Solely focused on one goal: a cure
“Our generous donors are Making Progress Possible, enabling us to expand upon groundbreaking initiatives, explore the newest frontiers of science and help us reach the most exciting time in our history by developing the DRI BioHub.”
What they saw and felt during their visit – an overwhelming connection in a place that cares about people with diabetes – inspired their growing involvement and generous support of our efforts to cure this disease. From that initial phone call and tour, Susan and Mitchell have since attended many events, served as a sponsor and rallied others to support our research. They have also undertaken a significant fund-raising initiative on our behalf and have committed to other event leadership roles.

The Rubinsteins, like all of our generous donors, are Making Progress Possible, enabling us to expand upon groundbreaking initiatives, explore the newest frontiers of science and help us reach the most exciting time in our history.

This past year, in a roll-out comprised of several phases, we unveiled the DRI BioHub, a bioengineered “mini organ” that mimics the native pancreas, containing thousands of insulin-producing cells that sense blood sugar and release the precise amount of insulin needed in real time.

The BioHub is the evolution of the DRI’s success with islet cell transplantation, which has established proof-of-concept that cell replacement therapy can allow patients with diabetes to live without the need for insulin injections. The DRI BioHub brings the promise of restoring natural insulin production to millions of children and adults by providing a platform for addressing three major challenges: the site, sustainability and supply.

In the Research Review section of this report, we summarize some of the priority projects underway for making the BioHub a reality. You can also learn more about this groundbreaking initiative on our website at DiabetesResearch.org. Recently redesigned, the website has been updated with new functionality, fresh research content and an entire section dedicated to the BioHub, featuring an animated video and extensive FAQ (frequently asked questions) addressing key issues.

This section also includes a rebroadcast of our first DRI BioHub webcast, in which Drs. Camillo Ricordi and Cherie Stabler laid out the strategy for developing the mini organ and answered many questions that were submitted by viewers prior to and during the event. Questions that could not be answered in the allotted time have been posted to the site as well.

Viewed around the world by people in more than 50 countries, the webcast generated great interest and we look forward to holding more of these online forums as progress on the BioHub unfolds. We’ll also continue to bring you research updates through our many publications, e-news and DRI tv, a new video series on our website that reports on the latest from the labs.

While funding is critical for making progress possible, equally important is the commitment of our DRI scientists. I want to highly commend Dr. Ricordi and his entire research team for their dedication to making a cure for diabetes a reality. With their scientific vision, relentless pursuit of our mission and ongoing accomplishments, I have no doubt that we will reach our shared goal of putting an end to this devastating disease.
As we all work to discover a biological cure, it became incumbent upon us to present our definition of what is meant by “a cure.” We embarked upon a long research process and sought the input of countless individuals and families affected by diabetes. That research process was completed this past year and culminated in the following definition of a biological cure for diabetes:

The ability to restore natural insulin production and normalize blood sugar levels without imposing other risks.

While a cure may mean different things to different people, we hope that this statement resonates with those living with diabetes as well as their loved ones. We feel confident in the DRI’s ability to achieve this goal, particularly with the development of the DRI BioHub.

This past year has certainly been a period of great progress and accomplishment. As always, these achievements are made while maintaining strict fiscal oversight by the National Board of Directors, which recommended we take several steps for increased efficiency. Among these was a consolidation of our regional offices in the Northeast. After analyzing operations within that geographic area, we implemented reductions in the staff, who now report to one regional director, down from two. The regional director oversees our two offices in Manhattan and Jericho. This new structure streamlines expenses while maintaining the service to our donors and the coordination of numerous events throughout the area. In a further cost-cutting measure, reductions in staff were also taken in our National Office/Florida Region. These actions were necessary for funding the DRI’s research program at the highest levels possible, which remains our top priority.

Despite these challenges, we are moving forward with great optimism. We are grateful for the extraordinary support we’ve received from individuals, families, foundations and corporations that have made significant gifts, hosted receptions, spearheaded events and undertook other activities to help further the DRI’s critical research.

Helping to fuel the excitement are the numerous individuals and families who take the opportunity to visit the DRI, see the research underway and meet our researchers. In turn, they return to their local communities with a renewed sense of hope and enthusiasm which they inject into their respective events and other activities undertaken on our behalf. Oftentimes, they connect with a particular scientist, who ignites their interest in his or her research area. The DRI and Foundation truly value these connections and we welcome anyone with an interest in visiting the DRI to let us know.

