Letter from the CEO

ALS is a race against time. Every year when I look back at what we have accomplished, I see the faces of the people living with ALS today and the faces of those whose journey has ended. There is no shortage of either. ALS isn’t going to stop being a problem unless we do something about it.

With that in mind, I am excited to share this report with you. We have tried to highlight some of the most exciting and important advances over the past year at the Institute, including two potential treatments that we are eagerly moving toward the clinic. It is my honor to inform you that we have entered into an important research agreement with Biogen Idec and UCB Pharma on moving one of those projects forward. Being able to leverage the clinical development expertise of these two world-class biopharmaceutical companies is a tremendous advantage for TDI and an asset for the entire ALS community.

ALS is a complex neurodegenerative disorder. It is also a heterogeneous one, both in terms of site and age of onset, progression direction and rates. It has become clear that it will take more than a single “drug” to stop this disease in all those diagnosed. Therefore, our strategy has been and remains focused on tackling this disease from all sides. With that in mind, and in addition to moving two projects into clinical development for ALS patients today (TDI 846 and TDI 132), the team at TDI completed 12 full efficacy studies on other potential treatments for ALS. They also generated 20 new therapeutic strategies aimed at modulating novel biological targets, and executed 10 pharmacogeneomic studies generating billions of data points. The mantra: let the data drive us. The mission: end ALS.

This past year has been filled with great excitement. The progress we have made would not have been possible without the continued charitable support we receive from ALS patients, families, and foundations. In fact, we received some 14,000 individual donations in 2011. The strength of our finances and commitments to transparency and efficiency again made ALS TDI the highest rated ALS-charity in the US according to CharityNavigator.com.

Next year will be filled with great anticipation and new challenges. We look forward to moving our candidate therapeutics TDI-132 (Gilenya) and TDI-846 (together with Biogen Idec and UCB Pharma) forward into the clinic. We are also planning a major expansion of the Institute – the first in nearly seven years. That move will allow us to take on more and move faster. That is our commitment and that is what is needed as we continue to strive forward in our mission to end ALS.

Sincerely,

Steve Perrin, Ph.D.
CEO & Chief Scientific Officer
ALS TDI has long thought ALS was a disease of the motor neurons (pictured here). Recent research shows it is a much more complex disorder.
**Biogen Idec & UCB Pharma Partnership**

In the first ever three-way research agreement in ALS, we announced an exciting research agreement with two major global pharmaceutical companies – Biogen Idec and UCB Pharma – to investigate a novel potential treatment for ALS.

**World’s First TDP-43 Mouse to be Characterized**

ALS TDI will be the first to characterize this newly discovered model, and to determine its use in validating potential treatments. The MDA, Alzheimer’s Drug Development Foundation, and the Association for Frontotemporal Degeneration partnered with us to fund this project as there is shared TDP43 pathology across many diseases.

**Inaugural White Coat Affair Gala**

More than 350 people attended the first White Coat Affair gala held at the world-famous Fairmont Copley Hotel in Boston. U.S. Congressman Michael Capuano of Somerville, Mass. received the first ever ALS TDI Iron Horse Award in recognition of his leadership and support of ALS patients and research.

**New Website Launched**

We were the first to launch an online forum to help PALS interact online, and one of the first to build our own online fundraising and social network for families affected by this disease. Keeping up with the latest web-based technology is a non-stop job. Our new website was launched in collaboration with MadPow! after an extensive interview and case study process that involved PALS, CALS, funders, and board members.

**7th Annual Leadership Summit**

Featured speakers included Stan Appel, Christopher Austin, Robert Blum, Doug Onsi, Steve Perrin, Jeffrey Rothstein, George Scangos, Henri Termeer. Leadership Awards went to Sharon Illes, Thomas Ohlson, Megan Mishork, and Frank Provost.

**Promising Preclinical Research on FDA-Approved Compound**

TDI preclinical research on the FDA-approved compound Gilenya® showed it to be a strong candidate therapeutic for ALS. The Institute hopes to advance it to clinical trial in 2012.
Where did the data lead us?

The human body is complex; interconnected systems work together to enable proper function. In ALS, we typically think of the nervous system as the key to controlling function, and it has therefore been the target of decades of research and development.

At TDI, our mantra has been to let the data drive us, and following a major genomic research project initiated in 2007 with our partnership with the MDA, funded in part through the work of Augie’s Quest, we identified several previously unknown aspects of the disease that changes the way we think about ALS and the speed at which we would be able to move potential treatments into the clinic.

