At IDRI, the true impact of our work is moving from discovery and development to production and distribution of products that improve the health of millions of people around the world.
Many of the diseases we seek to diagnose and treat, or prevent through vaccination, such as leishmaniasis and Chagas disease, are unfamiliar to Americans. Other diseases such as tuberculosis and leprosy are thought of as being solved. Unfortunately tuberculosis, leprosy and other infectious diseases still wreak havoc in many parts of the world. The diseases we focus on are major healthcare problems globally; for instance, TB still kills more than 1.5 million people every year and 12 million people are infected with leishmaniasis today.

A variety of skills, often residing in different organizations, are required to battle these diseases; that is why we seek to collaborate with others that have complementary skills, including some of the world’s major pharmaceutical companies. Combatting the world’s most devastating diseases is an expensive – and long-term – business, and we couldn’t do it without the contributions of individuals, government agencies and foundations. We thank you.

IDRI is an important contributor to global health. While we use innovative science to research how to combat these infections, our focus on developing and delivering products to eliminate infectious diseases of global importance has distinguished us from our very beginning. This is our mission.
As you’ll read in the next few pages, IDRI’s 2015 Annual Report is focused on partnering – within our four walls as well as around the world. What makes others want to partner with us, fund us, advocate for us? Why IDRI? To me, the answer is simple: I believe the world’s poorest populations deserve the world’s best technologies. At IDRI, we take a multi-faceted approach to fulfilling the goal of bringing practical solutions to seemingly intractable problems. To achieve this we need not only research and development, but also implementation and local deployment.

Within the last year, we’ve made important progress. IDRI’s technology continues to attract the attention of big pharma and biotech, and we have closed on yet another major relationship with a large vaccine company, Sanofi. In South Africa, we are building local capacity, partnering with experts and training scientists to manufacture key vaccines and vaccine components.

Building biotech capabilities in developing countries is key to global economic growth and ensures local access to vaccines. This is important on two fronts: it builds trust in vaccines that are created locally, as well as capacity to respond rapidly to a disease outbreak on the ground as it’s unfolding. We are pursuing a similar strategy in South America, and I will have more to report on that front soon.

Our model focused on building local capacity is working because IDRI has technological assets, developed internally and licensed, around which such activities can be centered, and because we are willing to use them to create local jobs and infrastructure.

Thank you for your role as an IDRI partner. With your help, we are taking the technologies we develop here in Seattle and making them available to improve the health of the world.

Steven G. Reed, Ph.D.
Founder, President & Chief Scientific Officer
History has shown us that vaccines are one of the best ways to improve public health. Unfortunately, today’s world, we are faced with newly emerging infectious diseases, as well as age-old threats, that either have no vaccines or vaccines that are not effective enough. These factors – combined with how quickly infectious diseases can travel in our highly mobile world – prove that the demand to rapidly produce new vaccines at a lower cost is greater than ever. To meet that need, IDRI is teaming with two powerhouses, Sanofi Pasteur, a leading multi-national vaccine developer, manufacturer and seller, and the Bill & Melinda Gates Foundation, a leader in global health interventions, to establish the Global Health Vaccine Center of Innovation (GHVCI), to be headquartered at IDRI in Seattle.

The GHVCI is focused on accelerating the development of vaccines and associated technologies to fight a wide range of global infectious diseases, and ensuring that these critical vaccines are accessible globally, especially to people in need in developing countries. This distinctive collaboration leverages the potential power of the three partners’ collective expertise, including IDRI’s vaccine adjuvant technologies, which are uniquely designed to improve immune responses, broaden vaccine protection and significantly save costs by reducing the amount of vaccine needed. Funding for the establishment, operation and growth of the GHVCI comes from Sanofi and the Gates Foundation, and additional funding will be sought to support collaborative research activities with respect to specific vaccines to be developed at the GHVCI.

“We are excited to be involved in this novel partnership and proud of the confidence shown in IDRI’s technology and our science team’s expertise by Sanofi and the Gates Foundation,” said Erik Iverson, IDRI’s President, Business & Operations. “IDRI has a proven history of developing global health products that have a positive impact. This alliance will significantly accelerate the development of a wide range of vaccines and other health interventions that will save the lives of millions of people globally.”
Disease Burden is High: South Africa

Rhea Coler, Ph.D., had one mission of antibiotics. Recovered from TB after a course as this trial needed people who had volunteers for the study—particularly was visiting could provide enough... whether or not the clinics she was visiting could provide enough volunteers for the study—particularly this trial needed people who had recovered from TB after a course of antibiotics.

