



# Beyond Celiac Investments Case for Support







# BEYOND CELIAC INVESTMENTS CASE FOR SUPPORT

## EXECUTIVE SUMMARY

- There is a significant opportunity now to invest in companies with potential treatments for celiac disease that need the funding to accelerate a cure.
- Beyond Celiac launched a venture philanthropy program called Beyond Celiac Investments (BCI) in 2024 to direct capital toward the most promising investment opportunities among these companies. Donors can make contributions to Beyond Celiac to support the initiative.
- BCI is the first-ever investment program with a specific focus on celiac disease and autoimmune disorders.
- When there are gains from the investments BCI makes, the dollars will flow back to the organization to support both Beyond Celiac operations and future BCI investments.
- Our internal resources, network of partner organizations, dedicated venture capital advisors, patient community connections, and proven track record in supporting scientific research and clinical trials all make Beyond Celiac the ideal organization to select the most promising investment target companies; attract other investors to follow our lead and multiply the impact of our capital commitments; and accelerate the scientific, regulatory, and business progress of those companies toward treatments and a cure.
- As a program of Beyond Celiac, BCI is overseen by the Beyond Celiac Board of Directors and is integrated into the organization's comprehensive science plan.

# AN URGENT OPPORTUNITY:

## Targeted Investments to Advance Treatments and a Cure

### **THROUGHOUT ITS PRODUCTIVE 22-YEAR HISTORY, BEYOND CELIAC HAS FOCUSED ON AREAS OF HIGHEST NEED FOR THE CELIAC COMMUNITY.**

When there was limited awareness of this serious autoimmune condition, we drove increased understanding and diagnosis. When there were few offerings of gluten-free food readily available, we partnered with food companies and distributors to address the issues of accessibility and affordability. When breakthrough treatments were not emerging quickly enough, we expanded our support for scientific discovery by directly funding research, established internal expertise in clinical trial design and execution, and built an extensive set of capabilities to help recruit for clinical trials.

Now BCI is targeting the biggest opportunity of all. We desperately need treatments and a cure—leading to a world where people with celiac disease no longer need to fear

gluten exposure and its associated short- and long-term health risks. These risks can include intestinal issues, infertility, migraines, related autoimmune conditions, and increased risk of certain cancers. There are more than 90 companies across seven different therapeutic focus areas that have compounds or platforms applicable to the treatment of celiac disease. Limited funding is the primary impediment to progress; these companies need the financial resources to complete their work. BCI is uniquely positioned to provide the financial, scientific, and business expertise, as well as a network of aligned commercial investors, that accelerate development of treatments and a cure.

The addressable market is potentially \$75 billion, with celiac disease affecting more than 80 million people worldwide. The work that startups and biotechs are doing in this field is particularly important now, as the FDA has recently formally recognized celiac disease as a serious condition with an unmet medical need. That recognition means drugs submitted

for review will receive an FDA Fast Track designation for expedited consideration.

Every investor looks for an appropriate return on investment, and the societal and financial benefits of investing in celiac disease treatments are enormous. According to the National Institutes of Health, about 8% of the US population—or more than 27 million people—are living with at least one autoimmune disease. In many cases these conditions are chronic and often debilitating, costing families, workplaces and the economy enormous sums, with some estimates approaching \$200 billion per year. Celiac disease is particularly important, as it is the only autoimmune condition with a known trigger, and unlocking celiac disease could lead to progress across the entire autoimmune spectrum. By donating to the work of BCI, investors can make a meaningful difference in the lives of millions of Americans and leverage the scientific work in celiac disease across a range of other diseases as well.







# THE VENTURE PHILANTHROPY MODEL OF BEYOND CELIAC INVESTMENTS

A venture philanthropy program invests nonprofit donations into for-profit companies to generate both social outcomes—in our case, treatments leading to a cure for celiac disease—and financial returns. These programs are particularly valuable in disease areas that are not receiving adequate market attention or funding because they invest early and enable companies to demonstrate the market potential of their therapeutics.

Some of the skill sets required for an operation such as BCI are similar to those in traditional venture investing, but there are key differences: (1) the profit motive does not have to be paramount, provided an investment moves potential treatments forward; (2) we leverage all of the Beyond Celiac team's expertise and the donated time of scientists, experts and professional investors to identify the most attractive assets and attract additional funding; (3) profits earned funnel back to Beyond Celiac to fund additional investments

and serve our patient community; and (4) investments can be made earlier in the development of a company than commercial investors otherwise would, accelerating novel approaches and therapies.