One of the discoveries we made about the pathobiology of ALS led us to understand the potential role that the immune system played in both the onset and progression of the disease. Coupled with that finding was the fact that immunomodulatory drugs are vastly available for preclinical screening, and many of them were already FDA-approved for other disease indications. Hundreds of people living with ALS, as well as many control subjects, provided blood and other tissue samples that led us to making these important discoveries, and the value of those donations of self cannot be understated. Much of this work was published by Lincecum and Vieira in *Nature Genetics* in 2010, linking the findings from mice to humans to drug.

Last December, a crucial new piece of the puzzle came together when we announced a research agreement with two world-leading pharmaceutical companies, Biogen Idec and UCB Pharma. This relationship made ALS TDI the only nonprofit research institute focused on an orphan disease in the world to have partnered with two global pharmaceutical companies to develop treatments for ALS patients today. Under the terms of this agreement, TDI will test “CDP7657” in the SOD1 model. This project is codenamed TDI 167 and can be tracked in real-time on our website. On conclusion of the study, expected by the end of the 3rd quarter this year, Biogen Idec and UCB will have the option to license global rights to develop and commercialize compounds targeting the CD40L pathway in ALS. A ‘go/no-go’ decision is expected before the end of 2012.

ALS TDI has always valued openness and transparency from the start. With these in mind, Steve Perrin hosted a webinar with nearly 200 PALS, CALS, and researchers on this historic step forward toward achievement of our mission. In opening, he stated that, “We are grateful to have such knowledgeable and passionate partners such as Biogen Idec and UCB Pharma in the battle to end ALS. The data will continue to tell us where we go from here.”
“ALS is a devastating and deadly disease, and Biogen Idec and UCB are both committed to finding therapies for severe neurological diseases with high unmet medical need. We are excited about this project and look forward to working with ALS-TDI in this investigation,” said Douglas Kerr, M.D., Ph.D., Biogen Idec.

“By combining ALS TDI’s innovative approach to bridging the translational research gap with our companies’ strengths in developing and commercializing novel therapies, we hope to advance this promising compound for ALS patients,” added Neil Weir, Senior Vice President Discovery Research, at UCB.
Hundreds of Families, Thousands of Donors

Hundreds of families and thousands of donors join us to discover and develop effective treatments for ALS patients today. For every single step along the way, the ALS community has been with us. We are grateful for the support we receive over the years. Here are just a few reasons people give for supporting YOUR lab:

William Hassel
PALS, Victoria Texas
I know the people at ALSTD1 are committed to give all they can as we research for treatments and a cure.

Katrina DeVinny
Gilbert, Ariz.
Mother had ALS
I support ALS TDI because all they do is work towards finding a treatment and cure for ALS.

Alison Greenspan
Los Angeles, Calif., Daughter of PALS
ALS TDI was my lifeline for my family when my father had ALS, and because scientifically ALS TDI is at the forefront of the quest to find a cure for this cruel disease.

Mary Murray
PALS, Beverly, Mass.
Here is a photo of Bob and me, and two of the reasons we are so interested in TDI’s research into slowing down this disease. I can no longer read out loud to Teddy and Simon, but I can still enjoy their company and hold them and even run after them.
Mike Winston is a huge inspiration to all of his friends, and we have a lot of love for him. There is no better way to support Mike then to team up with ALS TDI to fight this horrible disease. Together, we can find a cure!

Zach Freeman  
Chicago, Ill., Friend of PALS

We host an annual golf outing to help raise funds and awareness for ALS, so other families don’t have to lose a loved one like we did. Our children will never know their grandmother due to this disease and a cure must be found.

Jess Antal  
Ohio, Grandmother had ALS

We have seen over 20 family members lost to this disease, so we partner with ALS TDI because we believe that their research focus will put an end to our kids losing moms, dads, aunts and uncles before their time.

Connie Becker  
Amboy, Ill., FALS Family

ALS TDI offers the best hope for discovery and development of therapies for those of us afflicted with ALS.

Tom Anderson  
PALS, McKinney, Texas

The Olson family (over 60 members) have been affected by this terrible disease; we are united in our efforts to support TDI to find a cure.

Scott Grausnick  
Minn., Son has ALS

My son Alex is a 22-year-old senior at the University of St Thomas. He was diagnosed with ALS about 4 years ago. ALS TDI is an organization that our family has chosen to support because we believe that they will help us to find a cure for ALS ......for Alex and our family, nothing is more important than that!

Rick Olson  
Illinois, FALS Family

I support ALS TDI to fulfill a dying promise to my mother that I would ALWAYS help raise awareness & funds to put a stop to this disease & TDI is the ONLY organization I can truly say that I know that is what they are trying to do!

