INVEST IN **SOLAXA PBC**

Restoring people's lives suffering from nerve dysfunction with FDA approved drug

solaxa.com Bethesda MD

Technology Healthcare Science & R&D

LEAD INVESTOR

Luis Gutierrez

I have worked with the Solaxa team over the last six months and am excited to write the first check, be the lead investor, and have joined Solaxa's Board of Directors as an independent member. The recent announcement in 2023 of a new hereditary spinal cerebellar ataxia (SCA27b) is an exciting discovery and an amazing opportunity to repurpose dalfampridine (4-AP). The reasons I invested are I believe Solaxa has a clear path to market, and the speed and cost compared to typical drug development is faster and lower. The Solaxa team has done a great job derisking the SCA27b approach and have even more exciting things planned in the future with nerve injury. I also love supporting a company that has a clear mission and a public benefit while also being a great investment.

Invested $10,000 this round

Highlights

1. NEW uses of an FDA-approved drug for UNTAPPED $300M+ nerve dysfunction market
2. Targeting hereditary ataxias and nerve injuries
3. 1st FDA approval 2025 & aiming for revenue in 2026; pipeline of patented products (not guaranteed)
4. $8M grants to founders, 15 issued & pending patents licensed, Investigator-IND FDA trials enrolling
5. Team has decades researching & commercializing dalfampridine from FDA approval to new patented uses
6. CEO has 20+ yrs in commercialization of nerve drugs, devices, biologics & combo products
7. Targeting hereditary ataxia called SCA27b published in New England Journal of Medicine January 2023
8. Repurposing an already FDA approved drug reduces risk, and lowers costs and time to bring to market.

Our Team

Christian Walker Chief Executive Officer & Founder

CEO Christian Walker has 20 years of neurology industry experience including AxoGen and Neuraptive commercializing drugs, biologics, and combination nerve products and served as Director of the Peripheral Nerve Institute at Walter Reed.

Our CEO worked with surgeons at Walter Reed, and they often did not know whether to amputate or reconstruct mangled limbs. Dalfampridine gave them valuable information on saving limbs. Recently, he met someone with Ataxia, whom without dalfampridine, he couldn't ride a bike. With the drug, he can ride 20 miles. Dalfampridine does amazing things!

Jennifer Butler Head of Commercial

Jennifer brings 25 years of commercial leadership with both large pharma and early stage biotechnology companies. She launched Innate Pharma's first rare, oncology product in the US. In 2019, she was part of the team to raise $79M in Innate's IPO.

Mark Noble, PhD CSO & Scientific Co-Founder

Mark is Professor of Neuroscience at the U of Rochester and a regenerative medicine nerve expert. He has been researching and patenting new forms of dalfampridine for over 20 years and was instrumental in the original commercialization of the drug.

John Elfar, MD CMO & Medical Co-Founder

John is Chair of Orthopedics, and a hand surgeon scientist at the U of Arizona. Graduate of Johns Hopkins and Harvard Medical, he is also an inventor and currently running clinical trials using dalfampridine for nerve injury detection and treatment.

Dushon Riley Director of Business

Dushon is an accomplished leader with expertise in business strategy across the biopharma industry. This is his third time working with the CEO, including AxoGen and Johns Hopkins. He received his PhD from the U of Maryland School of Medicine.

Mary Hogan Director of Patient Access

Mary has been serving as a liaison between SCA27b Ataxia patients and researchers for 16 years. She earned graduate degrees in biochemistry/ neuroscience, public health, and epidemiology and served in the US Army.

Treatment using FDA Approved Multiple Sclerosis Drug for Hereditary Ataxias & Nerve Injury

Solaxa is a neuro-focused biopharmaceutical start-up, public benefit corporation (PBC) bringing a **revolution** to the treatment of nerve dysfunction.

