THE STUNNING VISION improvements made possible by Leber congenital amaurosis (LCA2) gene therapy have been highly inspiring for Jeffrey D. Marrazzo in his new role as chief executive officer of Spark Therapeutics.

“It’s remarkable to see a patient go from having significant visual impairment — from not even being able to see their feet — to navigating a mobility course without missing a beat,” he says. “I really see the huge impact that our treatment will have on children and people in formative stages of life. It’s what gets me out of bed every morning.”

His company, a spin-off of The Children’s Hospital of Philadelphia (CHOP), is the latest to emerge in the burgeoning field of retinal-disease gene therapies. Spark has received an initial capital commitment of $50 million to clinically develop and commercialize gene therapies for inherited retinal diseases as well as neurodegenerative and blood disorders.

Spark follows in the footsteps of other retinal gene-therapy companies — including Oxford BioMedica, Applied Genetic Technologies Corporation and GenSight — which have recently garnered tens of millions of dollars to move their treatments into the marketplace. The Foundation Fighting Blindness funded critical lab research that made many of these companies’ clinical trials possible.

“It’s an important role the Foundation plays, helping researchers ‘de-risk’ their work early on and advance it to the point of attracting additional large-scale funding,” says Stephen Rose, Ph.D., chief research officer of the Foundation. “We’re seeing more and more of these game-changing investments into companies committed to taking retinal-disease gene therapies through clinical trials and on to the next step: commercialization for patients.”

Spark’s lead project is the gene therapy to address blindness caused by RPE65 mutations, which leads to LCA2 and retinitis pigmentosa. The treatment is now in a Phase III clinical trial at CHOP and the University of Iowa. Clinical development of the program was initiated in 2007 and initially funded by CHOP’s Center for Cellular and Molecular Therapeutics, with support from the Foundation. It is now the most clinically advanced gene therapy for any retinal degenerative disease. Vision improvements made possible for 12 children and adults in the Phase I trial have received acclaim from the international science community and media.

In the recently launched Phase III trial, at least 24 participants, including children as young as 3 years of age, are having both eyes treated on different days within a two-week period. The company plans to seek marketing approval for the treatment from the U.S. Food and Drug Administration at the conclusion of the study, which is expected in 2015.

“With CHOP having been the first to get a retinal gene therapy into Phase III, there was a lot of important know-how and experience to build a strong platform for ocular gene therapies,” says Marrazzo. “It presented an opportunity to create a company in a different way, to incubate and finance the company from within and with the academic institution as the partner.”

“It’s remarkable to see a patient go from having significant visual impairment — from not even being able to see their feet — to navigating a mobility course without missing a beat.”

— Jeffrey D. Marrazzo

Much of the Spark team — which includes Jean Bennett, M.D., Ph.D., a pioneering scientific advisor for the LCA (RPE65) trial — came from CHOP’s Center for Cellular and Molecular Therapeutics. Many of its members have been working together in gene therapy development for 10 or more years.

“It was critical to keep that team together — a team that has clearly shown the ability to execute successfully,” says Marrazzo, whose past professional endeavors have helped raise or place more than $150 million in start-up companies. “That’s what got me really excited about the opportunity to join them.”

“It’s great to see such strong entrepreneurial talent moving into the retinal disease sector. They’re providing the business skills and industry expertise we need to get the job done,” says Dr. Rose. “The emergence of companies like Spark to advance and commercialize vision-saving therapies is incredibly exciting for the Foundation and our constituents.”
It’s clear that time is of the essence for the Foundation’s constituents, and our partners know this. In fact, we’re currently in talks with a big pharma company interested in supporting clinical trials of a treatment we support. And, as covered in “Seal of Approval,” a story in the fall 2013 InFocus, our financial support of two start-up companies developing a few treatments between them helped bring each $40 million in venture capital money.

In fact, this issue’s cover story, “The Next Step: Commercializing Retinal Gene Therapies,” tells another successful teamwork effort, this one supported by funding the Foundation provided for the LCA gene therapy taking place at Children’s Hospital of Philadelphia. The hospital recently founded Spark Therapeutics, a company that plans to move the LCA therapy as well as others for retinal and non-retinal diseases to market.