Specialized knowledge, like that of Beyond Celiac and BCI, leads to insightful selection and support of the companies in which we invest. Other investors, in turn, value that specialized knowledge and may be more likely to put capital to work in those companies alongside BCI. Similar to venture capital, the success rate of investments in venture philanthropy is generally not high, with only a few winners. Those few, however, can be transformational in their impact.

Beyond Celiac is not the first organization to create a venture philanthropy operation. The legal and tax framework is well-established. BCI's approach has been directly informed by the best-in-class operations of our peers, including

the Cystic Fibrosis Foundation, whose program has extended patient life expectancy by decades, and networks of support through the Milken Institute FasterCures TRAIN programs. Since we are working with donations, securities restrictions regarding investor participation do not apply, and anyone can support the program.

Here's the secret sauce: because of the deep expertise and rigorous due diligence the Beyond Celiac team brings to any investment BCI makes, our sponsorship serves as a seal of approval that attracts significant attention from potential investors. We can focus on moving the most promising science forward, whether it is in late stages of development or on the edges of emerging science. Our approach enables us to shine a light on new, potentially transformative treatments to accelerate the race for a cure.

# HOW DONORS CAN MULTIPLY THE IMPACT OF THEIR DOLLARS WITH BCI

WITH BCI, DONORS TO BEYOND CELIAC CAN MAKE THEIR DOLLARS GO FURTHER IN ACCELERATING TREATMENTS AND A CURE FOR CELIAC DISEASE. ANY PROFITS FROM BCI INVESTMENTS RETURN TO BEYOND CELIAC TO BE REALLOCATED TOWARD OTHER MEANINGFUL OPPORTUNITIES. DONORS SUPPORTING BOTH BEYOND CELIAC AND BCI HELP CREATE A CYCLE OF INVESTMENT THAT WILL BENEFIT EVERYONE IN THE CELIAC COMMUNITY.

BCI is uniquely positioned to be successful in venture philanthropy:

- Beyond Celiac has a 22-year history serving as the trusted voice of the community, an expert Scientific Advisory Board, connections to 250,000 representatives of the celiac community, and relationships with the key researchers working globally in the field today.
- BCI has recruited a deep pool of venture investing talent to supplement our already strong team of both internal and advisory scientific and investment expertise.
- Beyond Celiac has a broad network of the top pharmaceutical companies working in celiac

disease and with the FDA. Our knowledge and experience in the areas of drug development, clinical trial design, and clinical trial recruitment can provide a real benefit to companies with promising drug assets.

- Because we understand that celiac disease is the only autoimmune condition with a known trigger (the ingestion of gluten), we can encourage platform autoimmune solutions to focus first on celiac disease.
- The reputation, expertise, depth of knowledge, and connections that Beyond Celiac brings to the process mean that companies want our support, other investors value

our investment opinions, and our BCI team can “de-risk” our venture philanthropy investments through our unique due diligence process.

- BCI is an integrated part of the Beyond Celiac Strategic Science Plan. This structure provides ultimate flexibility to funnel unrestricted donor dollars where they will do the most good in advancing a cure while also enabling donors to designate their funds to BCI. This integrated approach also gives BCI access to the Beyond Celiac team’s knowledge of clinical trial design and recruitment services, relationship with the FDA, latest scientific research, and engagement with the community.

## ROLES IN DRUG DEVELOPMENT PROGRESSION

BASIC RESEARCH



Beyond Celiac

DISCOVERY



DEVELOPMENT & REGULATORY



COMMERCIALIZATION



Beyond Celiac Investments

DONORS WHO WANT THEIR DOLLARS TO GO AS FAR AS POSSIBLE TOWARD ADVANCING A CURE WILL FIND NO BETTER OUTLET THAN BEYOND CELIAC AND BCI FOR THEIR COMMITMENTS.

# THE INVESTMENT PHILOSOPHY, GOVERNANCE AND STRUCTURE OF BCI

BCI serves as a value-added “scout” investor, identifying, improving, and championing the most promising assets and emerging companies in celiac disease. We provide specialized expertise in celiac disease science, regulatory processes, clinical trial design and recruitment, and syndicate building. Because we intentionally serve in that scout investor role, our due diligence and initial investment are designed to create a seal of approval, “scouting” the best assets to attract additional capital to complete funding rounds as needed.

