The following report details some of the important learnings and progress that, thanks to your generous support, has occurred over the past year in each of our priority research areas.

It has often been said that the road to progress is rarely a straight line. At JDRF, we know nothing holds truer when it comes to progress in developing improved treatments and a cure for type 1 diabetes (T1D). This is why, with the generous help of supporters like you, JDRF is pursuing a diversified, dynamic research agenda aimed at moving us toward a world without T1D, where normal physiology, including reversal of complications, is restored for all those living with the disease.

JDRF is the only global organization with a strategic plan to end T1D. Our plan ensures that there will be an ongoing stream of life-changing therapies that lessen the impact of the disease and keep people healthy until we are able to find a cure. JDRF research focuses on six key therapy areas. They are:

- **ARTIFICIAL PANCREAS**
  - Systems that can deliver more effective and precise insulin therapy

- **COMPLICATIONS**
  - Therapies that prevent or better treat T1D-related damage such as eye and kidney disease

- **ENCAPSULATION**
  - Replacement cell therapies that can provide long-term relief from insulin therapy

- **SMART INSULIN**
  - That can turn on and off in response to changing blood-glucose levels

- **RESTORATION**
  - Of the body’s ability to produce insulin, which would provide a biological cure for T1D

- **PREVENTION**
  - Therapies that will keep individuals, especially those at higher risk, from ever developing T1D

The following report details some of the important learnings and progress that, thanks to your generous support, has occurred over the past year in each of our priority research areas.
LEVERAGING OUR RESEARCH RESOURCES

Throughout fiscal year 2014, JDRF took action to broaden the resources available in the TID research and development (R&D) arena. Each of these well-considered moves will help increase progress across our research portfolio and speed development and delivery of novel TID therapies in our priority areas.

JDRF collaborates with a wide spectrum of partners at every stage of the drug-delivery pipeline.

In October 2013, JDRF unveiled TID Innovations. Together with PureTech, a technology-development company, TID Innovations will create and fund companies that are developing innovative, high-impact TID therapies. Our support will enable these fledgling enterprises to successfully cross the notorious biomedical valley of death—a funding gap that often prevents promising discoveries from being translated into lifesaving treatments.

In November 2013, JDRF and Pfizer’s Center for Therapeutic Innovation (CTI) launched a new partnership that will support development and translation of promising TID research. The collaboration will initially focus on supporting research in the areas of immune tolerance, diabetic nephropathy, and beta cell health. It will capitalize on JDRF’s TID research expertise and CTI’s network of academic medical centers, which will act as hubs for clinical trials. By pairing these resources, we can speed development and delivery of new and improved TID therapies.

In March 2014, the federally funded Special Diabetes Program (SDP) was granted a one-year funding extension by Congress due in large part to JDRF’s advocacy efforts. The SDP accounts for roughly one-third of all federally funded TID research, and the extension provides $150 million for the National Institutes of Health (NIH) to fund diabetes-research projects.

In March 2014, the federally funded Special Diabetes Program (SDP) was granted a one-year funding extension by Congress due in large part to JDRF’s advocacy efforts.
Eight years ago, JDRF created the Artificial Pancreas Project, and through the generosity of our supporters, we have been able to invest more than $98 million to fund artificial pancreas (AP) research and development. Today, this project is spurring innovation and bringing us closer to our goal of creating AP systems that automatically measure blood-glucose levels and seamlessly deliver the appropriate amount of insulin and other blood-sugar-regulating hormones, allowing individuals with T1D to maintain healthy glucose levels throughout the day and night with little to no involvement in monitoring and dosing activities. Among other benefits, AP systems will help eliminate the life-threatening hypoglycemic (low-blood sugar) and hyperglycemic (high-blood sugar) episodes that people with T1D can experience even when their disease is well managed.

Several JDRF-funded research projects are pushing towards the creation of fully automated AP systems. Included in this mix of promising research are projects focused on developing near-market predictive-low-glucose-suspend (pLGS) AP systems aimed at preventing hypoglycemia, next-generation treat-to-range AP systems that will keep blood-sugar levels within a specific range, and new formulations of glucose-regulating hormones that will allow AP systems to better mimic the body’s natural metabolic response.