On her first stop in Nyanza—about 16 miles from Cape Town—she asked the clinic director how many TB cases he sees each month. The answer: 2,600. "I thought to myself, 'Our vaccine has got to work.'"

As evidenced by Coler’s clinic visits, TB is one of the most widespread, persistent and deadly global health problems in the world today, particularly in South Africa, where almost 1 in 10 people develop active TB each year. Dormant in one-third of the world’s population, TB kills 1.5 million people each year.

The currently available TB vaccine, Bacille Calmette-Guérin (BCG), developed nearly 60 years ago, reduces the risk of severe forms of TB in early childhood but is not effective in adults.

"TB is one of a number of serious infections that is becoming harder to treat as the bacteria evolve resistance to even our most effective drugs," said Stephen Caddick, Ph.D., Director of Innovations at the Wellcome Trust. "We urgently need new ways of preventing and treating the infection in high-risk populations. The trial of this promising experimental vaccine candidate to reduce the recurrence of TB after a patient has been successfully treated for active TB represents a new and important development, and one which could eventually give us a 21st century weapon against this centuries-old disease."

Funding from the Wellcome Trust will support an initial Phase 2a safety and immunogenicity clinical trial involving 60 participants. A larger dose-finding trial and first phase of clinical trials will be conducted in high-risk populations. The trial of this promising experimental vaccine candidate to reduce the recurrence of TB after a patient has been successfully treated for active TB represents a new and important development, and one which could eventually give us a 21st century weapon against this centuries-old disease.

Funding from the Wellcome Trust will support an initial Phase 2a safety and immunogenicity clinical trial involving 60 participants. A larger dose-finding trial, for which IDRI is seeking additional funding, is planned to start in 2017 with 900 participants. Both trials will take place relapse within one year, continuing the cycle of TB. Funding from the Wellcome Trust will support an initial Phase 2a safety and immunogenicity clinical trial involving 60 participants. A larger dose-finding trial and first phase of clinical trials will be conducted in high-risk populations. The trial of this promising experimental vaccine candidate to reduce the recurrence of TB after a patient has been successfully treated for active TB represents a new and important development, and one which could eventually give us a 21st century weapon against this centuries-old disease.

Focus on Recurrence

"The Phase 2a trial will be the first dose-escalating TB vaccine trial conducted in persons who have previously had active TB and been successfully treated with a full course of antibiotic therapy," said Coler, who serves as Vice President of Preclinical Development for IDRI. "This is an important study population, since the incidence of TB is higher in people recently cured of the disease. About 5-8 percent of the population in the area where the clinical trials takes place relapse within one year, continuing the cycle of TB."

IDRI’s TB vaccine candidate has been designed to recognize both active TB and latent TB. The candidate, ID93 + GLA-SE, is composed of a recombinant fusion-protein antigen plus IDRI’s proprietary adjuvant, GLA-SE, and has been previously tested in humans.

"Our candidate also shows efficacy in drug-shortening regimens," said Coler. "We urgently need new ways of preventing and treating the infection in high-risk populations. The trial of this promising experimental vaccine candidate to reduce the recurrence of TB after a patient has been successfully treated for active TB represents a new and important development, and one which could eventually give us a 21st century weapon against this centuries-old disease.

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Funding for preclinical development and testing of ID93 + GLA-SE to this point has come from a variety of sources, including the National Institutes of Health, Paul G. Allen Family Foundation, the Bill & Melinda Gates Foundation and Aeras.

As Rhea Coler, Ph.D., visits tuberculosis clinics in South Africa, she realizes the burden of disease was greater than she’d imagined.
Tanya Parish, Ph.D., is leading efforts to develop a new host-pathogen interaction facility at IDRI. With a new host-pathogen interaction facility funded in part by the Murdock Trust, the Life Sciences Discovery Fund and the Washington Research Foundation, IDRI scientists, led by Tanya Parish, Ph.D., Vice President of Drug Discovery, will have the ability to gain greater insight into a variety of diseases. "The new facility will enable us to broaden the range of diseases we work on as well as incorporate sophisticated imaging technology to look at both the infectious organism and the human response at the same time," said Parish. "This technology will expand our ability to find novel drugs and adjutants for important global diseases." The facility will utilize highly sophisticated, novel equipment to monitor pathogen and host (human) cell behavior simultaneously in disease models, a marked improvement over traditional approaches, which monitor only the pathogen. It will complement existing technology at IDRI, which is already used to run high throughput screens against bacteria that causes tuberculosis and staph infections.

