Today, millions of people around the world are living with devastating infectious diseases. IDRI is on a mission to change that.
A Letter From H. Stewart Parker

Chief Executive Officer

2013 is a banner year for IDRI, as we celebrate our 20th anniversary along with a new home. As you read this report, you’ll learn more about our achievements and plans for the future.

In 2011, I joined IDRI because I believe in this organization’s unique, high-impact approach to global health. The result is solutions – in the form of products – for millions burdened by devastating infectious diseases.

As CEO, my goal is developing resources – financial, human and physical – to support IDRI’s world-class research and the outstanding scientists you’ll read about in this report.

Earlier this year, we took yet another step toward that goal as we moved into new headquarters in Seattle’s South Lake Union neighborhood, allowing us to strengthen our research, development and translational science programs and accelerate our work. This marks an important milestone in IDRI’s 20-year history.

IDRI’s success of the past two decades is due to many factors, and one of those is you: our donors, funders, colleagues, partners and advocates. Thank you for your support. Working together, we will ensure IDRI’s continued success.

Sincerely,

H. Stewart Parker

Who is IDRI

Founded in 1993 by Steven G. Reed, PhD, IDRI (Infectious Disease Research Institute) is a 501(c)(3) non-profit organization dedicated to the eradication of infectious diseases. Our mission is to develop comprehensive field friendly solutions, including low-cost diagnostics, vaccines and drugs in three key disease areas: tuberculosis, leprosy and leishmaniasis.

What sets IDRI apart is our comprehensive approach to address infectious diseases, combining the high-quality science of a research organization with the product development capabilities of a biotech company. And, IDRI is a world leader in the development of adjuvants, a key component of vaccine development.

Headquartered in Seattle, IDRI collaborates with key partners around the world, including in-country development and commercialization partners, as we believe that the best place to develop new products are in the countries where the diseases we tackle are endemic.

Over the past 20 years, IDRI has made remarkable success towards providing low-cost solutions that significantly reduce the global burden of disease – and IDRI’s pipeline of products is expected to save millions of lives.

Facilities

In May 2013, IDRI moved into a new home in Seattle’s South Lake Union neighborhood, a growing hub for global health/life sciences. Housing over 120 employees, 80 percent of whom are scientists (including more than 50 PhDs/MDs), this space has substantial internal core laboratory and manufacturing competencies – including drug screening, protein expression, assay development and testing, vivarium facilities, BSL2/3 facilities and others.

Capabilities

IDRI has the capacity and expertise to originate, coordinate and execute preclinical and clinical programs, with the infrastructure required for financial compliance, scientific reporting, and other obligations required for productive collaborations and the broad dissemination of results. Our capabilities include:

- Drug Discovery
- Antigen Discovery and Expression
- Adjuvants and Formulations Development
- Process Sciences
- GMP Manufacturing
- Quality Assurance/Quality Control
- Clinical/Regulatory
- Human Immune Monitoring
- Diagnostic Test Development
- Comprehensive Project Management

Celebrating 20 Years

As IDRI celebrates its 20th anniversary this year, we are proud of what we’ve accomplished and look forward to what the next decades bring as we continue our mission to develop products that will improve health. We believe good health brings a world of possibilities: thriving families, flourishing communities and stable economies.
A Letter From David J. Maki
Chair, Board of Directors

I’m privileged to be associated with IDRI, an organization that takes a comprehensive approach to the treatment and prevention of infectious diseases.

Developing products that solve intractable global health challenges is IDRI’s reason for being, and we work passionately to provide solutions that positively impact the world’s most underserved populations. After 20 years, IDRI has concrete progress to celebrate: diagnostics on the market, vaccines in clinical trials and drugs in development.

I’m confident that our success in this mission will continue, in large part due to the trusted long-term relationships IDRI has forged in the academic world, with biotech and large pharma, throughout the non-profit ecosystem and with the world’s medical research agencies. These meaningful alliances provide us with unprecedented access to cutting-edge technology and financial support that will extend our efforts for our second 20 years and beyond.

This is what IDRI can do. This is what IDRI is doing. And this is what IDRI will continue to do.

Sincerely,
David J. Maki

A Letter From Steven G. Reed
Founder, President and Chief Scientific Officer

In 1993, I established IDRI in order to apply advances in immunology to the development of novel diagnostics, vaccines, and therapeutic products that could transform the lives of the millions of people at risk for infectious diseases throughout the developing world. I haven’t looked back since.