Innovative collaboration is now the way of doing biomedical business, a way pioneered by the Foundation since its early days. We knew that, more than anything, we’d serve as a matchmaker of sorts, bringing together researchers with government agencies, venture capitalists and companies to produce treatments and cures for retinal diseases. For even more evidence on that front, see the update on the Foundation’s Translational Research Acceleration Program (TRAP) annual meeting in Las Vegas, where researchers behind FFB-funded projects reported on their progress (pg. 3). “Leverage” is what I call it. One of the Foundation’s primary responsibilities is to compound our own funding by attracting outside investments and resources to move promising treatments into clinical trials. And to do it soon, matching the urgency of millions losing their vision. Here’s wishing the Foundation, and all of you, who make its work possible, a productive, prosperous and healthy new year.

WILLIAM T. SCHMIDT
Chief Executive Officer
Foundation Fighting Blindness

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Physicians differ in their approach to incorporating research results into their clinical practice. You should always consult with and be guided by your physician’s advice when considering treatment based on research results.
RESEARCH NEWS

Impressive Returns on $70 Million Translational Research Investment

EIGHTEEN OF THE WORLD’S LEADING retinal researchers convened in Las Vegas November 18-20 to present their progress in advancing clinically focused research made possible by the Foundation’s Translational Research Acceleration Program (TRAP). Seventy million dollars has been allocated to the program since 2008 to move promising retinal-disease treatments into human studies.

A major goal of TRAP is to develop therapies to the point where they attract outside investment from biopharmaceutical companies and venture capital firms, which have the financial resources necessary for supporting clinical trials that lead to commercial availability of treatments. One case in point is an optogenetic treatment now being developed by GenSight Biologics, a French gene-therapy development company. Thanks, in part, to the promise of this TRAP-funded therapy — designed to restore vision for people with advanced retinitis pigmentosa — José Sahel, M.D., and his GenSight collaborators have garnered venture-capital funding.

“We are delighted by the commercial investment being attracted to TRAP-funded research,” says Gordon Gund, chairman and co-founder of the Foundation and a lead TRAP investor. “These partnerships are providing the capital and development expertise needed to get human studies off the ground.”

“Our researchers are innovators with great ideas that have strong potential for saving vision. Industry is recognizing that fact and eager to include TRAP-funded projects in their portfolios,” says Stephen Rose, Ph.D., chief research officer of the Foundation.

TRAP currently funds a broad range of research projects, including stem cells, gene therapies, pharmaceuticals, gene discovery and knowledge-advancing clinical and genetic studies. Most of the projects involve emerging therapies that are two to five years away from human studies.

A full report on all TRAP-funded projects is available at www.FightBlindness.org/TRAP2013.

Orphan Designation Boosts Clinical Development of RP Stem Cell Therapy
ReNeuron, a stem-cell therapy development company in the United Kingdom, has been granted an orphan designation by the U.S. Food and Drug Administration (FDA) and the European Commission for its emerging retinitis pigmentosa (RP) treatment, known as ReN003. Given to potential treatments for rare conditions that are life-threatening or chronically debilitating, “orphan” status provides a company with development incentives, tax credits and market protections for therapy development.

The designation bolsters ReNeuron’s plan to launch a Phase I/II clinical trial for ReN003 in mid-2014. The company is partnering with the Schepens Eye Research Institute at the Massachusetts Eye and Ear Infirmary to develop the treatment. According to Michael Young, Ph.D., a lead investigator on the project at Schepens, ReNeuron plans to initiate the study in the United States and later extend it to Europe. The Foundation funded earlier research that helped make this therapy possible.

The emerging treatment involves the transplantation of retinal progenitor cells, which are more mature than embryonic stem cells, but haven’t completely developed into photoreceptors, the cells in the retina that make vision possible.

Canadian Team to Conduct Clinical Trial for Choroideremia Gene Therapy
The Alberta Ocular Gene Therapy Team at the University of Alberta in Edmonton is planning to launch a Phase I human study of a gene therapy for choroideremia in the first half of 2014. The 12-person trial will be the first-ever in Canada for an inherited retinal-disease gene therapy. According to Ian MacDonald, M.D., who leads the team with Tania Bubela, J.D., Ph.D., the long-range plan is to conduct additional studies for other retinal conditions, including Stargardt disease and Usher syndrome type 1B.

