Fiscal Year 2024 Annual Report
July 1, 2023 through June 30, 2024

Driving T1D Breakthroughs: Now & Next

Breakthrough T1D™
Formerly JDRF

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Charity Navigator FOUR-STAR

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

Driving T1D Breakthroughs

There's never been a more exciting time for type 1 diabetes (T1D) research.

Right now, we are in the midst of a scientific revolution that is transforming the trajectory of T1D. Breakthroughs that we never dreamed possible are improving lives.

However, challenges stemming from an unpredictable landscape threaten our progress.

Cures and other T1D advances are within reach.

We cannot afford to lose momentum now.

We must anticipate future opportunities and demands.

We must rally more people to champion our cause.

We must expand our influence.

The more people we engage, the more we will amplify our voice, and the faster we will drive toward curing T1D while making everyday life better for the people who face it.

The T1D community is relying on us.

As leaders, we have an obligation to act.

With your help, we will succeed. We know this because of where we are today, which is a result of your support and decades of relentless work.

In this report, you'll learn about some of our most exciting breakthroughs: where we are now, how we got here, and the next breakthroughs on the horizon.

Let's keep pushing to advance breakthroughs, unlock access, and deepen support for Breakthrough T1D.

Warm regards,

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

In Your Words

Why you support Breakthrough T1D

No one should face type 1 diabetes (T1D) alone. Because of your support, no one has to. This is more than a moment—together, we're creating a movement for the entire T1D community. You, our supporters, fuel our progress. In your words, you share why you volunteer, advocate, fundraise, and come together to help advance our mission.

"When the day comes that our son can take the devices off his body and stop filling his prescription for insulin, it will be because of Breakthrough T1D."

Margaret Kelley
Breakthrough T1D Run participant
Parent to Edgar, who lives with T1D

"I often feel like type 1 diabetes is overlooked. Any way I'm able to give back and represent those who aren't able to use their voices is really important to me."

Bryce Mack
Breakthrough T1D
Young Adult Advocacy Council
LIVES WITH T1D

"The freedom I've been able to experience as a result of Breakthrough T1D's investments in diabetes technology has really been life-changing."

Hale Johnston
Northern California Chapter
Community Board Member
LIVES WITH T1D

We are *opening the doors* that were once closed by T1D diagnosis.

“I think it’s fantastic that we’re making the umbrella wider to encompass more people and more communities.”

Julie Calidonio
Florida Advocate
Parent to Luke, who lives with T1D

“T1D can feel like an island sometimes. The Breakthrough T1D Walk is a reminder that we have a support group. It takes a village, and I am thankful for ours.”

Karla Christy
Breakthrough T1D Walk Participant
Parent to three children with T1D: Oliver, Miles, and Stella

“I remember the days when I was checking my blood sugar, guessing how much insulin to give and whether to treat or not. Now we’re at a point where I can get all of that information on my phone within five minutes. It has allowed me to really take control of my diabetes.”

Parth Gami
Breakthrough T1D
Young Adult Advocacy Council
LIVES WITH T1D

Breakthrough Initiatives

JDRF is now Breakthrough T1D

Same mission. New brand.

When we were founded in 1970 as JDF—the Juvenile Diabetes Foundation—T1D was thought of as a disease only diagnosed in children.

Today, we know people of all ages are diagnosed with type 1 diabetes. For all intents and purposes, "juvenile diabetes" does not exist.

We realized we needed a new name to better reflect who we are, what we do, and the impact of our work for every person living with T1D.

That's why we became Breakthrough T1D.

For more than 50 years, we have fueled progress to improve life with T1D, playing a pivotal role in nearly every T1D breakthrough.

Our new brand reflects who we are today—the leading global type 1 diabetes research, advocacy, and medical affairs organization—as well as the future breakthroughs we're advancing for the T1D community.

We unveiled our new brand to 230 of our most enthusiastic volunteer advocates on June 4, 2024, at our Government Day event in Washington, D.C.—the response was nothing short of incredible.

Our mission remains steadfast: to accelerate life-changing breakthroughs to cure, prevent, and treat T1D and its complications.

Our new purpose statement says it best:

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

Project ACT *(Accelerate Cell Therapies)*

Accelerating cell therapies today for cures tomorrow.

Breakthrough T1D has a clear mission: to accelerate life-changing breakthroughs to cure, prevent, and treat T1D and its complications.

We also have a clear vision of how to achieve that mission: our cures strategy, which includes cell therapies.

Project ACT is our strategy to make cell therapies a reality for millions around the world who live with T1D. It will do for cell therapies what our Artificial Pancreas Project did for automated insulin delivery (AID) systems: make them a reality, faster.

We know that cell therapies will allow us to walk away from T1D. Project ACT is the roadmap for getting there sooner—and here's what that looks like:

Research and Development Invest in novel protection strategies by providing cells to researchers, funding innovative research, and building on the work being done in our Centers of Excellence.

Clinical Testing Develop guidelines for clinical trial models, recruitment, and endpoints to expedite the pathway to approval.

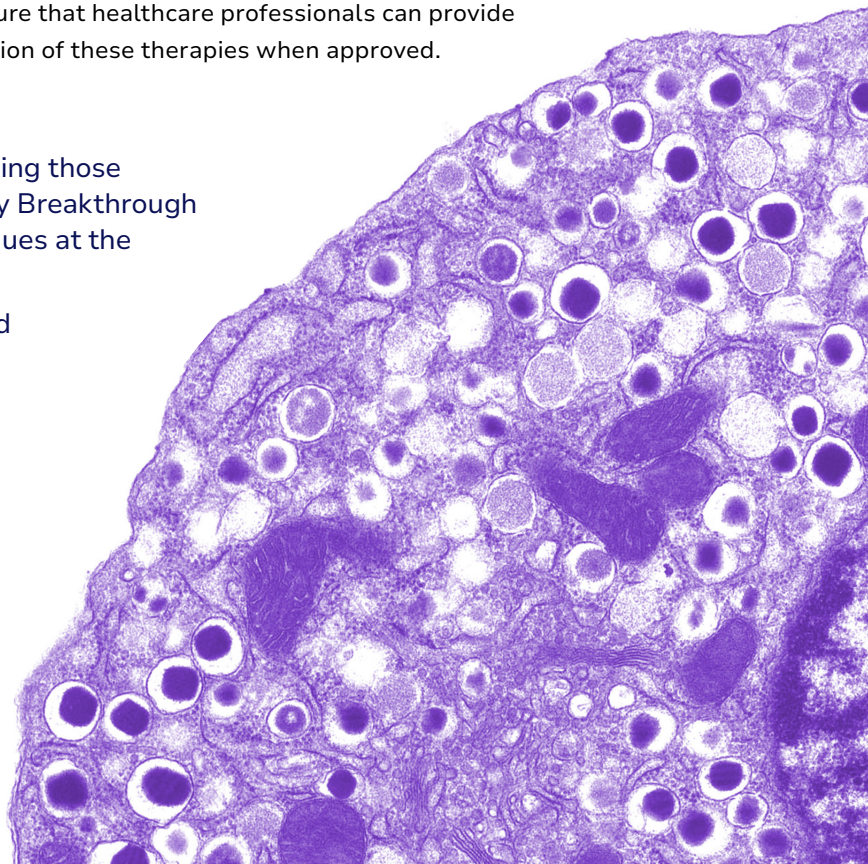
Regulatory Policy Influence and de-risk regulatory pathways to further accelerate approvals for cell therapies.