Since IDRI’s founding, we have attracted a dedicated team of scientists who have keen minds, compassionate hearts and entrepreneurial spirits. Together, we have created a unique institution that has the flexibility to collaborate with a diverse group of partners, bringing resources together to solve difficult global health challenges.

IDRI was founded to develop products that save lives, and I’m proud of what we have done to achieve that goal over the past 20 years. Now, I look forward to what the future holds: the next generation of vaccines, made more powerful by adjuvants; diagnostics enabled by the latest technology; and drugs that can battle the rise of drug-resistant pathogens.

Sincerely,
Steven G. Reed
**Areas of Focus**

**TUBERCULOSIS:** a bacterial disease that kills nearly 2 million people per year and infects one-third of the world’s population, attacking the lungs, kidneys, spine and brain. Cases of extreme drug resistant (XDR) and multidrug-resistant (MDR) TB are increasing rapidly, and some cases of totally drug-resistant TB have been reported in several countries.

**LEISHMANIASIS:** a parasitic disease caused by the bite of a sand fly; threatens 350 million people in 88 countries. Most deadly form is visceral, which affects vital organs and bone marrow and destroys blood cells. Available drugs are toxic, expensive and require long-term daily injections.

**LEPROSY:** a chronic infectious disease that remains endemic in 24 countries. Thought to be transmitted by a respiratory route, leprosy causes progressive skin sores, nerve damage, loss of muscle control and blindness. There has been no reliable diagnostic available that can detect the disease before the onset of advanced disease symptoms, and no vaccine exists to prevent the spread of the disease.

**CHAGAS:** a parasitic disease, commonly transmitted through insects, blood transfusions or from mother to baby during pregnancy. If left untreated, the disease usually impairs the heart and digestive system. It is estimated that as many as 8 to 11 million people in Mexico, Central America and South America are infected with Chagas.

**ADJUVANTS:** Overlaid on these disease targets is a focus on the development of adjuvants, which have broad applicability and are key to the development of successful, low-cost vaccines. Through worldwide collaborations, IDRI makes its adjuvants widely available for use in multiple disease programs, including HIV, malaria, schistosomiasis and others.
Passion – one of the distinctive traits of a scientist. Tanya Parish, PhD, has it in spades. Parish, Vice President of Drug Discovery for IDRI, speaks with great passion on a number of topics: soccer (she is an avid Arsenal fan turned Seattle Sounders supporter); cricket (she readily describes the intricate rules of the game); opera (La Bohème is a favorite). Her biggest passion? Finding new drugs to combat an age-old disease – tuberculosis.

“The huge resurgence of TB in the developed world, along with TB’s toll on developing countries and the rise of drug-resistant TB, adds to the great need for new drugs to combat this disease,” said Parish. Most importantly to her, TB is an issue of lost opportunity. “TB is often compounded by poverty, which limits access to the drugs,” she said. “And, the length of therapy for current TB drugs creates an even greater burden for those in developing countries.”

UNIQUE OPPORTUNITY
While IDRI has focused on TB for many years, the emphasis was primarily on vaccines and diagnostics. Drug discovery was a natural next step, and soon a unique opportunity was presented. When Eli Lilly purchased Washington-based Icos in 2007, Lilly wanted to continue its work on TB.

Through a partnership forged by IDRI President and Founder Steve Reed, IDRI acquired equipment, supplies and personnel from Icos/Lilly, along with access to Lilly’s comprehensive compound library to screen for hits against TB. The ultimate goal: developing drugs that are faster acting and cost effective.

Parish, who comes from a TB microbiology background, was a natural fit to lead IDRI’s TB drug discovery efforts.

Today, IDRI has leadership roles in two distinct consortia focused on finding new drugs to combat tuberculosis: the Lilly TB Drug Discovery Initiative and the TB Drug Accelerator, funded by the Bill & Melinda Gates Foundation.

TESTING, TESTING
IDRI’s drug discovery efforts are focused on testing thousands of potential drugs in its screening facility – often using robots to speed the process – to find new compounds that kill the bacteria that cause TB. “One of the key issues with TB is its cell wall, which has a thick, waxy coating, making it hard for compounds to penetrate,” explained Parish. “We’re working on ways to overcome that.”

Within a multi-disciplinary approach, chemists develop new molecules, then biologists test those to determine what works against TB and why. “This approach – working as a team, not as individuals – makes it all happen,” said Parish. “The quicker we can test and refine, the quicker we’ll have new drugs to combat TB.”