“Our immediate goal is choroideremia, but we are looking to establish a center of excellence for ocular gene therapies to treat other inherited forms of vision loss, including conditions that affect the cornea,” says Dr. MacDonald. “Once we clear the regulatory hurdles for choroideremia, it will be easier for us and others to undertake the same process for other diseases.”

Cone-Rod Dystrophy Gene Therapy Rescues Vision in Canines
A French research team led by Fabienne Rolling, Ph.D., of INSERM, has used gene therapy to restore vision in a canine model of cone-rod dystrophy caused by mutations in the gene RPRGR1P1. Reported in the journal Molecular Therapy, the advancement marks the first time RPRGR1P1 gene therapy has been used successfully in a large-animal model of cone-rod dystrophy. Demonstration of safety and efficacy in a large animal is an important step in moving the therapy into human studies. Dr. Rolling says that her team is now adapting the RPRGR1P1 for evaluation in humans.

In humans and the canine model, cone-rod dystrophy affects cones first, leading to loss of visual acuity and color vision in childhood. Loss of peripheral and night vision follow as the disease progresses and affects rods.

In the RPRGR1P1 gene therapy study, cone function was significantly rescued in the canines while rod function was preserved. The therapy’s effect on vision persisted for 24 months — the length of time vision was monitored by the INSERM team.

Go to our website at www.FightBlindness.org to find more information on our progress.
It might not be obvious, but one of the biggest challenges in moving inherited retinal-disease treatments through clinical trials is demonstrating in a reasonable amount of time that they’re saving or restoring vision. It would be nice if we could just have patients read an eye chart a few weeks after receiving a therapy to see if their vision improved, but in most cases, that simple approach will not work.

The Foundation is meeting this challenge head-on by funding studies that will give us the clinical trial endpoints we need to quickly and cost-effectively determine if therapies are helping patients. While endpoints are critical to the success of human studies, let me explain briefly why they are difficult to come by:

First, vision loss from retinal conditions often progresses slowly. It can take years to tell if a potential therapy is actually having an effect.

Second, there is variability in the measures we use to assess efficacy. Tests that measure visual field, dark adaptation, night vision and even visual acuity can vary significantly for a given patient, even when the tests are given on the same day. It takes several observations over a long period of time — often several months — to factor out the testing variability.

In the world of clinical trials, time is very, very expensive; a single five- to seven-year study can cost tens or hundreds of millions of dollars. We don’t have the luxury of waiting many years to see if a therapy is having a beneficial effect in a clinical trial. We simply can’t afford it.

So the Foundation has made it a priority to develop and identify new endpoints that correlate with vision improvements, but can reliably be measured and quantified well before changes in vision can.

For example, the Foundation recently launched a $5 million natural history study for people with Stargardt disease to identify such an endpoint. Known as ProgSTAR, the two-year investigation will enroll 250 people — reviewing their medical records and monitoring their vision changes prospectively — to come up with an endpoint that can be used in future clinical trials of potential treatments. The investment may sound like a lot of money for assessing the progression of a disease, but it will be well worth the resources if we come up with an endpoint that will help expeditiously move even one therapy through a human study.

So what might that endpoint be? It will likely be something that has to do with the retina’s structure. We have preliminary evidence that changes in structure can be correlated with vision changes, but much more quickly.

In developing new endpoints, we have to make sure they are acceptable to the U.S. Food and Drug Administration, so we really have to do our homework in our studies of them. That’s what makes a comprehensive study such as ProgSTAR necessary.

But once we come up with an endpoint, it can be used by any company or organization developing a therapy. We’re happy to share it with the industry, because the more it can be used to advance sight-saving therapies, the better.

The Foundation’s Clinical Research Institute was established to accelerate the translation of laboratory-based research into clinical trials for treatments and cures of retinal degenerative diseases.
IN THEIR OWN WORDS:

Kathryn Birch
Age, 77
Naples, Florida

Disease: Age-related macular degeneration, or AMD. The leading cause of blindness in people 55 and older, it is characterized by progressive central vision loss.

