Breakthrough T1D®
Formerly JDRF

SEE T1D

Driving Global Innovation

Fiscal Year 2025 Annual Report
July 1, 2024 through June 30, 2025

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Platinum Transparency 2026 Candid.

BBB ACCREDITED CHARITY

Breakthrough T1D is a Charity Navigator four-star charity, Platinum Level Guide Star participant, and a Better Business Bureau (BBB) Accredited Charity.

SEE T1D

Driving Global Innovation

You've seen it on social media and in headlines: several people with type 1 diabetes (T1D) receiving islet cell replacement therapies in clinical trials are coming off insulin.

The research is mostly in early phases, and for safety reasons, it's limited to a specific subset of the adult T1D population. This includes trials of therapies from Eledon and Vertex Pharmaceuticals, both of which are advancing work we have long supported for safe, scalable cures for everyone with T1D through research grants and T1D Fund support.

The excitement is real: we are closing in on cures.

It's a moment Breakthrough T1D has been working toward for more than 50 years, one I've been working toward my entire career, and one I've wanted to reach since my younger brother and I were diagnosed with T1D as kids.

We are far from done.

Our ultimate goal is safe, scalable cures for adults, teens, and children living with T1D. At the same time, we have to ensure that everyone with T1D has what they need to live full, healthy lives: access to more affordable insulin; other drugs to better manage T1D and prevent or treat complications; and reliable, advanced devices that are as easy to use as they are accurate.

It's a "yes and" situation with no compromises. People with T1D deserve nothing less; Breakthrough T1D won't stop until we get there.

And to get there, we have to do more. We have to rally more people, expand our influence, and accelerate the most promising research and the best clinical care around the world. We must rally more people to See T1D and drive global innovation.

On the following pages, you'll learn about how we are doing just that, thanks to your support.

Warm regards,

Aaron J. Kowalski, Ph.D.
Chief Executive Officer,
Breakthrough T1D

SEE T1D

YOUR VOICES

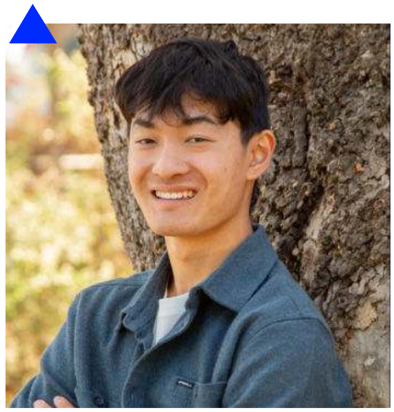
With your support, we are creating a movement to improve and change life with type 1 diabetes (T1D), advancing breakthroughs on the way to cure the condition. Your actions are changing lives in real time! Here, in your words, you share why you support Breakthrough T1D.

"Now we get to play with something that has T1D like us."

CAREMY, Children's Congress Pennsylvania Delegate in reaction to Barbie Doll with T1D.

"I've lived with T1D for 11 years now, and the improved access to technology in that time is, honestly, incredible."

EVAN OSHIMA, Breakthrough T1D advocate



"The future of type 1 diabetes is bright. We are on the cusp of living longer, experiencing fewer complications, and enjoying a life without limits."

KRIS LEEPER, Breakthrough T1D influencer partner

"We walk knowing that research funded by Breakthrough T1D will improve our son's way of life and take us a step closer to cures."

MATT CORSARO, T1D parent and Breakthrough T1D Walk participant

"The changes have been enormous since my daughters were diagnosed. T1D has become far more manageable—it allows them to think about everyday life instead of always thinking about their blood sugar."

PAT MCFEELEY, T1D parent, Breakthrough T1D Ride participant, and volunteer

WHAT A DOLL!
Barbie+Breakthrough T1D

In December 2023, renowned toy company Mattel approached Breakthrough T1D with an unprecedented partnership opportunity: to create the first Barbie® doll with type 1 diabetes! Less than two years later, in July 2025, Barbie with T1D was launched.

The collaboration reflects our commitment to ensuring that the millions of people living with T1D are seen, heard, and empowered. Barbie with T1D was thoughtfully created with input from Breakthrough T1D employees who live with T1D and members of our T1D community.

For the doll's launch, Barbie donated dolls to all 170 Breakthrough T1D 2025 Children's Congress delegates, who couldn't have been more thrilled. The youth delegates, ages 4 to 17, traveled to Washington, D.C., from all 50 states and from each of Breakthrough T1D's five international affiliates to advocate for our priorities.

As part of the launch, Barbie also honored two global role models and type 1 diabetes advocates—American Peloton Instructor Robin Arzón and English model Lila Moss with their own one-of-a-kind Barbie dolls. Arzón unveiled the new Barbie doll with type 1 diabetes and her one-of-a-kind Barbie doll at Peloton Studios in New York on July 8, 2025. Attendees and members of the type 1 diabetes community were tickled pink—Barbie Pink, of course—to experience this first-of-its-kind unveiling moment.

The doll sold out in record time and has been going strong ever since!

PROJECT ACT ACCELERATE CELL THERAPIES

One Year in Review

Project ACT, Breakthrough T1D's initiative to dramatically speed cell therapy products as T1D cures, launched in November 2024. Since then, we've seen great progress via the constant, coordinated efforts by Breakthrough T1D's Research, Advocacy, and Medical Affairs teams.

NOVEMBER 2024
Breakthrough T1D launches Project ACT to accelerate the development of curative therapies through the research and development pipeline.

DECEMBER 2024
Breakthrough T1D introduces accredited, on-demand educational offerings to inform healthcare professionals about T1D—including cell therapies and clinical trial recruitment.

APRIL 2025
Breakthrough T1D advocates for the acceleration of T1D cell therapies and real-world steps to make them happen in landmark publication published in *Diabetes Therapy.*

MAY 2025
Breakthrough T1D workshop convenes world leaders in cell therapies to develop clinical implementation guidelines to ensure that the medical community can deliver cell therapies once they are widely available.

JULY 2025
Breakthrough T1D publishes a roadmap to further speed cell therapies for T1D in the medical journal *Diabetes*.

OCTOBER 2025
Breakthrough T1D launches a new funding opportunity for projects that aim to develop biomaterials and technologies to advance encapsulated cell therapies.

