



TREATMENTS TOWARD A CURE BY 2030



ANNUAL REPORT 2020



Vision

A world in which people with celiac disease can live healthy lives free from fear of gluten exposure — a world Beyond Celiac.

Mission

Beyond Celiac unites with patients and partners to drive diagnosis, advance research and accelerate the discovery of new treatments and a cure.



These are the real faces of celiac disease. To our community, a cure will mean treatment options so that we can live healthy lives and eat without fear. Beyond Celiac is dedicating our work to driving research for treatments beyond the gluten-free diet and toward a cure by 2030.

You can learn the stories behind these faces and many more who are part of the Beyond Celiac community at BeyondCeliac.org/voices-of-celiac.



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Alan Ehrlich, MD



Alice Bast

Letter from Board Chair and CEO: **TREATMENTS TOWARD A CURE BY 2030**

2020 was a year none of us expected. Just as a celiac disease diagnosis blindsides some people, the novel coronavirus SARS CoV-2 upended life for the entire world at the beginning of last year. While we at Beyond Celiac pivoted to address the unexpected and urgent needs of our community, including providing evidence-based information on the risk and impact of COVID-19 on people with celiac disease, we remained focused on our goal to accelerate treatments leading to a cure for our community by 2030. We were able to continue this critically important work, led by Salvo Alesci, MD, PhD, and Ken Kilgore, PhD, MBA, and informed by the new scientific strategy they developed, during these challenging times because of your continued interest and investment. Our research grant program provided ongoing support to Paul Klenerman, PhD, who is studying the role of CD8+ T cells in celiac disease at the University in Oxford; Marisa Stahl, MD, who is studying population screening at Children's Hospital Colorado; and Jocelyn Silvester, MD, who is performing RNA sequencing on celiac disease at Boston Children's Hospital. We continued to partner with researchers in order to increase clinical trial enrollment while prioritizing the patient experience, and forged new strategic partnerships, such as the one with the National Minority Quality Forum, with whom we are working to identify communities and places where celiac disease diagnoses are being missed.

Beyond Celiac is the only organization that has committed itself to achieve treatments toward a cure by 2030. It has the people, passion and strategic scientific plan to achieve this goal while providing unmatched support for the celiac disease and gluten-sensitive communities.

We are grateful for the many ways you support our work to drive treatments toward a cure. Despite the extraordinary circumstances we all experienced last year, you'll see in this report how we came together by funding research, running virtually with Step Beyond Celiac, celebrating virtually during An Evening Beyond Celiac, sharing our patient experiences to advance research in *Go Beyond Celiac*, fostering increased community participation in clinical trials, and launching a college intern program that has evolved into our broader ambassador program, Reach Beyond Celiac. You'll also learn about some of our 2021 initiatives. Together, we all — our community, our team, our Board, our ambassadors, our Scientific Advisory Board and other advisory councils — are changing the future of celiac disease for ourselves, our children and grandchildren. For being part of our community, and for all of the support you have shown us, we want to express our gratitude. Thank you!

To the health of all in our community,

Alice Bast, CEO

Alan Ehrlich, MD, Board Chair

SCIENTIFIC STRATEGY

Currently, the only treatment for celiac disease is the gluten-free diet. To Beyond Celiac, a cure means real treatment options so those with celiac disease can eat without fear.

SCIENTIFIC PRIORITIES

EVIDENCE GENERATION



Highlighting the seriousness of celiac disease

Collect, analyze and share data on the burden of celiac disease to make a compelling case for additional funding from government agencies, pharmaceutical companies, biotech and more.

Accelerating science toward a cure

Directly fund promising new research that translates quickly and bridges scientific investigation to clinical use to speed up development of celiac disease treatments.

TRANSLATIONAL RESEARCH



CLINICAL TRIALS



Enabling faster treatment approval

Actively recruit for celiac disease clinical trials and work with pharmaceutical companies to ensure trials are designed with the patient perspective in mind.

Leveraging existing solutions

Invest significant resources to identify treatments researched for other purposes that might also benefit celiac disease patients.

