Institute for OneWorld Health

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FROM VISION TO REALITY

2006 Annual Report

Institute for OneWorld Health

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A vision became reality.

In 2006 we achieved
our first drug approval,
expanded our portfolio
with the addition of a
new disease program,
and intensified our
efforts to develop a
semisynthetic derived
form of artemisinin
to cure malaria.

Andy Berry / Orange Photography

When I founded the first nonprofit pharmaceutical company in the United States in 2000, I looked forward to a year like 2006. It has been a long journey and my dreams of what the Institute for OneWorld Health could accomplish are becoming more real with each passing year. 2006 has been a breakthrough year for us across all of our program areas. Our hard work and efforts of the past six years were rewarded in many ways, most importantly with the approval of our first drug, Paromomycin IM Injection, in India. We funded a scientific breakthrough in our malaria program, forged new partnerships, and received new grants to continue researching and working to develop safe, effective, and affordable new medicines for people with infectious diseases in the developing world.

Our success with Paromomycin IM Injection demonstrates proof of concept for a new model of pharmaceutical development, and now we look forward to applying this model to our other disease programs. We have proven that with a clear vision of tomorrow, a strong dose of determination, and the hard work of many dedicated people, we can ease suffering and save lives around the world. We are looking forward to continuing these successes and striving for more in the years to come.

Sincerely,

Victoria G. Hale, Ph.D.
Founder & CEO

Institute for OneWorld Health

The Institute for OneWorld Health is a US-based nonprofit pharmaceutical company that develops safe, effective, and affordable new medicines for people with infectious diseases in the developing world. Committed to saving lives, improving health, and increasing accessibility to medicines for those with the most need, we at OneWorld Health are seeking to address some of the vast inequities in global health. Through our innovative business model, we are bringing the promise of medicine to those who need it most.

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Visceral Leishmaniasis

BY THE NUMBERS

Visceral leishmaniasis (kala-azar) is a systemic infection caused by various species of Leishmania parasites. If left untreated, VL is almost always fatal.

More than 400,000 deaths occur annually in the Indian Subcontinent, representing more than 80% of worldwide estimated VL cases.

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Drug Approval

In August 2006 our first drug, Paromomycin IM Injection, was approved by the Drug Controller General of India for the treatment of Visceral Leishmaniasis (VL)—the second most deadly parasitic disease in the world following malaria. The Drug Controller General of India's approval of Paromomycin IM Injection came less than three months after the submission of the application for approval, which was prepared by OneWorld Health in collaboration with our drug manufacturing partner, Hyderabad-based Gland Pharma Limited. The drug is expected to be a key tool for India's National Vector Borne Disease Control Programme, which aims to rid the country of VL by 2010, and for disease control programs in other VL-endemic countries. Gland Pharma will make the medicine available at cost, currently $10-15 per treatment course, a significantly lower price than currently approved VL therapies.

"We are pleased that the first drug in our portfolio will enable the Indian government to safely and affordably control visceral leishmaniasis. This approval is a major step in our effort to help all stakeholders eliminate VL in India, Bangladesh, and Nepal and is aligned with our global mission of developing safe, effective, and affordable treatments for infectious diseases."

— Ahvie Herskowitz, M.D.
Co-Founder and Chief Medical Officer, Institute for OneWorld Health

OneWorld Health's first drug product, Paromomycin IM Injection, was approved in August 2006 by the Drug Controller General of India. We can now offer effective and lower-cost treatment for the hundreds of thousands of people who contract VL in India each year.

Malaria

BY THE NUMBERS

More than 40 percent of the world's population lives in areas where malaria is transmitted. It is a preventable and treatable disease, but nonetheless kills more than one million people each year[1], primarily young children. In Africa, one in five childhood deaths are due to malaria.[2]

The World Health Organization recommends using artemisinin-based combination therapies (ACTs) as a first line treatment for malaria in regions where traditional first line treatments are no longer effective due to increasing drug resistance.

Lowering the cost of ACTs will allow millions of people infected with malaria greater access to these life-saving drugs.

"This project will use some of the latest advances in molecular biology to engineer a microbial chemical factory and reduce the cost of a much-needed drug."