Health Policy Build and expand pathways for access and coverage of cell therapies.

Medical Affairs Lead efforts to ensure that healthcare professionals can provide seamless implementation and adoption of these therapies when approved.

Cell therapies in human clinical trials, including those developed by Vertex, were made possible by Breakthrough T1D funding and critical work by our colleagues at the T1D Fund: A Breakthrough T1D Venture.

We have the people, history, experience, and supporters required to deliver.



Together, we will *break* through T1D.

Curing T1D

Today's most promising cures research involves three key areas:

Cell Therapies

Replace beta cells so that people with T1D can again produce their own insulin.

Disease-Modifying Therapies

Prevent, slow, halt, or reverse T1D progression.

Early Detection Initiatives

Identify and support people at risk for T1D before insulin is required.

Cures: Now

Incredible Progress in Cell Therapies

Through grants, we are supporting cell therapies research in 114 preclinical projects and 4 projects that are in human clinical testing. More than a dozen recipients of these therapies have been able to stop taking insulin.

Manufactured Cell Therapies: Amazing Firsts

In an amazing first, one islet cell replacement therapy from Vertex Pharmaceuticals, VX-880 (now called zimislecel), has advanced to a phase III trial. Phase III trials are often the final phase of clinical testing before a therapy is submitted for regulatory approval. Vertex is slated to submit zimislecel for regulatory approval in 2026. Another amazing first, supported by investment from the T1D Fund: A Breakthrough T1D Venture, is Sana Biotechnology's UP421, which uses deceased donor islets engineered to evade the immune system. One participant has received the therapy and early clinical data shows that individual has started producing insulin without requiring immunosuppression!

Seraxis, another T1D Fund portfolio company, is working on a few different manufactured cell therapies: SR-02 and SR-03. SR-02 is in a phase I/II clinical trial for people with severe hypoglycemia. This therapy is implanted onto the omentum (a fatty, protective layer around organs) and requires immunosuppression. The trial is evaluating safety and insulin production as measured by C-peptide, a biomarker for insulin production. SR-03 is a gene-edited therapy that will aim to eliminate the need for immunosuppressants.

Better Protection for Transplanted Islets

A phase I/II clinical trial found that tegoprubart, a novel immune therapy from T1D Fund portfolio company Eledon Pharmaceuticals, has the potential to protect transplanted islet cell therapies from rejection without the severe side effects associated with standard immunosuppressants.

Breakthrough T1D has also been supporting the development of Cell Pouch™, an implantable device from Sernova that provides a safe, immune-protected environment for transplanted islet cells. In early human clinical trials, all six people who received donor islets within the Cell Pouch™ achieved sustained insulin therapy independence with immunosuppressants, including long-term islet survival and function during a five-year time period without harmful side effects. It is on track to meet clinical endpoints of safety and tolerability. After this trial is complete, Sernova will launch a new trial for Cell Pouch™ implanted with manufactured islets.

Beta Cell Factories

For cell therapies to become commercialized products, we need an unlimited supply of healthy, insulin-producing islets. The Advanced Regenerative Manufacturing Institute (ARMI) will focus on scaling up Breakthrough T1D-funded researcher Dr. Jeffrey Millman's protocol to generate an unlimited supply of manufactured islets in a reliable, automated, and reproducible way. To accomplish this goal faster, we are also building a partnership with the Cedars-Sinai Biomanufacturing Center—a leader in the manufactured cells space.

Amazing Advances in Disease-Modifying Therapies

Through grants, we are supporting disease-modifying therapies (DMT) research in 159 preclinical projects and 14 projects that are in human clinical testing.

DMTs in Advanced Clinical Testing

In projects we've supported, one therapy—Diamyd®—has entered into a phase III trial. Several other therapies are in phase I/II trials, including combinations of DMTs using an adaptive design to help accelerate trial progress.

Activating Regulatory T Cells

One project in the earlier phase of clinical testing is MTX-101 from T1D Fund portfolio company Mozart Therapeutics. This therapy activates regulatory T cells to eliminate the other types of T cells that destroy beta cells. Regulatory T cells, which are a part of the immune system, normally prevent the immune system from overreacting. The goal is to eventually decrease dependence on external insulin.

Early Detection Key to Progress

Through grants, Breakthrough T1D is supporting 63 Early Detection research projects.

TEDDY Family Follow-Up

One project we funded through early 2024 is a family follow up to the TEDDY study (The Environmental Determinants of Diabetes in the Young). This project focuses on screening and monitoring siblings and parents of TEDDY participants, who have an increased genetic risk for T1D. The goal is to further optimize early detection and prevention programs, better understand the natural progression of T1D, and potentially identify additional T1D biomarkers.

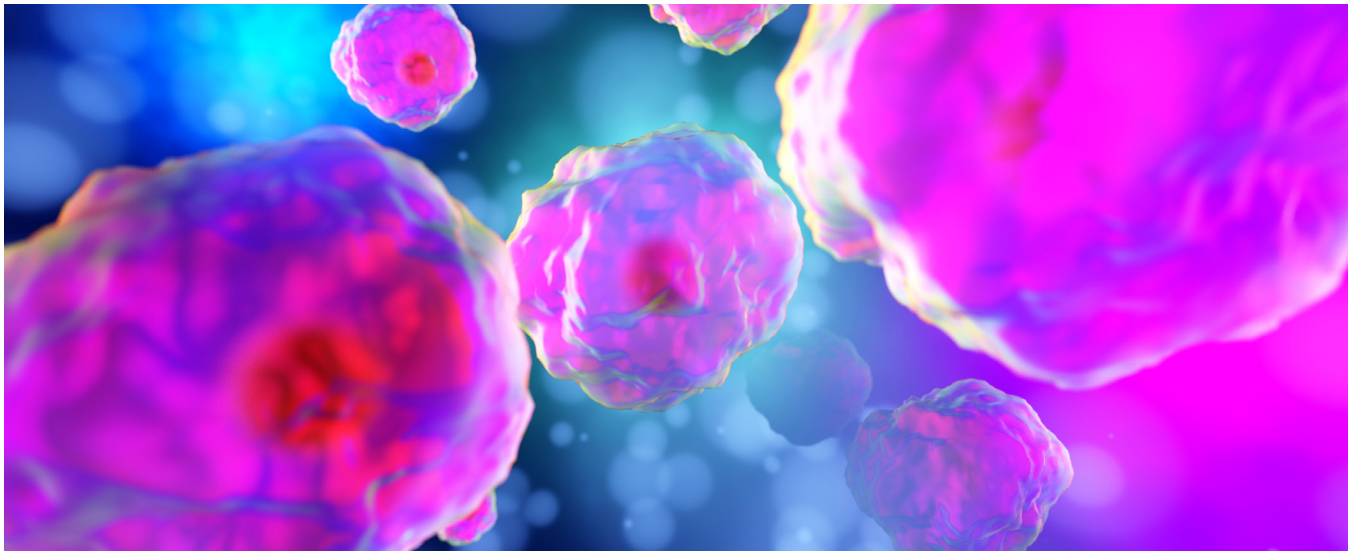
Addressing Anxiety from Testing Positive for Autoantibodies

Another study explores adjusting an existing cognitive behavioral therapy model to reduce high anxiety experienced by teens who test positive for T1D autoantibodies but have not yet developed symptoms and their guardians.

