BUSINESS CONCEPT

NEUREVO is developing and will out-licence first-in-class neuroprotective therapeutics that effectively protect against multiple neurological disorders. It offers pharma partners the opportunity to provide a medical solution to over 4 Mio. patients and increase revenues substantially.

FUNDING REQUIREMENTS

To reach the cPOC we are looking for funding

- Series A: GLP-toxicity study for stroke and ALS
- Series B: stroke clinical trial, start ALS clinical trial

CONTACT

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UNIQUE SELLING PROPOSITION, TECHNOLOGY AND IP

- **NEUREVO has identified two innovative neuroprotective therapeutic lead candidates that effectively protect against neuronal death in multiple neurological disorders.**
- Our innovative therapy has shown to prevent neuronal death and improve symptoms in more than one neurological disease through the protection and enhancement of mitochondrial function, thereby increasing cellular energy production.
- Our treatment uses a novel MoA and we aim to develop **first-in-class** treatments against stroke, ALS, Parkinson´s disease and potentially other neurological disorders.
- Preclinical studies have shown efficacy of the treatment without toxicity in animal models and in **first-in-man studies**, only additional GLP-toxicity studies have been requested from the medicines agency (BfArM) in order to start clinical trials.
- The therapeutic use of our substances is protected by two medical use and a formulation patent applications that provide a **strong IP protection**. The off-label use is not possible without our formulation that prevents toxicity. Additionally, substances cannot be freely acquired on the market for human consumption and ALS and some other neurological diseases are considered rare diseases and new treatments fall under the orphan drug act. FTO analysis performed by our patent attorneys showed no relevant third-party patents.
- **To extend our IP Portfolio/Pipeline** we will use our unique knowledge of the MoA to develop our substances in further medical applications.

REVENUE MODEL / EXIT

We plan to license the rights of use for particular indications to pharmaceutical companies. However, an **exit option** could be to sell the rights/assets or shares of the company to a strategic investor after achieving the clinical proof of concept (cPOC).

CUSTOMERS AND PARTNERS

- Direct customers are pharmaceutical companies.
- NEUREVO has selected strategic partners for all the initial steps of the value chain: Prof. Horacio Perez Sanchez for *in silico* modelling, Accelera, FGK and/or SSS as CROs, Granzer as Regulatory Consulting and the pharmacy of the University Hospital Erlangen for CMC with GMP-production of the investigational drug.

CUSTOMER BENEFIT

- Current treatments for neurological diseases are mostly symptomatic and no neuroprotective treatments are available in the market.
- Our treatment will allow the pharma industry to cover this medical need and physicians to offer patients a new treatment to effectively tackle these diseases. This will have a huge impact in the quality of life of the patients and their families.
- We expect a significant gain in “Quality Adjusted Life Years” compared to the current standard treatments which makes it an ideal candidate to be classified as reimbursable treatment by health insurances.

POSITIONING IN THE MARKET ENVIRONMENT AND RELEVANT COMPETITORS

Neurological disorders, especially due to neurodegeneration, are a major concern for the aging population in developed countries. Neuroprotective agents able to disrupt the status-quo like first-in-class treatments will enter the market with no or low competition. We expect market shares from 2% at the beginning and up to 45% in stroke and Parkinson´s markets and even up to 80% in the orphan disease market of ALS.

Based on our competitive analysis we identified 6 pipeline products in Phase II or III for ALS, 5 for stroke and 11 for Parkinson's (PD). The information available shows that most of them: i) show lower efficacy than ours, ii) lack scalability to other diseases, iii) target small subgroups or classify as symptomatic treatments, iv) are more expensive than ours and v) have a different MoA (i.e. **do not necessarily represent a direct competition** and could be used in combination with our substances).

MARKET(VOLUME) AND FORECAST

Worldwide more than 1 billion people suffer from neurological disorders. Out of the overall market for neurological disorders, at the beginning, we will focus on the markets and indications shown below:

USA & EU	ALS	Stroke	Parkinson
Number of patients in .000	50	1.900	2.000
Expected anual growth rate	*1,0%*	*1,4%*	*2,4%*
Sales of drugs in m€ 2017	160	5.200	2.200
Expected annual growth rate	*19,4%*	*3,9%*	*11,9%*

MARKET ENTRY, SALES AND MARKETING

- Market access to prescribing doctors and insurance companies will be handled by a pharma partner.
- Very positive feedback from the first contacts with the pharma industry.
- We will use presentations in specialized congresses and publications in high ranking scientific journals to further attract the attention of potential clients and establish new contacts.
- The barriers for approval are expected to be low. "FDA is likely to approve any drug that shows any efficacy for extending patient survival, even if the difference is not substantial"[GlobalData Market Research 2018].
- In case of licensing we calculate a potential midterm revenue of over 200 million Euros p.a.

STATUS AND SUCCESSES

Stroke: Reperfusion with our treatment exerts a 100% protection against ischemia in vitro (OGD model) and in a global ischemia mouse model when applied i.a. in the carotid artery.

ALS: Our treatment completely rescues mitochondrial activity in human iPS derived motor neurons from ALS patients *in vitro,* delays the progression of symptoms in the ALS SOD-1 mouse model and in first-in-man studies (individual experimental treatments) with no liver or kidney toxicity observed.

PD: 100% protection against dopaminergic cell death in a toxic *in vivo* mouse model (paraquat).

Committee conclusions at the Kick-off-Meeting with the BfArM: Existing data on drug efficacy are sufficient.

Last steps until Phase I/II Clinical studies: i) conduct GLP toxicity studies matching the respective administration forms and durations of the stroke and ALS clinical trials, ii) determine the shelf life of the investigational drug formulation and iii) write and submit the clinical trial application.

Currently the project is financed by the "EXIST-Forschungstransfer" grant from the German government. Total non-dilutive investments until now are around **2 million Euros**.

MANAGEMENT AND TEAM

- **Bernd Zimmermann:** Dipl. Betriebswirt (FH), Graduated in Applied Science for Business and Administration, Long experience as CFO from biotechnology companies (Essex Pharma, Biogen, Gilead)
  CEO
- **Dr. med. Francisco Pan-Montojo Puga**, PhD, MD (Neurologist), Clinical Trial Investigator (Certificate in Good Clinical Practice), PhD in Neuroscience, 15 years of clinical and research experience
  CMO and CSO
- **Alexandra Chovsepian**: PhD in Neurobiology, BSc Biology and MSc Cognitive Neuroscience
  - Drug testing in *in vivo* models
- **Yanina Dening**: BSc Molecular Biotechnology - *In vitro* drug screening and testing

The team is supported by an extensive network of experienced advisors from industry, finance, clinics and academia.