Sharon Iles  
New Orleans, La., Mother had ALS
Keeping Outside Things Out

With a single goal in mind – end ALS – our drug development team is never content with the pace of research. We are constantly learning from new data and looking for ways to simultaneously screen many potential treatments at once, always with a focus on our greatest value – patients today.

One of the considerable challenges in developing a treatment for ALS is that over the course of the disease, the blood brain barrier breaks down and circulating white blood cells, called T-lymphocytes, infiltrate the central nervous system (CNS). The illustration to the right depicts microglia (purple) and astrocytes (light blue) becoming activated due to the T-lymphocytes’ (dark blue) presence. This in turn triggers the inflammation of motor nerves, further fueling the progression of the disease.

TDI first began preclinical testing of TDI 132 in 2011 for its ability to block T-lymphocytes from entering the CNS where they can cause neuroinflammation, resulting in this damage to motor neurons. TDI 132 (aka fingolimod) is an FDA-approved, orally available compound produced by Novartis, called Gilenya®. It is used to treat certain forms of multiple sclerosis.

Research conducted at TDI in 2011 confirmed that TDI 132 significantly alters the trafficking of these immune cells through the bloodstream, resulting in fewer of them infiltrating into and damaging the nervous system. In vivo experiments confirmed that treatment with TDI 132 delayed the onset of ALS and extended survival in the SOD1 mouse model of ALS. The results from these experiments confirmed that TDI 132 was a potential treatment for ALS.

Just as important as finding a second compound that seemed to alter progression of disease, TDI stumbled upon one that came with an inherent biomarker of drug and dose response with Gilenya. Access to blood samples in a clinical trial would provide immediate feedback on whether or not the drug was “working” by measuring the number of T-lymphocytes in circulation. Approaching ALS like this has never been done before and such a well designed clinical trial could rapidly get an answer to the most important question: does it work? The same approach is used in MS to determine whether or not a person is responding to a specific medication. TDI is applying this approach to ALS, in hopes of reducing the time it takes to conduct a clinical trial and to empower patients and doctors to know if a potential treatment may work for them. This is an important step toward a personalized medicine approach so desperately needed for ALS.

A comprehensive review and analysis of these results, in consultation with outside experts, gives ALS TDI the confidence to push this potential therapeutic for ALS forward into the clinic. The trial is anticipated to launch sometime in 2012. We estimate the cost of this trial to be approximately $2 million and are committed to getting an answer for patients today.
T-lymphocytes take advantage of a compromised blood-brain barrier in ALS patients. Once in the CNS, these cells cause others to become agitated, leading to neuroinflammation.
2011 Financial Review

For the fiscal year ending December 31, 2011, ALS TDI recognized just shy of $8 million in revenue – nearly flat with the previous year. The largest area of decrease was seen in grants and contracts, which comes as no surprise given the continued slow recovery being experienced by many grant making organizations. However, thanks to efforts of new families and supporters, special events and contributions revenue increased by nearly half a million dollars, providing crucial funding to help the Institute prepare for a major and necessary expansion in 2012. Thanks to their continued support and that of major foundations such as the MDA, RGK, and Driskill Foundations, the Institute remains in excellent financial health.

A full breakdown of our assets, liabilities, revenue, and expenses is below. For a complete copy of our IRS Form 990 or Independent Auditors Report, please visit our website at www.als.net or call us at 617-441-7200.

### Assets

#### Unrestricted Assets

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<tr>
<th>Asset</th>
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<tr>
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#### Restricted Assets

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**Net Assets EOY 2011** 5,421,510

### Liabilities & Net Assets

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<td>Total EOY Net Assets</td>
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**Total Liabilities & Net Assets** 5,421,510

### Public Support

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<tr>
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**Net Public** 7,997,504

### Expenses

#### Program

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<tr>
<th>Category</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>R&amp;D</td>
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<tr>
<td>Science</td>
<td>2,158,132</td>
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<tr>
<td>Lab</td>
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<tr>
<td>Informatics</td>
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<tr>
<td>Patient Services</td>
<td>258,419</td>
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<tr>
<td>Clinical</td>
<td>10,409</td>
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<tr>
<td>Communications</td>
<td>861,249</td>
</tr>
<tr>
<td>BD</td>
<td>117,892</td>
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**Total Program** 6,707,315

#### Support

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<th>Category</th>
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<tbody>
<tr>
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<tr>
<td>Fundraising</td>
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**Total Support** 1,035,726

**Total Expenses** 7,743,041
In 2011, ALS TDI was again recognized for its commitment to transparency and efficiency by CharityNavigator.com. The Institute once again out-performed every other non-profit reviewed in 2011, according to the world’s top independent nonprofit rating resource. We are proud of this rating and to be recognized for our commitment to spend as much funding as possible every day on research toward our single mission: end ALS.