CURES: NOW

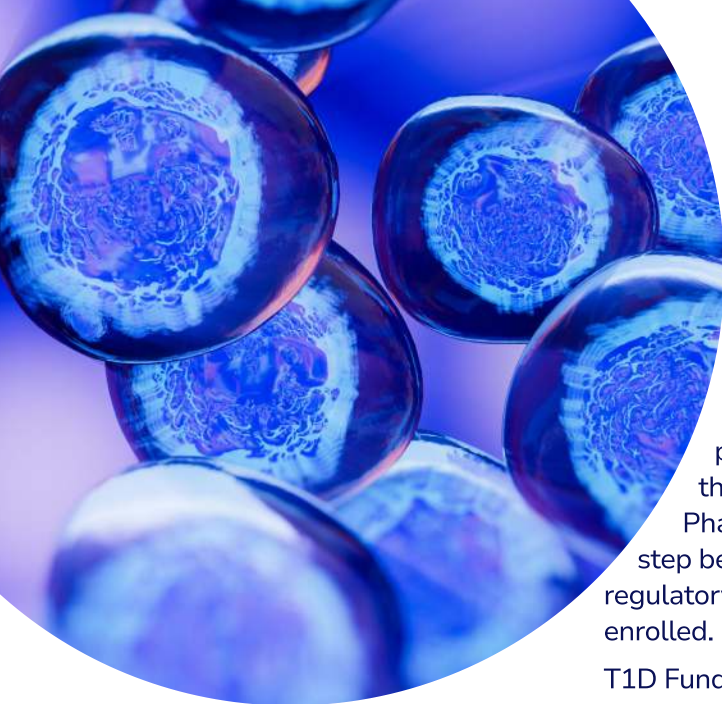
Breakthrough T1D has been funding research into cures for over 40 years.

Our support grew to include efforts that led to zimislecel, the first manufactured islet cell therapy for T1D in late-phase clinical testing. This was made possible through critical T1D Fund investments into Semma Therapeutics and ViaCyte, which were later acquired by Vertex to accelerate this therapy.

Now, in conjunction with continued investments from the T1D Fund into companies like Orizuru Therapeutics, GentiBio, COUR Pharmaceuticals, SAB Bio, and more, Breakthrough T1D has laid the groundwork for next-generation cell therapies and disease-modifying therapies in the pipeline today—bringing us closer than ever to cures.

CELL THERAPY MILESTONES

Through grants, we are supporting cell therapies research in 54 preclinical projects. A dozen cell therapies as functional cures are in human clinical trials right now, including five that we support. *Most recipients are making insulin again, and many have been able to stop taking insulin therapy.*



Exciting Progress in Cell Therapies

Vertex Pharmaceuticals continues to hit milestones with zimislecel, a manufactured islet cell therapy that Breakthrough T1D has had a hand in for decades. Promising results from phases I/II of the clinical trial were published in *The New England Journal of Medicine*, showing that 10 out of 12 participants are insulin therapy independent. Phase III—the final step before submission for regulatory approval—is fully enrolled.

T1D Fund portfolio company Sana Biotechnology engineered donor islets (UP421) to be invisible to the immune system. Incredibly, the islets are still making insulin for more than a year after the first person was treated—without immunosuppression. The results were published in *The New England Journal of Medicine*.

An ongoing phase I/II clinical trial for Cell Pouch, an implantable device developed by Sernova to help islets survive, is on track to meet safety and tolerability endpoints, and people are achieving insulin therapy independence. The final cohort of this trial will receive Cell Pouch with Eledon's tegoprubart as an alternative to standard immunosuppressants, and future trials will use Evotec's manufactured islets—accelerating progress on two fronts at once.

The first person to receive Lantidra, the first deceased donor islet cell therapy for T1D approved by the FDA, no longer needs insulin therapy.

Protecting Islets from the Immune System

Tegoprubart, an immunomodulatory drug made by the T1D Fund portfolio company Eledon Pharmaceuticals, has shown promise as an alternative to standard anti-rejection immunosuppressants with fewer side effects. In a Breakthrough T1D-funded phase I/II trial, so far 10 out of 12 people who received deceased donor islets and tegoprubart are insulin therapy independent, and the study is ongoing. These results helped initiate another Breakthrough T1D-funded study that will include people with T1D and chronic kidney disease (CKD), who have previously been excluded from islet transplants due to side effects from standard immunosuppressants.

Beta Cell Factories

Manufacturing islets at large scale—so there is an unlimited supply for everyone with T1D who wants them once they become available—is a Breakthrough T1D priority. We continue to partner with ARMI (Advanced Regenerative Manufacturing Institute) and the Cedars-Sinai Biomanufacturing Center to optimize manufacturing protocols for islets. We are also funding research projects to develop technologies to support manufacturing processes and publishing a manufacturing regulatory roadmap to assist companies. Importantly, Vertex has forged collaborations with Lonza and TreeFrog to build an advanced, large-scale manufacturing facility to eventually produce zimislecel in large quantities.

Cures on a Global Scale

Breakthrough T1D is an international organization driving toward cures on a global scale. In 2025 and 2026, we hosted meetings with the European Parliament to bring the unmet needs of the T1D community to the forefront and discuss with EU policymakers how we can collectively accelerate cures—especially cell therapies. By engaging in dialogue about living with T1D with key decision-makers, we are driving conversations about what the future of cures can look like in the EU and beyond.

DISEASE-MODIFYING THERAPIES ADVANCES

Through grants, we are supporting disease-modifying therapies research in 140 preclinical projects. At least 20 DMTs are in human clinical trials right now, including 18 that we are supporting.

Tzield (teplizumab): The First Approved DMT for T1D

At publication, Tzield was approved in the United States for ages 1 and older with stage 2 T1D to delay the onset of stage 3 T1D, when insulin therapy is required. It is now also approved in numerous geographies for ages 8 and older in stage 2, including nations in North America, Europe, Asia, and the Middle East. This means that more people than ever in early-stage T1D have the chance to delay disease progression—and the mental, physical, and financial burdens of living with T1D—by an average of 2 years.

