somagenetix
Cure with genes

Somagenetix AG

Somagenetix is a spin-off of the University of Zurich, Switzerland, with the mission to become the global leader in precision phagocyte gene therapy. The team has discovered and filed for patent unique promoter technologies overcoming known limitations of other viral vectors.

The ex-vivo (lentivirus transduced autologous stem cell) gene therapy platform allows for targeted and safe cure of a wide range of genetic phagocyte disorders, such as macrophage related immunodeficiencies, e.g., Chronic Granulomatous disease (CGD), or microglia related neurological disorders, e.g., Fronto-Temporal-Dementia (FTD).

The team has previously shown clinical proof-of-concept of viral ex-vivo gene therapy through clinical trial in CGD patients. The past observed durability and safety limitations have been overcome with the novel break-through pomoter technology, validated with a strong pre-clinical data package

- **Specificity:** targeted transgene expression in blood and brain phagocytes
- **Efficacy:** Physiological and sustainable gene expression - no silencing of transgene
- **Safety:** Absence of overexpression and oncogenic potential up to very high vector concentration

Development status lead indication: **Chronic Granulomatous Disease (CGD)**

- p47 CGD (30% of all CGD patients) pre-cinical package completed (pre-clinical data generated based on favorable scientific advice received from Swissmedic, EMA & PEI)
- Pivotal/licensure trial (N = 12) to start late 2023/ early 2024: Protocol finalized, CRO selected, clinical vector material produced
- Anticipated market approval as early as end of 2025
- Orphan drug designation granted by the EMA (submitted at the FDA)
- X-CGD (60% of all CGD patients) through simple gene exchange in pre-clinical development

Follow-on program: **Progranulin-deficient Fronto-Temporal-Dementia (FTD)**

- Strong scientific case for superiority over competing technologies (e.g., AAV, protein substitution)
- Lead candidate vector identified *in-vitro*
- Transfer to *in-vivo* PoC in mouse models of the disease ongoing, expected readout Q2 2023
- Existing clear clinical trial plan, in preparation for regulatory meetings with FDA and EMA
- Strong interest from US opinion leader in neurology

Deliver value for patients

- Focused on high unmet medical need, devastating diseases with high morbidity, mortality and limited treatment options
- Comparably low development risk thanks to established biological PoC in CGD
- 2 First & best-in-class products approved within 3/4 y to cure > 3'500 CGD patients
- Early proof of concept on FTD

Unlock shareholders value

- Nimble financing, clear path to cash flow break-even within 5 years
- Anticipated market exclusivity in CGD, compelling commercial opportunity, reaching peak sales 0.5 – 1 b$ in targeted markets,
- FTD with a market opportunity factor 5 times higher
- PRV (100 $M) enabling cash flow break-even within 4-5 years (including PRV)
- Efficient and focused capital utilisation, USD 7 raised to date, incremental USD 35 mio (Series A) to first potential product approval within 3 years

Highly experienced and lean leadership team

- Company is run by scientific and medical leaders (founders) with > 18 years of experience in gene therapy research and clinical development and experienced CEO/COO with extensive executive experience in large and small pharma
- Strong CMC team combines existing excellent laboratory capacity and technical team (15 FTE) with market-proven GMP producers, allowing for accelerated path towards approval
- Pre-established relationships with experienced CDMOs and CROs for rapid clinical execution

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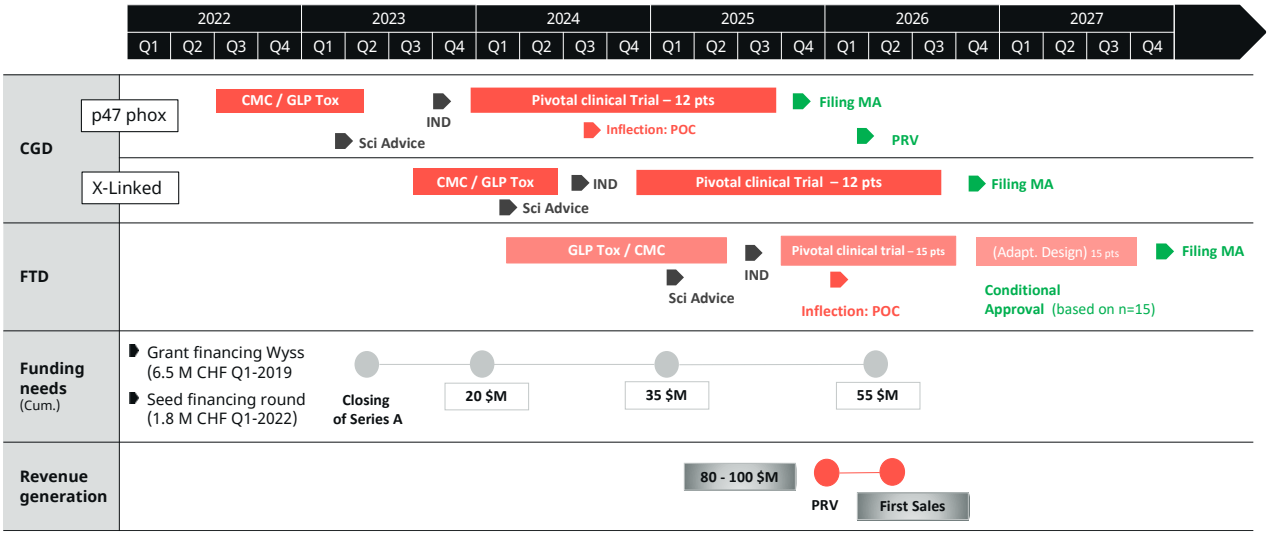
Business Plan Roadmap



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