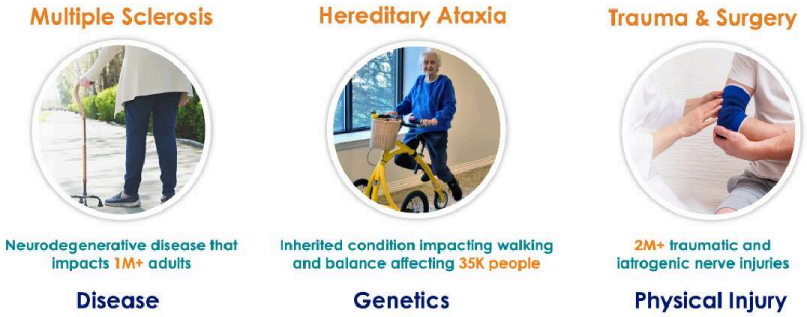
Nerve Dysfunction is Life-Changing

Nerves control everything we feel and do. Nerve damage can occur from disease, genetic condition or traumatic injury. When nerves are damaged, people can lose function and sensation, severely impacting their quality of life and even reduce life expectancy.

Nerves Control Everything we Say and Do

Solaxa is first targeting nerve dysfunction caused by hereditary ataxia followed by nerve injuries using a type of small molecule drug called 4-Aminopyridine (4-AP) , whose generic drug name is dalfampridine.

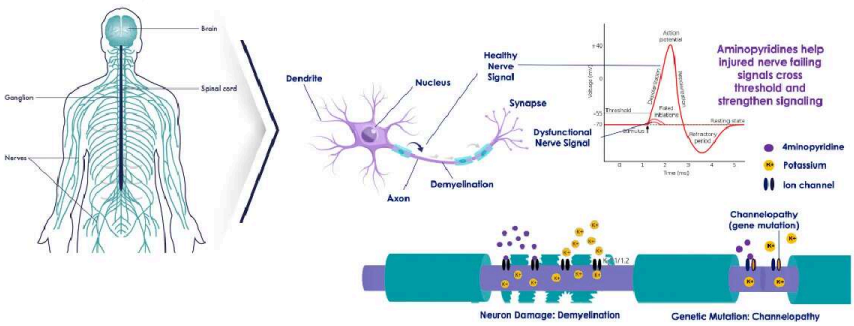
Dalfampridine is already FDA approved to improve walking in adults with multiple sclerosis (MS). But it can do so much more!



Solaxa aims to commercialize newly patented formulations of dalfampridine to treat nerve dysfunction with this amazing drug. It already works to improve walking in the worst types of neurodegenerative disease, we are going to get approval for people who have the same type of walking problems (ataxia) whose cause is an inherited genetic mutation. Finally we think this amazing drug can help heal nerve injuries caused by trauma such as a car accident or a fall.

How Nerves & Aminopyridines Work

All movement and feeling are controlled by nerves. When the nerves are damaged by either disease or injury the injured nerve is unable to properly signal. Aminopyridines are potassium ion channel blockers that helps damaged nerves signal in diseases like MS.



Nerve injury studies conducted by Solaxa founders have established that dalfampridine, can do even more!

In humans dalfampridine has been shown to work in certain ataxias to help with balance, trouble walking and vision problems. The hereditary ataxias where

dalfampridine has been shown to work include episodic ataxia type 2 (EA-2) and spinocerebellar ataxia type 27b (SCA27b).

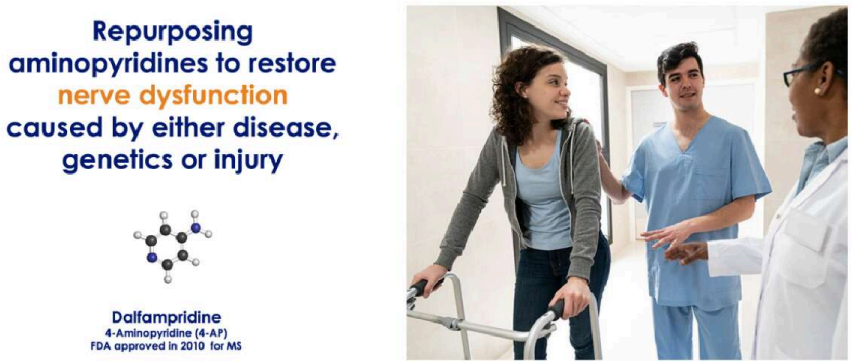
In humans, dalfampridine has been shown in a pilot study to be able to detect nerve injuries that are recoverable, helping surgeeons make better decisions about surgical options.