Why Early Detection Matters

From a therapy and research development perspective, T1D early detection is a key part of identifying people who could benefit from Tzield® or from participating in clinical trials of other DMTs in development. Clinically, it can help prevent DKA at diagnosis and help families prepare for T1D onset. Our early detection research augments our Advocacy and Medical Affairs efforts to champion T1D early detection. These include our support of the SCREEN for Type 1 Diabetes Act; our leadership of a campaign to expand access to early detection of T1D in the United States; our accredited Healthcare Professional education and resources, including our consensus monitoring guidance which is now an international standard of care for people who test positive for autoantibodies; and our Early Detection and Clinical Trial Education programs.

Cures: Then



Cell Therapies

Past 10 Years: Through research grants, we have invested $163 million in 246 cell therapy research projects.

40+ Years Ago: We started funding research to develop beta cell transplantation therapies in the 1980s. Over the years, our support expanded to include the researchers whose proprietary work is now being advanced by companies like Vertex.

Transformative Investments:
The T1D Fund invested in novel companies that are now advancing cell therapy projects, including Semma and ViaCyte, which were later acquired by Vertex; Sana Biotechnology; Seraxis; and others.

Disease-Modifying Therapies

Past 10 Years: Through research grants, we have invested $257 million in 487 DMT research projects.

40+ Years Ago: We started funding research in support of developing DMTs for T1D in the 1980s. Over the years, our support grew to include efforts that specifically led to Tzield®, the first DMT for T1D, which the FDA approved in 2022. Through our efforts to establish a regulatory approval pathway for Tzield, we laid critical groundwork to improve the regulatory prospects for future DMTs in the pipeline.

Transformative Investments:
The T1D Fund invested in novel companies that are now advancing DMTs, including Provention Bio, which first made Tzield and was later acquired by Sanofi; Pandion Therapeutics, which was later acquired by Merck Pharmaceuticals; Mozart; and others. Sanofi's and Merck's respective acquisitions were endorsements by some of the world's leading pharmaceutical companies of the potential of DMTs for T1D—endorsements that are helping to inspire an expanded development of these therapies.

Early Detection

Past 10 Years: Through research grants, we have invested $109 million in 156 Early Detection research projects.

40+ Years Ago: We started funding research in support of T1D Early detection in the 1980s when a scientist we funded made a discovery instrumental to determining that T1D is an autoimmune disease: diabetes is associated with the development of islet cell antibodies.

TEDDY: A Trove of T1D Data

While the final samples from the TEDDY study were collected in early 2025, scientists and clinicians have conducted numerous analyses of the mass amounts of data collected from the participants during the course of many years. These studies investigated how genetics, infectious agents, celiac disease, diet, and psychosocial factors could contribute to the development of autoantibodies and eventual progression to symptomatic, clinical T1D. More studies are needed to better understand how these factors affect initiation of islet autoimmunity and T1D progression early in life and during adolescence.

Cures: Next

Broader, More Scalable Cell Therapies Approved Breakthrough T1D's Project ACT will accelerate all of the exciting momentum we are seeing now and bring us closer to manufactured cell therapy cures, faster. Our ultimate goal is to accelerate commercialized cell therapies that do not require broad immunosuppression. In the future, these therapies will create a path for people with T1D to remove their devices and walk away from the condition for good.

Accelerating DMT Development As we see more DMT clinical trials advance to later stage human testing, we expect to see additional DMTs submitted for regulatory approval. To help further accelerate this process, we published an expert perspective on the significance of C-peptide—a biomarker for insulin production—as a key measure of the efficacy of DMTs in clinical trials (an "endpoint"). Use of C-peptide in drug development will be key to accelerating DMT development and these expert recommendations will be used to advocate to regulators.

Improving Early Detection, Expanding Access As research into Early Detection continues, we expect to improve ways to detect T1D early and prevent it by attaining a better understanding of the natural progression of T1D, potentially including additional biomarkers for the disease. By understanding which interventions best help individuals and families manage anxiety that may result from testing positive for T1D biomarkers, we expect to find ways to improve the standard of care for early T1D. Through our Advocacy and Medical Affairs efforts, we expect to spread awareness of and expand access to T1D Early Detection.

With your *support*, we will make this condition a thing of the past.

The T1D Fund: A Breakthrough T1D Venture

Founded in 2016, The T1D Fund is a wholly owned subsidiary of Breakthrough T1D that is run on a unique evergreen model: donor funded to support investments in for-profit entities, with exit proceeds recycled back into the Fund.

The T1D Fund is the largest disease-focused venture impact fund with ~$200M+ in assets under management and ~$125M of liquid capital to support legacy and new investments. To date, the T1D Fund has an active company portfolio of ~30 companies with a mix of T1D-focused and multi-indication/platform companies across the prevention, treatment, and cures spectrum.

Since its launch, the T1D Fund has made 45 investments with multiple successful company exits ranging from trade sales to big pharma (Semma Therapeutics, Pandion Therapeutics, Inversago Pharma, and Protomer Technologies) to IPOs (Provention Bio and Immunocore). There are now a significant number of industry-sponsored clinical trials ongoing in type 1 diabetes where we anticipate 10+ of the Fund's active portfolio companies entering the clinic for T1D within the next year or two.

A New CEO and New Chapter

In January 2025, Elizabeth Mily was appointed T1D Fund CEO after having most recently served as Executive Vice President, Strategy & Business Development, at Bristol Myers Squibb, and in senior roles at Barclays, Thermo Fisher Scientific, and Goldman Sachs.

Her appointment comes as the T1D Fund begins its next chapter. The Fund looks to boost its presence with large biopharma, in particular, as they have the wherewithal and resources to bring therapies over the finish line.

Under Mily's leadership, the Fund will execute an expansion of its current strategy focused on accelerating T1D cures by placing greater bets in promising companies and proactively engaging big pharma to grow the Fund's network and influence.

Improving Lives

Today's most promising life-improving opportunities focus on two main areas:

Glucometabolic Control

to improve glucose and other metabolic outcomes and make it easier to manage T1D. These include novel technologies, better insulins, and adjunctive therapies that complement insulin.

Complications and Behavioral Health

to delay or prevent long-term eye, heart, and kidney disease and improve mental health and well-being.

