

## A Simple Yes

### *The FDA gives Spring Point Project the go-ahead*

Monday, October 20, 2008, Bernhard Hering of the Diabetes Institute for Immunology and Transplantation and Henk Schuurman from Spring Point Project met with the Food and Drug Administration (FDA) for an important Pre-Investigational New Drug (Pre-IND) meeting. Bernhard and Henk presented data to the FDA on the progress Spring Point has made since our beginnings. The FDA gave Spring Point guidance on source pigs, pig islet products and preclinical studies. The main Spring Point Project purpose of the meeting however was to pose the vital question:

**“Does the FDA agree that the present second generation source pigs in the Islet Resource Facility**

**(pigs who were born from parents that were delivered by C-section into the barrier facility) can serve as donor animals for the planned clinical trial in compliance with FDA guidances?”**

Following a thorough review of the submitted data, the FDA’s answer was a simple, **Yes.**

“This represents a milestone in the development of Spring Point Project premier ‘medical grade’ source pigs,” said Henk. “It reflects the care and efforts of all our staff since our very beginning.”

“Work remains to be done preparing the Investigational New Drug filing for FDA permission to proceed with clinical trials, but this simple confirmation indicates we are on the right path towards a cure for diabetes,” said Bernhard.

## Pig Postings

from the Diabetes Research and Wellness Foundation Islet Resource Facility, home of Spring Point Project

- As a result of our extremely successful internal breeding program, we are at full capacity with a large (both in numbers and in size) and healthy pig population. We are on track to produce the animals needed for clinical trials slated to start in 2009!
- We are actively sourcing animals to the Diabetes Institute for Immunology and Transplantation to conduct final protocol refinement work in islet isolation and effective immunosuppression in order to proceed with the pivotal preclinical study.
- Work is underway to initiate pancreas harvests on site, paving the way for both preclinical and clinical studies to come.



## Change a Life this Holiday Season

### *Sponsor a Pig*

You could change the life of someone with diabetes forever this holiday season by doing something as simple as sponsoring a pig.

Spring Point Project is working in partnership with the Diabetes Institute for Immunology and Transplantation at the University of Minnesota to develop a cure for insulin-dependent diabetes that will be widely available and affordable. Because many people with diabetes lack sufficient insulin-producing islet cells, the cure in development involves producing safe, reliable islets that can be transplanted to reverse the effects of diabetes.

This new and virtually unlimited supply of insulin-producing islet cells is now being produced—from

“medical grade” pigs. By sponsoring one of these pigs, you can help defray the \$50 daily cost to maintain a pig at the Diabetes Research and Wellness Foundation Islet Resource Facility.

Sponsor a pig for a day, week, month, quarter, or year in the name of a family member, friend, or yourself and support our work on the path to find a cure for diabetes. For more information about Spring Point Project, and the exciting cure in development, please go to [springpointproject.org](http://springpointproject.org).

Since our *Sponsor a Pig* campaign launched in late 2007, over \$210,000 has been donated in order to find a cure.

## Lion and Lioness Pride Shines Through

### *New outreach projects take off*

Since our inception in 2004, the Lions and Lioness clubs have supported our work to find a cure for diabetes. Their support has helped us tremendously and has led to increasing awareness throughout the midwest for the work being done at the Diabetes Institute for Immunology and Transplantation and Spring Point Project. Recently, their support has been brought to a higher level:

- A Diabetes Foundation to support Spring Point Project and the Diabetes Institute has been approved for creation at the Lions multiple district 5M meeting. The 5M district includes Minnesota and parts of Manitoba and Ontario.
- Diabetes Evenings have been initiated at Lions Clubs throughout Minnesota and Wisconsin. These evenings

are designed to let the public, as well as professionals involved in diabetes care, know about our mission and our progress. Three events have been held in the last month. One in Benson, Minnesota led by Woody Dokken and his club, another in Jackson, Minnesota with Tim Olson and his club, and one in Hudson, Wisconsin with Judi Schmitt and her club. Each event was well attended and very successful.

- Spring Point Project is now approved as a project at the multiple district 5M (Minnesota and parts of Manitoba and Ontario) level, paving the way for individual club support of our efforts.

We are very grateful to all the local Lions Clubs for their activities, initiatives and continued support.



*Tim Olson and his two boys with Henk Schuurman at the Jackson Lions Club Diabetes Event organized under the leadership of Tim and his club: his 7-year-old son Carter just had his 4th diabetes anniversary on November 15*



*Henk Schuurman talking to a large crowd that assembled at Our Savior's Lutheran Church in Jackson, MN to hear about Spring Point Project and its Partnership with the Diabetes Institute, an evening organized by the Jackson Lions Club*

## 2008 Reflections



Tom Cartier



Henk Schuurman

As 2008 comes to an end, we would like to take a few minutes to reflect on Spring Point Project's achievements and to thank all of you—our donors and supporters—for helping us continue to move towards a cure for diabetes.