Breakthrough T1D has supported the development of Tzield for decades, and we are encouraged by the progress we have seen with it and other disease-modifying therapies. We anticipate this progress will give more people with early-stage T1D the opportunity to benefit from these advanced therapies.

A Personal Tzield Story

Chris Dunn is a parent of four children, two of whom live with T1D. Knowing that immediate family connections are a risk factor for developing T1D, Chris and her children without T1D participated in screening. Much to her surprise, Chris learned that she was in Stage 2. Chris knew that Tzield could potentially delay her need for insulin therapy, so she made the informed decision to undergo treatment.

“I am so grateful to the people who trusted Breakthrough T1D to bring these types of therapies to life,” she said.

“I’ve had a front row seat to this disease for nearly 20 years. Any day that you can save yourself from having to be on insulin therapy and all of the risks that come with that is worth it to me.”

Phase III Trials Launched by Eli Lilly

Building on results from a promising study funded by Breakthrough T1D, Eli Lilly launched two new phase III clinical trials for baricitinib, a drug already approved for other autoimmune diseases. The trials will test whether this medication—taken as a once-daily oral pill—can delay the progression of stage 2 to stage 3 T1D (BARICADE-DELAY) or preserve beta cells in newly diagnosed stage 3 T1D (BARICADE-PRESERVE). Industry investment in late-phase trials for this DMT is an indicator of its potential to impact the T1D community.

ATG: An Early-Phase Therapy on the Horizon

Another DMT making steady progress through the pipeline is ATG (anti-thymocyte globulin, an immunosuppressant). Following prior studies, the phase II MELD-ATG clinical trial found that low-dose ATG has the potential to preserve insulin-producing beta cells in children and young adults, and it was generally well-tolerated. In line with ATG’s potential, SAB Biotherapeutics—a T1D Fund company—is developing a next-generation ATG therapy.

Advocating for C-peptide as a Clinical Trial Endpoint

Breakthrough T1D’s Advocacy team has been engaging with regulators at the FDA to advocate for acceptance of C-peptide as a validated clinical endpoint for DMT trials. Through our advocacy work, Congress appropriated $2.5 million in funding to the FDA to advance new endpoints for DMT clinical trials, focusing on C-peptide. If approved, DMT clinical trials could move more quickly, and people with T1D could access therapies sooner.

What is C-peptide and Why Should It Be a Clinical Endpoint?

C-peptide is a marker of how much insulin the body’s beta cells are making. Current clinical trial endpoints, such as HbA1c levels or hypoglycemia, are not the most effective way to gauge the clinical benefits of DMTs. On the other hand, C-peptide can measure beta cell preservation—the primary goal of many DMT clinical trials.

EARLY DETECTION AND SCREENING PROGRESS

Early detection has been a cornerstone of Breakthrough T1D's cures strategy since the 1980s, when a scientist we funded discovered that T1D is an autoimmune disease. Now, through grants, we are supporting 26 early detection clinical trials and 56 preclinical research projects.

Building Evidence to Support General Population Screening Breakthrough T1D is pushing for general population screening for T1D. The ELSA (EarLy Surveillance for Autoimmune diabetes) study, which is funded by Breakthrough T1D and Diabetes UK, is successfully screening thousands of children and adolescents in the UK between ages 2 to 17 years old, while at the same time acquiring data on the best methods to approach screening and help families manage the results. Similar efforts in part supported by Breakthrough T1D or our affiliates are underway in Europe (the EDENT1FI study), Australia, Canada, and Israel—in conjunction with our affiliates—to help identify T1D as early as possible in as many people as possible.

Increasing Our Understanding of Adult T1D Onset T1D in adults is often misclassified as type 2 diabetes (T2D). Breakthrough T1D is funding research to understand adult T1D onset and prevent misclassification. Our partnership with IQVIA is refining an artificial intelligence-based method to correct T1D misclassifications, with the goal of eventually integrating this technology into clinics to ensure diabetes diagnoses are as accurate as possible. We also recently funded new research projects to further address this challenge and better understand the factors that contribute to adult onset of T1D to identify people who may be at risk and diagnose them appropriately.

Clinical Studies Aimed at Early-Stage T1D An advantage of detecting T1D early is that people may have the opportunity to intervene with Tzield, or experimental therapies that could delay T1D progression or onset. Clinical trials that stem from Breakthrough T1D-funded research are assessing new treatments for people with Stage 2 T1D, including baricitinib, and efforts underway to expand the population that is eligible for Tzield.

Identifying T1D Risk Factors Several ongoing Breakthrough T1D-funded studies seek to identify measurable factors that may predict onset or progression of T1D. These research projects include screening of newborns to uncover their risk of developing T1D, understanding how people may transition from having one autoantibody to multiple and why this matters, and genetic characteristics that can identify people at high-risk for developing T1D or progress from early-stage disease to symptomatic, clinical T1D. We are also supporting research to identify new biomarkers and better understand how monitoring blood sugars, ketones, and beta cell function (through C-peptide) can predict T1D onset in individuals at risk.

Advocacy and Medical Affairs Efforts to Expand T1D Early Detection

Breakthrough T1D's Advocacy team submitted an application to the U.S. Preventative Services Task Force (USPSTF) to secure a positive recommendation for T1D screening, which has been shown to increase utilization. Our Medical Affairs team is developing early detection pilot clinics across the country to support the clinical implementation of T1D screening in the general population. Education and resources available to HCPs and the T1D community are providing critical information about how to screen and why it's important. Both teams worked collaboratively to establish a unique ICD-10 code for early-stage T1D, which can now be used by HCPs to document the electronic health record with accurate staging information so individuals in early-stage T1D receive appropriate care and can realize the benefits of early detection. These efforts demonstrate the important crosstalk between Research, Advocacy, and Medical Affairs in accelerating breakthroughs in early detection and beyond.

CURES: FUTURE

Driving Toward a World without T1D

Scalable Cell Therapies Approved Breakthrough T1D envisions a future in which scalable cell replacement therapies are approved, opening the doors to large-scale production of insulin-producing cells. Next-generation, immune-protected cell therapies will continue to make their way down the pipeline, clearing the path for even more people with T1D to have the chance to benefit. Project ACT will accelerate this process and lead the way to a reality where curative cell therapies are available to anyone with T1D who wants them.