The Importance of Improving Lives Research

Our Improving Lives program supports research to improve health and quality of life for people with T1D. Among people with T1D in the United States, nearly 70% do not consistently meet target blood-glucose levels; two-thirds of adults struggle to maintain a healthy weight; and all remain at higher risk of long-term complications, such as heart, kidney, and eye disease. Moreover, thirty percent of people with T1D surveyed report elevated levels of depression and stress; and mental health issues are associated with higher HbA1c levels. Breakthrough T1D is building on our impressive momentum in the improving lives space to address these needs and reduce disease management burden so that everyone with T1D can live full, healthy lives until we have cures.

Improving Lives: Now

Through grants, we are supporting improving lives research in 51 preclinical projects and 62 projects that are in human clinical testing.

Next Generation Insulins

Liver-targeted, ultra-rapid, and glucose-responsive insulins (GRIs) are the high-performing insulins of the future, and we are supporting work to advance all three.

Liver-targeted insulins enhance glucose storage, potentially improving blood-glucose management while decreasing the risk of severe hypoglycemia.

Ultra-rapid insulins act faster than traditional rapid insulins, which could help improve blood-glucose management.

Glucose-responsive insulins rebalance blood-sugar levels only when needed.

Diasome Pharmaceuticals, a T1D Fund portfolio company, has launched a phase II/b clinical trial of its liver-targeted insulin. A Breakthrough T1D-funded phase I clinical trial of insulin tregopil, also a liver-targeted insulin that is administered orally, wrapped up in late 2024. We support several ongoing preclinical GRI projects, including those for which we have partnered with the best and brightest in the insulin therapy space. Two companies—Lilly and Novo Nordisk—have advanced GRI work we supported into early human clinical testing. Lilly's GRI is from the acquisition of the biotech, Protomer, which was previously supported by both Breakthrough T1D and T1D Fund.

Phase II clinical trials can sometimes be divided into phase II/a and phase II/b clinical trials. Phase II/a trials determine the safety and efficacy of a promising new therapy. Phase II/b trials build on the findings of phase II/a to further determine the safety and efficacy of the therapy and can help determine optimal dosing.

More Affordable Insulin

Our support of nonprofit pharmaceutical company Civica Rx will result in three broadly available and more affordable biosimilar insulins—the equivalents of glargine (Lantus®), lispro (Humalog®), and aspart (NovoLog®). Each will cost no more than $30/vial or $55/box of five pens, regardless of insurance status.

We also had two big wins for insulin affordability. First, the Inflation Reduction Act included something we fought hard to secure—a $35 monthly out-of-pocket co-pay cap for those on Medicare. We are working to expand this cap to other populations. Second, the major insulin companies announced voluntary reductions to the prices of some of their insulins. We're continuing to support legislation to ensure that insulin is affordable to all who need it.

Adjunctive Therapies

Right now, five ongoing Breakthrough T1D trials are examining the use of GLP-1 agonist Ozempic® for use in T1D as adjunctive therapies. Real-world use of these types of medications in people with T1D shows that they can lead to improved weight control, improved HbA1c levels and time-in-range, and even reduce the amount of insulin someone needs to take.

The phase III clinical trial of first-in-class insulin adjunct therapy cadisegliatin from vTv Therapeutics, previously funded by Breakthrough T1D and currently a T1D Fund portfolio company, continues. Cadisegliatin is a liver-selective glucokinase (GCK) activator. GCK—an enzyme your body makes—acts as a critical regulator of sugar levels in the body. The phase III trial builds on the results of a phase II trial in which the therapy significantly improved HbA1c in people with T1D. Additionally, those who received the drug showed a reduction in insulin dose, reduced hypoglycemia, and no increase in DKA.

Breakthrough T1D is also supporting a phase II clinical trial of a first-in-class adjunctive therapy from Zucara Therapeutics, ZT-01. The drug aims to prevent hypoglycemia in people with T1D using external insulin.

Conquering Complications

New therapies—GLP-1 agonists, SGLT inhibitors (like Jardiance®), and finerenone (brand name Kerendia®) are transforming heart and kidney care for people with T2D and obesity. Previously, people with T1D had been left out of testing these therapies, even though they could offer this population similar benefits. Breakthrough T1D is changing that by funding several projects that examine the effects of these advanced drugs on people with T1D. One of these is SUGARNSALT, which is investigating the effectiveness and safety of SGLT inhibitor sotagliflozin (Inpefa®) in slowing kidney function decline in those living with T1D and moderate to severe diabetic kidney disease. A second clinical trial with Breakthrough T1D support, SOPHIST, will investigate whether sotagliflozin can improve quality of life in people with T1D and heart failure. SOPHIST will also assess the safety and tolerability of sotagliflozin in this population.

We are also seeing progress for treating diabetic eye disease—the FDA recently approved Susvimo™, an anti-VEGF therapy, for diabetic macular edema (DME). In Breakthrough T1D-funded clinical trials, fenofibrate, an oral cholesterol drug, is also showing promise for diabetic eye disease.

T1D Management Technology

CGMs. Insulin pumps. AID systems. Smart insulin pens and pen caps. People with T1D in the United States now have 20+ technologies to choose from when it comes to how they administer insulin and monitor blood-glucose levels. Nearly half of these technologies are AID systems—many of which were developed at some point with our funding. These technologies are leading to better health for people with T1D by reducing dangerous highs and lows, improving time-in-range, and even leading to better sleep and healthier pregnancies. Still, more needs to be done. We are making progress toward fully closing the loop and using new strategies, like additional medications, to help people do better until we have cures.

Developing continuous ketone monitoring (CKM) systems is also a priority of our improving lives work. Diabetic ketoacidosis (DKA) remains a significant and dangerous risk for people with T1D. CKMs have the potential to prevent DKA by informing people when ketones are rising so they can take steps to mitigate it before it becomes a crisis. CKMs may also allow for the safe use of SGLT inhibitors for complications or as adjunct therapies. To enable safe and effective use and adoption of CKMs, our Medical Affairs team is leading the charge to establish and publish consensus guidelines among medical professionals.

Improving Mental Health

When it comes to behavioral interventions, tools that are developed too often face barriers to integration into daily practice. Breakthrough T1D is funding studies evaluating how interventions already established as effective for other conditions can be adjusted and integrated into clinical practice on a large scale for people with T1D. These interventions aim to reduce diabetes distress in different populations, as well as help emerging adults prepare to independently and effectively manage their T1D.

Improving Lives: Then

Past 10 Years: Through research grants, we have invested $196 million in 278 Improving Lives research projects.

Transformative Investments: The T1D Fund invested in novel companies that are now advancing life-improving therapies for T1D. These include T1D management technologies (Bigfoot Biomedical, later acquired by Abbott; Bioling; Capillary Biomedical, later acquired by Tandem Diabetes Care; and Glusense); next generation insulins (Diasome and Protomer Technologies, later acquired by Lilly); insulin adjunct therapies (vTv); and complications therapies (Inversago Pharma, later acquired by Novo Nordisk).

Advanced Insulins

Since our founding in 1970, we have consistently supported the development of new and improved insulins, including biosimilar and interchangeable insulins. Lilly's 2021 acquisition of Protomer Technologies, a company developing a GRI that benefitted from Breakthrough T1D and T1D Fund investment, endorses the promise of GRI.