**pLGS SYSTEMS ON THE HORIZON**

Predictive-low-glucose-suspend software systems are budding first-generation AP technologies that aim to significantly reduce low-blood-sugar episodes. The integrated continuous glucose monitor (CGM)/insulin pump systems will feature pLGS software that predicts when a user’s glucose will become too low and then signals the pump to automatically reduce or turn off insulin delivery before low blood sugar can occur.

Stanford University researcher Bruce Buckingham, M.D., and his team have conducted a series of studies testing overnight accuracy of a pLGS software they are developing for potential use in AP systems. The most recent study—a JDRF-funded randomized home-based trial that tracked 45 T1D patients aged 15 to 45 who were fitted with the researcher’s novel software — was published in the May 7 online issue of Diabetes Care. For the study, each participant was connected to the system for 42 nights, and investigators randomly activated and deactivated the pLGS software so that the subjects spent 21 nights with the intervention turned on and 21 nights with it turned off. Participants didn't know on any given night whether the software was functioning. Investigators found that hypoglycemic episodes that lasted 30 to 60 minutes were reduced by roughly half, and episodes lasting 180 minutes or more were reduced by 81 percent on nights when the software was active compared to nights when it was inactive.

The study adds to a growing body of research showing that pLGS-enabled systems used during sleep are safe and effective, and the findings help bring people with T1D closer to having fully integrated AP systems that offer 24-hour protection against life-threatening hypoglycemic episodes. The researchers are now evaluating pLGS when used in 3 to 6 year olds with T1D. Making these systems available for use by children not only improves the short- and long-term health of the youngest individuals with T1D, it also allows their families to sleep without fear of the disease’s potentially deadly consequences.
TREAT-TO-RANGE SOFTWARE ADVANCES

For several years, the JDRF Artificial Pancreas Consortium has lent support to University of Virginia researcher Boris Kovatchev, Ph.D., and his team’s efforts to design and study the feasibility of their novel treat-to-range AP system software. In June, the team received Food and Drug Administration (FDA) approval to conduct a pilot study testing the safety and effectiveness of the technology when used under real-world conditions. The pilot, which began this past summer, is the first U.S.-based long-term study to test unsupervised daily and overnight use of an artificial pancreas system that, when coupled with mealtime bolusing, automatically controls insulin delivery and keeps blood glucose within a specific range.

Investigators will enroll up to 48 adults with T1D to test the technology over an 11- to 14-week period, and up to six months in a subset of patients. Participants will be asked to use the experimental system (which combines a Dexcom CGM, a Roche Accu-Chek insulin pump, and a cell phone fitted with the University of Virginia’s novel predictive software) to monitor their blood-glucose levels and automatically adjust insulin delivery throughout the day, evening, and while sleeping. If the technology proves safe under these real-world conditions, researchers plan to launch a large-scale international study by mid-2015 to further test the system’s safety and effectiveness.

FAST-ACTING INHALED INSULIN AIDS AP EFFECTIVENESS

Meal management remains one of the biggest challenges to the development of fully automated AP systems. Currently, people with T1D typically give themselves a pre-mealtime bolus of insulin to prevent their blood sugar from spiking too high after eating. JDRF is funding research aimed at making mealtime bolusing in conjunction with AP system use more precise and effective.

JDRF has provided funding to the Sansum Diabetes Research Institute and the College of Engineering at University of California, Santa Barbara, to focus on the use of inhaled insulin with AP systems. This past fall, Sansum announced positive preliminary results from the first clinical trial testing combined use of an AP system and rapid-acting inhaled insulin by individuals with T1D. The findings showed that utilization of inhaled insulin prior to mealtime allowed AP users’ bodies to better replicate a healthy response to food-related blood-glucose increases, and that they needed smaller amounts of inhaled insulin than pump-supplied insulin to properly manage blood sugar levels.

