-abstract/187604
Validation in Animals

Telomerase is proven to reverse the aging process in animal studies, resulting in improved behavioral\textsuperscript{1,2,3}, musculoskeletal\textsuperscript{2}, and cardiovascular\textsuperscript{2} function.

\textsuperscript{1}\texttt{https://pubmed.ncbi.nlm.nih.gov/21211774/}
\textsuperscript{2}\texttt{https://www.embopress.org/doi/full/10.1002/emmm.201200245}
\textsuperscript{3}\texttt{https://doi.org/10.1038/nature09603}
Validation in Human Cells/Tissues

Human cells

Fibroblasts¹: *Science*, 1998

Neurons²: *J Neuroscience*, 2015

Medical textbooks

• *Cells, Aging, and Human Disease*
  Michael Fossel, 2004

• Aging: How aging works, how we can reverse aging, and prospects for curing aging diseases
  Michael Fossel, 2023 (in preparation)

Human tissues


Cardiac Vessels⁵: *Circ Res*, 2001

¹https://www.science.org/doi/10.1126/science.279.5349.349
²https://www.jneurosci.org/content/35/4/1659
⁵https://doi.org/10.1161/hh2101.098443
As cells age, telomeres shorten and cells become dysfunctional, resulting in age-related diseases. The telomerase protocol restores a younger pattern of gene expression and normal cell function. Telocyte’s solution brings telomerase to humans.

Telocyte’s proprietary telomerase-based protocol will reverse cell aging in humans, curing age-related diseases.

Telocyte Products

**Therapeutic**
Proprietary telomerase-based protocol will reverse cell aging, curing age-related diseases

**Knowledge Platform**
- Blockchain, data provenance
- Built-in governance and compliance (HIPAA, OHRP, FDA)
- Identity, data ownership, dynamic consent
- Federated AI
- Support decentralized clinical trials

**AI Therapeutics**
- AI-enhanced diagnostics
- Alerting and signaling
- Personalized therapeutics
- Pre-treatment targeting
- Treatment outcome prediction
The First and Only Human Telomerase Protocol

**Dose:** Adjusted to patient’s body/brain weight

**Route:** Carefully chosen for safety & efficacy

**Vector & Plasmid:** Optimized to target cells

**FDA Compliant**¹: Rigorous & credible

### Specific targets

- **Alzheimer’s (CNS):**
  - Neurons
  - Microglia
  - Astrocytes

- **Cardiovascular Disease:**
  - Vascular cells
  - Cardiac myocytes
  - Fibroblasts

### General targets

- All aging, dysfunctional cells

¹https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber
Knowledge Platform

DATA AS AN ASSET
- Secure data exchange network and custody of user’s digital assets
- Identity management and verification capabilities, dynamic consent
- Auditability and data provenance authentication via hybrid blockchain
- Data trust and quality persistence

COMPLIANCE
- Built-in governance and compliance for healthcare data (HIPAA, OHRP, FDA)
- Integration with EMRs, CROs, partners, and government platforms, 21 CFR 11 compatible

DATA SOURCE AND INTEGRATION
- Healthcare data (EHR, clinical)
- Biometrics data (real-time, historical)
- Lifestyle, contextual, and financial data
- Consumer, social, and impression data
- Daily data through VR interaction and capture

ANALYTICS & AI
- Therapeutic program personalization
- Digital similars
- Treatment outcome prediction
- AI for diagnostics, monitoring, virtual healthcare
- Derived data through federated AI for marketplace participation and services

PROGRAM SUPPORT
- Clinical decision support
- Accelerate therapeutic deployment
- Cost reduction through AI-based clinical optimization
- AI-enhanced therapeutic population targeting

CUSTOMER VALUE
- User engagement and loyalty through privacy and earned trust
- Therapeutic and lifestyle care using AI and VR platform
- Health assessment and monitoring for holistic and precision preventative care
Data Strategy

Traceability & Compliance

- Hybrid blockchain platform
- Operational data network
- Built-in compliance
- Access management and control
- Auditable API integration with clinical endpoints
- Indisputable record of clinical results

Clinical Cost Reduction

- Data compliance and architecture yields over 30% cost reduction of expenses and time in clinical trial expenses, worth $ billions in later trial phases

Personalization

- Hyper-personalization
- Granular consent
- Health knowledge platform
- Increased patient engagement and participation in trials and preventative care

Digital DNA

- Digital graph with trust and context built in captures all patient data, relationships, and events
- Multi-source data validation increases the quality and value of the data
Virtual Personalized Care
- Ethical AI+VR
- Personalized therapeutic program
- Preventative care, alerting
- Health assessment and outcome prediction via continuous learning

Extend Support Circle
- Remote patient monitoring reduces hospitalizations¹
- Remote medication management
- Personal healthcare assistance
- Virtual visits

Trust and value
- HIPAA and FDA compliant
- Secure and safe
- Personalization
- Ethical and compliant AI

E-Learn & Engage
- Educate about age-related diseases and preventative care
- Information on decentralized clinical trials

"Dr. Fossel’s unwavering dedication to unraveling the pathogenesis of neurodegenerative diseases led him to conceive both a unified model and a novel gene therapy with the potential to become the first agent to alter the course of neurodegenerative diseases such as Alzheimer’s.