IDRI’s DISCOVERY EFFORTS

Tuberculosis
- Characterized molecular targets to better understand the specific host immune responses to TB.
- Produced world’s largest collection of TB antigens and screened them for promising prophylactic, therapeutic and diagnostic potential.
- Screened thousands of compounds for hits against TB with the goal of developing new drugs to shorten therapy and combat drug resistance.

Leishmaniasis
- Produced world’s largest collection of leishmaniasis antigens, promising for prophylactic and diagnostic applications.

Leprosy
- Produced world’s largest collection of leprosy antigens and screened them for promising prophylactic, therapeutic and diagnostic potential.
- Designed the first leprosy vaccine candidate.

Adjuvants
- Established a world class library of adjuvant molecules and formulations.

Animal Vaccines
- Entered into numerous collaborations to design a range of animal vaccines to improve animal health.

“The huge resurgence of TB in the developed world, along with TB’s toll on developing countries and the rise of drug-resistant TB, adds to the great need for new drugs to combat this disease.”
What is an Adjuvant?

An adjuvant is a substance added to a vaccine to increase the body’s immune response. “Adjuvant” comes from the Latin word adiuvare, meaning “to help.” And, that’s just what these substances do by boosting immune response, broadening vaccine protection and reducing the amount of antigen and/or injections needed.

A world leader in adjuvant development, IDRI produces adjuvants that are used in our own vaccines for leishmaniasis and tuberculosis, as well as in vaccines our partners are developing for HIV/AIDS, malaria, hookworm, pandemic influenza and other diseases.

Preclinical and Clinical

Rhea Coler, PhD, recalls a shyly smiling boy, standing beside her at a hospital in Ethiopia. He was being treated for leishmaniasis, a disease that has serious consequences — ranging from severe scarring to death — dependent on its form.

But the effects are even more far-reaching. “Abraham and his father, who stayed with him in the hospital, were separated from the rest of their family for several weeks,” explained Coler, Vice President of Preclinical Biology at IDRI. She also pointed out that by caring for his son, Abraham’s father was unable to work, creating another burden for their family.

Leishmaniasis is one of several devastating infectious diseases that do not have viable vaccines for either prevention or treatment. IDRI is working to change that, with pre-clinical studies and clinical trials under way for vaccines to combat leishmaniasis, tuberculosis and leprosy.

The Long Road of Development

An incredible amount of work and energy are needed to design vaccines and see them successfully through the development cycle. IDRI screens and tests hundreds of recombinant proteins as potential vaccine candidates. “We have identified and successfully characterized several proteins that have been studied across multiple animal models and human cells,” said Coler. From there, scientists develop vaccine candidates, composed of IDRI designed recombinant fusion-protein antigens plus IDRI’s proprietary adjuvants.

Creating a Vaccine for Leishmaniasis

For IDRI’s leishmaniasis vaccine, preclinical studies in animal models resulted in the identification of two prominent Leishmania proteins, leading to the development of a unique fusion protein called LEISH-F3. “When coupled with our GLA-SE adjuvant, LEISH-F3 has produced an immune response and is protective against infection from at least two different forms of Leishmania parasites,” explained Coler.

With promising preclinical results, IDRI received approval from the U.S. Food & Drug Administration (FDA) to conduct Phase I clinical trials in the U.S. to evaluate its vaccine candidate in healthy adult volunteers. Trials in Tacoma, WA, and Iowa City, IA, are ending, and safety and immunogenicity data are being generated.

“The data from the U.S. trials provides direction for our next step — trials in countries such as India, Bangladesh and Sudan where prevalence is high and the need for an effective vaccine is of utmost importance,” said Coler.
Early in his career, IDRI founder Steven Reed traveled to Brazil and observed something that set the course for his life’s work and forged the basis of IDRI’s mission. Time again, he saw children being forcibly held down to test for leishmaniasis, a parasitic disease caused by the bite of a sand fly. “At that time, diagnosis consisted of putting a needle in a kid’s sternum or spleen to look for parasites,” Reed explained. “There had to be a better way.”

And today there is, because of Reed’s vision and hard work. IDRI’s diagnostic requires just a single drop of blood, with results appearing within minutes.

“I’m happy to say the test is being used now, around the world, and is saving lives,” said Reed. In fact, on a recent trip to Bangladesh, Reed visited a hospital where, on a list of tests provided by the hospital, IDRI’s leishmaniasis diagnostic appeared, free of charge.

But IDRI hasn’t stopped at developing a diagnostic for just one disease.