In July, the FDA approved the use of Afrezza—the rapid-acting inhaled insulin used in the JDRF/Sansum study—in combination with a form of pumped or injectable insulin by adults with T1D. This recent approval could provide an important avenue for improving the function of AP systems.
Despite advances in treatment, episodes of hyperglycemia remain a problem for many people with T1D, putting them at long-term risk for diabetic complications. An estimated 45 percent of Americans diagnosed with diabetes have some stage of diabetic retinopathy (DR), making it a leading cause of adult blindness, and one-third of people with T1D develop kidney disease as a result of high blood sugar. Finding ways to prevent these complications and keep individuals with T1D healthy until we find a cure is a major goal of JDRF’s complications therapy research, and in recent months our supported research has offered promising discoveries that could lead to new preventive treatments.

**THWARTING DIABETIC RETINOPATHY**

Clinical trial results published this past March in the online-first edition of *JAMA Ophthalmology* suggest that doxycycline, a common antibiotic, may be useful in preventing DR. The JDRF-funded study looked at whether the inexpensive, generic antibiotic could delay or prevent deterioration of certain eye functions that may contribute to DR. Researchers at Penn State Hershey Eye Center and Denmark’s Glostrup Hospital followed 30 T1D patients who were randomized into two groups: one receiving 50 mg of doxycycline daily and the other placebo pills. By the end of the 24 month trial, half the patients receiving doxycycline experienced improved sensitivity in their fovea—a nerve-concentrated region of the retina—but none of the patients receiving placebo experienced this improvement.

While foveal sensitivity is not a measure of visual acuity, investigators believe that it may prove to be a good predictor of DR damage and potential vision loss. Additional clinical trials are needed, however, to determine whether foveal damage is a biomarker for vision loss and, if so, whether taking doxycycline or other similar drugs can help T1D patients avoid this complication.

Identifying DR biomarkers is a critical step towards prevention and diagnosis of this T1D complication at its earliest stage. As noted in our January 2014 General Progress Report, JDRF along with the FDA and other partners will host a one-day workshop on DR biomarkers and endpoints sometime in 2015.

**KEEPING KIDNEYS HEALTHY**

A promising JDRF-funded feasibility study that looked at the potential for allopurinol—a 50-year-old gout treatment drug—to slow or stop loss of kidney function in people living with T1D is spawning further studies into the drug’s effectiveness. This past spring, a network of scientists from eight research centers around the world formed the PERL (Preventing Early Renal Function Loss in Diabetes) Consortium to focus on designing and conducting a multi-site international study of allopurinol as an intervention for T1D-related kidney disease. The drug works to lower uric acid, which in high levels correlates with the progression of kidney disease.

The PERL Consortium study will be funded by the NIH through the SDP, and it will receive continued support and involvement from JDRF scientists. Should the study demonstrate allopurinol’s effectiveness in averting the loss of kidney function in people with T1D, it could lead to a low-cost, safe and effective preventive treatment.
Thanks to donors’ support of JDRF’s pioneering research, we know that it is possible to end an individual’s dependence on injected insulin and achieve normal blood-glucose control by transplanting pancreatic islet cells into people living with T1D. Despite this, widespread use of islet transplantation is not possible because of two major obstacles—a lack of available islets for transplantation and the need for transplant recipients to take immunosuppressive drugs to prevent the immune system from attacking the transplanted cells. Encapsulated cell therapies have the potential to overcome both obstacles. By wrapping either replacement islets or precursor cells with the ability to mature into islets in a protective barrier before implanting them in the body, the encapsulated cells would sense a person’s blood-glucose levels and produce insulin and other required hormones as needed. The protective barrier would shield them from the destructive immune responses associated with T1D, and the implanted cells would be effective for months—possibly years—at a time before needing to be replaced.

Several years ago, in support of developing these potentially life-changing therapies, JDRF created the JDRF Encapsulation Consortium, which brings together the world’s leading scientists and research institutions to work on solving critical challenges to developing next-generation encapsulated cell therapies for the treatment of T1D.

The JDRF Encapsulation Research Program is a crucial link in our commitment to advance more effective treatment and disease-management options along the way to a cure.