The new facility will also allow IDRI scientists to conduct high-content analysis (HCA), a powerful screening methodology that uses biologically relevant cell-based assays to extract multiplexed data from a single assay, differentiating host cells and pathogens. Studying interaction among a drug target, pathogen and host simultaneously will offer a more holistic view that will accelerate drug discovery and development across infectious diseases. While capacity for traditional screening is rare, there is even less capacity—only a handful of facilities around the world—available to conduct host/pathogen screening with HCA, particularly with the ability to test (under proper safety conditions) using highly infectious organisms like the bacterium that causes TB.

"Initially, we'll screen for potential drugs against tuberculosis, because of our extensive experience with this disease, as well as cryptosporidiosis, a worldwide parasitic diarrheal disease, in collaboration with one of our longtime partners," said Parish. "From this start, we intend to pursue additional collaborations for other antibiotic-resistant infections."

Having this facility will meet local funders' goals of catalyzing the region's competency in adapting innovative approaches to drug discovery and development, as well as producing intellectual capital focused on improving health. "Bringing such unique capabilities to IDRI will allow us to leverage our existing laboratory space and scientific expertise, as well as our niche in the Washington biotech community," said Erik Iverson, IDRI's President, Business & Operations.

Tanya Parish, Ph.D., is leading efforts to develop a new host-pathogen interaction facility at IDRI.
The ability to rapidly develop and deploy vaccines, while using less vaccine, can mean the difference in how successful the world is at combating the next outbreak. Steven G. Reed, Ph.D., IDRI President, Founder and Chief Scientific Officer

Today’s next-generation, rationally designed vaccines contain both an antigen (a non-infectious piece of a pathogen that the immune system learns to attack) and an adjuvant (substances added to vaccines to enhance the ability of antigens to stimulate the body’s immune response).

Adjuvants are an important part of the pandemic story, as they increase vaccine manufacturing capacity when vaccines are critically needed during an outbreak. Another key consideration is having enough vaccine. IDRI’s adjuvants can be used to increase the number of available vaccine doses through ‘dose sparing,’ reducing the amount of vaccine needed per individual.

As part of the BARDA-funded project, IDRI will partner with developing country vaccine manufacturers (DCVMs) to develop adjuvanted influenza vaccine capabilities. IDRI will supply sufficient oil-in-water emulsion adjuvant and partner with DCVMs to enhance their pandemic influenza vaccine programs. These adjuvants will be evaluated with antigen through preclinical and clinical studies.

In addition, IDRI will establish the capacity to manufacture 50 million doses of adjuvant within a three-month timeframe, to provide adjuvants to eligible DCVMs supported through the World Health Organization (WHO) Global Action Plan for Influenza Vaccines. IDRI will manufacture those doses onsite at its 4,000-square-foot, state-of-the-art cGMP manufacturing facility in Seattle.

Investigator for the project. “This project will represent a new approach in making the vaccine technology available to developing countries so there can be a rapid response where it’s needed most.”

While vaccines are one of the greatest triumphs of public health, the time and funding it takes to develop a vaccine – particularly for life-threatening diseases that offer modest financial returns – often means that a vaccine isn’t available when an outbreak occurs. The international outbreak of Ebola in 2014 brought this fact home, highlighting the need for a new model of vaccine development.

IDRI scientists have teamed up with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services, to develop an adjuvant manufacturing hub with both preclinical and clinical expertise to facilitate pandemic influenza preparedness in developing countries. BARDA provided $8 million in funding.

Today’s global is local... and local is global.

Today’s global is local... and local is global.
Satya Remala smiles as she describes her sister: “She is a ball of energy, always in motion.” So when Satya saw her sister in pain, unable to move easily or even eat, she knew something was amiss. “She was not herself, but the doctors didn’t know what was wrong,” said Satya.

When the diagnosis came, it revealed Satya’s sister was suffering from chikungunya, an infectious disease that is just making its way into the United States, but all too familiar to Satya and her husband Rao, who hail from India. The hallmark of chikungunya, a virus spread through the bite of a mosquito, is its debilitating joint pain that can recur for months or even years.