Diagnosis and Treatment: By 2007, I had already lost some central vision. I had problems reading and was starting to close one eye, rather than see the fuzziness. An ophthalmologist told me I have “dry” AMD [triggered by the accumulation of cellular debris] in my right eye and “wet” AMD [caused by leaky blood vessels] in my left. There are no treatments for the dry, but there are a few [involving monthly to bi-monthly injections in the eye] for wet. AMD [caused by leaky blood vessels] in my left. There are no treatments for wet, but there are a few [involving monthly to bi-monthly injections in the eye] for wet.

I’ve tried different ones, 70 shots so far, which has stopped the blood vessels from leaking. The shots are uncomfortable, but they don’t hurt. Doctors put a numbing drop in there, and I’ve had so many, I don’t dread them as much. I don’t love it, but I only have to decide if I want to go blind or get treatment. It’s an easy decision.

Vision: My central vision is definitely better. I have central vision, period. It’s tough to look at things that are small, but looking at landscapes, houses, people’s faces — that’s fine. I’m a Catholic, so, before the treatments, when I was at church and looked up to see which priest was saying mass, I couldn’t see the face. Now I can. I would say it’s a plus if things don’t get worse, because before the treatments, my vision was progressively getting worse. The doctors have stopped that and improved my vision.

Involvement with FFB: I found out about FFB after my diagnosis. I went to a Vision Seminar in Naples with my husband, who has since passed away. They gave a very good presentation on the research, including how early Foundation funding helped with the development of wet AMD treatments. But I also heard about treatments in the research pipeline. And they had demonstrations of visual-aid products.

So I started donating, and, recently, I got involved with the local chapter. I help out at events by greeting people, handing out nametags. I’m not big on actually organizing these things. Others are better at that. But at one event, there was a silent auction, and I said I’d match it. I’ll do that again this year. I’m mostly a silent partner. I try to help that way. It suits me.

The Future: With my FFB donations, I’m giving toward the future. I’m investing in the research so that future generations — including my children and grandchildren, if they ever need them — can have better treatments or a cure. I’d like better treatments for myself, definitely, if they come along. But I’m already 77, so I’m not donating with the expectation that I’ll benefit directly.

If you’re going to give, you may as well give somewhere where it’s going to interest you. With FFB, I donate and get research reports, which I really read over carefully. That’s probably my main benefit. I can see that a lot of research advancements are being made, some funded by the Foundation, others not. But it all has to go on cooperatively, and it all has to go forward. I can help with that.

When you think about it, however, is there anything more important than doing what you can to ensure that your final wishes are known and carried out? The topic is not a popular one, and, appropriately enough, statistics show that 65 percent of the deceased leave neither a will nor estate plan behind. As an attorney who’s specialized in estate administration for almost 30 years, I advise you not to be in that majority. For everyone’s sake, your affairs need to be in order.

So get out that 2014 resolution list, and put the following as close to the top as possible: “Organize and implement my estate plan.” This should include advance directives, pre-planning your funeral and the like. If you already have a plan, resolve to review it in 2014 to make sure it accomplishes what you want. And please don’t think that the size of your estate matters, because whatever you’ve accumulated, regardless of monetary value, should be distributed in a manner of your choosing, not your state legislature’s. And that’s exactly who will decide if you don’t.

I hope, of course, that while you are putting your estate plan together, and after you’ve taken care of your family, you consider including the Foundation Fighting Blindness. Here, again, the amount of your legacy gift is not as important as the fact that you’ve done something to help the Foundation fulfill its mission.

There are many different ways to leave a meaningful legacy to the Foundation, most of which can be done at no additional cost while providing important tax-saving advantages to your family and estate. Examples include outright bequests in your will or trust, either in a specified amount or as a percentage of your estate, and naming the Foundation as a beneficiary of your life insurance policy, IRA, 401K or similar retirement accounts.

You can also purchase a charitable gift annuity, an investment that offers significant tax savings as well as an income stream during your lifetime at very attractive interest rates. A gift goes to the Foundation only after you’re gone.