We are happy to report that in April of 2008, the first of our second-generation medical grade animals were born at the Diabetes Research and Wellness Foundation Islet Resource Facility. In October, the FDA acknowledged our progress and gave us the go ahead to move toward clinical trials. (*See related A Simple Yes article on page 1*). Since April, our sows delivered additional piglets. As a result of these accomplishments, our state-of-the-art facility is now fully populated and we are squarely on

the way to producing the animals needed for clinical trials, which are slated to start in 2009.

Pig production at our Riverside Multiplier Unit, which we run together with our colleagues in the Hutterian Brethren Riverside Colony, continued in 2008 as well. Pigs from this facility supply the Diabetes Institute for Immunology and Transplantation at the University of

Minnesota with the islets needed for preclinical studies, including pig to primate transplantation. The Juvenile Diabetes Research Foundation supports this pivotal work on immunosuppression. The isolation of islets from the pancreas of juvenile pigs at the Riverside Multiplier Unit has taught us that these animals can provide high-islet cell yield, confirming that the best quality animal donors were selected at the inception of our work. Truly great results!

The Minnesota High Tech Association honored us as one of the state's most prominent technology companies in the biotechnology category. We also received attention from the international scientific community and had scientists from Canada, Sweden, China and Japan visit us to learn more about our work. Our staff gave presentations at scientific meetings and published work in peer-reviewed international biomedical journals.

We reinforced our board with the addition of Timothy Clark (Senior Partner, Carval Investors), Mack Traynor (CFO, Spring Point), Steven Murphy (former CEO, National Pork Board) and Scott Dee (Professor of Veterinary Population Medicine and Director, Swine Disease Eradication Center, University of Minnesota). We look forward to working with them to design the future of Spring Point Project. In addition, two big supports from our early beginnings, Liz Burns and James "Cub" Olson, resigned from our board. We are most grateful for their contributions in building Spring Point Project.

With the support of the community and our fantastic donors, we were able to hold several successful fundraisers including: the Annual Diabetes Memorial Ride in Duluth, Minnesota; the Spreading the Word event at West Bend Mutual Insurance Company in West Bend, Wisconsin; the Jeff Dobbs Golf Classic "fore" Diabetes Tournament in St. Paul, Minnesota; and the Chill at the Pool event in Minneapolis, Minnesota. The Lions Club also continues to widen their support for us, for which we are very grateful. (*See related Lion and Lioness Pride Shines Through article on page 2.*)

Together with the Diabetes Institute for Immunology and Transplantation, we have a clear vision to accelerate the availability and affordability of islet replacement with minimal or no immunosuppression. We thank everyone who has endorsed and supported us on our path to find a cure for diabetes. You make our work possible and we are most grateful. We wish all of you an enjoyable holiday and a happy and healthy 2009. The coming year will bring us one year closer to finding a cure for diabetes. Thanks to you.

With best wishes,

Tom Cartier, Founder and  
Chairman of the Board of Directors  
Henk Schuurman, CEO

### 2008 at a Glance

- Pig Herd at capacity in the Diabetes Research and Wellness Islet Resource Facility
- FDA gives Spring Point Project the go-ahead to use our medical grade pigs in clinical trials
- Four new board members join us—Scott Dee, Tim Clark, Steve Murphy, Mack Traynor
- Joint fundraising with the Juvenile Diabetes Research Foundation and University of Minnesota launched
- Golf Classic "Fore" Diabetes Research sets record raising nearly \$500,000
- Poolside dinner with matching funds sets record raising over \$60,000
- Lions Club International contributions to Spring Point go over \$60,000 mark
- University of Minnesota, our Partner, nets the largest gift to diabetes research in Minnesota history. A gift of \$40 million over five years from the Richard M. Schulze Family Foundation was announced on December 11.

## News from DIIT (Diabetes Institute for Immunology and Transplantation)

- A paper highlighting approaches to improve pancreas preservation for pancreas and islet transplantation was published by Drs. Iwanaga, Sutherland, Harmon, and Papas.
- Another paper by investigators in our group studied the molecular changes that occur within islet cells after they are isolated from a pancreas.
- Findings in both papers confirm the quality and quantity of islets obtained from both human and pig pancreas donors will be better when the preservation of the donor pancreas is improved and we have a greater understanding of what occurs within islets after isolation.
- During a productive meeting with the FDA, we presented our current studies focusing on preventing rejection in pig islet-to-nonhuman primate trials. The goal of these trials is to generate the data needed to obtain FDA approval for a clinical trial involving the use of pig islets in humans.
- Former board member, Jeffery Dobbs died in October 2007 at the age of 51. The Institute that he supported with such enthusiasm recently honored his longtime commitment to raising money for diabetes research by renaming the endowed chair held by pioneering physician-scientist David E.R. Sutherland, MD, PhD, head of the Transplant Division in the University's Department of Surgery and director of the DIIT. Historically called the Golf Classic "fore" Diabetes Research Chair, it will now be called the Jeffrey Dobbs and David E.R. Sutherland, MD, PhD, Diabetes Research Chair.

## Thanks, Merci, Gracias, Dankeschön

To our many donors and supporters, our sincere and heartfelt thanks for your contributions in 2008. You have helped us immeasurably as we push toward finding a cure for diabetes.



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