VIACYTE’S NOVEL ENCAPSULATED CELL THERAPY ENTERS CLINICAL TRIALS

JDRF began funding development of ViaCyte’s encapsulated cell therapy research in 2011. Since then, a total of $13 million in funding has been committed by JDRF provided certain milestones are achieved. ViaCyte’s current work was made possible by more than 10 previous years of investment by JDRF in stem-cell research. The stem-cell line derived from this earlier research is now being used by ViaCyte and other investigators to develop T1D therapies. ViaCyte has created a unique cell-replacement product called VC-01, which in preclinical trials proved capable of controlling blood-glucose levels in diabetic mice. The company uses various lab techniques to grow and coax human embryonic stem cells (hESC) into precursor islet cells. The precursor cells are placed into ViaCyte’s encapsulation device—called Encaptra—to create an implantable cell-replacement product. In studies, VC-01 cells that were implanted in animal models developed into fully functioning islets that secrete insulin and other blood-glucose controlling hormones. The novel device allows oxygen and other nutrients to feed the developing islets while protecting them from an immune system attack. This past August, the FDA approved ViaCyte’s application to begin evaluation of VC-01 in humans, and the clinical trial began with its first volunteers in October. The study will focus on assessing the safety of VC-01, but other information will be collected that may also provide hints of its benefits.
RESEARCH TO FIND THE BEST ENCAPSULATION MATERIALS ADVANCES

For the past eight years, JDRF has funded work by Robert Langer, Ph.D., to develop the best biomaterials for encapsulating replacement cells. Improving alginate encapsulation material is among Dr. Langer’s endeavors.

While alginate capsules can form a barrier that protects implanted islets from an autoimmune attack, the capsules themselves don’t always escape detection by the immune system. When that happens, scar tissue can form around the implanted capsules, preventing them from properly releasing insulin. To overcome this problem, Dr. Langer, along with his co-investigator Dan Anderson, Ph.D., and their team of researchers at the Massachusetts Institute of Technology and Boston Children’s Hospital are collaborating with researchers at Joslin Diabetes Center, University of Massachusetts Medical School, and University of Illinois of Chicago, to develop ways to help alginate capsules remain safe from detection or attack by the immune system. His team has generated thousands of novel materials, some of which have shown superior biocompatibility compared to existing alginate preparations. Another solution involves embedding encapsulation devices with anti-inflammatory drugs that are released the first few days after implantation takes place—when the immune system is most active.

In the coming months, Dr. Langer anticipates publishing findings on his recent encapsulation materials research, and he plans to begin preclinical testing of other novel materials for use in cell-replacement therapy.

Smart Insulin

Today, injected insulin doesn’t provide the kind of precise, tightly controlled regulation of blood-glucose levels that is provided by naturally produced insulin. Once insulin is injected, it is designed to be effective for a specific amount of time and to reach all organs of the body at comparable levels regardless of the specific need of each organ. This puts people with T1D at risk for hypoglycemia and hyperglycemia. In order to maintain good control, patients either test blood-glucose levels six to 10 times a day or wear a CGM attached to the body by a tube inserted under the skin. In addition, they inject insulin three to six times a day or wear an insulin pump that is also attached to the body through an inserted tube.

By contrast, smart insulin is a drug designed to circulate in the body in an inert form, turning on when it is needed and turning off when it is not, and in amounts proportional to the needs of specific organs. Smart insulin would ensure tightly controlled blood sugar throughout the day and night without the need for multiple glucose tests and insulin injections. One dose of smart insulin would cover all of a person’s insulin needs for that day. By design, the drug would release insulin in response to rising blood glucose and stop the release of insulin when levels return to normal, functioning just like the pancreatic islets of a person without T1D. Smart insulin will reduce the burden of managing T1D as its use will not require a device or the need to monitor blood glucose-levels multiple times during the day.
SMART INSULIN DRUG CANDIDATE MOVES TOWARD CLINICAL TRIALS

JDRF has been a pioneer in championing smart insulin research, and in May drugmaker Merck announced that its novel smart insulin drug candidate, acquired in 2010 from SmartCells—a diabetes drug development company that received early support from JDRF—has reached a development milestone. New data support advancing the smart insulin project to clinical trials. Merck is expected to seek FDA approval for its clinical trial, but no potential start date has yet been set.

The Merck smart insulin project is the most groundbreaking smart insulin product in development, and it was made possible by early JDRF funding provided more than a decade ago. While other research funding institutions were skeptical, JDRF saw promise in the fledgling company’s idea for developing a drug that could significantly improve the lives of people living with T1D.