In animal models, dalfampridine can even regenerate nerve injuries, resulting in durable improvement in function and regrowth of the myelin sheath that protects nerves.

Regrowing myelin is a **GAME CHANGER** and we have shown we can do just that!

Solaxa's Public Benefit Mission

As a biopharmaceutical PBC start-up, Solaxa is ***one-of-a-kind.*** While we are profit driven, we never compromise on our dedication to science, or our unwavering commitment to treating patients with nerve dysfunction.



Making sure everyone has access to impactful life-improving neuro-regenerative treatments is our mission!

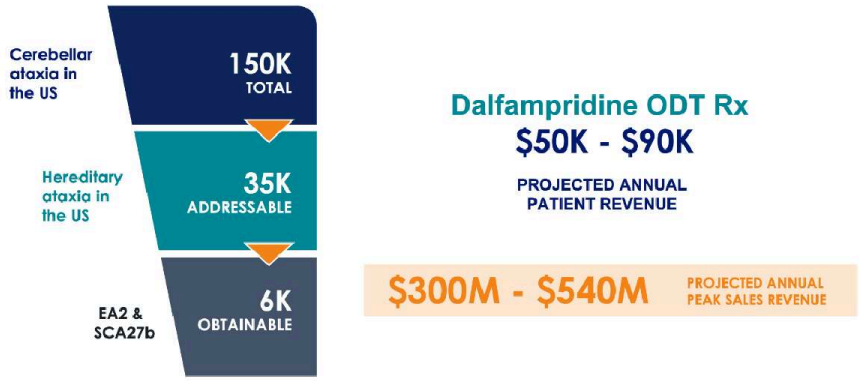
Investment Opportunity & Market Size

Solaxa is now for the first time offering outside investors the chance to invest. Solaxa is currently subscribing **$1.2M** in simple agreements for future equity (SAFEs) as part of a **$8M** Seed financing to complete our first human testing of our drug. We will need **$17M** to complete our final clinical trial and submit our FDA 505(b)(2) application.

Forward-looking projections cannot be guaranteed.

Solaxa founders have done a lot since incorporating in 2021. We are currently testing drugs in investigator-IND clinical trials and we have done all this with $8M in grants from the National Institutes of Health (NIH) and Department of Defense (DoD) that have been awarded to our co-founders (ie not directly to Solaxa).

Our initial total market size are the 150K patients with cerebellar ataxias. Solaxa's obtainable market are the 35K hereditary ataxia patients for whom our products provide unique characteristics that cannot be substituted with the current version of the drug. Our obtainable market are the two types of ataxia for whom we have evidence the drug already works. These two ataxias, EA-2 with a prevalence of aproximately 3,800 people in the US and SCA27b with a conservative 2,800 people in the US. It is estimated that SCA27b may become the largest group of hereditary ataxias totaling somewhere between 5,000 and 10,000 patients. The genetic test for SCA27b was firstCLIA approved on 4/20/2023.



Forward-looking projections cannot be guaranteed.

Source: National Ataxia Foundation Fact Sheets

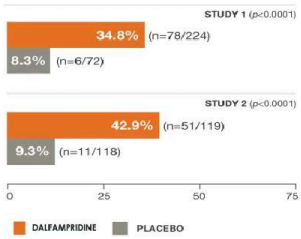
Based upon existing drug prices that are already insurance and Medicare reimbursed, we expect that our first product Dalfampridine ODT will generate between $50K and $90K in projected annual per patient revenue. Based upon our obtainable market size, Solaxa is projecting a range of $300M to $540M in projected annual gross sales revenue. (Projections are not guaranteed).

If this works in hereditary ataxia imagine what could happen when given to the 2M+ patients with nerve injuries each year. Hereditary ataxia is just the beginning!

Dalfampridine is FDA Approved

An extended release (ER) version of Dalfampridine was first marketed as Ampyra in 2010 by Acorda Therapeutics. No immediate release (IR) version of dalfampridine has ever been FDA approved for any indication. Since its release over 150K people with MS and other neuro-impactful conditions have taken Dalfampridine ER.

