ONE GOAL: A CURE
Thank you to every individual, family, foundation, and business that has given generously over the last year and through the years.
Throughout the year, Diabetes Research Institute scientists continued to build upon critical research programs while launching new scientific initiatives necessary for developing the DRI BioHub, a bioengineered mini organ that mimics the native pancreas to restore natural insulin production. It was an exciting year in which we witnessed progress across the three main research challenges of the Site, Sustainability and Supply, with some projects advancing to or nearing the clinical trial phase of testing. Below is a summary of the year’s research highlights that were made possible by your generous support.

THE SITE

The Food and Drug Administration (FDA) approved the DRI’s submission to initiate a Phase I/II clinical trial that will test islets transplanted in a new site in the body called the omentum, an apron-like lining inside the abdomen. The omentum closely replicates a biodegradable scaffold, a DRI BioHub platform. The biodegradable scaffold uses a patient’s own plasma, the liquid part of the pancreas, among other benefits. Several patients have completed the islet transplantation screening process and have been selected as candidates for the transplant.

SUSTAINABILITY

Dr. Alberto Pugliese and Thomas Malek have been collaborating with Paris-based Université Pierre et Marie Curie in Paris, France, which regulate the immune system and suppress autoimmunity. Results of these collaborative studies were published this year in several peer-reviewed journals, including Diabetes and the Journal of Autoimmunity. New trials are now enrolling patients with recent onset type 1 diabetes (within 3 months from diagnosis) to determine whether low-dose IL-2 can preserve or improve the ability of the pancreas to produce insulin.

Dr. Peter Buchwald, director of drug discovery, and his team are targeting a recently identified signaling pathway that leads to autoimmunity and suppress autoimmunity. Smad 7 not only controls the autoimmune destruction of the islet cells, but can also lead to islet regeneration. Dr. Buchwald and his team are investigating the possible beta cell-enhancing effects of this treatment with the goal of quickly translating this research to clinical therapies.

SUPPLY

The exocrine, or non-insulin-producing, cells of the pancreas have been shown to give rise to insulin-producing endocrine cells. However, previous attempts to achieve this have thus far relied on the use of genetic manipulation, which remains a translational hurdle for diabetes therapies. Drs. Juan Dominguez-Benlada and Ricardo Pastori and their teams have been able to convert adult human exocrine tissue into insulin-producing cells – and have done so using a single molecule that is already in clinical use for other conditions. The DRI team is the very first group in the world to achieve this result using human cells with a compound that is already FDA approved. The non-genetic conversion of human pancreatic exocrine to endocrine cells is a novel strategy and represents a safer and simpler alternative to genetic reprogramming, while opening the door to the design of new therapies.

Dr. Alice Tomei, assistant professor of surgery and cell transplantation, together with collaborators at the École Polytechnique Fédérale de Lausanne (EPFL) in Switzerland, demonstrated that their unique conformal coating process allows efficient encapsulation of islets without compromising viability and function of the cells. The team’s novel method encases the islets within complete, uniform, and thin capsules of similar density, and has been designed to specifically address what are considered to be the limitations of traditional cell encapsulation strategies. The results of their study earned the cover position in the prestigious journal Proceedings of the National Academy of Sciences.

Dr. Luca Invernardi and his team have continued their work with Myeloid-Derived Suppressor Cells (MDSCs), a special population of immunomodulatory cells that help tumors escape destruction by the immune system. MDSCs prevent tumor rejection by recruiting Regulatory T Cells to surround the cancer cells. The researchers are investigating the potential of MDSCs to protect insulin-producing cells from autoimmune destruction using a similar mechanism. MDSCs are usually harvested from the bone marrow, but this past year the team was the first to discover and characterize a novel subset of MDSCs that they have named fibrocyte-MDSC (f-MDSC). The cells were isolated from the umbilical cord blood of healthy newborn babies and have a powerful immunosuppressive effect. These particular cells are also easy to grow, expand, and bank. The team’s discovery and results of their studies were published in the European Journal of Immunology and Genomic Data. Their efforts are now focused on developing ideal conditions for expanding and preserving f-MDSC for their possible clinical use in achieving tolerance to transplanted insulin-producing cells in those with T1D.

In this three-dimensional model of human Smad 2 each colored region is believed to interact with a critical receptor (called TGF-β) in this important pathway under study at the DRI.

Human islet cells embedded in the biodegradable scaffold. The magnification of the micrograph shows the fibro filaments that hold the islets in place.

In its Phase I/II clinical trial, the DRI is testing the omentum as a new transplanted site. The omentum is rich with blood vessels, is easily accessed surgically, and has insulin drainage characteristics of the pancreas, among other benefits.
At the DRI Foundation, where the majority of volunteers and professionals have a loved one with diabetes, our resolve could not be stronger. We want a cure, period.