Affordable Insulin

As insulin prices have risen during the past 10+ years, we have worked with all stakeholders—including insulin manufacturers, health insurance providers, pharmacy benefit managers (PBMs), and employers—to help make insulin more affordable.

GLP-1s and GCK and T1D

In the 1980s, we supported the researcher who first cloned the hormone glucagon and discovered two new hormones, one of which was GLP-1. We've supported GCK (glucokinase—an enzyme your body makes that helps regulate blood-sugar levels) research since the early 1980s, including funding the physician-scientist who discovered GCK as the primary glucose sensor in the pancreas.

Advanced T1D Management Technology

For 50+ years, we have successfully led the charge to advance the standard of care for T1D management from finger pokes to CGMs, insulin pumps, and AID systems, with the first AID system hitting the U.S. market nearly 10 years ago. This includes efforts in research and development, regulatory approval, healthcare coverage, and adoption.

Complications Therapies

We have funded complications research since we were established, awarding one-third of our grants to find the causes of and treatments for heart, kidney, eye, and other T1D-related diseases.

Psychosocial Health

We started funding psychosocial health and T1D research in the late 1980s. Today, we fund psychosocial research exploring topics that include T1D and eating disorders, programs to reduce disparities in at-risk youth who have T1D, diabetes distress, and anxiety and T1D.

Improving Lives: Next

Advanced Insulins and Adjunct Therapies

Breakthrough T1D and T1D Fund's support of Zucara and vTv will continue those companies' partnerships with us and help move those two first-in-class therapies through the pipeline. Approval of adjunct therapies such as cadisegliatin, ZT-01, and GLP-1s—as well as next-generation insulins—could allow people with T1D to more effectively manage their blood-glucose levels, and in some cases, potentially with fewer or smaller insulin doses.

Affordable Insulins Available at Your Pharmacy Counter

Through Civica Rx, biosimilars to three of the most widely used insulins in the United States will be available at your pharmacy counter and at a reasonable price, regardless of your insurance status.

Better Drugs for Healthier Hearts, Kidneys, and Eyes

If the clinical trial results for existing GLP-1s, SGLT inhibitors, finerenone, and fenofibrate are positive for people with T1D, translation to clinical use could be streamlined, as these are already FDA-approved for the treatment of other conditions.

Smarter, Smaller, Better T1D Management Technologies

Until no one needs them, T1D management technologies will improve in functionality, user-friendliness, size, and interoperability, and will allow for better glucose control, DKA prevention, and improved quality of life. We will continue to advocate to ensure that these devices are covered by all major healthcare plans and will work to unlock access to them.

An Improved Standard of Care for T1D Mental Health

If our studies show that existing interventions are effective at helping reduce diabetes distress and in addressing other psychosocial challenges in people with T1D, we will establish a new model of T1D care that can be easily integrated into clinical practice and become widely available for people with T1D.

We're here to make every day with *type 1 diabetes* better.

Advocacy in Action

The Special Diabetes Program

Last year, our Advocacy Team and our volunteer advocates worked tirelessly for renewal and funding increases of the Special Diabetes Program (SDP), which resulted in two hard-won extensions of the program. The SDP is now funded at $160 million annually through September 2025. Breakthrough T1D is the chief advocate for the SDP—an NIH program that since its inception in 1997, has funded $3.5 billion in T1D research. The bipartisan program supports research at all stages of T1D, including cures, prevention, and treatments. It has yielded significant T1D advancements, including Tzield®, the first FDA-approved therapy to delay the onset of T1D; AID systems; and complication therapies.

"The ability to screen for and identify type 1 diabetes before the onset of symptoms is a major breakthrough with significant benefits. Breakthrough T1D is focused on expanding T1D screening education and access as part of our mission."

Lynn Starr
Breakthrough T1D
Chief Global Advocacy Officer

Efforts to Expand T1D Screening

Breakthrough T1D announced a campaign to secure a United States Preventive Services Task Force (USPSTF) recommendation for T1D screening. The USPSTF is a body that provides recommendations for preventative care. A positive USPSTF recommendation would require all insurance plans to cover the cost of screening and expand access to T1D early detection. Our campaign complements the Strengthening Collective Resources for Encouraging Education Needed (SCREEN) for Type 1 Diabetes Act. Introduced by Senators Jeanne Shaheen (D-NH) and Susan Collins (R-ME) and Representatives Kim Schrier (D-WA) and John Joyce (R-PA), the SCREEN for Type 1 Diabetes Act seeks to increase awareness of T1D screening through a national Centers for Disease Control and Prevention campaign.

Government Day

Our annual Government Day event brings dedicated volunteer advocates from across the country to Capitol Hill to advance our advocacy priorities. In 2024, Government Day coincided with the launch of our new brand, Breakthrough T1D. Our advocates' first task was to reintroduce us to their Members of Congress. In their most recent Government Day meetings (March 2025), our advocates championed renewal of and a funding increase for the SDP and emphasized that Congress must maintain the momentum toward finding cures and ensure strong funding and staffing for essential agencies like the NIH and FDA. They also provided a preview of Project ACT and asked that Members of Congress support policies to speed the way to cures.

Medical Affairs

A key part of our mission.

During the past decade, we've seen numerous breakthroughs for T1D come to market, including the first therapy approved to delay onset of the disease, AID systems, and the first islet replacement therapy (donor-derived). Frustratingly, adoption has been slow, delaying the life-changing potential of these T1D therapies.

Closing the gap between access to and adoption of T1D therapies is a mission priority for Breakthrough T1D. Enter our newest business unit, Medical Affairs. Led by Thomas Danne, M.D., the Medical Affairs team will address the issues behind slow adoption of advanced T1D therapies by:

- Creating a network of multidisciplinary T1D treatment reference centers for successful clinical implementation of emerging therapies, including cell therapies.
- Developing education materials for healthcare professionals in the U.S. and around the world
- Empowering people with T1D to participate in shared decision-making with their healthcare teams about emerging T1D therapies
- Helping establish and socialize clinical care guidelines tailored to regional needs
- Expanding clinical trial participation through community activation and HCP education

The team recently launched redesigned HCP education and training resources. These resources focus on early detection of the earliest stages of T1D, monitoring guidance for positive test results, clinical trial opportunities, and the latest on cutting edge T1D therapy research and development.

The HCP resources build on the extensive and successful work of the Community Screening and Clinical Trial Education team, including leading the development of the first international monitoring guidance to help clinicians support people with positive autoantibodies in stage 1 or stage 2 T1D; partnering with clinics and hospitals across the United States to expand access to T1D screening; and resources to increase clinical trial enrollment. The team is also leading efforts to establish and publish consensus guidelines for continuous ketone monitor (CKM) system use.

"By addressing systemic barriers and fostering clinical readiness, Breakthrough T1D will be pivotal in driving the timely adoption of emerging therapies and transforming care."