Acorda lost patent protection starting in 2017. While under patent protection, Acorda had peak sales of **$542M** in 2017 and has generated over **$3B** in sales (2010-2021). Generic entry began in 2018.



Significant improvement in walking speed in adults with MS

Only a 10mg extended-release (ER) tablet for adults taken twice daily.

One Size Does Not Fit All

Cannot be cut, crushed or dissolved titration not possible

Unfortunately, One-Size-Does-Not-Fit-All!

Dalfampridine ER was designed to only be available in a single dosage form, one-size-fits-all approach that **cannot be cut, chewed, or dissolved** and must be swallowed whole.

Introducing Dalfampridine ODT

This is where Solaxa's **Dalfampridine ODT** comes in! An orally dissolving tablet (ODT) of dalfampridine that doesn't require water to take and avoids gastric adsorption allowing for faster drug delivery. Dalfampridine ODT is perfect for hereditary ataxia and nerve injury. Dalfampridine ODT is manufactured by Catalent our strategic development and manufacturing partner who has over 300 patents protecting their oral dissolving drug delivery technology called Zydis.

Our Approach to Dalfampridine is Unique!

Bringing Dalfampridine and ODT together unlocks unique characteristics that provide important advantages that the current drug cannot match.

Perfect for children & dysphagia

Dissolves without water in 3 seconds

Expanded dosing regimens available

Drug delivery in minutes not hours

People with hereditary ataxias often have difficulty swallowing (dysphagia), leading to malnutrition, dehydration, risk of aspiration pneumonia and even death. Due to its novel dosage regimen and drug release characteristics, we believe Dalfampridine ODT when given to people with a hereditary ataxia will have a reduction in the severity and ffrequency of ataxic attacks

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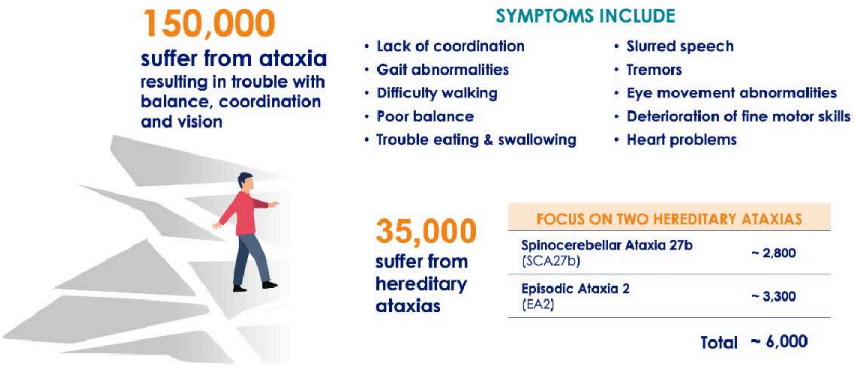
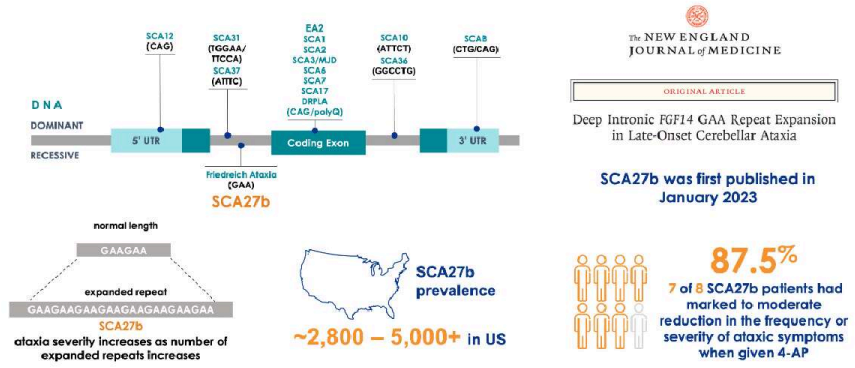
Hereditary Ataxia

Hereditary ataxias are a group of genetic conditions, that also result in difficulty walking, trouble with balance and eating, as well as vision problems.