At the DRI, our team of researchers — many of whom are also touched by this disease — are in lockstep with us. They passionately share the same mission.

Our passion and commitment drive us, but alone they will not defeat such a complex disease. It takes expertise, experience, and vision to achieve something so challenging. Thankfully, we have these, too, a fact that is evident to our supporters, as well as to the DRI’s esteemed colleagues throughout the scientific community.

On that point, several months ago we attended the two-day meeting of the DRI’s Scientific Advisory Board (SAB), an external council of distinguished investigators who meet every three years to review, and make recommendations on, the Institute’s research program. Their report is then presented to the Dean of the University of Miami Miller School of Medicine, of which the DRI is a part. The SAB’s members offered a glowing review of the DRI’s work, reporting that, “The committee was unanimous in its feeling that major strides have been made in both basic and translational research programs at the DRI… There is no better clinical translational group working on type 1 diabetes in the world.”

Receiving this impressive validation from such a distinguished panel of experts reinforces our belief that we have invested our time and resources in the right place. Yet for all of the accolades, we know there is still much work to be done, because tomorrow is not soon enough to cure this disease. That is why we would be remiss if we did not persistently ask ourselves: how do you take something that is clearly special and make it better? That is precisely what we are charged with doing, in the interest of our loved ones, each of you, and the millions of people living with diabetes.

One answer to that question is to continuously employ the highest standards of financial stewardship and accountability. Over the years, we have gone to great lengths to maintain expenses at acceptable levels, to meet the rigorous guidelines established by various non-profit oversight groups, and to provide the necessary transparency about our operations.

Another answer is to ensure that research progress continues, allowing us to keep moving toward our ultimate goal. Much of that depends on our ability to fund the DRI’s research initiatives.

In other words, we rely on you and all of our generous donors to help us meet this ongoing need. Highlights of the progress that you helped our researchers achieve are presented in this report.

This past year, many have made a significant investment in our research program. Thousands have led and/or participated in the various events held in our regions and other communities across the country. Others have generously donated whatever they could to help move the science along. We are grateful for each and every gift, regardless of the amount, because we will not get there any other way.

We are all a part of this special place. Our mission is to find a cure, and we need each and every one of you to join us. On behalf of all of us at the DRI and Foundation and the millions counting on us to cross the finish line, thank you for your continued support, trust, and friendship.

Sincerely,

Haro O. Dorn, Jr.
Chairman

Joshua W. Rednik
President and CEO

“There is no better clinical translational group working on type 1 diabetes in the world.”
Research Funding is Critical

The Diabetes Research Institute has become the world leader it is today as a result of the substantial funding provided by the Diabetes Research Institute Foundation (DRIF). This funding stream is at the heart of the DRI’s ability to make significant strides toward a cure. Supported by your donations, the DRIF ensures that our scientists can jump-start new ideas while continuing innovative, cure-focused research projects. Our mission – to provide the DRI with the funding necessary to cure diabetes now – is testament to the belief that tomorrow is not soon enough to cure this disease.

Diabetes Research Institute Foundation
Statement of Activities for the Year ended June 30, 2014.

Support and Revenue

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<th>Source</th>
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<tr>
<td>Contributions</td>
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<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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<td>Total Support and Revenue</td>
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Expenses and Fund Balances

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<td>Program Services</td>
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<tr>
<td>Research (Provided to the Diabetes Research Institute)</td>
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<td>Community Education</td>
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<td>Support Services</td>
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<td>Administration and General Fundraising</td>
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<td>Fundraising</td>
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<td>Total Support Services</td>
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<td>Change in Net Assets</td>
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<td>Net Assets, Beginning of Year</td>
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<td>Net Assets, End of Year</td>
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Fundraising Percentage

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<th>Category</th>
<th>Percentage</th>
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<tr>
<td>Fundraising Expense as a Percentage of Support and Revenue</td>
<td>12.5%</td>
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</tbody>
</table>
To our Generous Donors with Deepest Gratitude...

The Diabetes Research Institute and Foundation wish to gratefully acknowledge all of our donors and volunteers, who are enabling us to make great strides toward a biological cure for diabetes.

Thank you to every individual, family, foundation, and business, many of whom are pictured within this report, that have given generously over the last year and throughout the years. We would not have been able to come this far without you.

“We need to continue to bring this cause and our mission to find a cure to the forefront for the millions who suffer with diabetes, including my son.”

– Doug Donaldson (left)
The Heritage Society of the Diabetes Research Institute Foundation recognizes individuals who have generously made provisions in their estate plans, 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 all of our Heritage Society donors, who demonstrate the passion and vision to advance a cure beyond their lifetime.
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