The graph below depicts important information about how ALS TDI spends the funding it receives. The first column lists the type of spending for “program services” vs. “support services”. The next divides those down further into important sub-groups. The most important fact here is that we actually spent nearly $200,000 less on administration and fundraising costs compared to last year. This is a testament to the way that we fundraise and the tremendous ownership that patients, families, and communities take over ensuring our continued and rapid progress toward our mission: end ALS.

<table>
<thead>
<tr>
<th>Expenses</th>
<th>2011</th>
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</thead>
<tbody>
<tr>
<td><strong>Program</strong></td>
<td><strong>Amount</strong></td>
</tr>
<tr>
<td>R&amp;D</td>
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<tr>
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<td>BD</td>
<td>117,892</td>
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<tr>
<td><strong>Total Program</strong></td>
<td><strong>6,707,315</strong></td>
</tr>
<tr>
<td>Support</td>
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<td>General</td>
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<td><strong>Total Support</strong></td>
<td><strong>1,035,726</strong></td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td><strong>7,743,041</strong></td>
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Steve Perrin, Ph.D.
CEO & Chief Scientific Officer

ALS TDI Board of Directors
Augie Nieto
Chairman
Steve Perrin, Ph.D.
Vice Chairman
Stanley H. Appel, M.D.
Alexander Cappello
James Allen Heywood
John B. Heywood, Ph.D.
Spiros Jamas, Ed.D.
Keith Melanson
Leslie Michelson
Rob Rodin
Ted Reich, J.D. & CPA
John Sutherland

Corporate Officers
President, Steve Perrin, Ph.D.
Treasurer, Ted Reich, J.D. & CPA
Clerk, John Sutherland
Director of Operations & Assistant Clerk, Ken Thompson
The Family Funds at ALS TDI

There are more than 500 of these funds, each playing an important role in driving the research at ALS TDI. The following list recognizes Family Funds that have provided at least $10,000 over the past 12 years. A complete list, with links to bios and fund activities, is available on our website at www.als.net.

Cumulative Fund Totals

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<tr>
<th>$25M+</th>
<th>Year Started</th>
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<tr>
<td>MDA's Augie's Quest</td>
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<table>
<thead>
<tr>
<th>$6M+</th>
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<tbody>
<tr>
<td>Stephen Heywood Family Fund</td>
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<table>
<thead>
<tr>
<th>$3M+</th>
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<tbody>
<tr>
<td>Sean Forrester Scott Fund</td>
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<table>
<thead>
<tr>
<th>$2M+</th>
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<tbody>
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<tr>
<td>Kozmetsky Family Fund</td>
<td>2003</td>
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<tr>
<td>Corey Reich Fund</td>
<td>2007</td>
</tr>
<tr>
<td>Tri-State Trek</td>
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<table>
<thead>
<tr>
<th>$1M+</th>
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<tbody>
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<tr>
<td>Friends for Faye Fund</td>
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<tr>
<td>Mary Lou Krauseneck Fund</td>
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<tr>
<td>Stephen Milne Effort</td>
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<table>
<thead>
<tr>
<th>$500K-$999K</th>
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<tbody>
<tr>
<td>Bruce Edwards/Tom Watson Fund</td>
<td>2003</td>
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<tr>
<td>DeeDee Fornengo Fund</td>
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<tr>
<td>HMS Host Fund</td>
<td>2004</td>
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<tr>
<td>Jeff Julian Fund</td>
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<tr>
<td>Anthony Tucker Fund</td>
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<tr>
<td>Stanfield Family ALS Research Fund</td>
<td>2003</td>
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<tr>
<td>Michael Winston Research Fund</td>
<td>2008</td>
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<table>
<thead>
<tr>
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<td>ALS Family Charitable Fund</td>
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<td>Tom Becker Fund</td>
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<td>Jim Canty Fund</td>
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<tr>
<td>Pam Callahan Fund</td>
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<tr>
<td>Jeff Cronon Fund</td>
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<tr>
<td>Marie Garrett Memorial Fund/Dash for a Cure</td>
<td>2003</td>
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<td>Jeff Hadley Fund</td>
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<td>Larry Manes Fund</td>
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<td>The James and Alice McGonagle Charitable Trust</td>
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<td>Jack Orchard Effort</td>
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<td>Ride for Life Fund</td>
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<td>Margaret Roblin Fund</td>
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<td>Jenny Stoddard Family Fund</td>
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<td>Thysen Family Fund</td>
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<table>
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<td>Barretti Family Fund</td>
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<td>Blazeman Fund</td>
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<td>David Dorfman Fund</td>
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<td>Dallas ALS Fund</td>
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<td>Matt Dowd Fund</td>
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<td>Larry Ellis Fund</td>
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<td>David Green Fund</td>
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<td>Kevin Kelty ALS Research Fund</td>
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<td>Todd Ketchum Fund</td>
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<td>Kim Family Fund</td>
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<td>Team Gey</td>
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<td>Ternet Friends Fighting ALS Fund</td>
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<td>Edward Bingham Fund</td>
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<td>Lee Blaskovich Memorial ALS Research Fund</td>
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### The Family Funds at ALS TDI continued