Telocyte’s telomerase gene therapy will restore hope to Alzheimer’s disease patients. Applications to other neurodegenerative conditions such as Parkinson’s and age-related diseases (e.g., cardiovascular, renal, osteoarthritis) will follow.”

S. Nagendran MD
President of R&D and Chief Medical Officer, Jaguar Gene Therapy

"Dr. Fossel has set out a new model for dementia and age related brain dysfunction which presents a unifying theory [...] and potentially of an exciting new approach to disease causation and hence treatment.

His in-depth analysis is intellectually compelling and takes account of a wide range of experimental data from several fields. Dr. Fossel’s work presents radical new ideas and is extremely exciting.”

Sir Edward Byrne
AC FmedSci FTSE FAHMS MD DSc FRCP FRACPA
Vice Chancellor Monash University
President King’s College
Vice Chancellor’s Distinguished fellow ANU
Emeritus Professor of Neurology King’s College

“Dr. Fossel offers us a logical and potentially effective point of intervention for Parkinson’s, Alzheimer’s disease and other age-related neurodegenerative diseases. His model calls for clinical testing – rigorously and credibly – as his approach may well be the most promising approach that we have seen in decades.

I heartily and unreservedly recommend him for the Breakthrough Prize in Life Sciences.”

Z. Khachaturian PhD
President of Campaign to Prevent Alzheimer’s, former editor-in-chief Alzheimer’s & Dementia, Journal of the Alzheimer’s Association
Competitive Landscape

Companies are targeting the **symptoms**

- **β Amyloid**
  - Eli Lilly
  - Biogen
  - Alzheon
  - Vivoryon
  - Wren Therapeutics
  - Yumanity
  - AC Immune SA
  - Denali Therapeutics
  - Priaboid

- **Tau**
  - Voyager Therapeutics
  - AC Immune SA
  - Denali Therapeutics
  - Priaboid

- **Inflammation**
  - TBD Therapeutics

- **Mitochondria**
  - Alector
  - Amylyx Pharma
  - Codiak BioSciences
  - Oracion Biotech
  - Tetra

**Telocyte is targeting the underlying cause**

**Telomerase**

**TELOCYT**
Market Opportunity

Central Nervous System
Alzheimer’s
- global therapeutics market $4B in 2021
- growing at a CAGR of 16.2%
- global costs $1.7 trillion by 2030\(^1\)
Parkinson’s
- global costs over $51B by 2030\(^2\)
Other Dementias
- global MS costs $84B in 2030\(^3\)
- other Dementia costs $800B by 2030\(^4\)

Cardiovascular Disease
- global CVD drug market: $48B
- projected to reach $64B by 2026
- growing at a CAGR of 3.8%
- global costs to reach $1.0T by 2035

Other
- Myocardial Infarction
- Carotid Artery Disease
- Congestive Heart Failure

1\(^{https://www.alzint.org/about/dementia-facts-figures/dementia-statistics/}\)
2\(^{https://rdcu.be/cUFE0}\)
3\(^{https://n.neurology.org/content/98/18/e1810}\)
4\(^{https://www.rand.org/capabilities/solutions/planning-for-the-rising-costs-of-dementia.html}\)
Strategy

**OBJECTIVE**
Telocyte brand dominance in age-related and preventative Healthcare

**TARGET MARKET**
Age-related disease, beginning with Alzheimer’s (7M in US in 2028, 60M+ worldwide)

**VALUE**
An affordable and effective Telomerase Gene Therapy as a 5-yearly vaccination for Alzheimer’s and age-related diseases

**DISTRIBUTION**
Licensing agreements with NHS and Big Pharma, covering the costs of servicing the Alzheimer’s global population

**PRICING**
Initial pricing: 40% of the US 5-year patient cost of Alzheimer’s, approx. $104,600/dose

**REVENUE**
$52B over the first 10 years through licensing (5% royalty)

**INTEREST**
NHS UK, Eli Lilly, Jiangsu Province, China, GemVax, South Korea

**GROWTH**
- Target population increase (2x-3x)
- VR Clinic + AI: increase SAM
- Distribution + AI: Increase Adoption
Revenue

Initial Price: $104,600/dose (40% of 5-year Alzheimer’s cost/person)