DRUG REPURPOSING



OUR SCIENCE & RESEARCH PLAN

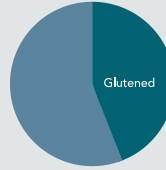
20% OF KIDS WITH
CELIAC DISEASE
are not healing on the gluten-free diet.



Celiac disease can lead to anemia, infertility, malnutrition, osteoporosis, and certain cancers



Celiac disease is associated with a higher risk of brain damage and mental health issues.



44% WITH CELIAC DISEASE
ARE “GLUTENED”
EACH MONTH

As self-reported by those with celiac disease.

KEYS TO SUCCESS



Diversified funding pools resources from a broad range of sources to invest in opportunities with the highest potential.



Strategic partnerships advance priorities, aid in overcoming challenges and maximize progress.



Targeted advocacy amplifies the patient voice, soliciting public funds into policies supporting treatment development and equitable access.



OUR SCIENCE TEAM



SALVATORE ALESCI, MD, PHD
Chief Scientist and
Strategy Officer

KEN KILGORE, PHD, MBA
Chief Scientific Investment
Officer



KATE AVERY, MPH
Director of Research & Patient
Engagement

AMY RATNER
Director of Scientific Affairs



And the Beyond Celiac Scientific Advisory Board

PATHWAYS TO TREATMENTS AND A CURE

To Beyond Celiac, a cure means real treatment options so those with celiac disease can live healthy lives and eat without fear.

Our mission advances the science of celiac disease because we firmly believe that with a strategic approach to funding focused research, an effective treatment or cure could be possible by 2030. To accomplish that goal, we are laser-focused and addressing the many barriers that currently exist.

Barriers to a Cure for Celiac Disease

- Celiac disease is poorly understood by the medical community
- Limited support for early career scholars/researchers
- Serious nature of the disease is underappreciated
- Too many people remain undiagnosed
- Lack of funding and strategic focus for research
- Assumption that the gluten-free diet is enough



Our Scientific Priorities

The large, diverse celiac disease community continues to suffer from high daily burdens in coping with the disease, and we need treatments and a cure. Beyond Celiac has crafted its science plan to change the future for the millions of Americans and their families living with this serious autoimmune disorder.

EVIDENCE GENERATION

Highlighting the seriousness of celiac disease

Through *Go Beyond Celiac* and other initiatives, we are collecting and analyzing comprehensive data on the burden of celiac disease and gluten sensitivity. With this information, we can increase awareness and make a compelling case for larger investments from government agencies, pharmaceutical companies, biotech and more.

How we're collecting and analyzing data:

■ **Patient Registry & Database:** We have built — and continue to expand — a patient database and registry called *Go Beyond Celiac*. The secure website and app collect self-reported data to learn more about life with celiac disease and help researchers better understand this serious autoimmune disease. With thousands of participants already enrolled, this rapidly expanding group has indicated a strong willingness to participate in research and clinical trials and to provide data that scientists need to make progress on a cure.

■ **NMQF Partnership:** We have formed a partnership with the National Minority Quality Forum to unearth and address health disparities across multiple populations in celiac disease diagnosis and treatment.

■ Research initiative to be launched later in 2021 focusing on the celiac disease gut-brain connection.

CLINICAL TRIALS

Enabling faster approval of treatments

Thanks to your support, Beyond Celiac is the nation's top recruiting partner for celiac disease clinical trials. As part of our important work in this space, we will continue educating the community about the importance of participating in trials and working with pharmaceutical companies to ensure trials are designed with patient perspectives in mind.

Beyond Celiac partnered with a record number of key biotechnology and pharmaceutical companies in 2020 to recruit patients for clinical trials of promising treatments for celiac disease. More information about our leadership in clinical trials recruitment can be found at beyondceliac.org/research/clinical-trials.

DRUG REPURPOSING

Leveraging existing solutions for our community

We will invest significant resources to identify treatments that have been investigated or approved for other purposes but might also benefit celiac disease patients, reducing risk, cost and time required to bring new treatments to market.

TRANSLATIONAL RESEARCH

Accelerating scientific progress toward a cure

We are funding promising research that quickly translates from scientific investigation to clinical use, speeding the development of treatments for patients.