Accelerating DMT Development and Access Tzield is a tremendous breakthrough, and Breakthrough T1D will continue to work hard until as many people as possible can experience its benefits and delay disease progression. It doesn't stop there—the goal is to prevent or reverse T1D entirely, and disease-modifying therapies in the pipeline with unique approaches have the potential to do just that. In a future where C-peptide is an accepted clinical endpoint for DMT clinical trials, the development of these transformative DMTs will accelerate faster than ever.

General Population Screening for T1D We are driving toward a future where as many people as possible may screen for T1D. Expanded screening access means more chances to intervene early, prevent diabetic ketoacidosis (DKA), and prepare for the onset of symptoms and the need for insulin therapy. We predict that widespread screening of the general population will help catch T1D early in people without a family history of the condition. Continued refinement of methods to detect T1D through blood tests will make this process as accurate as possible, and HCP education will ensure that clinicians can provide the best care possible to those who are screening or have confirmed early-stage T1D.

A BREAKTHROUGH T1D VENTURE

The T1D Fund: A Breakthrough T1D Venture is an independently operated subsidiary of Breakthrough T1D. Its mission is to accelerate the development of treatments, preventions, and cures for T1D by catalyzing investment in T1D-focused companies. Portfolio companies benefit from the Fund's broad network of scientific, clinical, and industry experts who help guide programs from early translational research through clinical development.

The T1D Fund supports companies that are advancing therapies for all stages of T1D, across multiple treatment modalities, including disease-modifying approaches such as cell therapy, beta cell replacement, beta cell health, beta cell regeneration and metabolic control solutions. Comprehensive support and expertise provided by the T1D Fund, Breakthrough T1D, and the Leona M. and Harry B. Helmsley Charitable Trust drive innovation and advancements in the most promising companies that are working toward our shared mission.

Since its launch in 2016, the T1D Fund has invested $175M+, with approximately $250M in assets currently under management and about $100M returned and reinvested. The T1D Fund has invested in 45+ companies, with 25+ currently active and 8 successful exits. Through these efforts, T1D Fund portfolio companies have raised about $2.75B in total capital, including about $1.6B of alongside dollars dedicated to T1D, representing an outsized impact on the T1D space.

More than 2,000 people with T1D have enrolled in clinical trials as a direct impact of the T1D Fund's investments, which include funding that drove the start of 10 phase I clinical trials, 7 phase II clinical trials, and 3 phase III clinical trials. The T1D Fund's support of Provention Bio helped accelerate the development of Tzield, giving more people around the globe the opportunity to delay stage 3 T1D.

To further scale its impact, the T1D Fund recently launched a $150M+ fundraising campaign to increase available capital and enable larger investments. Initial contributions have been made by Breakthrough T1D ($25M), the Bukhman Foundation ($12M), and an anonymous donation ($20M). These funds will allow the T1D Fund to invest in a broader range of next-generation therapies that have the potential to change lives within the T1D community.

BREAKTHROUGH T1D'S CLINICAL AND RESEARCH CONGRESS

This inaugural meeting is being organized by our expert Scientific Advisory Board from Breakthrough T1D

Thomas Danne, M.D., Ph.D.,
Chief Medical Officer International

Sanjoy Dutta, Ph.D.,
Chief Scientific Officer

Anastasia Albanese-O'Neill, Ph.D., APRN, CDCES,
Vice President of Medical Affairs

For the first time in history, Breakthrough T1D will be hosting our very own Clinical and Research Congress (CRC) in October 2026.

This scientific meeting that offers accredited education for healthcare professionals is a groundbreaking event, uniting researchers, scientists, HCPs, industry leaders, and the T1D community. Attendees will have the chance to discuss cutting-edge advancements in T1D discovery science, immunotherapies, automated insulin delivery (AID) systems, cell replacement therapies, psychosocial care, real world translation of breakthroughs into clinical care, health equity, and more.

The CRC will further position Breakthrough T1D as the leading type 1 diabetes organization and establish a first-of-its-kind annual gathering focused exclusively on T1D. The event will become the go-to forum for translational updates, collaborative dialogue, and cross-sector collaboration. Our agenda will be shaped by the voices of the T1D community, ensuring that the lived experience of T1D is at the center of the ongoing work to improve the lives of people with T1D and drive toward cures.

Breakthrough T1D's CRC will be hosted in Philadelphia, where Breakthrough T1D was founded 50+ years ago. The City of Brotherly Love—home to Pennsylvania Hospital, America's first chartered hospital—is a hub of medical innovation and scientific advancements, rendering it an ideal location for worldwide experts to convene and share T1D research, clinical progress, and milestones.

This meeting of the minds is designed to foster collaboration and spark innovation, with opportunities for interactive learning, accredited education, plenary lectures, workshops, and networking events. Through idea sharing and meaningful conversations, we will collectively work toward our shared goal of a world without T1D.

IMPROVING LIVES: NOW

Thanks to years of Breakthrough T1D support, over the last few decades we've seen incredible advancements in technology, insulins and insulin affordability, therapies that can improve management of complications and metabolic health, and interventions for mental and emotional well-being. Through grants, we are supporting 42 preclinical projects and 76 human clinical trials to continue to improve the lives of the T1D community while cures are on the way.

GLUCOSE AND METABOLIC CONTROL

Advanced Insulins in the Works

Breakthrough T1D funds the development of new and improved liver-targeted, glucose-responsive (GRI), and ultra-rapid insulins (URI). In 2021, Eli Lilly acquired Promoter Technologies, a company with support from Breakthrough T1D and the T1D Fund, to further drive the development of their GRI. We helped drive participation in the INHALE-1 clinical trial, which showed that the ultra-rapid insulin Afrezza is safe and provides greater treatment satisfaction for youth with T1D. Breakthrough T1D also partnered with Invictus Therapeutics to support a first-in-human clinical trial of a next-generation ultra-rapid insulin analog engineered for AID systems.

More Affordable Insulin Is Here

Breakthrough T1D has long advocated for greater insulin affordability and has supported research into biosimilar and interchangeable insulins. Civica Rx's insulin glargine-yfgn (which is interchangeable with Sanofi's Lantus) became available on January 1, 2026, for no more than $55 for five pens. Anyone with a prescription—regardless of insurance status—can purchase it at a pharmacy.