## OUR SEVEN KEY INVESTMENT AND OPERATING PHILOSOPHIES ARE:

- 1** We prioritize meaningful advances toward a cure over financial returns, yet we will always be good stewards of donor money.
- 2** We take our scout investor role seriously and always work to multiply our impact and the assistance we can deliver to investee companies.
- 3** We will build a portfolio of companies and assets diversified by funding stage and therapeutic pathway—both in individual assets and platform companies—investing in multiple opportunities each year at an initial targeted range of \$250,000–\$350,000 per investment. From a current universe of 90 companies working in celiac disease or autoimmune therapies, our immediate pipeline of investment opportunities includes nine companies designated as high priority for their scientific approach and progress. These nine also show a higher likelihood of an investment round in 2025. In addition, there are 16 companies in the next round that have scientific promise and are likely to raise capital beyond 2025.
- 4** We use internal and external resources to execute a thorough due diligence process for each potential investment focused on promising science, the operating skill of the companies’ management teams, the strength of the related investor syndicates, and the amount of capital needed to ensure companies successfully meet their next milestones.
- 5** BCI operates with a partnership orientation, working with other investors, companies, advisors and scientists to build not only individual assets, but also the broader ecosystem of celiac disease treatment development. BCI has established relationships with 16 biopharmaceutical venture capital firms thus far, starting with those that have invested in companies with celiac disease and/or autoimmune therapies, and will continue to grow that network into the future. For its first investments, BCI primarily focuses on companies where our identification and investment attracts other capital.
- 6** BCI is transparent with donors—reporting regularly on both our successes and on investments where we have learned significant lessons for the future—and accountable to those who rely on us.
- 7** While we move with a sense of urgency, we also have the patience of a long-term investor. We support the growth over time of the companies and assets in which we invest.

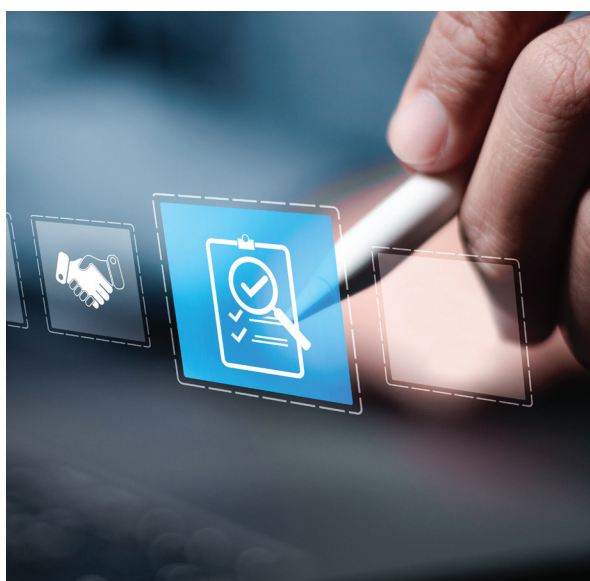
# INVESTMENT CRITERIA

BCI prioritizes investment in companies with celiac drug assets or broader autoimmune platforms that could be applicable to celiac disease. Within therapeutics, BCI seeks opportunities to:

- Re-energize existing clinical and preclinical celiac disease drug candidates that are stalled because of lack of funding or corporate de-prioritization.
- Accelerate assets that are on the leading edge of celiac disease science and reflect novel approaches to treatment.
- Expand the application of drugs already in development that are not currently focused on celiac disease.
- Repurpose or reposition existing drugs where the potential for application to celiac disease is particularly compelling.

Primary drug pathways currently under consideration are outlined in the appendix on page 11. Investment decisions will be made based on: analysis of the attractiveness and differentiation of the science; the strength of the management team; and the engagement and resources of the investment syndicates involved with BCI participation, all contingent on funding rounds being adequate to get the asset or company to its next inflection point.

BCI sources investments by reviewing scientific and investment databases, monitoring newsfeeds, and interacting with top scientists in the field. In addition, the team acquires direct knowledge of companies and drugs through Beyond Celiac staff, the extensive Beyond Celiac network (particularly leading venture capital firms with which BCI has established relationships), in-bound inquiries from BCI marketing, and presence at conferences and speaking engagements.



## GOVERNANCE AND OVERSIGHT

Nothing matters more than strong governance for a nonprofit organization. There are multiple layers of accountable governance for BCI. First, a BCI Advisory Committee, initially consisting of four designated Beyond Celiac Board members, oversees the BCI Operational Team and Investment Committee. That Advisory Committee, in turn, is accountable to the full Beyond Celiac Board of Directors. The BCI Investment Committee, as described above, is responsible for BCI investment decisions. The Beyond Celiac endowment is managed separately and with Board oversight to align with the organization's core investment policy statement.