I advise that you find a licensed professional locally to help you put together an estate plan. But I am also available to explain your options and help you come up with ideas. The Foundation also offers a free guide, If Something Should Happen to You: How to Organize Your Financial and Legal Affairs, which I can make available. I can be reached at (877) 254-3038 or jcornelle@FightBlindness.org.

In the meantime, a very healthy and Happy New Year to you! Good luck with those resolutions.
After 23 years, and $1.5 million raised, the **Western Classic fundraiser** was retired this past fall. It leaves behind a family legacy that mixes a love of music with dedication to a cause.

IT WAS 1989 when Haynes Lea, his wife, Liz, and Haynes’ three older brothers hatched a plan to cure retinitis pigmentosa (RP). The brothers part is important, because the Lea Brothers Band is an amateur country-and-western outfit that performs mostly for family and friends during get-togethers. And that Thanksgiving, six months after 5-year-old Elizabeth Lea was diagnosed with RP, Haynes — otherwise uncomfortable with the idea of asking for money — was moved to do something for his daughter.

“I used to play Jerry Jeff Walker songs,” he says of the band. “He’s the guy who wrote ‘Mr. Bojangles’, among other great songs. So I suggested to my brothers, one of whom knew Jerry Jeff, to bring him to Rocky Mount, our hometown in eastern North Carolina, and do a fundraiser for FFB.”

What became known as the Western Classic debuted in the fall of 1990, and by offering Walker, plenty of food and drink and an idyllic outdoor setting, it drew 600 people and netted $40,000, far exceeding expectations. Which is why the Leas kept it going for 23 years, retiring the event this past September, “when it was time to close the curtain,” as Haynes says. More than 800 people showed up to say goodbye, adding $150,000 to the coffers, for a total of $1.5 million overall.

“It was a great way to go out — with a grand crescendo,” says Haynes, whose work is far from over. He’s the Foundation’s treasurer, Liz is a national trustee, and the two are active in other fundraisers, including the Charlotte VisionWalk and North Carolina Dining in the Dark. And their daughter, Elizabeth — now 29, the mother of two and studying for a law degree and a master’s in public policy — has lost a lot of vision, to what was eventually diagnosed as Leber congenital amaurosis, a form of RP.

But the Western Classic had served its purpose. Explains Haynes: “As my mother would say whenever we were performing, ‘Be sure to leave them wanting more. Don’t wear out your welcome.’”

What a performance it was, a standard-bearer for what one family can achieve. Over the years, the event built up a “great time for a great cause” reputation, drawing individual attendees, at $100 a pop, as well as corporate sponsors ($2,500 to $10,000) and patron-level attendees ($325 to $500), who got reserved seats and a night-before party in return. “It grew each year, till we had over 800 people for a couple years,” Haynes recalls. “Then, it started to ebb with the economic downturn.”

One way to solve the challenge of asking the same people to attend every year was to find two locations — one in eastern, the other in western North Carolina — so as to make it a bi-annual event for each set of attendees. And when one location was moved to a mountain-resort area, the Leas turned it into a weekend event by recruiting “host compadres,” friends with homes in the area. “We considered those 70 people our sales team,” Haynes says. “We asked them to invite friends to stay for the weekend, and their friends, five or six per house, would buy tickets.”

The headline acts changed as well, and included Robert Earl Keen, Asleep at the Wheel, the Nitty Gritty Dirt Band and Eli “Paperboy” Reed. Every year, The Lea Brothers Band also made an appearance, prompting some, Haynes quips, “to accuse us of having the event just so we would have an audience.”

“It was a great way to go out — with a grand crescendo,” Haynes Lea says of the final Western Classic.

On a serious note, the event not only raised significant funds; it became a touchstone for the Lea family, Elizabeth, who spoke from the podium last fall, noted the many friendships that had grown and been rekindled each year, and that her parents and uncles and their friends “are the real rock stars” for putting the event together year after year. But Haynes, reminded of her speech, turns the spotlight on Elizabeth and Gordon Gund, FFB co-founder and chairman, who attended the last Western Classic.