“Satya’s sister isn’t the only case of chikungunya the Remalas have witnessed. They have many stories to share — a brother who had the disease three years ago and still suffers pain, a man who owns a bike shop but couldn’t work because of joint pain. When the diagnosis came, it revealed Satya’s sister was suffering from chikungunya, an infectious disease that is just making its way into the United States, but all too familiar to Satya and her husband Rao, who hail from India. The hallmark of chikungunya, a virus spread through the bite of a mosquito, is its debilitating joint pain that can recur for months or even years.”

But through their foundation, the Remalas are on a mission to change that. With a gift to IDRI that was matched by the Seattle Foundation, the Remalas have funded an initial proof of concept study, led by Neal Van Hoeven, Ph.D., to generate data to apply for larger grants, with the ultimate goal of developing a chikungunya vaccine.

Offering a Leg Up
“We believe that investing to improve health and education gives people a leg up out of poverty,” explained Rao, who rose from poverty to become the first Indian employee at Microsoft and is credited as one of the lead developers of the first version of Microsoft Windows. Born in a small village in southeastern India where he lived in a mud hut with no running water, Rao knows the importance of getting that helping hand along the way. “Without support from others, we wouldn’t be where we are today,” he said. “Now, we want to give back.”

Based in Bellevue, the Remala Foundation is truly a family affair. Satya and Rao, along with daughters Srilakshmi and Srilata, come together to make giving decisions, with Srilakshmi focused on funding education and Srilata on health. “We like to invest locally – in the Seattle area – with organizations and people that are doing impactful work in India,” explained Rao.

Srilata agreed, saying, “We are very deliberate in our giving, focusing on smaller organizations that have large impact and move quickly to seize opportunities. IDRI fits well into our giving strategy; it is a nimble organization and able to use its expertise to rapidly move into new areas of disease research.”

From IDRI’s standpoint having funders, like the Remala family, who understand the importance of initial support for pilot projects are key. “We deeply appreciate the insight of the Remalas, not only of the need to help raise awareness about the threat of chikungunya, but also to provide funding to help develop new solutions,” said Erik Iverson, IDRI’s President, Business and Operations.

Rao and Srilata Remala discuss the mission of their foundation on funding to improve health and education.
Erik Iverson, JD, LLM
President, Business & Operations

With the ease and speed of today’s travel, our world has, effectively, become borderless. As a result, disease travels freely and indiscriminately from one nation to another, regardless of Gross Domestic Product or standard of living. Without question, we’ve seen the powerful and profound risk that infectious diseases like Ebola, swine flu, HIV or avian flu have posed to people and health systems in recent years within both the poorest and richest countries – as well as all the nations in between. In 2015, media headlines are filled with stories of new threats in our own backyard: from leprosy cases increasing due to bacteria-toting armadillos to the relentless march of the chikungunya virus, a mosquito-borne disease that causes high fever and debilitating joint pain, into the U.S.

That’s why we, at IDRI, believe in the importance of investing in the research and tools that will help us detect, treat and prevent the possibility of future epidemics from unfolding right here in our own country.

Neal Van Hoeven, Ph.D., is leading IDRI’s efforts to discover new solutions for emerging diseases, including chikungunya and West Nile virus, now becoming more prevalent in the U.S.

From the World to Seattle

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Erik Iverson, JD, LLM
President, Business & Operations
When asked what he ultimately wants to achieve in his career, Christopher Fox, Ph.D., Director of Formulations at IDRI, sums it up quite simply: “I want to make products that benefit those most in need.” At the age of 36, he is achieving that goal.

Recognized for his efforts, Fox was selected as the 2015 “Rising Leader” by the Washington Global Health Alliance. The award honors a creative and inspirational young leader dedicated to solving global health inequity while partnering with other individual and organizations.

Unlike researchers who enjoy their work simply because of the excitement of unlocking the mysteries of infectious diseases, Fox, who received his Ph.D. in bioengineering from the University of Utah in 2007, knew that he didn’t want to do research in the proverbial “ivory tower.” He craved an applied, human component.

“I developed an interest in global health during grad school,” he said. “But I needed to do something where I could see, first-hand, how it would help people.”