By reporting to the full Board, BCI operates like any other program at Beyond Celiac and is accountable for results in alignment with the organization's mission, vision and values.



# INVESTMENT COMMITTEE

BCI's investment committee and core advisors consist of the following:



**ALICE BAST\***  
*Founder and  
Chief Executive Officer  
Beyond Celiac*



**JORDAN DUBOW\***  
*MD, Chief Medical Officer  
Beyond Celiac*



**DEBRA SILBERG\***  
*MD, PhD, FACG,  
Chief Scientific Officer  
Beyond Celiac*



**ERIC WHITE\***  
*Director, Investments &  
Strategic Alliances  
Beyond Celiac*



**ALTHEA STILLMAN\***  
*PhD, Biopharma Venture  
Capitalist*



**NISH RASTOGI\***  
*Biopharma Venture  
Capitalist*



**TURNER JENKINS\***  
*Biopharma Executive*



**ISABELLA CARDONA**  
*Special Advisor  
Biopharma and Patient  
Expertise*



**ELLA DETRIZIO**  
*JD, Special Advisor  
Venture Capital  
Transaction Law*

\*Voting Member

**BCI ADVISORY COMMITTEE** 4 members representing the Beyond Celiac Board  
**SCIENTIFIC ADVISORY BOARD** 11 members representing academics, hospital systems, pharmaceuticals

The investment process is overseen by Eric White, Director, Investments & Strategic Alliances. Eric has deep venture investment experience working on behalf of both for-profit and nonprofit firms. He works most closely with Chief Medical Officer Jordan Dubow, MD, who has served as the Chief Medical Officer with 10 companies resulting in 17 drug approvals. Jordan has also served as a consultant for nearly 200 biopharmaceutical start-ups. The full investment committee supplements these skills with expertise in venture investing, celiac disease, medicine, scientific research, biotechnology operations and commercialization and transaction law. In addition, the Scientific Advisory Board of Beyond Celiac, which also supports BCI's efforts, represents the best current thinking in celiac disease treatment and research and is available as a further resource to BCI.

# FINANCIALS

There is a significant advantage in the way BCI will be financed. Because BCI operates as a program of Beyond Celiac, there is meaningful shared expense and overhead provided that prevents duplication of costs and allows BCI to focus resources primarily on investments. Aside from paying direct investment-related expenses, BCI benefits from the donated time of outside experts, salaries supported by Beyond Celiac operations, and other services provided by Beyond Celiac, such as accounting.

Because of this unique set-up and BCI's positioning as a part of the overall Beyond Celiac Science Plan, donors are encouraged to make unrestricted contributions to Beyond Celiac whenever possible. This approach allows the organization to allocate capital to its highest and best use in the advancement of treatments and a cure. Donors who wish to restrict their gifts to BCI, however, may also make that election.

Initial fundraising has focused on Board members of Beyond Celiac and other major donors, generating large, sometimes multi-year commitments. Through the end of calendar year 2024, BCI has raised more than \$2 million. Following this initial investment into BCI, we will target raising at least \$2 million in each subsequent year of operations and will report on operations and progress on an interim basis as well as annually. BCI intends to raise and invest at least \$10 million before the end of 2030. The sooner we exceed that goal, the greater the acceleration of treatments and a cure for our community.

# A STRONG FOCUS ON EXECUTION

NO NEW INITIATIVE SEEKING TRANSFORMATIONAL CHANGE IS WITHOUT CHALLENGES, AND ANY FORM OF VENTURE INVESTMENT HAS FEWER (ALTHOUGH SOMETIMES LARGER) SUCCESSES RELATIVE TO THE NUMBER OF INVESTMENTS MADE AS COMPARED TO OTHER TYPES OF INVESTMENT. BELOW IS AN OVERVIEW OF THE MAJOR WAYS BCI IS FOCUSING ON SUPERIOR EXECUTION TO INCREASE THE LIKELIHOOD OF SUCCESS FOR OUR EFFORTS.

**1. MAINTAINING SUPERIOR CAPITAL ALLOCATION.** It is important to weigh the opportunity set for investments effectively, and our experienced investment committee is set up to do just that. Our deep bench of scientific and biotech expertise can de-risk investments through our extensive due diligence process. In addition, we are always careful to size our investments appropriately, considering our aggregate resources, the capital we are able to attract from other sources, and the preservation of funds to participate in additional funding rounds. Our ultimate framework for decision-making will be to evaluate the potential a particular use of funds has to move us closer to treatments and a cure.

