PRÓSPERA

MINI CIRCLE

*for **Innovation.***
*for **Startups.***
*for **Biotech.***

CASE STUDY:

# MINICIRCLE

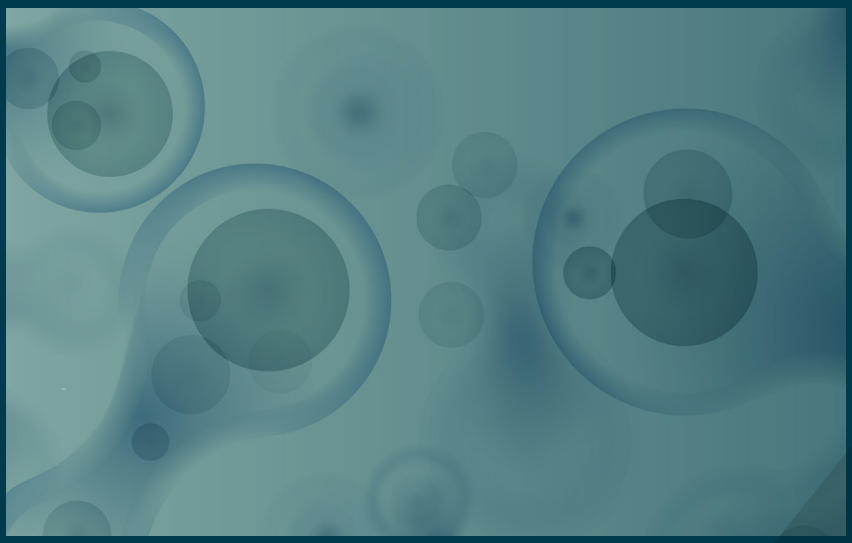
> *This just makes sense. This is the logical way things are supposed to work.*
>
> **Mac Davis | Founder & CEO of Minicircle**

# EXECUTIVE SUMMARY

Minicircle is a biotechnology company that is currently running Phase I clinical trials for gene therapies in Próspera. The company offers therapeutics aimed at life extension, especially for patients suffering from chronic debilitating diseases. After searching the world for a jurisdiction that would enable them to launch clinical trials more quickly, Minicircle selected Próspera. Próspera enabled Minicircle to launch a trial less than eight months after creating their legal entity, for 1/1,000th the cost of a trial in the United States. These efficiencies gave the startup an accelerated path to market, with massive positive impacts on their clinical results. The company is currently running multiple clinical trials, with plans to grow their offerings within Próspera.

**<8 months**
clinical trail launch after founding

**1/1000th**
the cost of a trial in the United States



*The quoted data and opinions expressed in this case study were provided by the subject, in interviews conducted by Erdös Associates, an independent third-party firm. Unless otherwise indicated, all direct quotes are attributable to Minicircle Founder Mac Davis. The study was funded and published by Honduras Próspera, Inc.*

# MINICIRCLE

In 2020, Minicircle was founded in the United States by Mac Davis. The startup was the culmination of years spent researching and pursuing novel delivery mechanisms for gene therapies. With a background in chemistry and physics, Davis partnered with experienced physicians and researchers to found Minicircle. Through early research and development efforts, the company created a number of gene therapy treatments aimed at life extension, especially for patients suffering from chronic conditions like HIV, ALS, muscular dystrophy, and Crohn's disease.

Minicircle's therapies involve the use of plasmids, a safe and effective way to treat debilitating diseases and improve a range of biomarkers. The company's plasmid therapy can be tailored to address multiple conditions, including to produce antibodies that address diseases like HIV. One broadly applicable therapy produces follistatin, a protein associated with a number of positive biomarkers. Research demonstrates that follistatin gene therapy can improve muscle size, endurance, and power, while reducing chronic inflammation.

Their process has demonstrated great promise from the outset. While U.S. regulations prevented them from marketing the therapy, the rules did allow for self-administration. The founders were so confident in the safety and efficacy of their treatments, they administered the follistatin to themselves, and the results were very positive. The market for effective therapeutics is huge, and Minicircle's therapies offer an accessible way to treat these chronic conditions using gene therapy. The company's vision and early success enabled them to raise seed capital from leaders in the longevity space and some of Silicon Valley's biggest private investors.

