MedGenesis is a privately-held biopharmaceutical company committed to developing innovative therapeutics to provide life-enhancing treatments to patients with serious neurologic diseases. It is a world leader in localized CNS therapy.

The MedGenesis team is composed of accomplished pharmaceutical executives with a significant track record in successful drug development, including multiple product approvals (NDAs/BLAs) and is led by Dr. Erich Mohr, a recognized expert in neurodegenerative disorders. In addition to a successful academic career (Professor of Medicine) Dr. Mohr is credited with multiple Life Science Company successes. The management team is supported by a high caliber Board of Directors, and a Scientific Advisory Board that includes key thought leaders in CNS disorders.

Erich Mohr, PhD, R.Psych.
Chairman & Chief Executive Officer
Founder of MedGenesis Therapeutix Inc.

H. Christian Fibiger, PhD
Chief Scientific Officer

Greg A. Johnson
President and Chief Financial Officer

Matthias Luz, MD
Chief Medical Officer

Opportunity Overview

GDNF - First in Class Disease Modifying Agent
Biological neurotrophic factor that has the potential to be a first in class disease modifying drug therapy. In 2004 despite early clinical successes, Amgen discontinued development of GDNF following equivocal Phase II results and perplexing primate data. In 2010 Amgen out-licensed the product to MedGenesis, satisfied that MedGenesis had solved the key technological barriers to effective GDNF therapy encountered in the original clinical trial program.

Disease Modifying
MedGenesis’ new convection enhanced delivery paradigm has overcome the limitations of the delivery technology used by Amgen in a previous Phase II study, setting the stage for definitive clinical proof of concept for this therapeutic. The first 6 subjects of a 42 subject Phase II clinical study are already undergoing treatment at one of the world’s leading movement disorders centres in the UK which was the site of the original successful Phase I study that demonstrated a profound clinical effect.

Intermittent Delivery to Putamen
- GDNF therapy via fully implantable catheter-port system using standard external infusion pumps
- High precision targeting and verification of accurate delivery to the putamen
- GDNF putaminal distribution with volume of interest coverage >50%
- Surgical approach comparable to standard of care deep brain stimulation
- Convection enhanced intermittent delivery (life-long) of GDNF at the community neurologist’s office

Compelling Economics
Biological disease modifying drugs such as Humira command significant premiums over palliative treatments. Following launch in 2018, conservative market share assumptions result in peak sales potential in the multi-billion dollar range. Well protected by intellectual property that extends to 2032 including extensions, partners can expect a significant return on the $75 million estimated cost of the Phase III clinical development program for this unencumbered asset.

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For additional information, please contact: ResearchPartnerships@michaeljfox.org
Details of MJFF Grant

The Michael J. Fox Foundation for Parkinson's Research (MJFF) awarded a $2.1 million LEAPS grant to MedGenesis Therapeutix Inc. in 2010 to further the development of glial cell line derived neurotrophic factor (GDNF). The grant is over a 3-year period, with the total amount being subject to the attainment of specific milestones.

Results and Potential Next Steps

Phase I Clinical Study
Sustained significant reductions in total UPDRS scores over 60 months

Phase II Clinical Study
- 6 patients successfully completed surgery and infusion in pilot study
- Main Phase II study with 36 additional patients due to start Q3 2013
- Full efficacy and safety data readout in 2015

The Phase II study is being conducted in Bristol, England, and is supported by significant direct funding to the site from Parkinson’s UK.

Phase III Clinical Study (with partner)
- Two multi center studies
- Approximately 180 patients per study
- Delivering 2018 marketing authorization

Intellectual Property Status

MedGenesis has developed a multi-layered intellectual property portfolio and strategy that provides protection through 2032 when potential patent term extensions are applied. The comprehensive intellectual property portfolio covers GDNF and the method of treatment as well as the delivery protocol including convection enhanced delivery methods, intermittent delivery of GDNF, and the device for proper delivery (catheter). MedGenesis has licensed the intellectual property from Amgen, the University of California San Francisco (UCSF), and the NIH, as well as developed intellectual property of its own.