For many of our donors, their commitment to our work is longstanding and no one embodies this more than the AFL-CIO’s Building and Construction Trades Department (BCTD). Continuing their decades-long commitment, the men and women of the BCTD have raised significant funds for our cure-focused research. Last year, they reinstated the Blueprint for Cure name, the original moniker, as the banner campaign for its two hallmark events, DAD’s Day (Dollars Against Diabetes) and the Labor of Love Golf Tournament. We are grateful to the leadership of the BCTD, who has taken the Labor of Love to new levels of support, as well as expanded the annual event to include many adjunct activities that raise additional funds.

Throughout our regions, dedicated supporters are developing new events, leading ongoing galas, elegant and fun dinners, and friendly competitive tournaments, and bringing in significant funding. These activities play a crucial role in helping us convey the DRI message to a growing circle of people who share our urgency to cure diabetes.

Our corporate partners continue to spearhead a variety of programs on our behalf. The Walk with Walgreens Family Fun Day and Health Fair has reached more than $1 million in fundraising in just three years and attracted thousands of participants to this year’s event. Boosting these funds were the sales of scannables throughout Walgreens stores in South Florida. Similar scannables fundraisers were held throughout the Insera Supermarkets in New Jersey, and a new Pump for a Cure scannable was sold at various retailers in conjunction with the Shell Key West Fishing Challenge. These creative programs bring in much-needed dollars for research.

We want to thank all of our donors for Making Progress Possible. As we continue to work feverishly to reach our goal of a cure for diabetes, we appreciate your support and friendship in helping us cross the finish line.

Sincerely,

Harold G. Doran, Jr.
Chairman
MISSION: To provide the Diabetes Research Institute with the funding necessary to cure diabetes now.
The Diabetes Research Institute Foundation (DRIF) is the organization of choice for those who are serious, passionate and committed to curing diabetes. Its mission – to provide the Diabetes Research Institute with the funding necessary to cure diabetes now – is a testament to the belief that tomorrow is not soon enough to cure those living with diabetes.

The Diabetes Research Institute has become the world leader it is today through the substantial funding provided by the Foundation. Supported by private philanthropy, the DRIF ensures the jumpstarting of new ideas and the continuation of innovative research projects that remain cure-focused and will ultimately benefit those with diabetes.

The DRIF’s history of commitment dates back to 1971 when it was founded by a small group of parents of children with diabetes who were dedicated to finding a cure. Driven by a shared mission, they banded together to support a promising research program at the University of Miami solely aimed at curing those living with diabetes. In an unprecedented partnership that spans more than two decades and continues today, the AFL-CIO’s Building and Construction Trades Department (BCTD) joined with the Foundation’s leadership to help fulfill its mission to cure diabetes. The DRIF’s largest contributor, the BCTD committed to funding – and building – the Diabetes Research Institute facility. Under its signature Blueprint for Cure campaign, the BCTD has raised tens of millions of dollars for the DRI, with its members undertaking fundraising projects nationwide to provide ongoing support.

The DRI Foundation is recognized as one of the world’s most respected diabetes organizations. Garnering the attention of influential people who are personally affected by diabetes, the Foundation has grown into an international coalition of business leaders, celebrities, scientists, clinicians, families and other concerned individuals who have elevated the importance of cure-focused research and provided meaningful support for the DRI’s multidisciplinary research program. This funding is provided through individual and corporate donations, special events, sponsorships, cause marketing relationships and planned giving, which allows donors to provide a gift in the form of a will, trust or other deferred giving vehicle.

In an effort to increase awareness about the latest advances toward a cure, the Foundation conducts a wide variety of activities both online and offline, hosts research updates and workshops for people with diabetes and their families, and produces numerous printed publications and e-communications to make this information accessible to people nationally and internationally.

A 501(c)(3) not-for-profit corporation, the DRI Foundation has thousands of supporters in the United States and worldwide, and, in addition to its headquarters in Florida, operates regional development offices in New York, Long Island and Washington, D.C.

The Diabetes Research Institute Foundation was created for one reason – to cure diabetes – which is and will continue to be its singular focus until that goal is reached. For the millions of individuals and families affected by diabetes, the Diabetes Research Institute Foundation is the best hope for a cure.
In 2012, the DRI unveiled its groundbreaking strategy to take the next quantum leap in cure-focused research: the DRI BioHub.