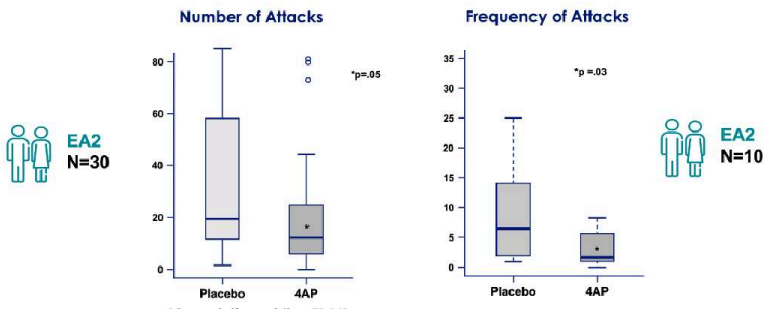


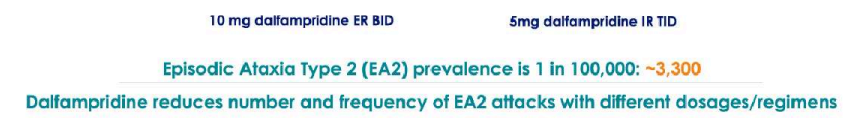
Hereditary ataxias are a group of genetic conditions, that results from inheriting mutated gene(s) from your parent(s) Each type of inherited ataxia is named by the type of ataxia and then labeled numerically in order of the genetic mutation discovery.

Solaxa is focusing on two groups of people with hereditary ataxia, EA-2 and SCA27b. SCA27b was just discovered in January of 2023 and is currently thought to have a prevalence of about 2,800. EA-2 has a prevalence of 3,300.



In the newly discovered population of SCA27b, eighty seven point five percent (87.5%) had a marketed to moderate reduction in frequency and severity of ataxia symptoms when taking dalfampridine. In EA-2 there is even more clinical data showing that dalfampridine works in hereditary ataxias and that one size does not fit all.



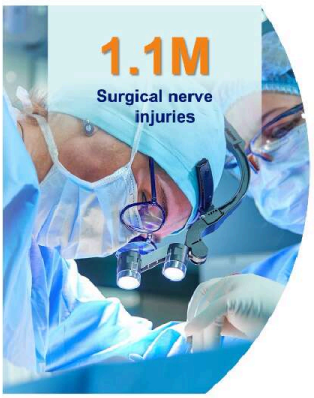


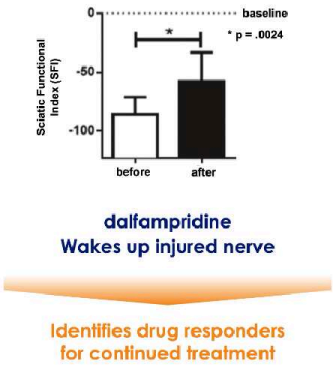
There is only a single dosage 10mg Dalfampridine ER version available. Even though a lower dose 5mg IR version of the same drug also works and with fewer side effects associated with lower dosages. However no 5my IR version of dalfampridine has ever been FDA approved.

Amazingly enough the American Academy of Neurology actually has a formal recommendation stating that people with EA-2 should take 5mg Dalfampridine TID, yet that version of the drug isn't available. Until now! Dalfampridine ODT will be available in a 5 mg IR formulation among others to be announced as truly one-size does not fit all!

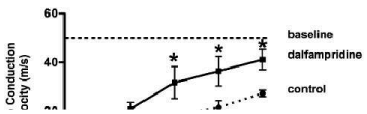
Traumatic & Surgical Nerve Injury

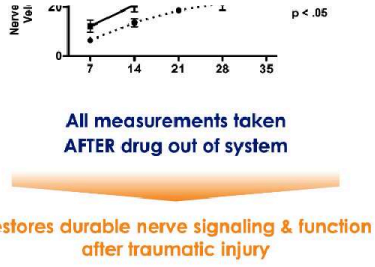
Nerve injuries are an important next chapter after hereditary ataxia. After a traumatic injury, patients must wait weeks before seeing a specialist to determine if the injured nerve can recover. Even if a signal is detected and surgery is avoided, the patient is sent home to heal on their own with no further treatment. There are over 2M+ nerve injuries that result from trauma and surgery each year.