Innovation Continues for Devices

Breakthrough T1D drove the development and coverage of the first-ever AID (automated Insulin delivery) systems—and they're getting better each year. The FDA approved the first AID system a decade ago; today, approximately 10 such systems are approved for use in the U.S. Through critical research funding and T1D Fund investments into promising companies like Bigfoot Biomedical (later acquired by Abbott), Capillary Biomedical (later acquired by Tandem Diabetes Care), and more, we are driving innovation in devices faster than ever before.

Newly available devices in the U.S. include Dexcom's G7 15-day sensor and Sequel Med Tech's twiist AID system, which is driven by Tidepool loop technology that Breakthrough T1D and the Helmsley Charitable Trust helped make possible. Soon, we'll see the launch of Tandem's SteadiSet 7-day infusion set, and Abbott's Freestyle Libre 3 Plus Sensor has integrated with twiist and T:slim X2 insulin pumps.

Continuous Ketone Monitoring (CKM) Consensus Statement

Continuous ketone monitoring (CKM) has substantial benefits for the T1D community, including preventing diabetic ketoacidosis. CKMs are coming—and to prepare, Breakthrough T1D's Medical Affairs leadership spearheaded an effort with expert collaborators to publish a consensus statement for use of CKM in T1D. This will help HCPs integrate CKM into clinics and establish best practices for their use in the T1D community.

How We Are Addressing Continuous Glucose Monitor (CGM) Challenges

T1D technologies, including CGMs, help millions of people with T1D manage their blood-sugar levels and achieve improved health outcomes. Still, technology isn't perfect, and issues can and do occur. We created a comprehensive online guide to help people with T1D manage sensor issues, such as using a glucometer as a back up measurement tool, and how to get sensor replacements as quickly as possible. We also sent a survey to 600,000 people impacted by T1D to capture their lived experiences with CGM challenges. We will use their feedback to determine what actions must be taken and will lead the charge to improve this critical T1D management technology.

GLP-1 Receptor Agonists for Blood-Sugar and Metabolic Management

Breakthrough T1D is driving research into non-insulin therapies, such as GLP-1 receptor agonists, so that people with T1D can optimize both their blood-sugar control and overall metabolic health. In the 1980s, Breakthrough T1D supported the researcher who first discovered GLP-1, opening the door to years of research that eventually led to a Breakthrough T1D-funded phase II trial showing that semaglutide (Ozempic) has the potential to help people with T1D manage both blood sugar and weight. Eli Lilly also recently launched two phase III studies testing whether tirzepatide (Zepbound/Mounjaro) can reduce blood-sugar levels in people with T1D living with obesity or who are overweight. Industry investment in this space is a key indicator of the potential of this class of drugs to have a significant impact on the quality of life of people living with T1D.

COMPLICATIONS

Breakthrough T1D has funded research to address complications since we were established, including long-term conditions such as heart, eye, and kidney disease. The T1D Fund is strategically investing in companies like vTv Therapeutics, Zucara, and Inversago Pharma (later acquired by Novo Nordisk) to help drive these efforts forward.

First Therapy in Decades Shows Promise for Kidney Disease in T1D

Breakthrough T1D was excited to see data from Bayer's phase III FINE-ONE clinical trial, which investigated finerenone (Kerendia)—a drug that is already approved for type 2 diabetes—for chronic kidney disease (CKD) associated with T1D. The results showed that finerenone significantly reduces a marker of kidney damage, marking the first treatment in nearly 30 years to achieve positive outcomes for CKD in people with T1D. This data will be submitted for regulatory review to expand finerenone's indication to include T1D. Breakthrough T1D was a strategic collaborator on this trial, and we are supporting even more clinical trials to help drive breakthroughs for people with kidney disease and T1D.

Ongoing Research to Drive Advancements in Cardiovascular Complications

Right now, there are only a few options available to lower cardiovascular disease (CVD) risk in people with T1D—and Breakthrough T1D is working hard to change that. We are supporting several clinical trials aimed at reducing and preventing CVD. The phase II SOPHIST trial is investigating the efficacy of the SGLT inhibitor sotagliflozin in improving the quality of life of people living with T1D and heart failure. Other projects we are actively supporting include identifying biomarkers to predict CVD risk and repurposing FDA-approved drugs successfully used in either type 2 diabetes or other autoimmune diseases to address CVD in people with T1D. To further drive breakthroughs in this area, we co-hosted an event with leading international diabetes organizations in Brussels, Belgium, to discuss how we can work together to drive innovation in CVD and T1D in Europe and beyond.

Eye Disease

Breakthrough T1D-funded research led the way to FDA approval of Lucentis, the first treatment for diabetic retinopathy (DR) and diabetic macular edema (DME), followed by a different drug called Vabysmo approved for DME. While these therapies represent major advancements, they require injections as frequent as every month. Building upon research we supported, the FDA most recently approved Susvimo, an alternative treatment for DME with fewer injections. Now, we are funding a clinical trial to assess whether a repurposed lipid-lowering medication, fenofibrate, can prevent worsening of DR, plus other studies around DR screening, and a trial for a repurposed drug called Xiflam that may provide benefits for people living with T1D and diabetic eye disease.

Psychosocial Health

To better understand the mental health needs of the T1D community, Breakthrough T1D and the Helmsley Charitable Trust co-hosted a Psychosocial Roundtable, convening mental and behavioral health experts across the T1D care spectrum. The discussion entailed challenges and gaps in psychosocial care for people with T1D and how we can work together to address them. To support these goals, we are funding studies to address diabetes distress in teens and young adults, eating disorder prevention, methods to improve sleep, and how to best address anxiety and depression following screening results and at later stages of the condition.

IMPROVING LIVES: FUTURE

Making Everyday Life Better on the Path to Cures

Fully Closed-Loop AID Systems on the Market Breakthrough T1D is dedicated to a future in which people with T1D will need little to no user input for their AID systems. Fully closed loop systems, which are under investigation right now, will require no meal announcements. Once approved, widely available, and covered by insurance, we believe these devices are the next step toward the best possible blood-sugar control for the T1D community, with the least amount of daily device management required.