> Minicircle's bioscientists have one of the most enlightened risk-taking calculi I have observed anywhere. In an environment where extreme hesitance to take any risk holds back scientific progress, they have the openness to imagine, try, and measure just about any legal intervention, putting them in a very strong position to both produce a significant measurable decrease in the human rate of aging, and to inspire more people to do what they never thought was possible."
>
> **Alex K. Chen | Venture Fellow at Healthspan Capital**

# AN AFFORDABLE, ACCELERATED PATHWAY FOR CLINICAL TRIALS

According to Davis, the regulatory environment in the United States created an arduous and costly process for developing and commercializing new biotech products. While the merits of this process are actively debated, the reality is that the time and cost associated with permitting and approval for new therapies impose high hurdles for startups in this industry. While new potential therapeutics are routinely discovered, the pathway to commercialization requires a clinical trial. The time and cost associated with trials makes it extremely difficult for researchers like Davis to test their treatments in a clinical trial setting.

The timeline to begin a clinical trial in the United States involves filing an Investigational New Drug ("IND") application with the Food and Drug Administration. Minicircle estimates that their cost to file such applications would be upwards of $300,000, and approval would take up to three years. This application is merely the first step towards beginning a clinical trial in the United States. In addition to the significant opportunity costs associated with a three-year waiting period, the company would need to expend $70,000 - $100,000 per month to continue its development efforts.

> The value of a post-clinical company is exponentially higher than pre-clinical.
>
> **– Mac Davis**

In the biotechnology industry, there is a steep difference between the value of pre- and post-clinical companies. "The value of a post-clinical company is exponentially higher than pre-clinical," according to Davis. Due to the extensive timelines and costs associated with pursuing a clinical trial, few biotech companies make it past the pre-clinical phase. Finding a way to safely and ethically reduce these timelines would dramatically increase Minicircle's odds of success, allowing them to deliver their products to the market much more quickly. It would also positively impact the company's valuation, giving the company's founders more flexibility when they decide to raise capital or go public in the future.

For Minicircle, the tangible costs associated with awaiting IND approval in the United States were **upwards of $2.5 million or more**.

# HUNTING FOR THE PERFECT JURISDICTION

Founder Mac Davis is well-traveled, and he spent a great deal of time researching jurisdictions for Minicircle. He searched the entire world to find the location that would best enable his company to succeed and begin delivering their life-changing therapies to patients at the soonest opportunity. Although most of his team was based in the United States, Davis knew the arduous regulatory process there was not favorable for startups like Minicircle. Mexico was also discarded as an option early-on, due to burdensome requirements there.

After much research examining special jurisdictions and economic zones around the globe, Davis narrowed his options to three top contenders: Ukraine, New Zealand, and Costa Rica. These countries would enable Minicircle to pursue a clinical trial much more quickly than in the United States, but each had their downsides as well. Regulatory guidelines were streamlined to some degree in each country, but still highly prescriptive. Political instability was a concern in Ukraine, and concentrated regulatory risks made it difficult to invest in others.

A more promising option emerged in a conversation with one of Davis' trusted advisors, a high-profile Silicon Valley investor with a dedicated interest in biotech. That advisor suggested that Davis consider Próspera, where the flexible regulatory code would enable Minicircle to rapidly proceed with clinical trials, while crafting a custom regulatory solution that perfectly addressed the company's needs. After examining the legal framework, Davis was impressed, and immediately booked a flight to Roatán to visit. His visit confirmed that Próspera was the perfect place for Minicircle. The regulatory environment would enable the company to run a clinical trial quickly, safely, and affordably. The location in Roatán made it easily accessible for patients traveling from the United States. After visiting, Davis made the decision to create a legal entity in Próspera and begin the process of pursuing clinical trials there.

# A REGULATORY FRAMEWORK THAT SAFELY FOSTERS INNOVATION

For Minicircle, the regulatory framework is one of the primary benefits of operating in Próspera. While most jurisdictions require companies operating in a specific industry to follow one specific set of rules, Próspera takes a different approach. Companies like Minicircle that operate in regulated industries like healthcare can choose among three options for regulatory compliance in Próspera.

## REGULATED INDUSTRIES CAN CHOOSE AMONG 3 OPTIONS:

**Regulatory Reciprocity:** Companies can choose to operate under the existing regulatory framework for the business in Honduras, the United States, or 19 other top OECD countries. This option can be useful for companies that are already accustomed to specific rules, allowing them to operate in Próspera using the same guidelines as they exist in Honduras, the United States, or other countries.

**Default Regulatory Framework:** (Common Law) Instead of choosing a specific regulatory framework, companies in regulated industries can choose to operate under Próspera's common law legal code, subject to prohibitory and mandatory injunctive relief for any violations.

