# A Cure is in the Works



HeartWorks

# The world's most common birth defect still has no cure.

Every 15 minutes, a baby is born with a congenital heart defect (CHD) - a structural problem in the heart that begins before birth.

For many of these children, early surgery keeps them alive, but not cured. Even the most advanced treatment options fail to provide long-term solutions. Families live in a cycle of invasive procedures, uncertainty and mounting medical costs.

*Watch for a snapshot of life with CHD*



## The Facts

**1 in 100** are born with a congenital heart defect

**40,000** CHD babies are born in the United States each year

Many face **multiple** open-heart surgeries before their fifth birthday

**<40%** of children with critical CHD live beyond 5 years

CHD is **4X** times more prevalent than childhood cancer

**<0.5%** of NIH and **<5%** of AHA funding is directed toward CHD

WE REFUSE TO WAIT FOR BETTER OUTCOMES >>>



# Building HeartWorks

In 2010, Todd Wanek, CEO of Ashley Furniture, and his wife, Karen Wanek, pioneered a platform for curing congenital heart disease. Motivated by their daughter Gabrielle's journey, they launched the Todd and Karen Wanek Family Program for Hypoplastic Left Heart Syndrome (HLHS) at Mayo Clinic, a groundbreaking initiative to advance stem cell research for individuals born with CHD.

Thanks to the program's remarkable work and the Wanek family's continued support, HeartWorks was created in 2020 to bring that research out of the lab and develop treatments and products for today's generation.



**Tim Nelson**
CEO and Co-Founder



**Matt Nelson**
COO and Co-Founder



**Jarett Anderson**
Chief Regulatory Officer



**Tim Klossner**
Director of Manufacturing



**Adam Armstrong**
Director of Clinical Operations



**Bin Zhang**
Director of Pre-Clinical



**Calla Huxtable**
Director of Marketing



**Kimera Way**
Director of Development



**5,400+**
Consecutive days spent maintaining our stem cell products

**5 & 3**
FDA-regulated clinical trials completed & 3 are currently open for enrollment

**519**
Pioneering families who have participated in our clinical trials

**10X**
Increase in manufacturing capabilities with 2026 Eau Claire, WI facility expansion

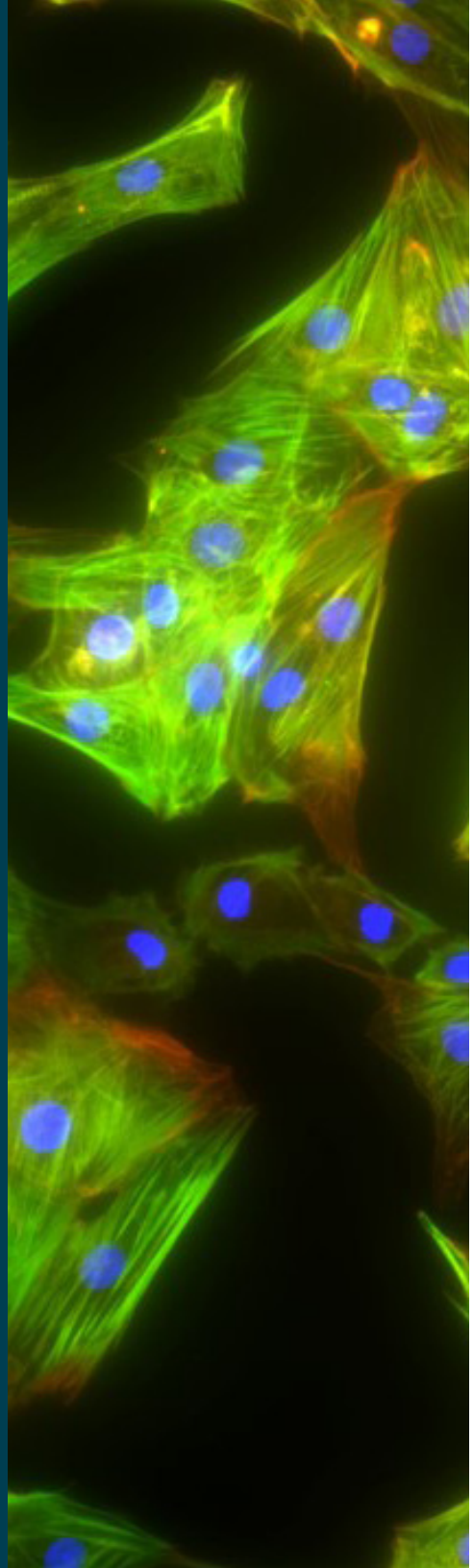
LET'S BUILD HEARTS >>>

# The HeartWorks Solution

HeartWorks is a pioneering team of clinicians, scientists, and families rewriting the future of CHD through regenerative medicine.