Licensing Royalty: 5% of net sales

Target Population (TAM): 7M US, 50M globally, to grow 2x to 3x²

Serviceable Population (SAM): 10% of TAM initially

Revenue Growth Projection (2028-2038)

Revenue projections with Total Addressable Market (TAM), Service Addressable Market (SAM), and Adoption estimates¹

¹https://invivo.pharmaintelligence.informa.com/IV146643/Strategies-To-Encourage-Universal-Access-To-Gene-Therapies

²https://www.who.int/news-room/fact-sheets/detail/ageing-and-health

## Gene Therapy Valuations

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>PURCHASER</th>
<th>DEAL VALUE</th>
<th>DRUG/TARGET</th>
</tr>
</thead>
<tbody>
<tr>
<td>AveXis</td>
<td>Novartis</td>
<td>$8.7 billion</td>
<td>Zolgensma - Spinal Muscular Atrophy</td>
</tr>
<tr>
<td>Spark Therapeutics</td>
<td>Roche Holdings</td>
<td>$4.8 billion</td>
<td>Luxterna - Genetic Retinal Diseases</td>
</tr>
<tr>
<td>Audentes Therapeutics</td>
<td>Astellas Pharma</td>
<td>$3.0 billion</td>
<td>Neuromuscular Diseases</td>
</tr>
<tr>
<td>Brammer Bio</td>
<td>Thermo Fisher</td>
<td>$1.7 billion</td>
<td>Viral Vectors for Gene Therapy</td>
</tr>
<tr>
<td>AskBio</td>
<td>Bayer</td>
<td>$4.0 billion</td>
<td>Neuromuscular, CNS, and Others</td>
</tr>
<tr>
<td>Sarepta Therapeutics</td>
<td>Roche Holdings</td>
<td>$1.2 billion</td>
<td>Duchene Muscular Dystrophy, etc.</td>
</tr>
<tr>
<td>Paragon Bioservices</td>
<td>Catalent</td>
<td>$1.2 billion</td>
<td>AAV &amp; Plasmids for Gene Therapy</td>
</tr>
</tbody>
</table>
The Journey

Partnerships

- Strategic partners for clinical trials: Houston Methodist
- Strategic partners for drug manufacturing and CRO services: Thermo Fisher
- Strategic partners for the build and operation of the data and technology platform
- Strategic partners for VR Clinic

Inception

- Founded in 2015 by Michael Fossel, MD, PhD, the leading expert on cell aging and age-related disease
- Seed investment of $600k

Telocyte Program

Disrupt global healthcare and pharma with telomerase therapy

Team

- Strong management team
- Globally recognized scientists, clinicians, and gene therapy experts on Scientific & Clinical Advisory Boards adding rigor and global credibility in protocol design and execution
- Accomplished Business and technical advisors

IP and Compliance

- Cleared legal/IP search
- Independent gap analysis by a global CRO confirmed readiness for FDA and regulatory trials
- Clinical trial protocol validated and peer-reviewed

Licensing Bidders

- Eli Lilly
- NHS UK
- GemVax
- Jiangsu Province, China
Multi Phased Roadmap

Phase 1
- Objectives:
  - Canine study
  - Dosing, distribution, safety, & toxicity data
  - Dev Knowledge Platform
  - Dev AI Therapeutics
  - Manufacturing and FDA feedback

Cost Budget $3.3m

Completed:
- Formation and Proprietary Product
- Executive Team and Advisory Board
- Partnerships for Clinical Trials, Data Platform, Drug Manufacturing
- IP Search, FDA Compliance

Cost Budget $1.0m + CXO invaluable hours

Phase 2
- Objectives:
  - File for FDA Phase 1 human trial
  - Manufacture of gene therapy product
  - File IP on canine and human protocols (Cooley LLP)
  - VR Clinic Prototype

Cost Budget $5.4m

Phase 3
- Objectives:
  - Begin FDA Phase 1 human trial
  - Knowledge Platform
  - Federated AI services
  - AI Therapeutics Launch
  - VR Clinic Beta

Cost Budget $4.7m

Phase 4
- Objectives:
  - Complete FDA Phase 1 human trial
  - FDA Phase 2 human trial
  - Increased valuation from proven human efficacy
  - Launch VR clinic
  - Enhanced Diagnostics

Cost Budget $3.7m

Phase 5

Approx. 12 months

1https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber
Next Steps

In partnership with Houston Methodist, a leading neurosciences clinical trial institution, to carry out simultaneous Telocyte CNS and CVD studies to permit human trials.

**Canine study**

**Objective:** obtain efficacy, distribution, and toxicity data  
**Protocol:** Houston-based 6-month study of 12 aged dogs  
**Measures:** imaging, labs, cognitive performance, etc.