With the BioHub, the DRI combines its multidisciplinary approach to create a “mini organ” that mimics the native pancreas, containing thousands of insulin-producing cells that sense blood sugar levels and release the precise amount of insulin needed – in real time. The DRI BioHub builds on the success of islet cell transplantation – a therapy that has restored natural insulin production in patients involved in clinical trials. Study patients have been able to live without the need for insulin injections, have experienced normalized blood sugar levels and have been freed from frightening hypoglycemic episodes after receiving infusions of the donor cells. Some study participants have lived insulin free for more than a decade. Yet many patients have had to resume insulin therapy due to a loss of the transplanted cells over time.
While islet transplantation has shown that cell replacement therapy can reverse diabetes, several challenges remain.

**THE DRI BIOHUB PROVIDES A PLATFORM FOR OVERCOMING THESE CHALLENGES WHICH PRIMARILY FALL INTO THREE AREAS:**

1. **Site** – the development of an optimal environment within the body to house the new cells
2. **Sustainability** – the need for the recipient to accept the cells long-term, without harmful anti-rejection drugs
3. **Supply** – the need for more insulin-producing cells for transplant

In 2012, the DRI made significant progress in each of these challenge areas, the highlights of which are described below:

**1. Site**

So far, researchers have been transplanting islets into the recipient’s liver. While the liver offers some benefits, this site has proven less than optimal.

With the BioHub, the DRI is creating an environment that more closely mimics the native pancreas. The physical form of a BioHub – what it looks like, what it’s made of, and where it’s placed – received intense focus in 2012.

**Bioengineered Scaffolds**

One potential physical platform for a DRI BioHub is a silicone “scaffold,” a sponge-like material slightly larger than a quarter and compatible with the human body. Most of a scaffold is open space, with tiny pores that can house thousands of insulin-producing cells of many shapes and sizes. This spacing and support structure mimics the pancreas environment. By giving each islet space, oxygen and other nutrients efficiently reach each cell. It also prevents cells from clumping together and choking off oxygen supply for all of these cells.

Oxygen is critically important. Islets make up only one to two percent of the pancreas, but they use almost 25 percent of the oxygen flowing through the organ. In 2012, a DRI study published in the *Proceedings of the National Academy of Science* demonstrated for the first time that oxygen can be delivered locally at the transplant site using an oxygen-generating biomaterial.

The scaffold has shown promising results, achieving insulin independence in pre-clinical study models. The DRI is hoping to begin clinical trials with islets implanted into the scaffold in early 2014.

**Venous Sac**

Researchers are testing another home for a BioHub: inside a vein. In 2012, in the journal *Transplantation*, the DRI and collaborators in Edmonton, Canada, and Tbilisi, Georgia, reported transplanting rodent islet cells in an isolated portion of a rodent vein. The cells successfully functioned and restored normal blood glucose levels. By “tying off” the ends of a section of the vein, researchers created a “venous sac” and filled
it with islets. An adjacent artery provided blood flow. To build on these important findings, the DRI and its partners in Edmonton are conducting trials of the venous sac in pre-clinical models and additional studies are ongoing with Tbilisi researchers.

Location
Since the liver is not an optimal transplant site, scientists are testing other sites within the body for a BioHub. The focus has moved to the abdomen, specifically the omentum, an apron-like tissue that covers the abdomen. Researchers are creating an abdominal “pouch” by folding over a small section of this tissue. This pouch is rich in blood vessels and may provide a safer and more suitable site, as well as being accessible post-transplant for retrieval of a BioHub or for adding agents as needed. Upcoming clinical trials using the scaffold will test the omentum as a transplant site.

2. Sustainability
When islet cells are transplanted, the recipient’s immune system sees the cells as “foreign” and wants to reject them. So, patients have to take powerful anti-rejection drugs (“immunosuppressants”) for life. The DRI is investigating several methods to protect the islets from immune attack – so they can sustain function – without the need for life-long immunosuppressants.