To support our grant-making, our diversified funding strategy pools resources from multiple sources to invest in opportunities with the highest potential assets and increases the overall level of capital supporting celiac disease research.

In addition to funded research projects already underway, Beyond Celiac is embarking on several new initiatives highlighted at beyondceliac.org/scienceplan, including a research granting program with Janssen for up to \$1 million dollars.

2020 HIGHLIGHTS

2020 was a year of significant challenges for each of us, our families and our communities. The lightning speed of the development of COVID-19 vaccines demonstrates that nothing can be more transformative than scientific discovery.

Even during such a tumultuous year, your generosity allowed us to drive important scientific progress to move us closer to the post-pandemic world we all want — one in which we can live healthy lives, free from social stigma and fear of gluten exposure.

Here are some of the accomplishments your contributions supported in 2020:

CELIAC DISEASE SCIENCE & RESEARCH

Clinical Trial Recruitment


In 2020, despite COVID-19, many in our community participated in clinical trials to move celiac disease treatments forward. As the primary nonprofit organization leading clinical trial recruitment for celiac disease studies, Beyond Celiac was named the sole 2020 nonprofit partner for the only Phase 3 celiac disease clinical trial to date. The organization continued to be a vital bridge between the celiac disease community and researchers to power progress. Recent partnerships include:

■ Since 2018, Beyond Celiac has been assisting ImmunogenX recruit for two clinical trials for their drug candidate latiglutenase. COVID-19 interrupted study progress, and Beyond Celiac created a survey for them to better understand the community's thoughts and lifestyle changes due to the pandemic. As a result, ImmunogenX updated their study protocols to meet the needs of future trial participants. The Celiac Shield study released preliminary encouraging evidence in early 2021, followed by the launch of the Solutions for Celiac study, which Beyond Celiac is currently assisting through the recruitment of study participants.

■ Clinical trial recruitment for Provention Bio, Inc.'s Phase 2b PROACTIVE (PROvention Amgen Celiac ProtecTIV) study of PRV-015 (an anti-interleukin-15 monoclonal antibody). This novel approach is designed to block interleukin-15, a cytokine that plays a central role in celiac disease, creating inflammation and damaging the intestines.

■ Partnering with Kanyos Bio, a wholly-owned subsidiary of Anokion SA, to recruit patients for the ACeD (Assessment of KAN-101 in Celiac Disease) study. Currently in a Phase 1 clinical trial, KAN-101 has the potential to induce immune tolerance to gluten.

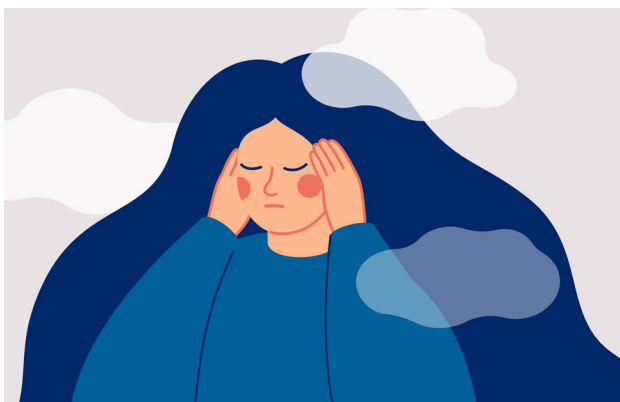
■ Exclusive 2020 recruitment partner for the 9 Meters Biopharma Phase 3 study of larazotide acetate, which aims to address leaky gut in celiac disease. Designed to tighten junctions between intestinal cells, larazotide acetate would act like shoelaces to help restore leaky junctions to a normal state.



Beyond Celiac
will partner on
additional clinical trial
recruitment efforts
throughout 2021.

Joint Research Funding with Janssen

Beyond Celiac proudly announced a two-year joint research grant program with Janssen Research & Development, LLC (Janssen) through its World Without Disease Accelerator group. Through a commitment of up to \$1 million in funds and services, Beyond Celiac and Janssen will co-fund research focusing on detecting, preventing, intercepting, and curing celiac disease. Emphasis will be placed on gaining an increased understanding of the gut microbiome, induction of immune tolerance and biomarkers of risk and progression.