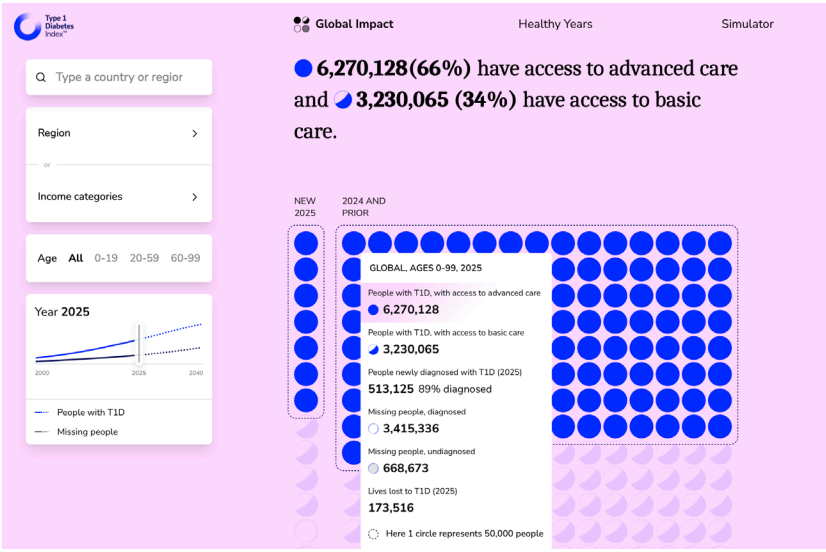
Thomas Danne, M.D.
Breakthrough T1D Chief Medical Officer, International

Global Responsibility

The T1D Index “2.0”

In 2022, Breakthrough T1D launched the T1D Index, a first-of-its kind data simulation tool that measures the true global health impact of T1D, bridging gaps in our knowledge of public health statistics.

Two years later, we launched the T1D Index “2.0.” The updated tool has new and improved functionality, including advanced simulation capabilities, validation of data, and enhanced user experience. The Index is critical in defining the intercontinental scope of T1D, driving us toward country-specific solutions and improved global health outcomes.



Africa: Reducing T1D Mortality at Diagnosis We are investing in clinical and patient-centered awareness campaigns to increase T1D diagnosis. We are funding projects to develop ways to increase diagnoses in low-income countries, specifically parts of Africa with the highest global death rates at diagnosis.

India: Focusing on Access to Basic T1D Care We are connecting and collaborating with local leaders in India—which has one of the biggest gaps in access to basic care—to bring affordable insulin and test strips to local communities.

Our International Affiliates: Increasing Device Access and Adoption We are building the human, scientific, and economic case for device adoption and sharing it in the U.S. and across our international affiliate footprint so they can advocate for devices like insulin pumps and CGMs to be covered by insurance or national health systems.

Worldwide: Driving Investments in Research and Care Empowered with data from the T1D Index, we are driving more and better-leveraged investments in T1D research and care through partnerships with international organizations.

Improving Health Around the World

Through our work, the global scope and impact of T1D is becoming clearer. Spearheading projects like the T1D Index for worldwide T1D data and our early detection program for advancing general population screening globally helps shed light on the condition and connects our global community.

We're creating a *movement* for the T1D community.

What Do We Know about People in the U.S. Living with T1D?

Nearly 2 million people in the United States live with T1D. What do we know about them? A Breakthrough T1D-funded study published in the *Journal of Health Economics and Outcomes Research* built a model based on healthcare claims datasets, population growth projections, and published literature to learn more about who in the U.S. is living with T1D now and who will be in 10 years.

According to the study, there are important differences in T1D prevalence and incidence across regions, insurance types, and ethnic groups. The study showed the majority of Americans living with T1D today are non-Hispanic white people, with a roughly even number of males and females and an average age of 47. The study also showed that nearly half of people with T1D in the U.S. are insured by commercial health plans, followed by nearly a third covered by Medicare and 15% by Medicaid. In the next 10 years, the T1D population is slated to increase at greater rates in African-American and Hispanic people than in white people, with the average age of someone living with T1D increasing by two years, and slightly more females than males living with the disease. The T1D population is expected to increase the most among children younger than 10 (38%) with the second highest increase occurring among people aged 65 and older (32%).

Expanding Our Engagement with Spanish Language Resources

Breakthrough T1D offers a robust Community Engagement Program and Resources focused on the Spanish-speaking community. These bilingual resources include the Bag of Hope, Teen Pack, and Adult Pack; our Begin with Hope guide; our website with T1D information and resources; our Breakthrough T1D Facebook page in Spanish; culturally relevant Breakthrough T1D Community Summits; in-person Breakthrough T1D Community Summits with a Spanish track, meet and greets, and support groups in Spanish at the Chapter level; our popular educational "One Pager" documents; and our Clinical Trial connections tool, powered by Antidote.

By the Numbers: Community Engagement

Our community members and Chapters across the country are dedicated to increasing T1D awareness, providing support for people living with T1D—including newly diagnosed families—and raising funds to advance our mission.

Walk

76,640+ Walkers
11,570+ Teams

Ride

2,150+ Riders
5 Destination Events
1 Virtual Event

Gala

23,500+ Guests
60 Events

Golf

2,800+ Golfers
25 Events

Run

662 Participants
14 Events

Your Way

1,100+ Participants
900+ Events

Bag of Hope & Care Packs

26,800+ Distributed

Virtual Community Summits (English & Spanish)

66,500+ Viewers
10 Events

Community Summits (English & Spanish)

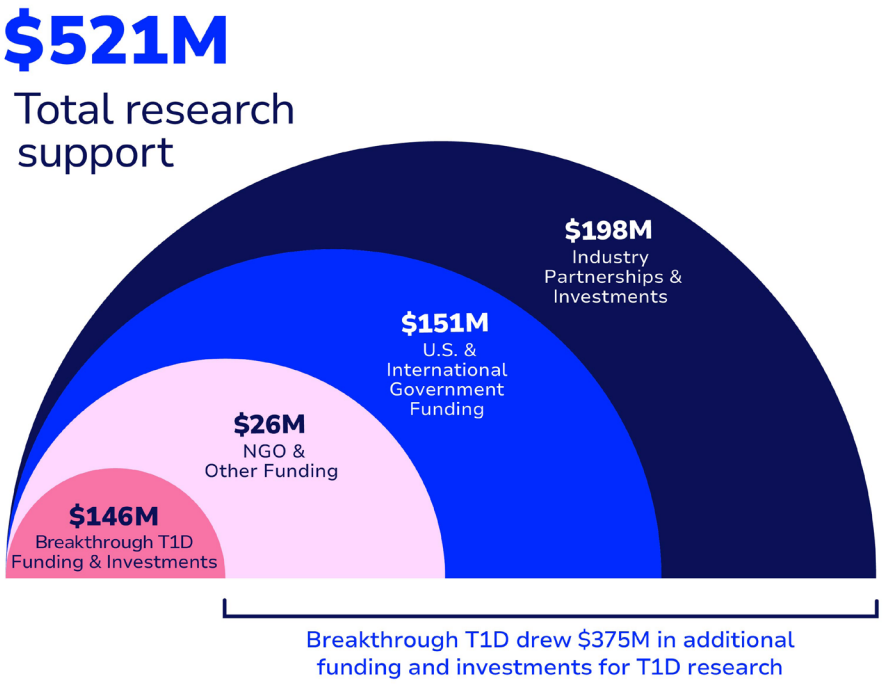
7,200+ Attendees
40+ Events

Play

96,100+ Game Bundles Sold
300+ Streaming Fundraiser Events

By the Numbers: 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.