Greater Choice and Affordability for Insulins Through our support of advanced next-generation insulins and continued efforts with Civica Rx, we are excited for a time when more insulins than ever will be available to people with T1D. The T1D community deserves to have as many choices as possible when it comes to insulin, and we will tirelessly advocate for as many affordable insulin options as possible to increase access in the U.S. and globally.

More Therapies Approved for Complications and Metabolic Control Through our diverse portfolio of preclinical and clinical research projects aimed at addressing blood-sugar management, weight control, and reduced complications, we are driving toward a future in which people with T1D will one day have numerous options for optimizing their overall health. We are encouraged by industry investment in clinical trials for these therapies and look forward to seeing the readouts from late-phase testing. We will continue to support promising therapies as they move through the clinical pipeline and closer to people with T1D.

Interventions to Improve Psychosocial Health Integrated into Clinics Interventions that have proven to be successful in improving the mental and emotional well-being of people with T1D will be integrated into clinics. With the help of our newly established Medical Affairs unit, we can make this possible through increasing the number of psychosocial professionals trained in T1D issues, increasing the number of available psychosocial interventions, and supporting their integration into clinics around the globe. Breakthrough T1D's vision for the future includes psychosocial care combined with routine T1D clinical visits to ensure that the T1D community has access to the help they need at their fingertips.

MEDICAL AFFAIRS

Bridging the Gap between Access and Adoption

The launch of our Medical Affairs unit—established to bridge the gap between access to and adoption of T1D therapies and devices—marked a notable organizational expansion for Breakthrough T1D and our mission. The team is addressing the challenges associated with slow clinical adoption of T1D therapies so that more people with T1D can benefit from them.

In a little more than a year, the Medical Affairs team has had some incredible accomplishments:

- **4,900+ People screened** for T1D at 40 Breakthrough T1D Early Detection pilot sites
- **15,000+ Constituents** opted in for more information about clinical trials from us
- **12,000+ HCPs accessed** our HCP education and resources on our website
- **120+ Participant Advisory Council members** who advise researchers, T1D Fund companies, industry partners, and federal agencies on the lived experiences of people with T1D
- **60+ Clinical Trial Education Volunteers** (one for every chapter!)
- **10 Full-time Breakthrough T1D Medical Affairs staff members** with wide-ranging clinical expertise
- **7 Global Centers of Reference** being trained to administer cell therapies

Leading Publications

Breakthrough T1D's Medical Affairs team is leading the way in partnering with international experts on publications that provide a framework to elevate T1D care. First were the International Monitoring Consensus Guidelines, which since its publication in 2024 has been accessed 85,000+ times and translated into multiple languages. Soon after came the International Consensus Statement on Continuous Ketone Monitoring, published in *The Lancet*. Next up: International Consensus Recommendations for integrating population-level screening into clinical care, a draft document that has already been endorsed by 18 global diabetes societies.

ADVOCACY

Major Advocacy Win: SDP

Our relentless Grassroots Advocates and Advocacy team members always achieve great things, and this year's SDP win ranks among the top! In a major victory, Congress passed a bipartisan extension of the Special Diabetes Program (SDP) through the end of 2026 AND a funding increase from $160 million to $200 million annually. We also secured an additional $10 million for diabetes research at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a $415 million funding increase for the National Institutes of Health (NIH), and a block on the 15% cap on indirect research costs.

Breakthrough T1D played an important role in the establishment of the SDP in 1997 and in its many renewals over the past three decades, working alongside bipartisan champions in Congress, particularly Senate Diabetes Caucus Co-chairs Susan Collins (R-ME) and Jeanne Shaheen (D-NH) and Congressional Diabetes Caucus Co-chairs Diana DeGette (D-CO) and Gus Bilirakis (R-FL), to sustain and strengthen this critical research investment.

An Avalere Health report shows that of the nearly $3.5 billion invested into the SDP by Congress since the program's establishment, the Federal Government has realized $50 billion in healthcare savings, demonstrating an incredible return on investment for taxpayers.

Children's Congress: Kids on the Hill

For three inspiring days, 170 Delegates ages 4 to 17 with T1D from all corners of the United States—and around the world!—made new friends, advocated for themselves and their community, and made an indelible mark on Members of Congress and their staff.

The Delegates focused on renewing the SDP, securing strong funding for the NIH and the FDA, and supporting policies that accelerate cell therapies research. As evidenced by the SDP extension and funding increase 7 months later, their efforts strongly paid off!

Seven incredible T1D Role Models—including Breakthrough T1D CEO Aaron J. Kowalski, Ph.D., pro-athlete Marlee Fray, fashion designer Thom Solo, *American Idol* finalist Ava August, *American Ninja Warrior* champion Katie Bone, journalist Madison Carter, and international super model Bambi Northwood-Blyth—joined our Delegates in D.C. to share their stories of success with T1D. They discussed the obstacles they've had to overcome, and tips on how to thrive with T1D. Delegates also had the privilege of being some of the first members of the T1D community to see our groundbreaking collaboration with Mattel: the first Barbie® doll with T1D. Delegates all received their very own Barbie doll—complete with an insulin pump and CGM.

GLOBAL RESPONSIBILITY

Aligning with Key Partners on Global Responsibility

Breakthrough T1D and the Helmsley Charitable Trust, together with Roche, Novo Nordisk, and Sanofi's Global Health Unit, launched the Alliance for Integrated, Government-led Networks for T1D (ALIGN-T1D) on World Diabetes Day, 2025. Comprising the largest funders of global type 1 diabetes (T1D) programs, leading producers of diabetes medicines and technologies, and members of the T1D community, the Alliance represents an exciting new chapter in collaboration for integrated diabetes care. ALIGN-T1D partners have committed to a multi-year strategy to improve access to comprehensive T1D care in low- and middle-income countries, where people with T1D lose an estimated 40 years of healthy life compared to their peers in high-income countries.

Advancing Access, Equity, and Action in India and Around the World

Breakthrough T1D was honored to lead the T1D Summit in Udaipur, India, bringing together government leaders, type 1 diabetes (T1D) organizations, people living with T1D, and health experts to work toward a collaborative roadmap for strengthening T1D care across India. The summit was hosted by Friends of Mewars Founder and Breakthrough T1D Global Ambassador Princess Padmaja Kumari Parmar, whose leadership is driving meaningful progress in access to care for people living with T1D.