Brain Fog Study

The "Brain Fog" study, research conducted by Beyond Celiac, Northeastern University and Takeda Pharmaceutical Company was published in 2021 in the *Journal of Gastroenterology*. This study details the analysis of nearly 500 open-ended survey responses in which those who have celiac disease and non-celiac gluten sensitivity described neurocognitive symptoms after gluten exposure. The responses were part of a larger survey of nearly 1,400 patients who reported difficulty concentrating, forgetfulness and grogginess, often one to four hours after being exposed to gluten. The portion of the survey in which patients described symptoms in their own words is the basis of the new analysis. Cognitive, psychological and quality-of-life symptoms were most commonly mentioned and emerged as themes.

National Minority Quality Forum (NMQF) Partnership

Beyond Celiac formed a multiyear partnership with NMQF to examine and address health inequities in the diagnosis and treatment of celiac disease. NMQF is a research and education organization dedicated to ensuring that high-risk racial and ethnic populations and communities receive optimal healthcare.

ADVOCACY, AWARENESS, COMMUNITY SUPPORT & ENGAGEMENT



Advocacy

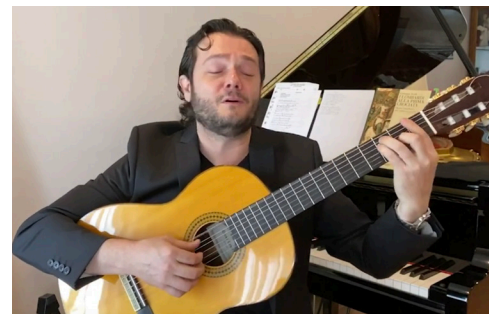
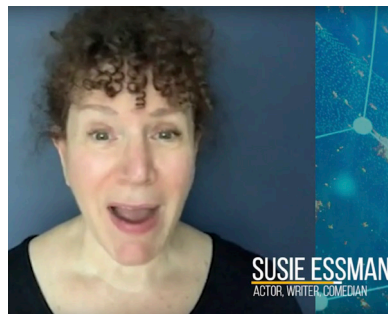
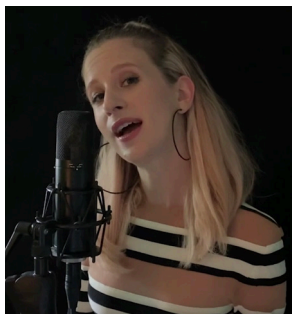
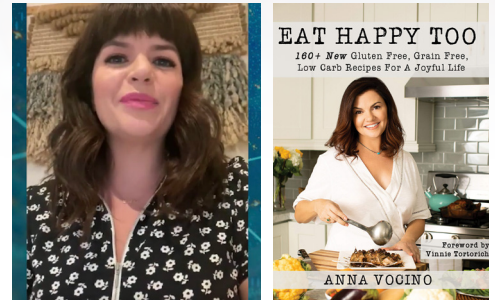
As the leading celiac disease organization accelerating discovery, development and access to new treatments and a cure, Beyond Celiac focuses our advocacy efforts on maximizing investment of public funds in research and public policy supporting these desired outcomes. Beyond Celiac continues to be a leader in supporting legislation that, if passed, will enhance the health and well-being of our community. Recent efforts include:

- Urging Congress to support the Gluten in Medicine Disclosure Act of 2019 (HR2074/S3021) which sought to secure labeling of gluten in medication.
- Advocating for increased federal funding to advance research in the field of digestive diseases.
- Encouraging legislative support for the Safe Step Act (HR 2279 / S. 2546) to remove fail-first protocols and let our doctors decide what medicines to prescribe.
- Participating, developing and signing on to numerous joint initiatives with our advocacy partners.