After seven years at IDRI, Fox is leading projects ranging from developing a freeze-dried tuberculosis vaccine that defies the cold chain to transferring adjuvant technology into developing countries so that vaccines can be developed rapidly when there is a pandemic flu outbreak. In the last year alone, Fox has been named principal investigator for three major projects, responsible for more than $20 million in funding.

Fox believes a key component of product development is manufacturing on site where needs are most critical. “We’ve transferred our technologies to Romania, Brazil and India where we are teaching very capable scientists and engineers how to manufacture adjuvants for their own vaccines,” he said, “so to me, that’s what it’s all about.”

Christopher Fox, Ph.D., is one of IDRI’s up-and-coming young scientific leaders, recently named a “Rising Leader” by the Washington Global Health Alliance.

No Ivory Towers for this Rising Leader

FINANCIALS

Funding Sources

By Disease

By Activity

Statement of Activities – Unrestricted Only

Balance Sheet

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<tr>
<th>ASSETS</th>
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<th>Liables &amp; NET ASSETS</th>
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<td>Total Liability &amp; NET Assets</td>
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2014 2013
ASSETS
Total Current Assets 15,458,107 20,556,533
Property & equipment, net 15,015,611 15,707,680
Pledges receivable - long term 5,061,470 8,367,475
Investment - long term 628,433 583,000
Total Assets 36,163,621 45,214,688

LIABILITIES & NET ASSETS
Accounts payable & accrued expenses 1,726,256 1,503,405
Deferred rent & unearned revenues 1,449,316 1,627,960
Total current liabilities 3,175,572 3,131,365
Deferred rent - long term 16,673,834 16,744,525
Total Liabilities 19,849,406 19,875,890

Net Assets
Unrestricted (857,454) 276,042
Temporarily Restricted 17,171,669 25,062,756
Total Net Assets 16,314,215 25,338,798

Total Liabilities & Net Assets 36,163,621 45,214,688

Revenues
Public Support 6,762,354 6,685,429
Private grants & contributions 12,638,498 14,319,401
Earned Income 2,302,017 1,646,456
Investment & Other Revenues 1,153,459 204,240
Total Revenues 22,856,328 22,855,526

Expenses
Program expenses 18,726,678 19,952,713
Management & General expenses 5,025,300 5,424,242
Fundraising 237,846 287,851
Total Expenses 23,989,824 25,664,806

Change in Unrestricted Net Assets (1,133,496) (2,809,280)

Funding Sources

By Disease

By Activity

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<tr>
<td>By Disease</td>
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<td>Tuberculosis 50%</td>
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<tr>
<td>Vaccines 43%</td>
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<tr>
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<table>
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<tr>
<td>Corporate Funding 14%</td>
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No Ivory Towers for this Rising Leader

When asked what he ultimately wants to achieve in his career, Christopher Fox, Ph.D., Director of Formulations at IDRI, sums it up quite simply: “I want to make products that benefit those most in need.” At the age of 36, he is achieving that goal.

Recognized for his efforts, Fox was selected as the 2015 “Rising Leader” by the Washington Global Health Alliance. The award honors a creative and inspirational young leader dedicated to solving global health inequity while partnering with other individual and organizations. Unlike researchers who enjoy their work simply because of the excitement of unlocking the mysteries of infectious diseases, Fox, who received his Ph.D. in bioengineering from the University of Utah in 2007, knew that he didn’t want to do research in the proverbial “ivory tower.” He craved an applied, human component.

“I developed an interest in global health during grad school,” he said. “But I needed to do something where I could see, first-hand, how it would help people.”

After seven years at IDRI, Fox is leading projects ranging from developing a freeze-dried tuberculosis vaccine that defies the cold chain to transferring adjuvant technology into developing countries so that vaccines can be developed rapidly when there is a pandemic flu outbreak. In the last year alone, Fox has been named principal investigator for three major projects, responsible for more than $20 million in funding.

Fox believes a key component of product development is manufacturing on site where needs are most critical. “We’ve transferred our technologies to Romania, Brazil and India where we are teaching very capable scientists and engineers how to manufacture adjuvants for their own vaccines,” he said, “so to me, that’s what it’s all about.”

Christopher Fox, Ph.D., is one of IDRI’s up-and-coming young scientific leaders, recently named a “Rising Leader” by the Washington Global Health Alliance.

Financials

For the year ending Dec. 31, 2014, audited financial statements are available upon request or on our website at www.idri.org.

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To learn more about supporting IDRI’s global health mission, please contact development@idri.org.