Dalfampridine delivers symptomatic relief, enhances remyelination, and provides durable improvement in nerve function when taken after injury.





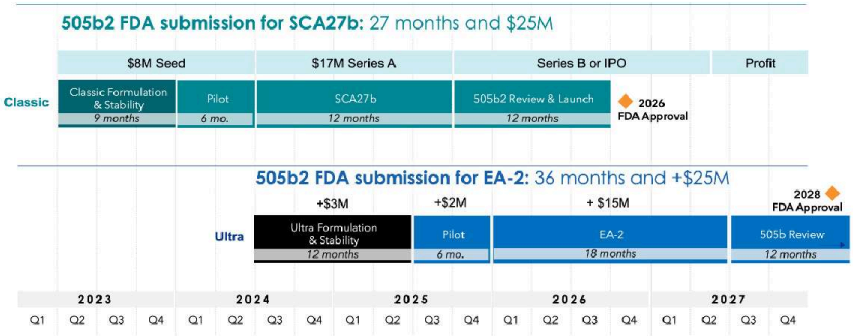
In other words, dalfampridine doesn't just treat nerve damage, it heals nerve injury!

Development Timeline

We are aware that drug development can be a long road. Starting with an already FDA approved drug the path to market for our products is lower cost, quicker and less risky.

We aim to bring Dalfampridine ODT to market in 3 years at a cost of $25M!

Solaxa began development of Dalfampridine ODT in 2022 with market-entry expected in 2026. The total process from start through submitting our first application to the FDA approval, is expected to take 27 months and cost $25M for dalfampridine ODT in SCA27b. (Projections cannot be guaranteed).



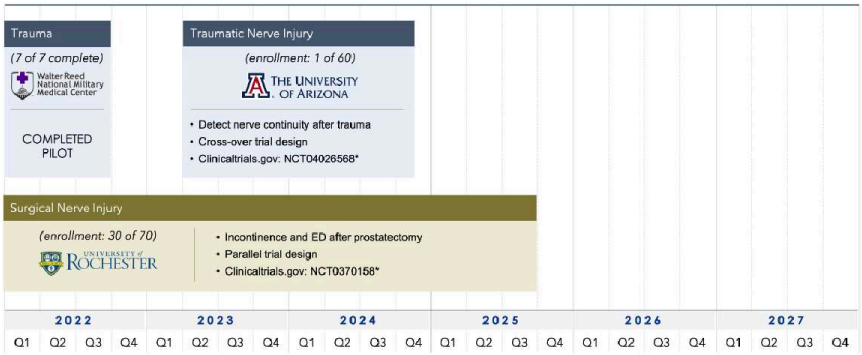
Solaxa will next pursue EA-2 hereditary ataxia claims which will require 36 months and an additional $25M claims for traumatic and surgical nerve injury through post-marketing trials conducted after initial regulatory approval in 2026 (Phase 4).

Catalent. Development & Manufacturing Partner PPD Regulatory & Clinical Partner

We have chosen two critical strategic partners: Catalent, our contract development and manufacturing partner, and PPD as our regulatory and clinical research organization.

Human Trials Enrolling

Solaxa co-founders are already running dalfampridine human trials! Our next indication after hereditary ataxia will be traumatic nerve injury. A pilot study at Walter Reed (7 patients) was completed that showed that dalfampridine could identify and treat injured nerves.



Trial 1: Dalfampridine for Traumatic Nerve Injury

This trial at the University of Arizona has enrolled 1 of 60 patients to evaluate dalfampridine in traumatic and iatrogenic nerve injuries. This trial is funded by a $2M NIH grant to co-founder Dr. John Elfar. **ClinicalTrials.gov: NCT04026568**

2022 Press Release: $2M NIH grant to run 4-AP nerve injury trial awarded

Trial 2: Dalfampridine for Surgical Nerve Injury

This trial at the University of Rochester has enrolled 30 of 70 patients to evaluate dalfampridine treatment on erectile dysfunction and incontinence following prostatectomy. **ClinicalTrials.gov: NCT0370158**

These trials are investigator-initiated trials paid for by grants and not sponsored by Solaxa.