Summer Intern Council

With schools closed and many service jobs on hiatus, young people were doubly hit with the impact of COVID-19, so a generous donor helped us create the Summer Intern Council to engage younger members of our community, provide them with paid internships for the summer and help them gain new insight and perspective into the celiac disease community. Seven interns from around the country engaged with the Beyond Celiac staff, provided input and support on several projects, created videos, hosted an Instagram takeover and more. Two of the summer interns continued their internship into the school year.



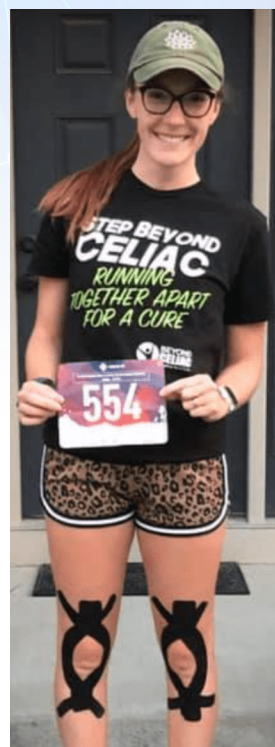
Top left: The Beyond Celiac 2020 Virtual Gala featured discussion about the challenges of living with celiac disease and the importance of driving research for treatments toward a cure. CEO Alice Bast, Chief Science & Strategy Officer Salvo Alesci, MD, Chief Scientific Investment Officer Ken Kilgore, PhD; Beyond Celiac Board Chair Alan Ehrlich, MD. Top right: Diana Rocco, television reporter for ABC7 in New York, hosted the 2020 Beyond Celiac Virtual Gala. Diana also has celiac disease. Inset left: Actor and comedian Casey Wilson, whose son has celiac disease, welcomed the live audience. Inset right: Comedian and cookbook author Anna Vocino demonstrated a fast and elegant gluten-free salmon recipe. Bottom row, left to right: Ritu Verma, MD, answered audience questions about pediatric celiac disease; Samantha Gongol from pop band Marian Hill performed their hit single "Down"; actor and comedian Susie Essman gave a shout out to Barb Powers, the evening's honoree; internationally renowned opera tenor Arturo Chacón-Cruz shared his music.

A Virtual Evening Beyond Celiac

Participants from every state in the US joined us for the biggest night of the year in celiac disease with a virtual night of science and fun, featuring world-renowned performers and key discussions with scientists about driving treatments toward a cure for celiac disease by 2030. Led by news reporter Diana Rocco, our audience was entertained and informed by Grammy-nominated duo Marian Hill, internationally-renowned opera singer Arturo Chacón-Cruz, nationally-recognized wellness expert Mark Hyman, MD, and the head of the University of Chicago Celiac Disease Center Ritu Verma, MD. Plus, the leaders of the Beyond Celiac science team — Alice Bast, Alan Ehrlich, MD, Salvo Alesci, MD, and Ken Kilgore, PhD — highlighted the need for treatments beyond the gluten-free diet and our resolve to drive treatments toward a cure by 2030.

Barb Powers, secretary of the Beyond Celiac Board of Directors and long-time supporter of the organization, was the recipient of the 2020 Samuel Gee Award, presented at the virtual gala. Barb has devoted more than a decade of volunteer service to Beyond Celiac, including serving as secretary on the Board of Directors since 2014. Barb and her husband Bruce have a daughter with celiac disease and understand all too well how serious this autoimmune disease can be. In addition to working to increase the availability of safe gluten-free options in schools and universities, Barb has dedicated herself to Beyond Celiac research efforts for treatments and a cure.

2020 HIGHLIGHTS



Step Beyond Celiac 5Ks all Virtual

Beyond Celiac took its entire 2020 Step Beyond Celiac 5K series to the virtual streets with a multi-city tour for individuals and teams across the country to support Beyond Celiac research initiatives. Five event dates between August and October had participants running or walking 3.1 miles right where they were to bring us that many steps closer to treatments toward a cure.

Public Service Announcement

In partnership with Comcast, Beyond Celiac produced a 30-second public service announcement that aired 84,828 times around the country on Comcast channels and also reached more than 20,000 people online.