Our Future Impact

This leverage will continue to be a key part of our strategy to accelerate as many breakthroughs as quickly as possible. As we expand our role as the leading global T1D organization, our leverage will increase and will empower us to more quickly grow global support of, and investment in, T1D research. It will also continue to directly engage more sources of capital in the investment and pharmaceutical sectors, which are essential to achieving our goal of driving cures while improving lives.

By the Numbers:
T1D Therapy Research and Development

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

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

22

Active Projects

400+

Early-Career Scientists Received New Funding

20

New Research Grants

130

Clinical Trials

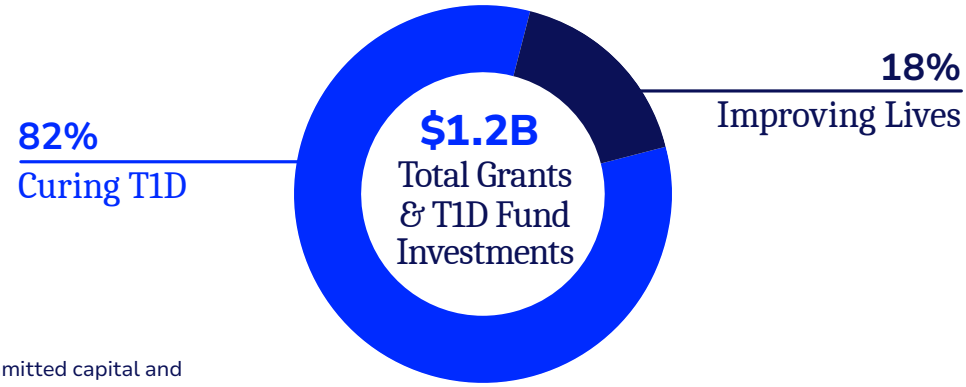
11

To New Clinical Trials

$18M

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.

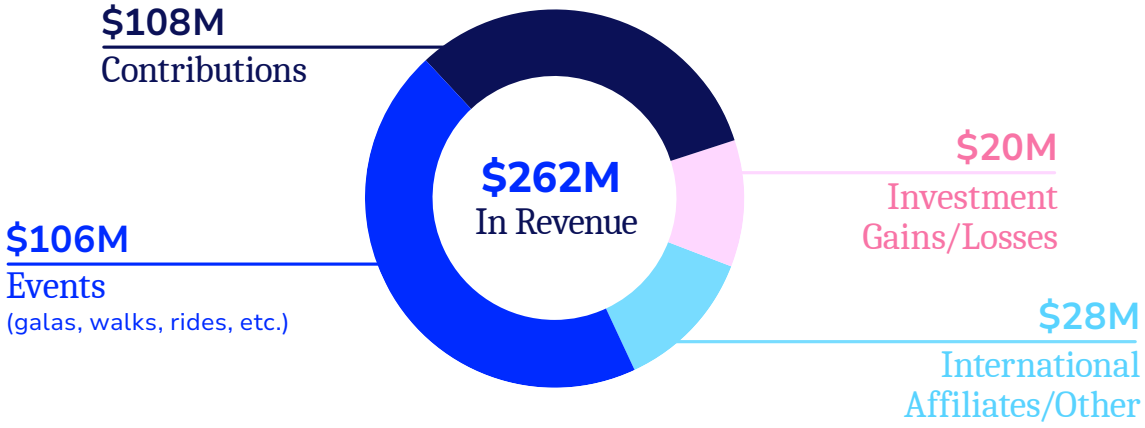


*This is committed capital and includes tranched financings that may not have capital deployed yet.

By the Numbers: FY24 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 FY24, we saw a 16% increase in our total revenue over that of FY23.



Our Future Revenue

To move as many cures and advanced therapies forward as quickly possible, we must raise more funds. Our fundraising strategy seeks to maximize revenue growth by tailoring our fundraising programs to our communities—empowering us to raise more funds, more efficiently.

Thank you for taking *breakthrough* action.

By the Numbers: FY24 Mission Spend

In FY24 we spent 7% more on advancing our mission than we did in FY23. This includes a 5.5% spending increase over FY23 for research funding and investments (grants, support, advocacy, and new T1D Fund investment), and a 12% spending increase over FY23 in public education/community engagement.

Our Future Mission Spend

Breakthrough T1D is driving a scientific revolution that is transforming the trajectory of T1D. We have ambitious goals to move more cures and advanced therapies forward, as quickly as possible. Increasingly, external challenges threaten our progress. Cures and other T1D advances are within reach. We cannot afford to lose momentum now. We must anticipate future opportunities and demands. We must rally more people to champion our cause. We must expand our influence. The more people we engage, the more we will amplify our voice, and the faster we will drive toward curing T1D while making everyday life better for the people who face it. The T1D community is relying on us. With your help, we will succeed.

No organization does more to *improve everyday life* with T1D.

By the Numbers: FY24 Local and Global Reach

29 Chapters

Supporting more than

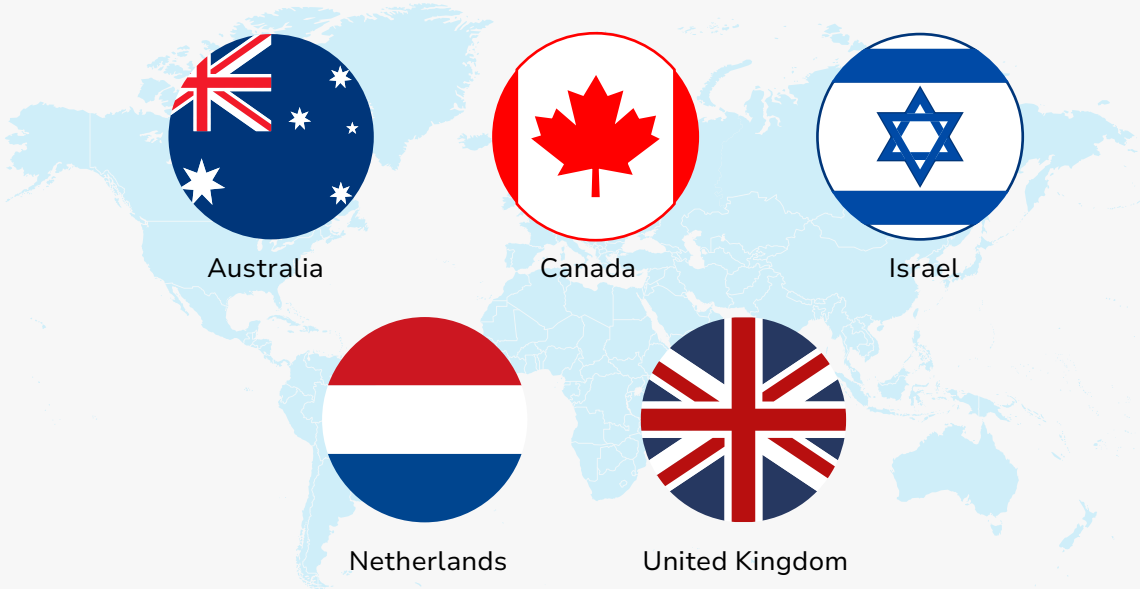
1 million people

Breakthrough T1D Chapters engage and support people with T1D and their loved ones in every major area of the United States. Our Chapters empower families through community connections, educational resources, events, and opportunities to volunteer.