Adding “Helper” Cells
Researchers have discovered that certain cells of the body may help protect transplanted insulin-producing cells. Among them: a group of adult stem cells known as mesenchymal stem cells (MSCs). MSCs are found throughout the body and develop into cartilage, bone, fat and other tissues. Several years ago, the researchers discovered that MSCs obtained from bone marrow have unique properties to help the recipient’s body accept the transplant. MSCs can limit inflammation, stimulate blood vessel growth, prevent rejection and promote the long-term function of islets. In 2012, the DRI co-transplanted insulin-producing cells with MSCs into a bioengineered scaffold placed within the omental pouch (explained above) within experimental models. Early studies show that this combined transplant approach can enhance acceptance and extend the viability of the transplanted insulin-producing cells.

Protective Cell Coatings
DRI researchers are finding new ways to “camouflage” islets by encasing the cells in a protective barrier that allows them to go unnoticed by the body and avoid inflammatory reactions or immune attack. They’ve developed a system that creates a tight-fitting shield around each islet – as if they are “shrink-wrapping” each cell. This innovative conformal coating approach builds upon traditional cell encapsulation methods that had little success.

In 2012, the DRI also developed and tested a new technique to double-coat the islets to further protect and stabilize the encapsulated cells. Researchers also are developing ways to make the conformal coatings more “active,” by attaching special molecules to the surface that can help to decrease or eliminate inflammation and ward off an attack on the transplanted cells.

Local Drug Delivery
Currently, transplant recipients must take anti-rejection drugs that shut down the entire immune system, putting the patients at risk for harmful side effects. Rather than suppressing the entire immune system, in 2012 the DRI continued to investigate how to deliver time-released, low dose anti-rejection drugs locally – only at the site of the transplant, within a DRI BioHub.

Tolerance
Scientists are developing and testing several strategies to teach the immune system to see transplanted islet cells as “self” and allow them to exist. This is called “transplant tolerance.” But the issue is not just getting the body to accept transplanted islet cells. Type 1 diabetes occurs when the immune system mistakenly sees a person’s own islet cells as foreign (a process called “autoimmunity”). So, DRI researchers are studying ways to make the body see one’s own cells as “self.” This is “self tolerance.”

In 2012, one focus at the DRI was on a part of the immune system known as myeloid-derived suppressor cells (MDSCs). These special cells, in fact, surround cancerous tumors and allow them to go unnoticed by the immune system so they survive and grow. DRI researchers are trying to harness this
for a more positive purpose – to prevent the immune attack on transplanted islets. During the past year, we have made significant progress in further defining MDSCs as a tool to induce tolerance to transplanted islets. We now have data that MDSCs have immunosuppressive properties that may result in prolonged islet graft survival in experimental models. The population of MDSCs we are testing are obtained from the umbilical cord blood of healthy, newborn babies.

Another approach focuses on cells of the immune system known as regulatory T cells, or “Tregs” that prevent autoimmunity – the body’s attack on its own cells and tissues. Impaired Treg balance and function leads to autoimmunity. In experiments so far, DRI researchers have shown Treg therapy can induce tolerance to transplanted tissue and prevent the recurrence of autoimmunity.

Immune tolerance already has been achieved in pre-clinical models by using bone marrow transplantation. The co-existence of donor and recipient bone marrow cells is called “chimerism.” In this approach, the recipient’s immune system recognizes its own bone marrow as “self,” and simultaneously accepts the donor tissue as “self.” The use of bone marrow also provides opportunities to reset the immune system to correct autoimmunity. These studies are underway.

3. Supply

A DRI BioHub can provide an optimal environment and protection for insulin-producing cells – but there must be enough cells to begin with. At the DRI, researchers are pursuing several strategies to create an unlimited supply of insulin-producing cells. They’re also looking at ways to regenerate – or regrow – islets that have been destroyed by the immune system.

Stem cells

DRI scientists are working with a variety of adult stem cells – pushing them down the path to sense glucose and secrete insulin. One area of focus is on mesenchymal stem cells (MSCs). As mentioned above, MSCs can become cartilage, bone, fat, blood vessels and other types of cells. They are plentiful and pose no ethical barriers.

The fat cells – also known as adipose cells – are the subject of preliminary studies with our collaborators in Milan, Italy. They have been able to transform a portion of adipose-derived cells into insulin-
producing cells. Another promising approach involves the use of pancreatic precursor cells which line the duct that connects the liver and the pancreas, known as the biliary tree. In 2012, DRI researchers began a collaboration with the world’s foremost expert in liver development and regeneration. Having joined forces, the research groups have shown that these precursor cells within the biliary tree can transform into both liver and pancreatic cells, including insulin-producing beta cells.

