

# MJFF PARTNERING PROGRAM

## Sapiens Steering Brain Stimulation B.V. (“Sapiens”) Michel Decré, PhD (Lead PI)

### Organization and Team Overview

Sapiens is an emerging medical device company whose mission is to bring a revolutionized concept of Deep Brain Stimulation (DBS) to more patients who can benefit from this advanced treatment of degenerative or functional brain disorders, such as Parkinson’s disease, dystonia and other currently emerging indications.

Sapiens’ ambition is to improve the therapeutic outcome of DBS, to shorten and simplify the clinical procedure, and to improve patient comfort. Sapiens’ high-resolution lead enables the reduction of stimulation-induced side-effects by precisely steering the tiny stimulation currents to the intended target area. The SureSuite products – SurePlan, SurePlace and SureTune – provide an integrated, image-based solution for planning and programming an optimal DBS treatment. SureStim, the Sapiens implant, aims MRI-conditional safety, and controls the steering.

With offices in Eindhoven, the Netherlands and Munich, Germany, Sapiens has been founded in 2011 as a spin-out of Royal Philips Electronics by Sjaak Deckers (CEO), Michel Decré (CTO) and Hubert Martens (Director Clinical Science and Applications).

### Opportunity Overview

Deep Brain Stimulation (DBS) can provide a radical improvement in the quality of life of patients with Parkinson’s Disease (PD). Both the large incidence of side-effects, and the complicated procedures, have proven to be significant barriers for a wider adoption though. The Michael J. Fox TDI project “Next Generation Parkinson’s Disease Treatment through Steering Brain Stimulation” (NEXT) enables accurately delivering stimulation exclusively to the intended functionally therapeutic brain structures, which will both improve therapeutic outcome and drastically reduce stimulation-induced side effects for Parkinson’s patients.

### Details of MJFF Grant

DBS implants require both an implantable pulse generator (IPG) as well as a lead that delivers the electrical stimulation. Our advanced local stimulation of a small brain region – often the SubThalamic Nucleus (STN) – is achieved through Steering Brain Stimulation (SBS) which requires a resolution that exceeds that of leads that are currently commercially available. A specific requirement for DBS is that the IPG should be replaceable which in the case of SBS means that a hermetic and biocompatible connector should be realized that reliably connects several tens of electrical wires and is easily connected during surgery. The advanced connector is developed within NEXT and can be considered a premiere for DBS implants in general and PD treatment in particular.

SBS aims at offering optimal electrical stimulation to all patients. In that case, the impact of DBS is spectacular: motor skills are strongly improved, levodopa doses can on average be lowered by 60%, with levodopa-induced dyskinesias and disability reducing accordingly, and sleep duration and quality improve. The NEXT project is crucial for the realization of the Sapiens SBSImplantable products.

## Results and Potential Next Steps

In the first project year, the feedthrough and interconnect specifications have been determined and a test plan has been established. The requirement documents and test plan have been reviewed and approved. The feedthrough supplier has been selected, feedthrough feasibility has been proven, and the feasibility of thin-film to feedthrough electrical interconnection has been proven. A break-through approach has been taken in the project, which allows for building as much as possible on commercially available interconnect technology.

Next steps in the second project year will focus on integrating the NEXT solution into the final implant design:

- Implementation of the design improvements as identified in the prototype builds
- Selection of the integration supplier while focusing on usage of medical grade materials only.
- Establish reliability assessment of the interconnect technology and product.

We are also discussing with the Foundation the potential inclusion of local field potential (LFP) recording and/or development and testing of MR-conditional performance in the award scope for year 2.

## Intellectual Property Status

Sapiens' Steering Brain Stimulation lead, implant and image-guided programming are based upon patents-pending technologies.