In partnership with Friends of Mewar, Clinton Health Access Initiative, Inc, and UNICEF, we highlighted urgent priorities including:

- Early diagnosis
- Affordable access to insulin and diabetes technologies
- Psychosocial support
- Tackling diabetes-related stigma
- Integrating T1D into national programs

Together, we are building a future where every person with T1D in India has the support, tools, and care they need to thrive.

Bilingual Resources and Support

Breakthrough T1D provides a strong Community Engagement Program and resources specifically designed for the Spanish-speaking community. These bilingual resources include the Bag of Hope, Teen Pack, and Adult Pack; the Begin with Hope guide; a website offering T1D information and resources; and the Breakthrough T1D Facebook and Instagram pages in Spanish. The organization also hosts culturally relevant virtual Community Summits and other virtual and in-person connection opportunities at the chapter level. Additional resources include popular educational "One Pager" documents and a Clinical Trial Connections tool.

BY THE NUMBERS

Community Engagement

WALK
89,500+ walkers
8,900+ teams

RIDE
2,000+ riders
5 destinations

RUN
700+ participants
23 events

YOUR WAY
900+ participants
500+ events

GALA
29,000+ guests
68 events

GOLF
2,500+ golfers
19 events

PLAY
195,100+ game bundles sold
275+ streaming fundraiser events

BAG OF HOPE & CARE PACKS
28,400+ distributed
(27,000+ English; 1,400+ Spanish)

VIRTUAL COMMUNITY SUMMITS
65,600+ viewers
8 events
(English & Spanish)

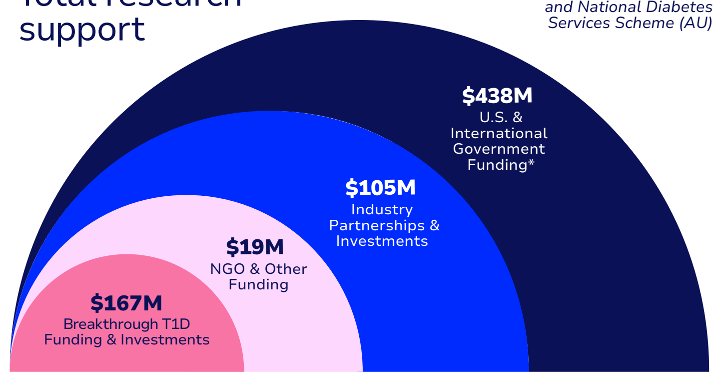
COMMUNITY SUMMITS
6,000+ attendees
42 events
(English & Spanish)

OUR IMPACT

We accelerate life-changing breakthroughs by raising funds and allocating them to T1D research and therapy development, as well as by leveraging our expertise and leadership to bring in additional funding and supporters from around the world.

$729M
Total research support

*Includes Special Diabetes Program (US) and National Diabetes Services Scheme (AU)



Breakthrough T1D drew $562M in additional funding and investments for T1D research

T1D THERAPY RESEARCH AND DEVELOPMENT

Our researchers work with the world's leading scientists and institutions to advance the most promising T1D innovations.

24
Countries with Breakthrough T1D Supported Research *(includes U.S.)*

500+
Active Projects

20
Early-Career Scientists Received New Funding

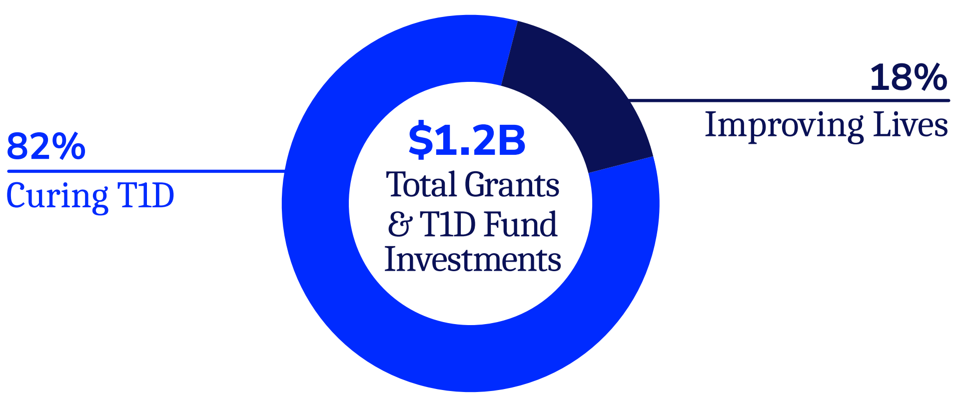
146
New Research Grants

16
New Clinical Trials

$28M
To New Clinical Trials

More Than $1.2 Billion to Cures and Improving Lives

During the past five fiscal years, through our research grants and T1D Fund investments* (those that we have made, as well as private, alongside investments), **more than $1.2 billion** has been directed to cure T1D and improve lives—with most of it (approximately 82 percent) focused on cures.

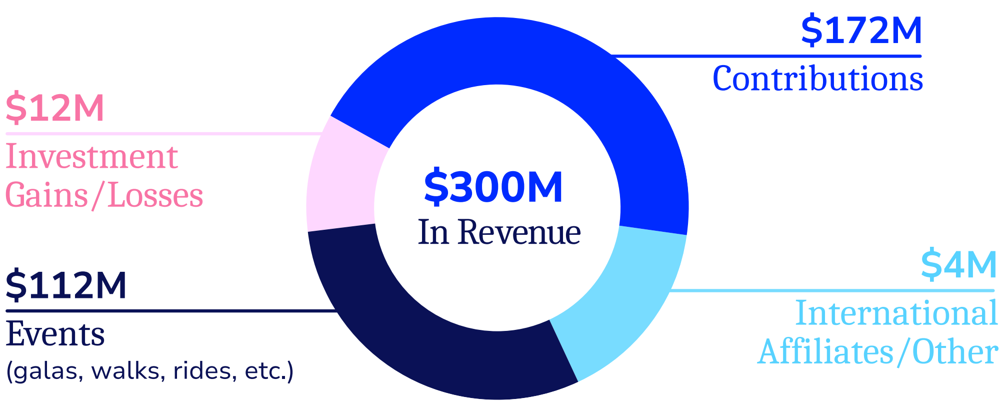


*This is committed capital and includes tranched financings that may not have had capital deployed yet.

