



BrainDTech srl

Short Project Description: BrainDTech srl is an innovative Start up Company with the mission to develop new biomarkers for early detection and monitoring of neurological and neurodegenerative diseases. BrainDTech is based on a newly identified and patented molecular mechanism (miRNA inside microglia microvesicles) which occurs in the very early stages of neuroinflammation, when neurodegeneration has not yet caused clinical manifestation. We found that selected miRNAs are specifically associated to a disease indication, thus creating unique relationships between selected molecular markers and a specific pathology. The possibility of detecting brain diseases before clinical symptoms represents a revolution in brain disease diagnosis, allowing therapeutic intervention before degeneration compromises neuronal viability.

One-Line Pitch: BrainDTech develops early diagnosis solutions for brain diseases via liquid biopsy, based on miRNA patterns inside microglia microvesicles

Business Summary: Brain diseases are diagnosed when symptoms appear, after cellular damage. Microglia microvesicles are produced early in neuroinflammation, years before clinical symptoms and neuronal damage. We have evidence that each pathology has a specific MicroRNA pattern, which BrainDTech has discovered and patented. BrainDTech is a revolutionary approach to brain disease diagnosis allowing disease identification years before clinical symptoms appear

Customer Problem: Early diagnosis of neurological, neurodegenerative and neuroinflammatory diseases is very challenging, because most brain diseases are diagnosed observing clinical symptoms, which appear when neuronal damage has already occurred; existing biomarkers on the market allow disease characterization only after clinical manifestation.

Products and Services: BrainDTech allows very early diagnosis of brain diseases, because it detects a molecular signature released by immune cells of the brain, microglia, years before any clinical manifestation. BrainDTech identifies and characterizes brain pathology specific miRNA patterns to be used as biomarkers for very early diagnosis as well as companion diagnostics in drug development.

Target Market: The global market for biomarkers was \$24 Billion in 2015 and is expected to reach \$45 Billion by 2020. Currently, no MicroRNA-based early diagnostic solutions for neurodegenerative diseases exists. Within the liquid biopsy market, BrainDTech develops biomarkers in three different segments: 1. neurodegenerative disease staging 2. early diagnosis and companion diagnostics 3. non-invasive liquid biopsies such as blood

Sales & Marketing Strategy: BrainDTech will take advantage of the business network of its shareholder biotech companies in order to deliver microvesicles related services (using its proprietary protocols). Moreover, it will take advantage of the recognized leadership of its management team in order to create awareness of its products through partnering meetings and face-to-face encounters with pharms and biotechs.

Business Model: The Business Model of BrainDTech is to exploit specific miRNA profiles in microglial microvesicles in order to: •Develop pathology-specific patterns to be outlicensed for early diagnosis or companion diagnostics in drug development. •Identify novel therapeutical targets controlled by unique miRNA expressed in a specific pathology

Competitors: Most pharma companies, especially in recently set up research consortia, are promoting research with innovative approaches to identify clear biomarkers for early diagnosis and disease staging. BrainDTech represents a highly competitive approach because it develops biomarkers with a clear specificity and uniqueness for each brain disease indication.

Competitive Advantage: Current approaches in miRNA-based biomarkers lack specificity, because the collected miRNAs are produced by many different cell types. In our approach, miRNAs are specifically obtained from microglia, thus optimizing data specificity. The patent filed covers the use of this approach in all liquid biopsies; moreover, the established partnership

Company Profile

City: Bresso
State/Province: MI
Country: ITALY
URL: www.braindtech.com
Industry: Healthcare & Medical Devices
Sector: Other Healthcare
Subsector: Healthcare: Other
Founded in: 2016

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Financial Information

Company Stage: Concept Only
Previous Capital: 576.407,00
For capital seeking and other economics, please refer to company presentation.



with IBM for microfluidic tools to catch microvesicles in blood represent a strong barrier to entry.

Management Team: BrainDTech Management Team is characterized by young entrepreneurs as well as internationally recognized professionals with long-standing expertise in different areas of life science, pharma, healthcare and finance.

Advisory Board: BrainDTech International Advisory Board (IAB) is currently being formed, and already acknowledges key opinion leaders in clinical as well as technological areas belonging to both academic and industrial institutions. We expect to have completed the IAB within the first semester of 2017.

Revenue Model: The revenue model of BrainDTech is focused on outlicensing of pathology specific miRNA patterns for early diagnosis and companion diagnostic purposes as well as patenting and outlicensing of novel therapeutical targets derived from the miRNA knowhow. Moreover BrainDTech is exploiting its know how on microglia microvesicles providing drug discovery services to biotech and pharma.

Break-Even Analysis: BrainDTech expects to break even on the third year (2019) when the first outlicensing deal with Pharma for a specific pathology miRNA pattern. BrainDTech has already ongoing negotiations with three top pharma on Alzheimer and Parkinson.

Previous Investments: BrainDTech has raised so far 1.4 Mln EUR in equity (0.9Mln EUR already done , 0.5Mln to be executed within March 2017) from private investors and companies

Use of Funds: The investment breakdown plan is as follows: •1.2 Mln for performing characterization in CSF (100 AD vs 100 PD patients) and identification and isolation of microvesicles from blood •3 Mln for performing AD staging in CSF (900 vs 900 patients) •0.8 Mln for performing miRNA patterns analysis in blood from AD patients

Past Significant Milestones: •We provided first evidence of microvesicle shedding and performed a morphological and biochemical characterization •We observed specific miRNA patterns in different in vitro brain pathology models (AD,PD) •We filed an Italian patent, then an international PCT •We extended the PCT to 13 more pathologies •We ran a successful technical Proof of Concept in human •We ran a successful biological Proof of Concept on 60 patients.

Exit Strategy: Several pharma are actively involved in biomarker research for brain diseases. Among them J&J, Pfizer, Merck, Eisai, Roche, Novartis, Genentech, UCB. BrainDTech has already ongoing negotiations with three top pharma for research agreements on selected pathologies. We expect pathology specific licencing deals to be the most likely exit strategy, along with an equity purchase justified by the wealth of info collected in the BrainDTech database.

Comparable Exit Markets: Current exits refer to biomarkers useful after clinical manifestation. No market case before clinical manifestation, which is the unmet need BrainDTech wants to fulfill. Among comparable exits examples: •Amarantus acquires AD test from Memory Dx enabling differentiation AD vs dementia (\$18 Mln equity + milestones + 9% royalties) •Eli Lilly acquires imaging agent for Abeta detection from Avid (\$300 Mln cash + Up to \$500 MLn in milestones)

Value Proposition: •Outlicensing of pathology specific miRNA patterns and related profit distribution •Selling of data information and related profit distribution •Equity purchase by big pharma.

Resources Beyond Capital: BrainDTech needs a Diagnostic expert with strong expertise in regulatory issues

Additional Information: BrainDTech is developing a strong network of industrial (IBM Precision Diagnostic Lab Switzerland, SAN srl , KOS Genetic srl, Neuro-Zone srl Italy) and clinical (Policlinico Milano Italy, Alzheimer's Research - Drug Development Institute Oxford UK, BioMediTech, Tampere Finland, Aalborg University Denmark) partnerships.