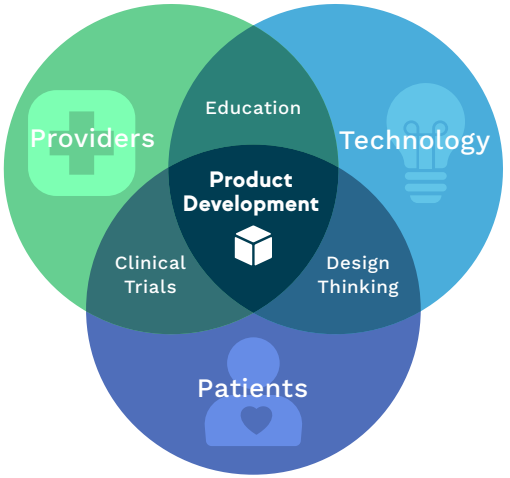
From skin cells to beating heart cells, we're creating living therapies to repair and rebuild hearts. We are redefining what is possible and bringing hope to one of the most underserved patient populations in cardiovascular medicine.

By focusing first on the urgency of CHD, we enable ourselves to transform product development for **everyone affected by heart failure.**



## Product Development Ecosystem

HeartWorks takes advantage of every piece of the puzzle to maximize product development. Our innovation is informed by CHD patients, accelerated by technology partners, and distributed by healthcare providers. These three groups are instrumental in creating tailored and accessible products efficently.




## Transformative Product Outcomes

Each HeartWorks innovation is designed to address the urgent needs of CHD and deliver one of three life-changing results.



### IMPROVING BLOOD FLOW

**Problem:** People with CHD often face poor circulation that limits energy, growth, and quality of life.

**Discovery:** HeartWorks has developed new ways to restore healthy blood flow improving strength, stamina, and everyday living.



### REBUILDING MUSCLE

**Problem:** Current CHD surgeries offer short-term fixes. Hearts stay weak, and many patients face the possibility of transplant.

**Discovery:** HeartWorks is the first in the world to earn FDA approval to test a therapy that grows new heart muscle - from the patient, for the patient.



### REFURBISHING HEARTS

**Problem:** Thousands wait for heart transplants each year, but many donated hearts never qualify for use.

**Discovery:** HeartWorks is developing technology to revive and restore donor hearts, turning once-discarded organs into lifesaving options.

*Clinical Trial Information:*
*heartworksinc.org/clinical-trials*

# Products



## YourHeart

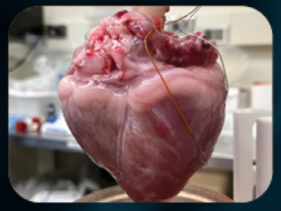
Revolutionary reprogramming of skin cells into beating heart cells to restore lost muscle and function

**actively enrolling 18+ CHD patients*



## Parallel Heart

Biological conduit designed to contract alongside the heart, improving blood flow to the lungs



## 2nd Heart

Restoring cardiac function for autologous re-transplantation & eliminating the need for immunosuppression in children



## TruFlow

Mechanical pump that improves blood flow to the lungs in single ventrical patients



## The Co-op

Centralized CHD database designed to bridge the gap between patients and clinical researchers

**actively enrolling all CHD patients/caregivers*




# Progress

As 2025 comes to a close, we're reflecting on an extraordinary year - one shaped by generosity, belief in possibility, and commitment to every child born with congenital heart disease. Because of supporters like you, our incredible team and the trust of heart families, HeartWorks has accelerated lifesaving innovation and delivered hope to families who need it most.

KEY ACCOMPLISHMENTS >>>

**Reached Clinical Readiness:** Implemented the YourHeart skin biopsy protocol and consented the first 100 patients - within its first year.

**Opened the HeartWorks Headquarters:** Our new research and manufacturing facility in Eau Claire, WI expands our capacity from 12 to 100 stem cell lines annually, fast-tracking personalized therapies and clinical progress.

**Advanced The Co-op @ HeartWorks**: A first-of-its-kind platform capturing the lived medical journey of CHD families, ensuring future clinical breakthroughs are driven by real experiences and real needs.

**Achieved the Wanek Circulation Breakthrough:** After 30 years without new solutions, we demonstrated that a precisely placed mechanical pump can significantly improve circulation in complex CHD - reshaping the future for countless children.

Dreaming Big With Half A Heart:
*Watch Frankie's Journey Filled With Bravery & Love*




# Our Why

Every story we tell, every therapy we create, and every milestone we reach begins with our Heart Families. These parents, children, and loved ones are not just supporters--they are partners in discovery, hope, and progress.

From coast to coast, families raise awareness, fund research, and open their homes, hospitals, and hearts to the mission of curing congenital heart disease. Their voices shape our direction, their courage fuels our science, and their stories remind us why **our work can't wait.**

# Your Impact

We have never met someone who cannot help build hearts. Your voice, your curiosity, and your compassion can change the future of congenital heart disease. Here are some important ways you can join us:

### SPREAD THE WORD

1 in 100 are born with a heart defect. Even if you don't have a direct connection, someone in your circle likely does. Sharing HeartWorks and The Co-op helps us reach more families, support more patients, and drive the research that changes lives.

### GIVE FROM THE HEART

Everything we do is for CHD families. Your support this year helped us grow, innovate, and bring new hope into the world. As 2025 ends, we hope you'll help us keep this momentum going with a year-end gift. Visit www.heartworksinc.org/donate to give today!

### CELEBRATE WITH US

Join us on February 19, 2025, for the 5th Annual HeartWorks Virtual Dinner! We'll ship a curated mealkit and bottle of wine to your home so you can cook live with Chef John and help raise critical awareness and support for CHD research.

Scan the QR Code to register for the Virtual Dinner + make a donation!

**Thank you!**