Our global footprint includes five international affiliates and research in 22 countries, including research conducted at our Breakthrough T1D Centers of Excellence located in the United States, Canada, and Australia.

22 Countries

5 Affiliates



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

Through our robust community engagement and educational programs, Breakthrough T1D empowers members of the T1D community to live better lives.

Diamond Partners

Contributing more than $2,500,000 annually

Ford · Marshalls

Platinum Partners

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

Lilly · Medtronic · sanofi · VERTEX · Wawa

Gold Partners

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

Abbott · Elevance Health Foundation · Food City · novo nordisk · veradigm

Silver Partners

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

- Dexcom
- Hy-Vee
- Humble Bundle
- Tops Friendly Markets
- Transcarent

Bronze Partners

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

- Amphastar Pharmaceuticals
- Cencora Foundation
- Charitable Adult Rides & Services, Inc. (CARS)
- Delta Tau Delta Fraternity
- Embecta
- Floyd's 99 Barbershop
- Harris Teeter
- Insulet
- Kemper Foundation
- MannKind
- Nationwide Foundation
- Tandem Diabetes Care
- Traveler's Insurance
- Xeris Biopharma

IBOD Welcomes New Leaders

In March 2024, Breakthrough T1D announced that Lisa Fishbone Wallack would serve as Breakthrough T1D International Board of Directors (IBOD) Chair, succeeding current Chair Grant Beard, and Matt Varey would serve as Breakthrough T1D IBOD Vice Chair, succeeding current Vice Chair Michelle Griffin.

Lisa is an attorney by training and long-time Breakthrough T1D volunteer leader. She first became involved with Breakthrough T1D when her parents Marilyn and Dr. Gerald Fishbone were among the founders of Breakthrough T1D (then known as "JDF") after her brother Scott was diagnosed with T1D in 1969 at the age of 18 months. Lisa then increased her involvement after her son Harris was diagnosed in 2001 at the age of 5.

Matt, a senior executive at the Royal Bank of Canada (RBC), began volunteering with Breakthrough T1D Canada in 2001. He brings a global voice as the first Canadian and the first person outside of the U.S. to serve in the role. We thank Grant and Michelle for their amazing leadership and unstoppable commitment to the diabetes community. We look forward to Lisa and Matt building on their success.

Remembering Dedicated Riders

The entire Breakthrough T1D community mourned the tragic, sudden loss of five T1D Champions on Friday, Nov. 1, 2024.

That night, five people who were pillars of the Breakthrough T1D Ride community died in a tragic, single-car accident. Jeff and Michelle Bauer; Josh and Tammy Stahl; and Barry Sievers were all very close friends and veteran Breakthrough T1D Ride participants.

Chris Eaton, a lead volunteer partner of Breakthrough T1D Ride and the Ride Advisory Council, knew all five people well. "It's said, 'Ride is the greatest group of people you wish you didn't need to know.' Our friends embodied that feeling of inclusion, hope, and a steadfast focus on getting to a cure," said Chris. "They will be sorely missed by their family, friends, and the Ride community."

FY24 International Board of Directors

Grant Beard, Chair
Michelle Griffin, Vice Chair
Michael Alter
Elizabeth Caswell
Claudia Graham, Ph.D., MPH
Karen Jordan
Joseph (Joe) P. Lacher, Jr.
Carlton McMillan
Jeff Plumer
Jennifer Schneider, M.D.
Christopher H. Turner
Matt Varey
Drayton Virkler
Karey L. Witty
Lisa Fishbone Wallack
Observer: **David Panzirer**

FY24 Global Mission Board

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

Jennifer Bennett, Chair
Matthew Cohn, Chair-Elect
Jeff Adams
Randy Anderson
Carmen Ashley
Cathy Baier
Tim Clark
Meredith Coors
Jennie Costner
Laura Cramer
Maarten deGroot
Nanette DeTurk
Pam Edmonds
Cynthia Ford
Ian Joyce
Mark Kacher
Marshall Lang
Mike Lee
James Lurie, Esq.
Gwen Malone
Mike Norona
Dayton Ogden
Carol Oxenreiter
Margery Perry
Derek Rapp
Lisa Reed
Travis Rhodes
Kim Roosevelt
Brad Schur
Lorne Schiff
David Schwab
Michael Soper
Jerry Wisler

FY24 T1D Fund Board of Directors

Timothy Clark, Chair
Jay Eastman
Karen Jordan
Aaron J. Kowalski, Ph.D.
Ellen Leake
David Nelms
Amy Raskin
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 HQ
@BreakthroughT1DHQ
@BreakthroughT1D
Breakthrough T1D
@BreakthroughT1D
Breakthrough T1D

FY24 Financial Statement Summary

Total Public Support and Revenue for the year ended June 30, 2024 were as follows (in $thousands):

Public Support	
Contributions	107,128
Events revenue, net	106,152
Contributions from international affiliates	5,908
Total Public Support	**219,188**
Investment return, net	**20,430**
Change in value of split-interest agreements	**207**
Bad debt expense	**(1,228)**
Other income	**23,266**
Total Public Support and Revenue	**261,863**
Allocation of Expenses	
Mission program services:	
Research and advocacy, net[1]	127,832
Public education and outreach	51,084
Total mission program services	**178,916**
Mission support services:	
Management and general	17,752
Fundraising	41,305
Total mission support services	**59,057**
Total mission program services and support services	**237,973**

[1]Does not include T1D Fund investments of $17.84 million; total research expenditures in FY24 were $145.67 million

Breakthrough T1D™
Formerly JDRF

Statement of Financial Position

June 30, 2024 (in $thousands)

Assets	
Cash and cash equivalents	13,824
Investments:	
Operating and restricted investments	219,796
Long-term investments	89,308
Programmatic investments	60,189
Contributions receivable, net	63,369
Programmatic notes receivable, net	5,457
Prepaid expenses and other	11,341
Operating and finance lease right-of-use assets, net	17,173
Fixed assets, net	7,660
Total assets	**488,117**
Liabilities and Net Assets	
Liabilities:	
Accounts payable and accrued expenses	17,100
Research grants payable	113,596
Deferred revenue	4,696
Operating and finance lease liability	19,225
Liabilities related to split-interest agreements	2,430
Total liabilities	**157,047**
Net assets:	
Without donor restrictions	262,670
With donor restrictions	68,400
Total net assets	**331,070**
Total liabilities and net assets	**488,117**