Preserving beta cells in newly diagnosed individuals with T1D may be one of the first steps towards a cure or delaying the onset of T1D in high-risk individuals. The JDRF Restoration Program aims to deliver therapies that regenerate insulin-producing beta cells and promote the survival and health of residual beta cells while simultaneously blocking or stopping the autoimmune attack that causes T1D. Our restoration work is based on a simple principle: the body can heal itself. If someone cuts their knee, for example, a scab forms and the wound heals. We believe the body can heal T1D as well—although it will need a little help to do so.

Our research is focused on expanding the number of beta cells present in someone with T1D so that normal insulin production can resume. Over the past several months, JDRF-funded research has made progress towards identifying drugs that have the potential to preserve beta cells in people with T1D.
CAN A CANCER DRUG HELP PRESERVE BETA CELLS?
Some years ago, JDRF funding helped to secure the first clinical study investigating whether the cancer drug imatinib (brand name Gleevec) has some effect on preserving beta cells in people with T1D. Since that time, numerous pre-clinical studies have suggested that the drug may slow the immune system attack on beta cells, reduce beta cell stress and death, and increase beta cell growth and replication.

With the help of JDRF funding, Dr. Stephen Gitelman, M.D., and his team of researchers at the University of California, San Francisco, are taking the next step towards determining whether imatinib is useful in preserving beta cell function. In April, researchers launched a new multi-site human clinical trial to assess whether newly diagnosed people with T1D who take the drug maintain greater beta cell function or experience slower disease progression than individuals with T1D who take placebo pills. The clinical trial will follow 66 volunteers for six months each over the next two years.

DRUG COCKTAIL SHOWS PROMISE IN STOPPING AUTOIMMUNE ATTACK
University of Florida researcher Michael Haller, M.D., and his team have conducted a series of studies comparing the effectiveness of existing drugs in facilitating beta cell survival when used either as monotherapy (singular drugs) or in drug-cocktail formulations (two or more drugs combined). The results of two recently completed pilot studies—one JDRF-supported and the other supported by JDRF funding partner The Helmsley Charitable Trust—suggest that a particular drug-cocktail formulation may be effective in preserving beta cell function where monotherapy is not.

For the JDRF-funded pilot study, 21 individuals with recent-onset T1D (less than six months) were randomly assigned to receive either a 12-week course of Neulasta (an FDA-approved drug used to reduce the risk of infection in chemotherapy patients) or placebo. Dr. Haller’s research team followed the participants for a year after treatment to see if those who received Neulasta had greater beta cell function than those who received placebo, but they found no difference in outcomes. Importantly, however, there were no substantial safety concerns found in the first trial of this drug in individuals with T1D.

In the second study supported by The Helmsley Charitable Trust, 25 study participants with established T1D (four to 24-months post-diagnosis) were randomly assigned to receive either a combination of Neulasta and Thymoglobulin (an immunosuppressant used by transplant patients to prevent organ rejection) or placebo. A year after treatment, Dr. Haller’s team found that those who received the drug cocktail had signs of significantly greater preservation of beta cell function than those who received placebo.

Researchers plan to follow participants from the combination-therapy study for a total of three to five years to see if their bodies will continue to preserve beta cell function over that course of time. The early findings from this study, however, were presented in June 2014 during a national scientific meeting, and Dr. Haller’s team is currently working on a journal paper that will detail the data. The research team has received funding through The Helmsley Charitable Trust, Sanofi and the National Institute of Diabetes and Digestive and Kidney Diseases to conduct a larger combination therapy trial in individuals newly diagnosed with T1D.
For JDRF, developing a biological cure for T1D so that those with the disease are no longer insulin dependent is only part of the solution. Ensuring that no one ever again develops it is equally important to achieving our goal of a world without T1D.

The ultimate aim of the JDRF Prevention Program is developing a childhood vaccine to immunize against the autoimmune attack that causes T1D. While we work towards that goal, the JDRF Prevention Program is also supporting research into anti-inflammatory agents and other therapies that would stall the progression of T1D and prevent insulin dependence from occurring. In addition, we are funding efforts to map the T1D disease process so that we can gain a full understanding of its causes and early mechanisms, which will enhance our ability to identify and halt the disease at its earliest stages.