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<td>Steve Greenspan Fund</td>
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<td>Wynne Gulden Fund</td>
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<td>Johnson &amp; Johnson Corporate Fund</td>
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<td>Mike Justice Fund</td>
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<td>Rubin Kuznitsky Fund</td>
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<td>Tom Larsen Fund</td>
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<td>Manhattan Fund</td>
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<td>Chris Martin Fund</td>
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<td>Meridiths Fight 4 Life</td>
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<td>Roby Molnar Swiss Fund</td>
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<td>Melba Moeck Fund</td>
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#### $10K-$25K

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<td>ALS Soccer Cup</td>
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<td>Tim Schneider Memorial Fund</td>
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<td>Teach to Fight ALS</td>
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<td>Team Sheila</td>
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<td>John Wake Fund</td>
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<td>Carla Zilbersmith Fund</td>
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#### $25K-$49K

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<td>Neil Brouman Fund</td>
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<td>Mary Lou Watkins Fund</td>
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</table>
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Kevin Chen
Kevin Turner
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Kreg Pearless
Kristen Pearless
Larry and Deborah Silver
Larry and San Rosen
Larry Knight
Larryyd and Brenda McNabb
Lauren Pretre
Lawrence Oshin
Layers Company
LeClaire Ryan
Lee Dellicker
Lee Wesley Group Inc.

Leisure Sports, Inc
Leslie E Cook
Lewis Bednarczuk
Libbey
Linda Hammer
Lisa Anderson
Lisa Bannon And George Steinmetz
LMI
London Family Charitable Fund of Tampa Orlando Pinellas (TOP) Jewish Foundation Inc
Lonestar Charity Llc
Lonestar Charity LLC
Lou and Celia Star Gody
Louis Ltd
M Medved Co Inc
Manchu Wok (USA) Inc
Marc and Jeri Shapiro Family Foundation
Marc Berman
Marcia Jacobson
Marcia Luisi
Margaret Hansatty
Marion Foundation
Maritech Windows LLC
Mark and Kym Williams
Mark Denton
Mark Elmdendorf
Mark Farrow
Mark Lilly
Mark Stone
Markstein
Martha Berardino
Martin Cox
Marwan Atalla
Mary Grave
Mary Hull Old
Mary Reasoner
Mary Scott Morton
Masergy Communications inc
Mass Bio Council
Massachusetts Resource
Matec Instrument Inc
Matt Gann
Matthew and Cathy Rosing
Matthew Roberto
Matthew Watkins
Maureen Goldfarb
McDonald Physical Therapy and Sports Rehab Center PC
Melanie Aebischer
Melanie Shugart
Merck Partnership for Giving
Michael Freeman AND Beverly Freeman
Michael and Debra Jaff
Michael and Jean Artin
Michael and Maureen Basak
Michael and Nancy Crosby
Michael Burr
Michael Connors
Michael Donnewald
Michael Foods Inc
Michael Keogh
Michael Krikorian
Michael Mazzocco
Michael Mazzola
Michael Metzger
Michael Millman
Michael Pennington
Mike Mulcahy
Mitchell Roberts
Motch Family Foundation Inc.
Mr. & Mrs. Daniel Boe
Mr. & Mrs. David Sabato
Mr. and Mrs. Roderick McRae
Mutual Of Omaha Insurance Company
Nancy and Edward Roberts
Nancy Houser
Natalia Klykova
National Philanthropic Trust
Nav Sooch
Nelson Fegtgetter
North Llc
Ogi Eyewear
Ogletree, Deakins, Nash, Smoak and Stewart, PC
Olivier Brandt