**Human trials**

**Objective:** obtain FDA safety and efficacy data in phase 1 trial  
**Protocol:** US-based 6-month study of 12 patients with moderate Alzheimer’s  
**Measures:** imaging, labs, cognitive testing, etc.
Executive Team

**Michael Fossel MD, PhD**
Founder, CMO

An experienced industry executive, Rayson provides leadership and business acumen for Telocyte. His background includes engineering management with Computer Vision Inc., as well as working with Rolls Royce Aerospace, Airbus, Ford, Jaguar Land Rover. He was the Associate Director of the Technology Innovation Center at Birmingham, UK but stepped down in 2011 when his mother was diagnosed with dementia.

**Rajesh Shukla, PhD**
CSO

Rajesh brings over 30 years of entrepreneurial biotechnology expertise with clinical and medical strategy, with over $300M in funding. Rajesh leads gene therapy clinical development leveraging discovery through registrational expertise in Neurology, Immunology, Infectious Diseases, Oncology, Surgical reconstruction, Asthma and Anaphylaxis clinical programs, with senior positions at Integra LifeSciences, Castle Creek Biosciences (VP, R&D), Motif Biosciences (VP), Acorda therapeutics (Sr Medical Director), Pfizer (Sr Director & R&D Head), Teva and Bristol-Myers Squibb.

**Michelle Hylan**
COO

Michelle Hylan is an internationally experienced Clinical Research Executive with demonstrated success partnering with clients to optimize clinical program outcomes through alignment of business strategy, processes, and org composition, as well as bringing biotech start-ups from proof of concept to IPO. Michelle has focused on advancing unique science solutions to address unmet medical needs. She has broad experience in industry best practices on global program, clinical, and quality management. She specializes in strategic development and implementation, clinical trial design, CRO/vendor selection and management.

**Georgi Gospodinov**
PhD
CTO

An executive, advisor, and investor, offering thought leadership and innovative ideas, Georgi has led the engineering and analytics teams of multiple enterprises to deliver strategic product vision, tech resource hire and management, enterprise security, architecture, and integration. He has managed product delivery and driven innovation in data and technology, directly contributing to the design and implementation of product.

**Radomir Julina, PhD**
CPO

Prior to his current role as Managing General Partner at Pharma Capital Partners, Radomir was head of New Molecular Entity Planning at Roche and ran an Alzheimer’s drug clinical trial through Phase III. He has worked in pharmaceutical, biotech and private equity for the last 25+ years. He was Managing Director at Celtic Pharma Management, a spin-off from Hoffmann-La Roche. He holds a Ph.D. in Organic Chemistry from the University of Zurich and has a passion for drug development, building virtual organizations and investment finance.

**Executive Team**

The **leader** in proposing the use of telomerase to treat age-related human disease, he has an MD and PhD in Neurobiology from Stanford University, was a clinical professor of medicine for almost three decades, and authored both *The Telomerase Revolution* (which the *Wall Street Journal* named as one of the best science books of 2015) and the Oxford University Press textbook, *Cells, Aging, and Human Disease.*
Board of Directors

Michael Fossel MD, PhD
Board Member

The leader in proposing the use of telomerase to treat age-related human disease, he has an MD and PhD in Neurobiology from Stanford University, was a clinical professor of medicine for almost three decades, and authored both The Telomerase Revolution (which the Wall Street Journal named as one of the best science books of 2015) and the Oxford University Press textbook, Cells, Aging, and Human Disease.

Peter Rayson
Chairman of the Board

An experienced industry executive, Rayson provides leadership and business acumen for Telocyte. His background includes engineering management with Computer Vision Inc., as well as working with Rolls Royce Aerospace, Airbus, Ford, Jaguar Land Rover. He was the Associate Director of the Technology Innovation Center at Birmingham, UK but stepped down in 2011 when his mother was diagnosed with dementia.

Mark Hodges
Board Member

An experienced technology executive, Hodges provides effective and inspiring leadership for all Telocyte programs and services. His background includes executive experience in the aerospace and defense industries, CAD business development, including at Computer Vision with Peter Rayson. He was the General Manager of China Operations, where he managed 500 engineers across 15 offices for PTC Inc., a listed Boston engineering software firm.
Technical Advisory Board

Professional expertise: gene therapy, telomerase, clinical trial design, and neurological disease
Strategic Investment & Partnership

Strategic investors can
Invest $5M in Telocyte for supporting Phase 2 milestones

Take care of Telocyte’s clinical trials costs in return for equity

Collaborate with Telocyte and take care of AI and Knowledge Platform development costs in return for equity

Build and operate Telocyte business in India
Books Authored by Dr Michael Fossel

1. *Reversing Human Aging* by Michael B. Fossel, Ph.D., M.D.
2. *Cells, Aging, and Human Disease* by Michael B. Fossel
3. *The Telomerase Revolution* by Michael Fossel, MD, PhD
A FUTURE BEYOND ALZHEIMER’S

www.telocyte.com