Complete the approval process, develop production, and expand to the United States.

1.- DESCRIPTION OF THE PROPOSAL

IDENTIFIED PROBLEM

Neovascular retinopathies are one of the leading causes of blindness and visual disability worldwide, affecting over 300 million people. The most prevalent forms include diabetic retinopathy (DR) and age-related macular degeneration (AMD).

Current treatments using biotherapeutics like Vabysmo™, Lucentis™, and Eylea™ primarily focus on neovascularization (uncontrolled blood vessel formation) but do not address the underlying neurodegenerative and inflammatory components of the disease.

TECHNOLOGICAL SOLUTION

Human erythropoietin (hEPO) is a biotherapeutic used to treat anemias due to its role in generating red blood cells in the body (erythropoiesis).

Additionally, this protein has neuroprotective and neuroplastic properties, protecting neurons from damage, reducing inflammation, and promoting synaptic connections. However, its erythropoietic activity poses significant risks, limiting its use as a neurotherapeutic agent.

BioSynaptica has developed an innovative molecule derived from hEPO that eliminates the erythropoietic activity while preserving and enhancing its neuroprotective and neuroplastic effects. These molecules have been validated in both in vitro and in vivo studies.

In preclinical models, our candidates demonstrated dual action:

Diabetic Retinopathy Model: Protection of retinal neurons from damage and apoptosis, and reduction of pathological neovascularization (a key cause of blindness).

Wet AMD Model: Significant attenuation of inflammation, inhibition of gliosis, and prevention of neovascular growth.

Therefore, our molecules offer a multimodal therapeutic advantage over current treatments for retinal diseases.

Our new hEPO molecules have patent applications in Europe, the U.S., and other key countries, covering approximately 60% of the global market. A favorable patentability opinion from the PCT strengthens our competitive position. Currently, our candidates are protected by patents in the U.S., Europe, Japan, Israel, and Russia, with exclusivity until 2039.

2.- BUSINESS MODEL

B2B: Licensing and Royalties

BioSynaptica will carry out investment rounds to conduct proof-of-concept studies in animal models of specific pathologies, starting with retinal disorders, until the corresponding preclinical trials are completed. Once these objectives are achieved, the technology will be sublicensed to one or more pharmaceutical companies for clinical trial phases, eventually leading to the market introduction of the drug. BioSynaptica will charge initial payments, milestone success payments, and royalties on net sales. Once clinical trials for these retinopathies advance significantly, this model will be replicated to cover other neurodegenerative conditions treatable with our technology.

MARKET

The neurodegenerative disease therapy market is expected to reach USD 60 billion by 2025, with a compound annual growth rate (CAGR) of 7.14% between 2025 and 2030. Specifically, retinopathies represent a USD 20 billion market, with an estimated CAGR of 6.4% (2024-2030).

The target market segment consists of biotechnology and/or pharmaceutical companies that can incorporate an innovative biotherapeutic for the treatment of retinopathies into their product portfolios. These companies will have the opportunity to market the drug exclusively for 8 to 10 years in the world's most significant markets.

3.- FINANCING

Previous Financing:

USD 124,000 - Founders

USD 100,000 - Litoral Accelerator

USD 200,000 - FONDCE – BICE

Required Investment:

USD 2M to be allocated to:

Operations (biomolecule production process development and analytical development).

Proof-of-concept studies in animal models of degenerative retinopathies.

Strengthening the patent strategy.

Beginning the preclinical toxicity trials phase.

4.- IRR AND INVESTOR PROFILE

The sought investor profile includes venture capital funds specializing in health and biopharmaceuticals, as well as pharmaceutical laboratories interested in early-stage innovative developments. In addition to financing, strategic partners are sought to provide support in critical areas such as formulation, regulatory compliance (with agencies such as the FDA and EMA), and the design and execution of clinical trials.

5.- EXECUTION PLAN

The short-term plan includes establishing a presence in the U.S. to connect with key opinion leaders in the sector and engage with venture capital funds specialized in biopharma.

Additionally, within the next 18 to 24 months, the development of the GMP production process is expected, which includes:

Analytical development

Preclinical trials (TLR5)

Proof of concept (POC) in models of degenerative retinopathies (AMD; retinitis pigmentosa, a rare disease)

OTHER BACKGROUND

Affiliated Institutions: UNL, CONICET, UNSAM

Strategic Alliances: Litoral Accelerator; Litoral Biotech Center (FBCB-UNL); Max-Planck-Institut für Multidisziplinäre Naturwissenschaften (Göttingen, Germany); ICIVET (UNL/CONICET); CAB-Startups (Argentine Chamber of Biotechnology); Litoral Center Technology Park (PTLC, Santa Fe).

Awards and Notable Mentions:

LATAM $100k 2020 (Pitch Category)

Cesar Milstein 2021 (Second Prize)

Scientific Excellence Award 2023 from Nucleate Global Activator

NTT Data Argentina 2024 (First Prize)

Perfil

BioSynaptica is a biotechnology startup that develops innovative biotherapeutics derived from human erythropoietin (hEPO) for the treatment of neurodegenerative disorders. It is currently in the stage of validating its therapeutic candidates in animal models of various diseases involving nervous system disorders and retinopathies.