FY25 REVENUE

We have four main revenue streams: Events (Walk, Ride, Gala, etc.); Contributions (gifts, etc.); Investment Gains/Losses (T1D Fund and other investments), and International Affiliates/Other (funding raised by our five International Affiliates, other sources).

For FY25, we saw a 15% increase in our total revenue over that of FY24.



FY25 MISSION SPEND

In FY25 we spent 14% more on advancing our mission than we did in FY24. This includes a 14% spending increase over FY24 for research funding and investments (grants, support, advocacy, medical affairs, and new T1D Fund investment), and a 15% spending increase over FY24 in public education (community engagement and medical affairs education reseources).

FY25 LOCAL AND GLOBAL REACH

Breakthrough T1D Chapters engage and support people with T1D and their loved ones in every major area of the United States. We now have 60 Chapters to build more community, raise more funds, amplify volunteer impact, and increase T1D awareness.

60 CHAPTERS
supporting more than
1M PEOPLE

Our global footprint includes five international affiliates and research in 24 countries, including research conducted at our Breakthrough T1D Centers of Excellence located in the United States, Canada, and Australia.

24 Countries

5 Affiliates

PARTNERS

Industry Partners, Governments, and Organizations

Our advocacy, leadership, and expertise attracts additional funding for cures and improving lives from:

- The U.S. government and international governments
- Other nonprofit organizations and foundations
- Industry partners—including pharmaceutical and technology companies

Together, we are a strong network focused on *advancing innovation*.

Corporate Partners

Our corporate partners support T1D breakthroughs in a variety of ways, from direct contributions and grant funding to engaging their employees, customers, and communities in giving initiatives and events.

Diamond Partners

Contributing more than $2,500,000 annually

Ford
Marshalls

Platinum Partners

Contributing between $1,000,000 & $2,499,999 annually

Lilly
minimed
sanofi
VERTEX
SANMAR

Gold Partners

Contributing between $500,000 & $999,999 annually

Abbott
Elevance Health Foundation
Food City
HyVee
novo nordisk
veradigm
Wawa

Silver Partners

Contributing between $250,000 & $499,999 annually

Dexcom
Transcarent
Humble Bundle
Veronica Beard
Insulet
Tandem Diabetes Care
Tops Friendly Markets

Bronze Partners

Contributing between $100,000 & $249,999 annually

Amphastar Pharmaceuticals
Cencora Foundation
Delta Tau Delta Fraternity
Floyd's 99 Barbershop
Harris Teeter
Kemper Foundation
Land O Frost
MannKind
Nationwide Foundation
Sub-Zero Group Foundation
Travelers Insurance
Xeris Biopharma

LEADERSHIP BOARDS

FY25 International Board of Directors

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Matt Varey, Vice Chair

Michael Alter

Elizabeth Caswell

Mike Gordon

Claudia Graham, Ph.D., MPH

Michelle Griffin

Karen Jordan

Joseph (Joe) P. Lacher, Jr.

Per Lundin

Carlton McMillan

Jennifer Schneider, M.D.

Christopher H. Turner

Drayton Virkler

Karey L. Witty

Observer: **David Panzirer**

FY25 Global Mission Board

Volunteer leaders who accelerate our mission progress through special projects and initiatives.

Matthew Cohn,
Chair
Jennifer Bennett,
Chair Emeritus

Jeff Adams

Randy Anderson

Cathy Baier

Timothy Clark

Maria Conroy

Meredith Coors

Jennie Costner

Laura Cramer

Maarten deGroot

Nanette DeTurk

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Ian Joyce

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James Lurie, Esq.

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Carol Oxenreiter

Margery Perry

Derek Rapp

Travis Rhodes

Kim Roosevelt

Brad Schur

Lorne Shiff

David Schwab

Michael Soper

Petra Vester

Jerry Wisler

FY25 T1D Fund Board of Directors

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Jay Eastman

Karen Jordan

Aaron J. Kowalski, Ph.D.

Ellen Leake

David Nelms

Amy Raskin

Jennifer Ross

Observer: **David Panzirer**

As we drive toward curing type 1 diabetes, we help make everyday life better for the people who face it.

Breakthrough T1D

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BreakthroughT1D.org

FY25 Financial Statement Summary

Total Public Support and Revenue for the year ended June 30, 2025 were as follows (in $thousands):

Public Support	
Contributions	172,120
Events revenue, net	112,345
Contributions from international affiliates	4,369
Total Public Support	**288,834**
Investment return, net	**11,699**
Change in value of split-interest agreements	**183**
Bad debt expense	**(1,867)**
Other income	**925**
Total Public Support and Revenue	**299,774**
Allocation of Expenses	
Mission program services:	
Research and advocacy, net[1]	150,924
Public education and outreach	59,332
Total mission program services	**210,256**
Mission support services:	
Management and general	19,265
Fundraising	50,747
Total mission support services	**70,012**
Total mission program services and support services	**280,268**

[1] *Does not include T1D Fund investments of $15.46 million; total research expenditures in FY25 were $166.38 million*

Breakthrough T1D®
Formerly JDRF

Statement of Financial Position

June 30, 2025 (in $thousands)

Assets	
Cash and cash equivalents	13,760
Investments:	
Operating and restricted investments	201,616
Long-term investments	96,903
Programmatic investments	65,519
Contributions receivable, net	114,927
Programmatic notes receivable, net	5,812
Prepaid expenses and other	7,923
Operating and finance lease right-of-use assets, net	20,867
Fixed assets, net	7,231
Total assets	**534,558**
Liabilities and Net Assets	
Liabilities:	
Accounts payable and accrued expenses	19,588
Research grants payable	138,373
Deferred revenue	434
Operating and finance lease liability	23,101
Liabilities related to split-interest agreements	2,486
Total liabilities	**183,982**
Net assets:	
Without donor restrictions	230,684
With donor restrictions	119,892
Total net assets	**350,576**
Total liabilities and net assets	**534,558**

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