Strong Intellectual Property

Assuming hereditary ataxia is granted an orphan drug designation and comes to market in 2026, orphan drug status will provide 7 years of regulatory protection and exclusivity from generic competition until at least 2033.

Solaxa has executed exclusive intellectual property (IP) licenses for 3 issued and 12 pending patents from the University of Rochester and Penn State.

Solaxa Has 15 Patents to Protect its Products Until 2034 and Beyond

Here are links to some of our published patents.

Patent 1: US 9,993,429 Composition & methods for treating nerve injury

Patent 2: Treatment of acute traumatic injury

Patent 3: Methods and materials for treating nerve injury and wound healing

Amazing Team

Our team brings decades at the forefront of dalfampridine research, ataxia and nerve industry specific experience. The three co-founders have worked together since 2017 and have raised $8M in non-dilutive grants funding for all pre-clinical and clinical development work done to date.

Christian Walker, MBA, MS
CEO & Founder
Member of the Board

Neuraptive
Walter Reed National Military Medical Center
axogen

Jennifer Butler
Head of Commercial

TESSA THERAPEUTICS
AstraZeneca
MedImmune

Mark Noble, PhD
Scientific Co-Founder
Professor, University of Rochester

University of Rochester
Q THERAPEUTICS
Stanford University

John Elfar, MD
Medical Co-Founder
Chair of Orthopedics, University of Arizona

The University of Arizona
Harvard Medical School
Johns Hopkins University

CEO Christian Walker has 20 years of neurology product development experience, commercializing tissue products, devices and biologics at AxoGen, developing a drug-device combination product at Neuraptive, and leading nerve injury trials at Walter Reed National Military Medical Center. Head of Commercial, Ms. Jennifer Butler has experience bringing a rare orphan pediatric oncology product to market and bringing companies to IPO. Solaxa also has additional co-founders and strategic advisors. CSO & Scientific co-founder Dr. Mark Noble at the University of Rochester is a professor-scientist and neuro-regenerative medicine expert who served on the scientific advisory board and was involved in the original commercialization of dalfampridine. CMO and Medical co-founder Dr. John Elfar is Chair of Orthopedics at the University of Arizona and a surgeon-scientist enrolling investigator-initiated dalfampridine clinical trials for nerve injuries. Director of Business Dr. Dushon Riley is focused on strategic and business operations and has worked with the CEO before. Ms. Mary Hogan is the Director of Patient Access working on the identification and recruitment of SCA27b patients.

Lauren Sabella
Chairwoman & Independent Member
Current COO & Former CCO

mannkind
ACORDA THERAPEUTICS

Luis Gutierrez, MBA
Independent Member of the Board
Current EIR, Former CEO & CCO

Veranex
COVANCE

Solaxa's Board of Directors consists of three members; Mr. Christian Walker, Ms. Lauren Sabella and Mr. Luis Gutierrez. Ms. Sabella has recently been announced the COO of Mannkind and was previously COO & CCO of Acorda Therapeutics and responsible for the original commercialization of Dalfampridine ER generating over $3B+ in lifetime sales. Mr. Luis Gutierrez is an accomplished life science entrepreneur and angel investor. Both are independent board members.