Monthly eNewsletters

Beyond Celiac covered findings from more than 30 research initiatives of interest to the celiac disease and gluten sensitive community for our Research News updates. The top five stories of the year were about long-term impact of celiac disease on the brain, progress of latiglutenase in clinical trials, a study on the usefulness of probiotics for people with celiac disease, the impact of COVID-19 on our community, and the amount of inadvertent gluten getting into the diet of people with celiac disease. Nearly 30,000 people have enrolled to receive regular research news updates. In addition, 36,000 people receive our monthly newsletter, chock-full of news, recipes, the latest in research and opportunities to learn more and get involved.

COVID-19 Resource Hub

As soon as the pandemic hit, our science team began providing updated, evidence-based information and guidance about the novel coronavirus and how it affects our community. Responses to a new survey about COVID-19 and celiac disease helped us learn our community's experiences and share results about the impact of the health crisis on families coping with celiac disease.



NEW IN 2021



Launch of the Reach Beyond Celiac Ambassador Program

The Reach Beyond Celiac Ambassador Program, a network of community ambassadors located throughout the country, has been designed to empower the celiac disease community by providing outlets to share their experiences, spread positivity

and create change in their communities. Ambassadors tailor the program to their unique passions and skills — using tools and resources provided by Beyond Celiac. They work individually, collaboratively, in-person, and remotely to extend the reach and message of Beyond Celiac and share our information and resources to newly diagnosed community members as well as celiac disease veterans.

Launch of the Town Hall Series

Beyond Celiac has premiered a new Virtual Town Hall series including interviews with top doctors, scientists and other professionals in the celiac disease field. By hosting these conversations via a live Zoom event open to the public, Beyond Celiac is delving deeper into the research and medical topics our community wants to learn more about and connecting them with the people making advancements happen. The first town hall was held in March 2021. The topic was a holistic approach to pediatric celiac disease management with doctors from the Children's Hospital of Philadelphia.

Recordings of past town halls can be watched here:

