Revolutionizing The Treatment of Nerve Dysfunction

Overview
6K orphan hereditary ataxia
$300M+ ataxia market size
2M+ with nerve injury
15 patents exclusively licensed
20 peer-reviewed publications
Human pilot studies complete
IND nerve injury trials enrolling
505b2 FDA submission in 2025
Product launch in 2026

Financing
Funding stage: Seed
Capital seeking: $8M
Grants: $8M to co-founders

Senior Management
CEO: Christian Walker, MBA
Business: Dushon Riley, PhD
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Solaxa is a clinical-stage, bio-pharmaceutical, start-up company developing and commercializing therapies to improve the lives of children and adults suffering from nerve dysfunction caused by either disease, genetics, or injury. Nerve dysfunction significantly reduces both the quality and length of life. Aminopyridines are closely related, FDA-approved small molecule drugs. Dalfampridine is indicated to improve walking speed in adults with multiple sclerosis (MS) and Amifampridine to treat Lambert Eaton Myasthenic syndrome (LEMS). Solaxa has discovered that aminopyridines can also reduce the severity and frequency of attacks in hereditary ataxias and can improve detection, treatment and healing of traumatic nerve injuries.

Team: CEO Christian Walker has 20 years of neurology industry experience including AxoGen and Neuraptive commercializing drugs, biologics, and combination nerve products. Head of Commercial, Jen Butler, has launched rare-orphan products and led commercialization efforts with both start-ups (Innate Pharma & Tessa Therapeutics) and large pharmaceuticals (Medimmune & AstraZeneca). Dr. Dushon Riley runs business operations and strategic planning and this is his third time working with the CEO. Solaxa has a robust board of directors, scientists and clinicians who serve as co-founders and advisors with aminopyridine specific nerve experience.

Nerve Dysfunction is a Life-Changing Problem: Diseases, genetics and injuries in nerve function can lead to serious health consequences. MS is a neurodegenerative disease characterized by lesions in the brain that result impaired coordination, trouble walking and vision loss. Hereditary ataxias are a group of closely related conditions of genetic origin that also result in many of the same problems as MS. Nerve injury represents a large unmet future opportunity to explore impacting more than 2M people a year.

Aminopyridines: Dalfampridine, also known as 4-Aminopyridine (4-AP) was first launched in 2010 by Acorda Therapeutics in an extended-release (ER) formulation branded as Ampyra®. It generated over $3B+ in life-time sales prior to generic entry in 2018. Ampyra and its generic competitors are only available to adults with MS in a single 10 mg extended release (ER) dosage that must be taken twice daily, 12 hours apart and cannot be cut, crushed, or dissolved, making titration and adjustments for body size or minimization of side effects impossible. Amifampridine, also known as 3-4 di-Aminopyridine (3,4 DAP) was first marketed in 2018 by Catalyst Pharmaceuticals as Firdapse® which is priced at $375K a person annually and generated $210M in 2022 sales to treat the 3,000 people with LEMS. Amifampridine is orphan and patent protected, in LEMS only, through 2032.

Treatments for Hereditary Ataxias: The FDA's February of 2023 orphan drug approval of Reata Pharmaceutical's Skyclarys (omaveloxolone) for Friedrich's Ataxia has set clear standards of safety and efficacy for the evaluation of hereditary ataxia treatments and carries a $370K annual price tag. Dalfampridine has already been used with success in two other forms hereditary ataxia that also fall comfortably within the parameters for orphan drug status. In Episodic Ataxia Type 2 (EA-2), forty people taking dalfampridine had a significant reduction in the frequency of attacks and improvements in quality of life. People with EA-2 taking 5mg immediate release dalfampridine 3 times a day had similar types of improvements as those taking the currently available dalfampridine ER version 10 mg twice daily but with fewer side effects. In a newly described (NEJM: January 2023) population of spinocerebellar ataxias called SCA27b, 7 out of 8 patients (87.5%) when given dalfampridine had a marked to moderate reduction in the frequency or severity of ataxic symptoms. SCA27b is expected to be the largest sub-group of hereditary ataxias with estimates ranging between 5,000 - 10,000 patients in the US.

Neurology Society Recommendations: Based on the published results above, the American Academy of Neurology (AAN) currently recommends that people with EA-2 and those with gait ataxias and vision problems (nystagmus) take immediate release dalfampridine 2-3 times a day and titrate to find the optimal balance between efficacy and minimizing side effects. No immediate release formulation of dalfampridine has ever been approved by the FDA for any indication. Currently following the AAN clinical recommendations requires prescriptions to be compounded, adding quality risk and high patient costs without insurance reimbursement.

Downstream Market in Nerve Injury: Aminopyridines also have application in other nerve injuries that are far more common than rare diseases like hereditary ataxia. A nerve injury pilot study was conducted at Walter Reed on wounded service members, correctly identified recoverable nerve injuries and promoted faster return to service. Animal studies conducted by Solaxa founders have shown that novel formulations of aminopyridines promotes remyelination, and provides durable recovery of function, resulting in neuro-regeneration and healing, when used in multiple different patented acute nerve injury settings. Solaxa founders are currently enrolling two grant funded investigator-initiated IND trials in patients with traumatic and surgical (iatrogenic) nerve injuries.

Product Differentiation: Solaxa's first product is an orally dissolving tablet (ODT) version of dalfampridine, manufactured by our strategic partner Catalent. Dalfampridine ODT will have novel dosages, dosing regimens and release characteristics that cannot be substituted with the currently approved generic version of the drug (10 mg ER BID). Solaxa will first pursue orphan drug designations for EA-2 and SCA27b using dalfampridine ODT. These two populations alone represent $300M-$540M in potential annual revenue assuming $50K-$90K annually per patient, which is modest for orphan drug prices. Future (non-orphan) markets include the 2M+ people with a nerve injury from accidents, injuries, and surgery, significantly raising Solaxa's annual revenue potential.

Why Invest in Solaxa? Developing novel formulations dalfampridine for hereditary ataxias represents a quick, low-risk, and high-reward path to market. Approval of an orphan indication offers 7 years of regulatory exclusivity. Solaxa has licensed 15 issued and pending patents that offer protection for numerous aminopyridine formulations through at least 2034 in acute nerve injury. Solaxa co-founders have raised $8M in non-dilutive grants, with over $2M awarded in 2022. Solaxa has been 100% founder funded to date. Raising $8M in in 2023 along with $17M in 2024 will allow Solaxa to complete all clinical trials and submit our FDA 505(b)(2) regulatory approval submission for SCA27b hereditary ataxia in 2025, with plans to undertake an initial public offering (IPO) in 2026.