— Professor Jay Keasling
UC Berkeley; Discover Magazine Scientist of the Year, 2006

Institute for OneWorld Health

Institute for OneWorld Health

OneWorld Health is developing the commercialization and regulatory strategy to allow integration of semisynthetic derived artemisinin into the ACT manufacturing supply chain for current and future ACTs.

Technical Milestone Achieved

Our malaria program began 2006 with a noteworthy technical achievement resulting from the unique three-way partnership between the Institute for OneWorld Health, UC Berkeley, and Amyris Biotechnologies. A report in the April 13, 2006 issue of *Nature* describes how UC Berkeley Professor Jay Keasling and his scientists worked with Amyris Biotechnologies to produce the antimalarial drug precursor, artemisinic acid, in engineered yeast. This achievement shows early promise that the semisynthetic derived manufacturing strategy can be achieved at the laboratory scale. The project continues to address the challenge of substantially improving the yield of artemisinic acid and developing a manufacturing process that is economically acceptable for large-scale manufacturing. We look forward to continued progress this year with our partners toward our goal of introducing semisynthetic derived artemisinin into Artemisinin-based Combination Therapies by 2010.

At commercial scale, semisynthetic derived artemisinin will supplement existing plant derived artemisinin with a non-seasonal, lower cost, high quality second source of artemisinin to help meet the projected worldwide demand for ACTs.

Diarrhea

BY THE NUMBERS

Every year, diarrheal diseases account for approximately 2 million deaths in children under five.[3]

An estimated 22% of deaths in children aged less than five years are estimated to be caused by diarrhea.[4]

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Major Grant Awarded

We also achieved a major milestone in 2006 with the award of a US$46 million grant from the Bill & Melinda Gates Foundation to develop new treatments that will complement current and traditional approaches for fighting diarrhea. The focus of this funding will be to develop safe, effective, and affordable new anti-secretory drugs that inhibit intestinal fluid loss, which leads to dehydration and rapid progression to death if untreated. These novel anti-secretory drugs will be administered with oral rehydration therapy for the treatment of acute secretory diarrhea, which is responsible for nearly 40% of reported cases of diarrheal disease globally. During 2006, the OneWorld Health Diarrheal Disease Program initiated several new collaborations, which include BioFocus DPI, who will apply their medicinal chemistry and early stage drug development expertise to identify new anti-secretory drug candidates, and the International Center for Diarrheal Disease Research in Bangladesh (ICDDR,B) to conduct pre-clinical studies.

“Childhood diarrhea is one of the world’s most serious global health problems – and also one of the most overlooked. We’re pleased to support OneWorld Health and its partners, and hope their innovative work encourages others to take action.”

— Regina Rabinovich, M.D., MPH
Director, Infectious Disease, Global Health Program, Bill & Melinda Gates Foundation

Opportunities to save lives are increasing due to research by OneWorld Health and our partners on the development of new medicines to inhibit intestinal fluid loss during diarrhea.

Partners & Donors

OneWorld Health's innovative model encourages a unique set of partnerships and investments. Pharmaceutical and biotechnology companies find an appealing outlet for idle intellectual property. Pharmaceutical scientists—drawn to a mission of saving lives and improving health worldwide—are eager to participate in groundbreaking and compassionate research and development. International health advocates, including governments, nongovernmental organizations, and hospitals in the US and abroad, welcome a powerful new ally for improving global health. Many investors and donors recognize the need and support our strategic and pioneering investment in the health of millions of people. Below is a list of some of the many individuals and organizations that supported us in 2006.

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Major Donors

$1,000,001+
Bill and Melinda Gates Foundation

$100,001 - 1,000,000
Anonymous
Lehman Brothers Foundation
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$10,001 - $100,000
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Kala-azar Research Centre
Kalazar Research Centre
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Symantec (through Tech Soup Stock)
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Endnotes

1. World Health Organization, *Fact Files: 10 Facts on Malaria*, April 25, 2007, <http://www.who.int/features/factfiles/malaria/en/index.html> (April 30, 2007).

2. Ibid.

3. Bryce, Boschi-Pinto, Shibuya & Black "WHO Estimates of the Causes of Death in Children" Lancet, March 26, 2005: 1147

4. Black, Morris & Bryce, "Where and Why are 10 Million Children Dying Every Year?" Lancet, June 28, 2003: 2230

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