**JDRF’S nPOD PROGRAM HELPS RESEARCHERS ID EARLY SIGNS OF T1D**

Researchers have been probing the mysteries of T1D for more than a century, but, due to the limited amount of human tissue available for study, little is known about the cellular mechanisms of the disease. The JDRF Network for Pancreatic Organ Donors with Diabetes (nPOD) program was created seven years ago in an effort to address this dearth of knowledge. Through nPOD, researchers gain access to tissue from organ donors with T1D and organ donors who have T1D antibodies but never developed insulin dependency. More than 130 research projects have been associated with nPOD since its inception.

The study of these tissues paired with the ongoing creation of a database of research findings has allowed scientists to acquire understandings about the T1D disease path that ultimately will guide development of preventive therapies and the journey towards a vaccine. Based on an analysis of nPOD samples, a group of JDRF-funded researchers were recently able to formulate and publish a consensus definition of insulitis—an early biomarker (biological signs of a disease’s existence) of T1D. Insulitis occurs when destructive immune cells infiltrate groups of insulin-producing beta cells within the pancreas. This process typically occurs at the earliest stages of T1D before symptoms develop.

The definition was formulated by leading T1D researchers during a scientific meeting, and it was published in the November 2013 issue of Diabetologia. Currently, there is no noninvasive method for detecting the presence of insulitis, and it can only be directly measured in donated human tissue. But the consensus definition clarifies the criteria for identifying the condition, and researchers can now work towards developing noninvasive methods for detecting and measuring insulitis in living individuals and using the findings to diagnose T1D at an earlier stage. In the future, an insulitis biomarker test combined with early treatment could prevent people with T1D from advancing toward insulin dependence.
LEADING THE PUSH FOR EARLIER DIAGNOSIS

An important aim of the JDRF Prevention Program is identifying biomarkers that point to the existence of T1D during the asymptomatic stage before insulin dependence has developed. In recent years, JDRF funding has helped scientists identify antibodies that indicate the activation of the autoimmune attack on insulin-producing beta cells. Now researchers are looking at whether these antibodies might be used as biomarkers to develop an earlier clinical diagnosis of T1D, and JDRF is once again leading the effort.

This past spring during the annual Rachmiel Levine Diabetes and Obesity Symposium, JDRF Chief Scientific Officer Richard Insel, M.D., addressed evidence of the need to change the diagnostic criteria for T1D so that it recognizes that disease onset begins before symptoms occur. Currently, T1D intervention only begins after the occurrence of symptoms, which means individuals with the disease and clinicians are missing an important window of opportunity to change the underlying course of T1D and potentially prevent insulin dependence from ever developing. Changing the criteria for T1D diagnosis to include the asymptomatic phase could have positive impact on the treatment of T1D.

WHAT’S AHEAD

Enabling people with T1D to become free of the disease and its complications and preventing those at risk from ever developing it are tangible goals that JDRF is committed to achieving. Doing so will take vision, scientifically rooted support of forward-thinking therapies, and the financial means to invest in their development. Thanks to supporters like you, JDRF has made tremendous progress in recent months in our priority research areas. But there is much more work to be done.

We have identified the following priorities for our ongoing work:

- Ensuring the continued development and flow of next-generation AP devices into the healthcare market place
- Advancing additional encapsulated cell therapy devices into clinical trials
- Identifying other promising research in the area of smart insulin development
- Supporting research that can lead to earlier diagnosis of T1D and opportunities to prevent onset of insulin dependence
- Exploring existing FDA-approved drugs that may prove useful in facilitating beta cell regeneration and survival by staving off the autoimmune attack that causes T1D

Each of the research projects supported by JDRF has the potential to lead to truly life-saving therapies for people with T1D. With dedicated partners like you, JDRF is confident we can realize a world without T1D.
## JDRF RESEARCH FUNDING HIGHLIGHTS

The following chart highlights selected JDRF research covered in this progress report. These projects are only a portion of the $500 million in active research being funded by JDRF, which is made possible through your generous support.

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<tr>
<th>RESEARCHER/PARTNER</th>
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<th>TOTAL JDRF FUNDING</th>
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