“They’re my two biggest inspirations,” he explains. “Gordon lost his vision, but he’s dedicated his life to this cause. And whenever I have a bad day, or I’m feeling hassled, I think of what Elizabeth goes through every day, and realize I can persevere with my challenges that seem so trivial by comparison.”

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**INTRODUCING**

**New Leaders — Helping to Drive Momentum**

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To read more about these individuals, visit www.FightBlindness.org/NewLeaders.
Dr. Julia Canestraro’s mother, Colomba, is 48 years old and has Stargardt disease, which affects central vision. Although Stargardt is considered a juvenile form of age-related macular degeneration, Colomba wasn’t diagnosed until she was in her twenties, well after the Canadian had learned how to drive. While her vision has gotten progressively worse, she doesn’t use a cane or a guide dog to get around. “But she had to give up driving,” Julia says. “And that was really difficult for her — to lose that independence.”

So two years ago, when Julia brought her mom down from Canada, to participate in the New York City VisionWalk, “I was parading her around, saying, ‘This is my mom.'” Julia recalls. “When you know someone with a retinal disease, you really feel like you’re doing something important.”

There’s another angle to both Julia’s and the NYC VisionWalk story. Julia is currently a resident optometrist with the State University of New York (SUNY) College of Optometry, which, for the past two years, has provided the walk with a team of roughly 200 people, most of them students in the optometric professional program, and many getting up to speed on what the Foundation has to offer.

“Before we participated, I’m embarrassed to say, I didn’t know anything about the NYC VisionWalk,” says the team’s faculty advisor, Dr. Susan Schuettenberg. “But now I’m more informed about the Foundation’s research, and we have doctors here participating in FFB lectures at the school. And we know that the money we’re raising is going into research that will eventually help our patients.”

The ball got rolling with the SUNY team after then-resident Dr. Sarah Harbove, who’d attended the NOVA Southeastern College of Optometry, told professors and fellow students about that college’s participation in the South Florida VisionWalk. Dr. Harbove’s family is also affected, with four generations’ worth of retinitis pigmentosa. “My family is the reason I decided to become an optometrist,” she explains.

And her enthusiasm, according to Dr. Schuettenberg, kicked off what has become a tradition at SUNY Optometry, with its team raising $8,000 in 2012 and $9,000 last year. This spring, it’s hoping to gather 250 members and raise at least $10,000, via a few tried-and-true fundraisers.

Among them:

- **Happy Hour at McFadden’s**, a local haunt for optometry students, where admission at the door grants patrons discounted drinks and the college’s dean and faculty members serve as bartenders. The door’s proceeds go to the VisionWalk team.

- A competition in which the four classes compete against each other to sell pop-eyes, or stickers indicating donations, with the amounts tracked by a class thermometer. The college awards prizes for the most money raised and the most donations made to each class. “These are young people,” Dr. Schuettenberg says, “and for them, it’s fun to compete this way.”

- A T-shirt contest, the team’s biggest fundraiser. Everyone’s invited to submit a T-shirt design, with the year’s logo and theme on the front and the SUNY team name on the back. The winner’s design is then used on the team’s shirts, which are worn the day of the walk and sold for a profit, which goes to the Foundation.

Now that the holidays, and end-of-semester exams, are over, a student committee will form and get these and other possible fundraisers rolling. There’s already talk of putting together a more upscale version of the Happy Hour, an event that might be called “Cocktails for a Cause” and involve mixed drinks, hors d’oeuvres and a dress code, to attract faculty and administrators, another source of funding. “But we’re just getting started,” says Dr. Schuettenberg. “Soon, we’ll have many ideas.”

And now that SUNY’s a yearly participant, she encourages other schools of optometry to participate. “It’s a great way,” she says, “to get student doctors involved in preserving vision.”

As it plans for its third VisionWalk in New York City, the team from the SUNY College of Optometry serves as a great example of what post-grad students invested in eye care can do for the Foundation’s cause.

The SUNY College of Optometry team in Central Park

Visit [www.VisionWalk.org](http://www.VisionWalk.org) to get involved. You can find a VisionWalk near you, [register](http://register) to participate, [donate](http://donate) to a participant or team, and even [watch](http://watch) featured videos.

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