



Institute for OneWorld Health

A Nonprofit Pharmaceutical Company



Partnering for Global Health

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iOWH Mission

**The Institute for OneWorld Health Develops
Safe, Effective, and Affordable
New Medicines for People with Infectious Diseases
in the Developing World**



Global health products: the 10/90 gap

10/90 GAP: only **10%** of global health R&D is devoted to conditions that account for **90%** of the global disease burden

98% of deaths of children occur in the developing world

Of the 1393 new drugs approved between 1975 and 1990, **only 13 (1%)** were for tropical diseases.

iOWH is closing the gap in neglected diseases

Top Neglected Diseases and iOWH Focus

Intestinal Worms	3 billion
Diarrheal diseases	>1 billion
Malaria	300-500 million
Schistosomiasis	200 million
Lymphatic filariasis	90 million
Chagas disease	14 million
River blindness	16 million
Leishmaniasis	14 million

Visceral Leishmaniasis Program (2000 –)

Develop a *safe, effective,* and *affordable* drug (paromomycin) to save lives of patients with VL



And ensure treatment access by optimizing a *scalable, sustainable,* and *transferable* access model through collaborative partnerships



First product: *Paromomycin IM Injection*

Achievements include:

- ✓ Registration in India – August 2006
- ✓ WHO Essential Medicines Listing
- ✓ Publication of pivotal study in the New England Journal of Medicine



Current effort:

Phase 4 study: Safety, Pharmacovigilance, Access pilot ((M&E, Operational optimization, impact)

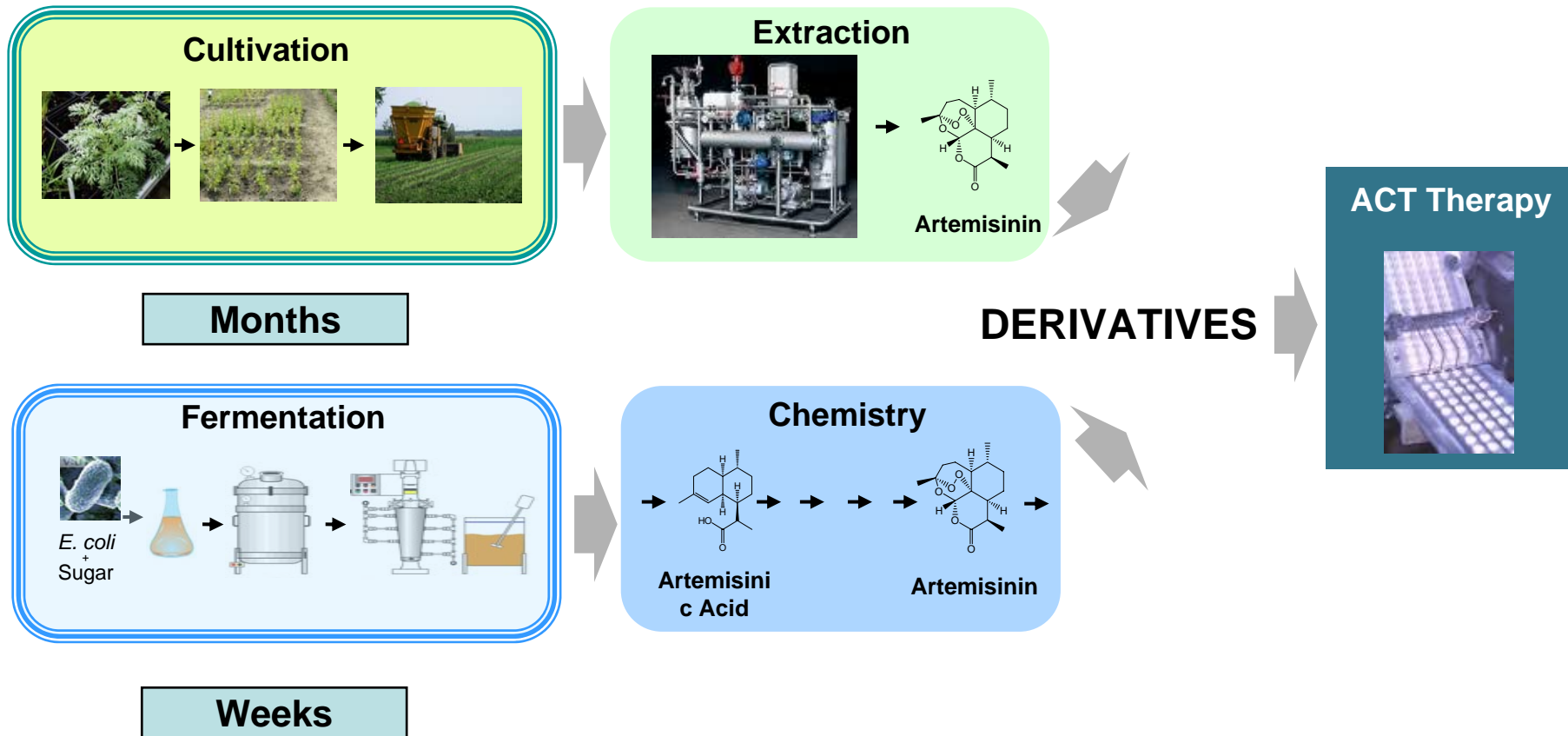
Malaria Disease Program (2004 –)