**Transdifferentiation**

Rather than educating a stem cell from its earliest stages of development – pushing it down the long path to become an islet-type cell – transdifferentiation can potentially offer a short cut. In this approach, scientists take a more mature cell type and “reprogram” it, transforming it directly into an insulin-producing cell. To accomplish this, the DRI has been focusing on the acinar tissue – or non-endocrine tissue – of the pancreas. Acinar cells make up almost 98 percent of the organ. They do not produce insulin; rather, they help process food by producing digestive enzymes. Acinar tissue typically is discarded after an islet isolation procedure. Since the DRI is a leading islet isolation facility, it has a plentiful supply of acinar tissue. In preliminary experiments, DRI researchers have reprogrammed human acinar tissue and have seen a detectable increase in insulin production from these cells.

The DRI’s multidisciplinary team of researchers, together with our collaborators, are simultaneously developing and testing all of these approaches to move the BioHub forward as quickly and efficiently as possible. For more information on the latest progress, please visit DiabetesResearch.org.
Diabetes Research Institute Foundation
Statement of Activities for the Year
ended June 30, 2012

Support and Revenue

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Contributions</td>
<td>3,198,995</td>
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<tr>
<td>Reimbursement Contracts</td>
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<td>Special Events, Net of Expenses</td>
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<td>Investment Income</td>
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<tr>
<td><strong>Total Support and Revenue</strong></td>
<td><strong>$7,402,961</strong></td>
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</table>

Expenses and Fund Balances

**Program Services**
- Research Provided to the Diabetes Research Institute: 7,365,949
- Community Education: 615,611
- **Total Program Services**: 7,981,560

**Support Services**
- Administration and General: 931,902
- Fundraising: 1,909,841
- **Total Support Services**: 2,841,743

Change in Net Assets: $(3,420,342)
- Net Assets, Beginning of Year: 28,271,045
- Net Assets, End of Year: $24,850,703

Fundraising Percentage
- Fundraising Expense as a Percentage of Support and Revenue: 25.8%

Through the support of private philanthropy, the Diabetes Research Institute Foundation has funded six chairs totaling almost $13 million:

- The J. Enloe and Eugenia J. Dodson Chair in Diabetes Research,
- Stacy Joy Goodman Chair in Diabetes Research,
- Mary Lou Held Chair for Diabetes Research,
- Martin Kleiman Endowed Investigatorship,
- Daniel H. Mintz Visiting Professorship,
- and the Ricordi Family Chair in Transplant Immunobiology.

An endowed chair is among the most important gifts in private philanthropy. It honors and recognizes the distinction of superior scientists while providing invaluable financial support to ensure the continuation of critical research to cure diabetes.
To our donors with our deepest gratitude...

We wish to gratefully acknowledge all of our donors who are Making Progress Possible through their ongoing support of our DRI scientists.

Our DRI family continues to grow and many new donors have joined us over the past year – from across the globe. We sincerely appreciate every gift we receive, no matter the size.

Your generosity has allowed us to make significant progress for restoring natural insulin production and toward our ultimate goal of discovering a biological cure for every child and adult living with diabetes.

Thank you to every individual, family, foundation and business that has given generously over the last year and through the years.
The Heritage Society of the Diabetes Research Institute Foundation was created to recognize individuals who have generously made provisions in their wills, through life insurance, charitable remainder trusts and gift annuities, or other deferred giving vehicles to ensure that critical funding for the Diabetes Research Institute continues into the future.

Over the years, planned giving programs have enabled many donors to make substantial gifts to the DRI in ways that have complemented their individual financial objectives. Heritage Society members have chosen to create their own personal legacies and perpetuate their philanthropic goals for all those affected by diabetes.

We are exceptionally grateful to our Heritage Society donors who demonstrate the passion and vision to advance a cure beyond their lifetime.

“We know the DRI is dedicated to the cure, and we’re funding a mission...We do everything we can now, but we can do so much more in our wills. Jake is the future, and we’re investing in our future – by leaving a legacy.”
- Irene Cohen
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Special Events Coordinator

Tricia Pellizzi  
Administrative Assistant

As of July 1, 2013
The Diabetes Research Institute leads the world in cure-focused research. As the largest and most comprehensive research center dedicated to curing diabetes, the DRI is aggressively working to shrink the timeline toward the discovery of a biological cure for this disease.