Andrew Blight, PhD
Scientific Advisor
Former CSO, Acorda Therapeutics

Andrew Goodman, MD
Clinical Advisor
Neurologist, University of Rochester

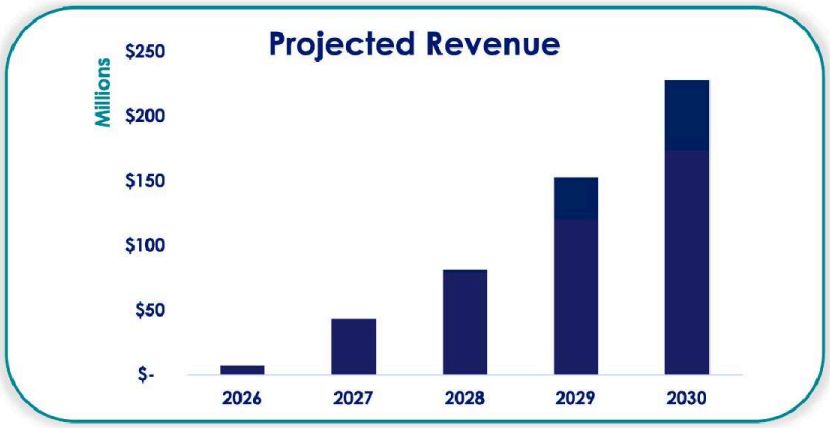
COL ret. Leon Nesti, MD, PhD
Military Medicine Advisor
Orthopedic Hand Surgeon

Dr. Andrew Blight was Chief Science Officer at Acorda Therapeutics for over 18 years and responsible for guiding all product and scientific development. Clinical Advisor Dr. Andrew Goodman, a neurologist was responsible for running the MS clinical trials for Dalfampridine ER for MS. Military Medicine Advisor Colonel (retired) Leon Nesti ran a 7 person pilot study using dalfampridine in traumatic nerve repair at Walter Reed.

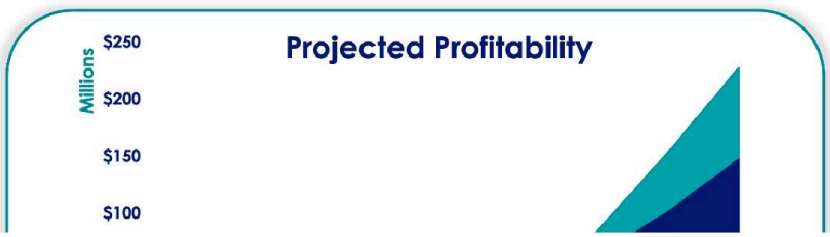
Revenue & Profitability

Solaxa forecasts that we will begin generating revenue in 2026 when we bring Dalfampridine ODT to market. Profitability is expected in 2028 and sales in 2030 are expected to exceed $225M.

Forward-looking projections cannot be guaranteed.



Neurologists and orthopedic surgeons are Solaxa's customers that will write prescriptions for their patients leading to revenue.



Forward-looking projections cannot be guaranteed. Please invest wisely and don't risk more than you can afford to lose!

Why Invest in Solaxa?

Solaxa is subscribing a **$1.2M** SAFE on Wefunder as part of our **$8M** Seed financing expected to close in 2023 to complete our first human pilot study. We will then close **$17M** in Series A financing in 2024 to complete our final human clinical trial. Solaxa does not expect to need additional investments before a potential liquidity event starting in 2026. (Projections cannot be guaranteed).

Large Market & Clear Path

Dalfampridine ODT has the potential to impact the lives of **6K** with SCA27b and EA-2 forms of hereditary ataxia and the **2M+** people living with acute nerve injuries that could benefit from Solaxa products. Solaxa anticipates annual revenue to each between $300M and $540M (not guaranteed). Raising **$25M** ($8M Seed + $17M Series A) will allow us to reach the market in 2026. Reaching these milestones will allow us to go public. We will need to raise $25M at IPO to reach profitability in 2028. (Projections cannot be guaranteed).

Amazing Team in Place

Solaxa founders, staff, and consultants have over **100+** years of nerve dysfunction and ataxia-specific experience. Solaxa founders are already running human trials that are currently enrolling to evaluate dalfampridine for the detection and treatment of nerve injuries. Our co-founders have raised **$8M** in grants, have **15** issued and pending patents resulting in over **20** publications. Solaxa is preparing to submit over $8M in new grants in 2023. (Projections cannot be guaranteed).

We are a Public Benefit Corporation

Solaxa is a **PBC** dedicated to improving the lives of children and adults suffering from nerve dysfunction by making neuro-focused therapies that are accessible and impactful. Solaxa believes we will be more profitable by doing good and by thinking differently about nerve dysfunction!

Together We Will Revolutionize The Treatment of Nerve Dysfunction!

Solaxa

Items for Download:

1. **Executive Summary**

2. **Pitch Deck**