**Custom Regulatory Option:** Companies have the option of proposing a unique regulatory framework to Próspera's governing council, which will then consider the proposed regulatory environment for adoption. If adopted by the council, this new regulatory framework will be among the menu of regulatory options for any other firms operating within the same industry as well.

These regulatory options afforded Minicircle a level of flexibility that was not available to them anywhere else in the world. Minicircle chose to move forward with the Default Regulatory Framework, allowing them to save millions of dollars in initial development costs that would have otherwise been required in other jurisdictions. This flexibility is coupled with accountability and guardrails that protect against fraud and dangerous activities.

In the United States, once a subject is in a clinical trial, companies conducting the trials are shielded from all liability. Before the company receives IND approval, there is unlimited risk. In Próspera, Minicircle can operate with appropriate liability, where they are held responsible for potential issues caused by their therapies. Davis believes this is the proper way to pursue medical therapies – allowing companies to innovate while still holding them responsible for potential harms caused. While most regulatory systems are based on extreme risk mitigation, Davis describes Próspera's approach as one that prioritizes functional safety. Waiting years or paying huge legal fees can serve as a useful tool to discourage people "selling snake oil," but it also creates massive barriers to entry for new companies that have real, tangible products.

> Próspera's balanced approach allowed Minicircle to begin their clinical trials less than eight months after creating their legal entity, while meeting or exceeding all FDA and international standards for quality and safety.

Minicircle is currently exploring the proposal of a custom regulatory option for future use that will enable their company, and others in the biotech space, to operate under an even-more-optimized framework for gene therapeutics. This potential for improved regulations is groundbreaking. Similar changes in the United States can require resource-intensive lobbying, the buy-in of large industry players, and a literal Act of Congress. In Próspera, startups like Minicircle have the ability to craft improved regulatory options in partnership with the jurisdiction. Davis highlights the benefits of helping shape the maturing regulatory environment in Próspera, which will allow Minicircle to stay at the forefront of industry innovations for years to come. FDA regulations adopted in 2022 place more restrictions on how companies can use human tissue in treatments, and will likely lead to even more companies like Minicircle seeking favorable jurisdictions to develop innovative treatments.

# DRAMATIC ACCELERATION AND SAVINGS

Time is a common destroyer of startups. Time is expensive, and investors can grow weary of waiting for results. Próspera enabled Minicircle to dramatically shorten their timeline for product development and deployment, creating an efficient way for the company to safely bring their groundbreaking therapies to market. The time and cost savings attributable to Próspera's regulatory environment are immense.

For the same amount of capital that Minicircle would dedicate to pursuing one (1) Phase 1 clinical trial in the United States, the company can pursue six (6) Phase I trials in Próspera. Further, there are no changes to the marginal cost of each successive trial in the US. **This means that for one (1) trial equivalent in the US, there are six (6) potential high-impact, life-enhancing gene therapies in Próspera that will get a chance to begin transforming lives. By allowing for rapid acceleration in product development, while still maintaining the highest safety standards, Próspera's regulatory environment is a game changer for biotech.**

*For the same cost of running one Phase I clinical trial in the U.S., Minicircle can run six Phase I trials in Próspera.*

# A GROWING ECOSYSTEM FOR MEDICAL INNOVATION

Minicircle's experience operating their business in Próspera has been overwhelmingly positive. As an early business in the jurisdiction, Davis expected that it would take some time for physical infrastructure and the community to develop. However, he has been surprised at the pace at which Próspera is growing. When asked to describe his experience doing business in Próspera, Davis said, "every expectation I had has been met or greatly exceeded."

The company is currently offering access to its clinical trial for follistatin therapy. They have hosted and received participants from around the globe, who each traveled to Roatán to receive the therapy from Minicircle. The company intends to grow its therapies and offerings in Próspera, with no immediate plans of offering the therapies in other locations. The Caribbean destination serves as an attractive destination for his customers. Visitors can stay at the Pristine Bay Resort, allowing them to fully experience Próspera while on the island. In Davis' opinion, the only identifiable downside of Próspera is that living on the island is more expensive than living in mainland Honduras and some other international locations. As Próspera grows, Davis anticipates the cost of living on the island will likely decrease.

Davis also finds value in the community of people living and working in Próspera. "There is a growing collection of moral, focused, and driven people, all located together with intentions of both being successful and supporting the local economy," he said. From his first visit until now, Davis has been consistently impressed with the caliber of people living and working in Próspera. Community impact is important to the company as well. As Minicircle grows, they plan to add Honduran staff and expand local access to therapeutics.

> "I am amazed at the speed they are moving.
> **– Mac Davis, on the growth of physical infrastructure in Próspera**

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