**2. PROTECTING THE REPUTATION OF BEYOND CELIAC AND BCI.** One of our filters for investment involves evaluation of not only the scientific approach of companies, but also the way their management leads. As Beyond Celiac has done for 22 years, BCI will be protective of the reputation of our operation as well as those of our associates and network. We are trusted by our extended community, and we will continue to earn that trust.

**3. PAYING ATTENTION TO THE DETAILS OF FUND OPERATIONS.** BCI has a highly qualified, motivated staff focused on making investments to drive treatments and a cure for celiac disease. For some members of our team, this effort is highly personal. Their energy and drive include a focus on the details necessary to

conduct our investment operations with rigor and appropriate oversight. In addition, a sub-committee of the Beyond Celiac Board of Directors will hold the team accountable for performance. Beyond Celiac also maintains insurance to protect the organization against any potential liability related to BCI, and BCI will gather external guidance on any associated legal, trading, contractual or partnership risks.

**4. ENSURING THE ONGOING 501(C)(3) STATUS OF BEYOND CELIAC.** The nonprofit status of Beyond Celiac has always been critical to our success and will continue to be so. Beyond Celiac has engaged outside counsel on all matters related to maintaining the nonprofit status of Beyond Celiac—including such details as the structure of investments, contracts and payments. Beyond Celiac will continue to be a nonprofit entity.

**5. SECURING SUSTAINABLE FUNDING TO SUPPORT A LONG-TERM EFFORT.** Your commitment to this important effort will help us fund drug developments leading to a cure for celiac disease. We have had a successful fundraising start during our foundational year, and we need to repeat and expand that initial success annually in 2025 and beyond. The more funding we can raise, the faster we can accelerate investments in companies with promising science that can create the breakthrough we all need.





# MAKE AN IMPACT NOW ON THIS IMPORTANT WORK

How can you help drive this vital effort?

Reach out today to learn more and make a BCI donation by contacting Eric White, Director, Investments and Strategic Alliances, via email at: [investments@beyondceliac.org](mailto:investments@beyondceliac.org) or by phone at 215-325-1306 (toll free 844-856-6692)

## APPENDIX: THERAPEUTIC TARGET AREAS FOR INVESTMENT

### IMMUNE TOLERANCE

Celiac disease is the only autoimmune condition with a known trigger: the protein gluten, found in wheat, barley and rye. Treatments that create immune tolerance would lessen or fully prevent the immune system from reacting to gluten.

### MICROBIOME

The microbiome refers to the community of microorganisms that live within all multicellular organisms; in the context of celiac disease, we often speak of the gut microbiome in particular. Research studies have shown that adjustments to the gut microbiome could impact multiple reactions in the human body, including immune responses to gluten.

### CYTOKINE INHIBITORS

Cytokines are signaling molecules. They are small proteins secreted by immune cells that help regulate immune reactions and inflammatory responses in the body. Targeted inhibition of their activity might create a pathway to stopping the inflammatory response to the ingestion of gluten in celiac disease patients.

### EPITHELIAL BARRIER MODULATORS

The epithelium of the gastrointestinal tract is a barrier made up of epithelial cells that line the intestine and tight junctions between the cells. These prevent harmful substances from passing into the body. When this barrier

is insufficient or "leaky," substances such as gluten may be able to pass through and come into contact with immune reactive cells in the body. Repairing the epithelial barrier in the gut might result in new therapies to treat celiac disease.

### T-CELL ACTIVATION BLOCKERS

T-cells are a type of white blood cell that helps the immune system in the human body fight disease and protect against germs. For those with celiac disease, any signal that causes it to fight gluten as a foreign substance can create unhealthy responses. Blocking the activation of these cells when gluten is ingested could hold promise as a way to treat celiac disease.

### TRANSGLUTAMINASE INHIBITORS

Transglutaminase is a naturally occurring enzyme found in nature and in many foods. It speeds up the linking of protein molecules and is believed to have some adverse effects related to those with celiac disease. Mitigation of transglutaminase could be another pathway toward effective treatments.

### GLUTENASES

Glutenases are enzymes that break down gluten proteins and aid in the digestion of gluten. By breaking down gluten proteins into smaller parts before they are able to stimulate the immune response, these enzymes may reduce the reaction to gluten in those with celiac disease.



P.O. Box 544  
Ambler, PA 19002-0544  
215-325-1306  
Toll Free 844-856-6692  
[info@BeyondCeliac.org](mailto:info@BeyondCeliac.org)

[BeyondCeliac.org](http://BeyondCeliac.org)