**Chagas: Screening the U.S. Blood Supply**

While most commonly spread by the bite of an insect called the “kissing bug,” Chagas disease, a parasitic disease prevalent in Latin America often resulting in serious heart and digestive issues, can also be passed through infected blood. IDRI developed technology to diagnose Chagas. That technology has been incorporated into a test, created by Abbott Laboratories, to identify whether *T. cruzi* (the parasite that causes Chagas) contaminates any portion of the blood supply.

“Blood donations in Latin American countries where Chagas is endemic have undergone screening for many years,” explained Reed. “Now countries, such as the U.S. that have growing populations who come from endemic areas, are recognizing the threat and testing all donated blood and tissues.”

**Leprosy: A Modern-Day Threat**

Earlier this year, IDRI registered another test for use in Brazil, offering new hope for early diagnosis and treatment of people infected with leprosy. An ailment most people associate with biblical times, leprosy is a chronic infectious disease prevalent in countries throughout Africa, Asia and South America – including Brazil. And there are reports of leprosy infection, carried by armadillos, in the southern U.S.

“Currently the method of detection for leprosy is by clinical and/or microscopic assessment,” explained Reed. “There is a great need to more rapidly diagnose infection, before nerve damage occurs.”

According to Malcolm Duthie, Senior Scientist at IDRI, the leprosy diagnostic test is simple and easy to use. “The test, which could detect infection up to a year before disease symptoms occur, requires just a single drop of blood, mixed with a developing reagent,” he explained. “From there, a line develops and it’s somewhat like a pregnancy test: the appearance of two lines indicates the test is positive.”

The first step to ending an infectious disease is accurately and rapidly diagnosing it. “Having our diagnostics on the market and available for use is one of IDRI’s greatest successes of the past 20 years,” said Reed.
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**IDRI’s Manufacturing Capabilities and Capacity**

With the move earlier this year into its new home, IDRI expanded manufacturing infrastructure to support vaccine development for our work as well as that of our partners. Industry veteran Erik D. Laursen directs IDRI’s GMP operations.

IDRI now has a 4,000-square-foot, state-of-the-art cGMP manufacturing facility for the formulation and vialing of its library of adjuvants, as well as the following capabilities and capacity for the fill/finish of large or small molecules in liquid, emulsion or liposome formulations:

- **Formulation development**
- **Analytical development for in-process and release testing**
- **Cell based biotests**
- **Method verification and qualification**
- **Engineering run for pre-clinical purposes**
  - [≤15,000 vials/batch]
- **cGMP run for Phase 1 and 2 clinical studies**
  - [≤15,000 vials/batch]
- **Vial size range:** 2-10 mL  
  - [with ability to expand to 20 mL]
- **Labeling of small lots** [≤2000 vials]
- **Release testing**
- **Stability study**

**Making IDRI Technologies Available to Support Global Health**

*Investing in Ourselves for the Future*

IDRI has licensed out products and technologies applicable diagnostic and vaccine technologies, and to generate licensing revenues to complement public and private investment provide critically important funding sources for non-profits typically include foundations, government and individuals. However, it’s a bit unusual to see “royalties, manufacturing and service” cited as revenue streams. This helps distinguish IDRI as we invest in our organization for the future.

In 1980, the U.S. Bayh-Dole Act was passed, permitting universities and non-profit institutions to own inventions resulting from federally funded research. IDRI follows this model to further develop our technologies into life-saving products, and to generate licensing revenues to complement grant funds to support our global health mission.

With specific products in development, and widely applicable diagnostic and vaccine technologies, IDRI has licensed out products and technologies to pharmaceutical and biotechnology companies while reserving rights necessary to continue the development of products for global health. The benefits to IDRI are twofold. First, IDRI receives licensing revenues used to support our charitable mission programs in tuberculosis, leishmaniasis and leprosy. Second, the scientific studies conducted by the companies and funded by private investment provide critically important data used by IDRI scientists to strengthen our global health programs.

We’ll continue to seek new opportunities to make our technologies available to support the achievement of our primary goal -- to transform our science into global health solutions.
The Power of One

The power of one is impressive, even in the face of a challenge as daunting as global health. Throughout this annual report, you’ve read about the power of people who make a positive difference in the lives of millions who bear the burden of infectious diseases.

Now we invite you to consider how you can contribute to improve global health. It’s simple.

• Tell someone about what you learned by reading this report.
• Visit our website at www.idri.org to learn more or to sign up for our electronic newsletter.
• Attend an IDRI event.
• Invite an IDRI scientist to speak at an educational or civic event.
• Donate to support our research and product development efforts.

We believe in the power of one – your contribution will improve the lives of many. With good health comes a world of possibilities: thriving families, flourishing communities and stable economies.