beyondceliac.org/town-halls



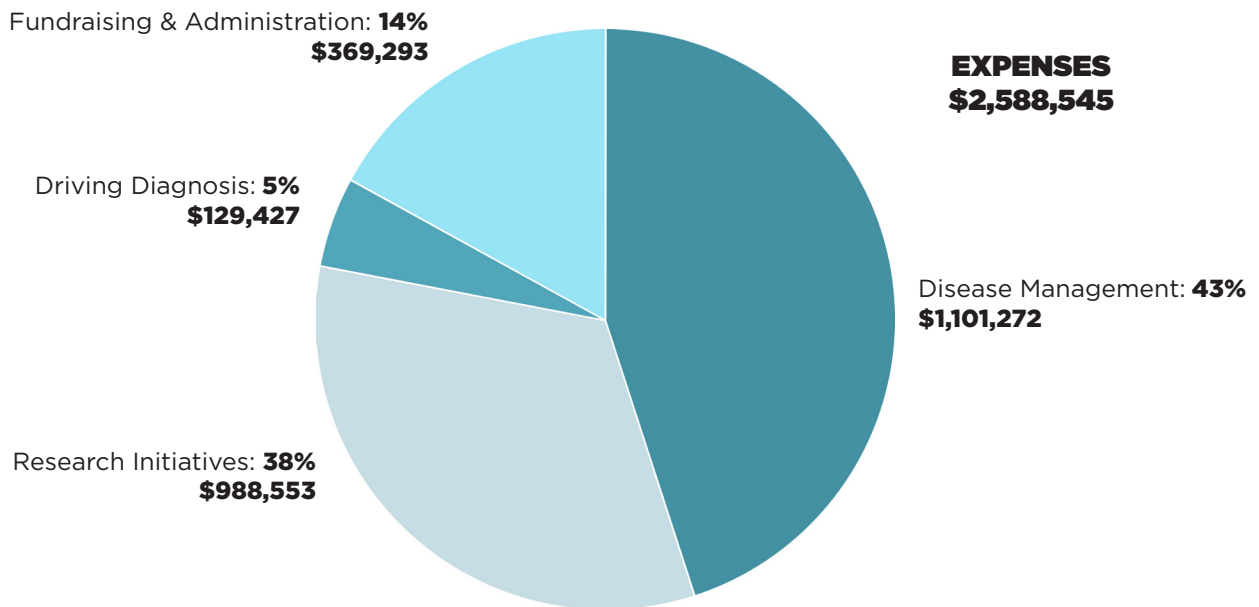
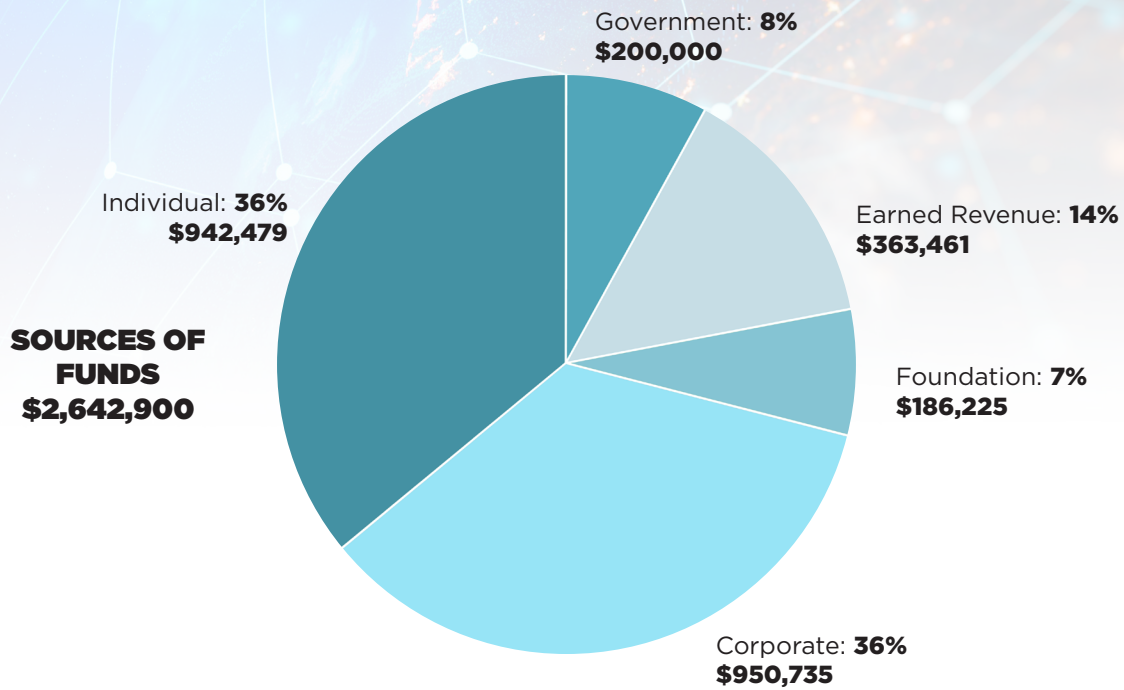
Coming in November

Celiac Disease, Hidden in Plain Sight: a Beyond Celiac Mini-Conference. Were you one of the many in our community who lived with celiac disease for years before getting a diagnosis? Join us in November (time and date TBD) for a virtual dive into why doctors might miss the signs and symptoms of celiac disease and how it could affect how quickly research can advance.

JOIN US!



THE 2021 BEYOND CELIAC BENEFIT WILL TAKE PLACE ON
OCTOBER 28 AT VUE ON 50 IN CENTER CITY PHILADELPHIA.



In fiscal year 2020 Beyond Celiac combined \$2,642,900 in new operational revenue and funds raised, investments income and cash covering expenses of \$2,588,545. Included in corporate support is \$764,033 in gifts in kind. We thank our generous donors and sponsors for supporting our aggressive research agenda geared to accelerate the discovery of new treatments toward a cure.

BEYOND CELIAC BOARD OF DIRECTORS & ADVISORY BOARD



Paula and Rich Mandel were the co-chairs of the virtual gala.

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Donald McGowan

Alison Clabaugh Seiferth

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2021 REACH BEYOND CELIAC AMBASSADORS

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