- Vector-borne **protozoan** disease from the bite of female **phlebotomine Anopheles mosquitoes**
- 300-500 million people infected annually
- **1+ million people die each year**
- Worsening problem of **resistance** to common/cheap drugs
- The compound **artemisinin** is extracted from the wormwood plant (*Artemisia annua*) and has **> 90% efficacy rate**



Source: World Malaria Report 2005, <http://rbm.who.int/wmr2005/html/1-2.htm>

A **Second Source** Supplements the Artemisinin Treatment Supply



Project Timeline

DISCOVERY **RESEARCH AND DEVELOPMENT** **MANUFACTURING** →



Discovery of the Metabolic Pathway and Identification of Genes from the Wormwood Plant Required to Make Artemisinic Acid →

Construct Biosynthetic Artemisinic Acid Pathway and Clone into Microbial Host →

Optimize Artemisinic Acid Production →



Optimize Microbial Strain →

Develop Scalable Processes for Manufacture and Purification of Artemisinin →

Demonstrate Comparability of Plant Derived Versus Semisynthetic Artemisinin →



Fermentation Process Development →

Chemistry Process Development →

Develop scalable industrial manufacturing process →



Enable 2nd Source Artemisinin Uptake into ACTs →

Apply WHO Sanctioned Global Health Goals to Malaria ACTs →

Identify Commercial Partner, Product Development and Strategic Management →

2nd Source of Artemisinin in ACT Therapy

2004 2005 2006 2007 2008 2009 2010

Diarrheal Disease Program (2006 -)

High Unmet Medical Need

- Diarrhea is a leading cause of death of children aged under 5 years in developing countries
- Diarrhea accounts for approximately 2 million pediatric deaths annually worldwide
- Diarrhea, malnutrition, and other childhood disease: a vicious cycle

Diarrhea is Caused by Multiple Agents

→ No single treatment can address all causes



Diarrheal Disease Program: *Mission and Goals*

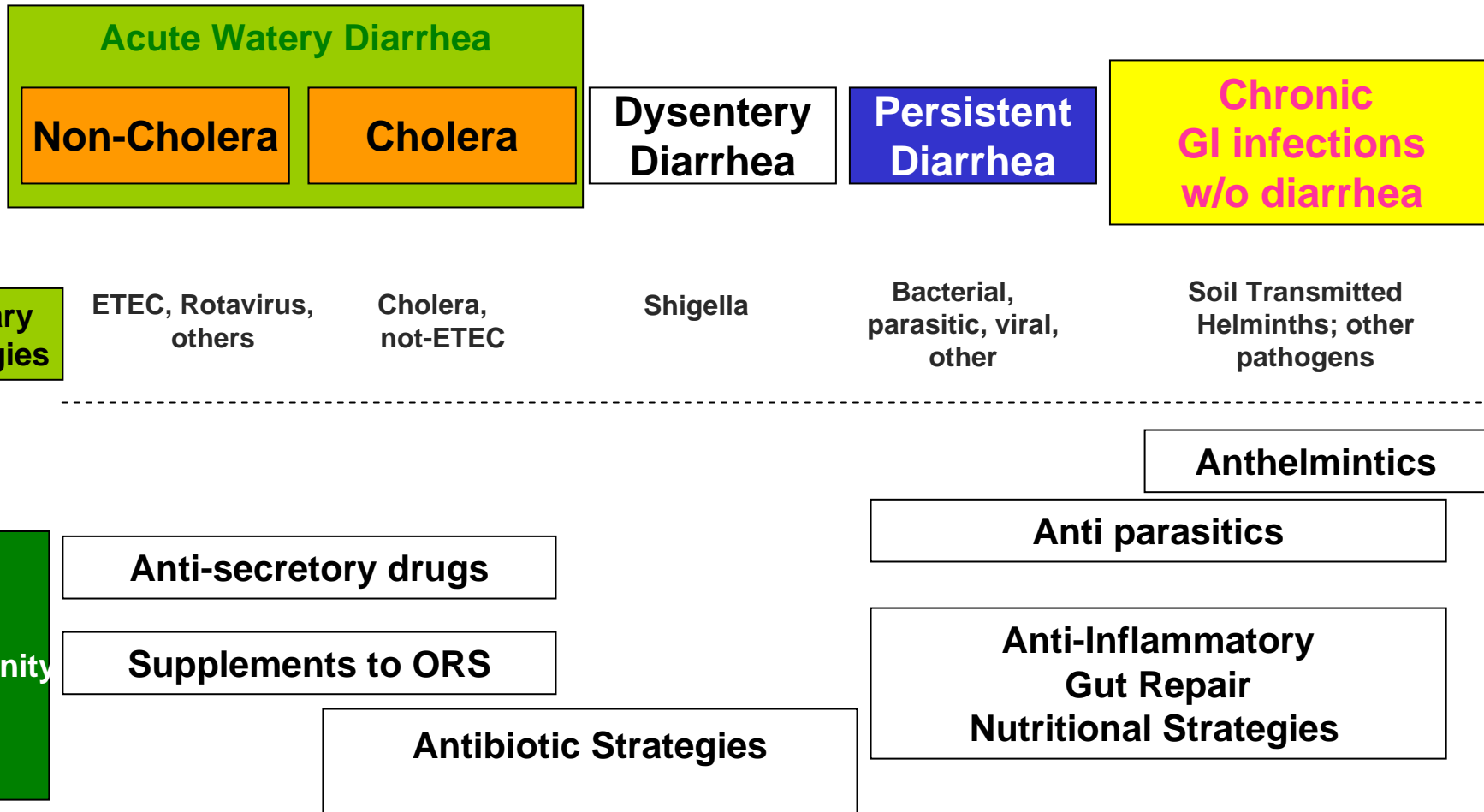
Program Vision

Develop a portfolio of safe, effective and affordable anti-diarrheal drugs as an adjunct to oral rehydration therapy (ORT) for the treatment of life-threatening diarrheal diseases in pediatrics and adults in developing countries

Program Goals

- 1 First funded project to develop novel anti-secretory drugs for use as an adjunct to ORT for the treatment of acute, watery diarrhea in pediatrics and adults
- 2 Buildout risk-balanced diarrheal disease drug portfolio with near term focus on identifying potential late-stage opportunities
- 3 Establish strategic partnerships and alliances with key stakeholders in Global Diarrheal Disease arena

Gastrointestinal Diseases Landscape



Future Opportunities

- Cutting edge technology platforms with potential to transform a unique sector of global health treatment
- Appropriately-designed treatment strategies that can prolong the useful lifespan of existing drugs for neglected diseases
- Combination and/or co-administration product strategies in VL and diarrhea to prevent resistance

iOWH Partnering Principles

- Employ innovative strategies to address NTDs in neglected populations
- Flexible partnering arrangements to afford greatest probability of success
- Provide industry with flexible and innovative partnership opportunities
 - Do not **compete; duplicate** available resources
 - Focus on **D**, versus R when possible
 - Be the **bridge** - industry & public sector
- Support/nurture growth of not-for-profit health sector

For Partnership inquiries



Photograph by Jonathan Torgovnik

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