



***TB Knows No Boundaries.***



**TB ALLIANCE**

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

2003/04 ANNUAL REPORT



Peerless

MULTIPROTECTOR

2



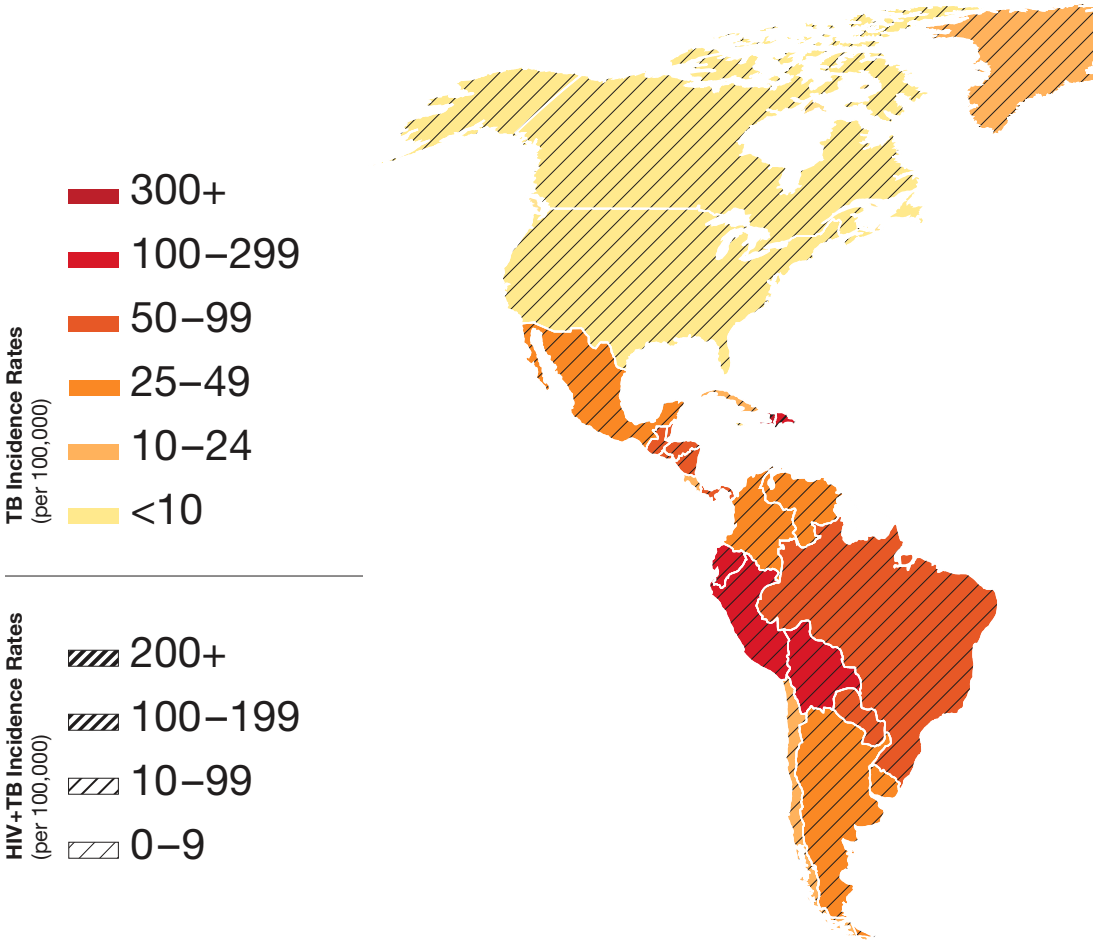
*No one is immune.*

From New York to New Delhi, Lima to London, Moscow to Mumbai, tuberculosis (TB) is airborne and does not discriminate.

TB overwhelmingly targets developing countries where it helps maintain the crippling cycle of poverty and disease. TB has also staged a comeback in the industrialized world.

New York had a severe outbreak of drug-resistant TB in the early 1990s and London now has areas with infection levels higher than Beijing. A decade ago, TB was not on the radar screen in Russia; but now only sub-Saharan Africa has higher TB growth rates. TB is a timebomb.

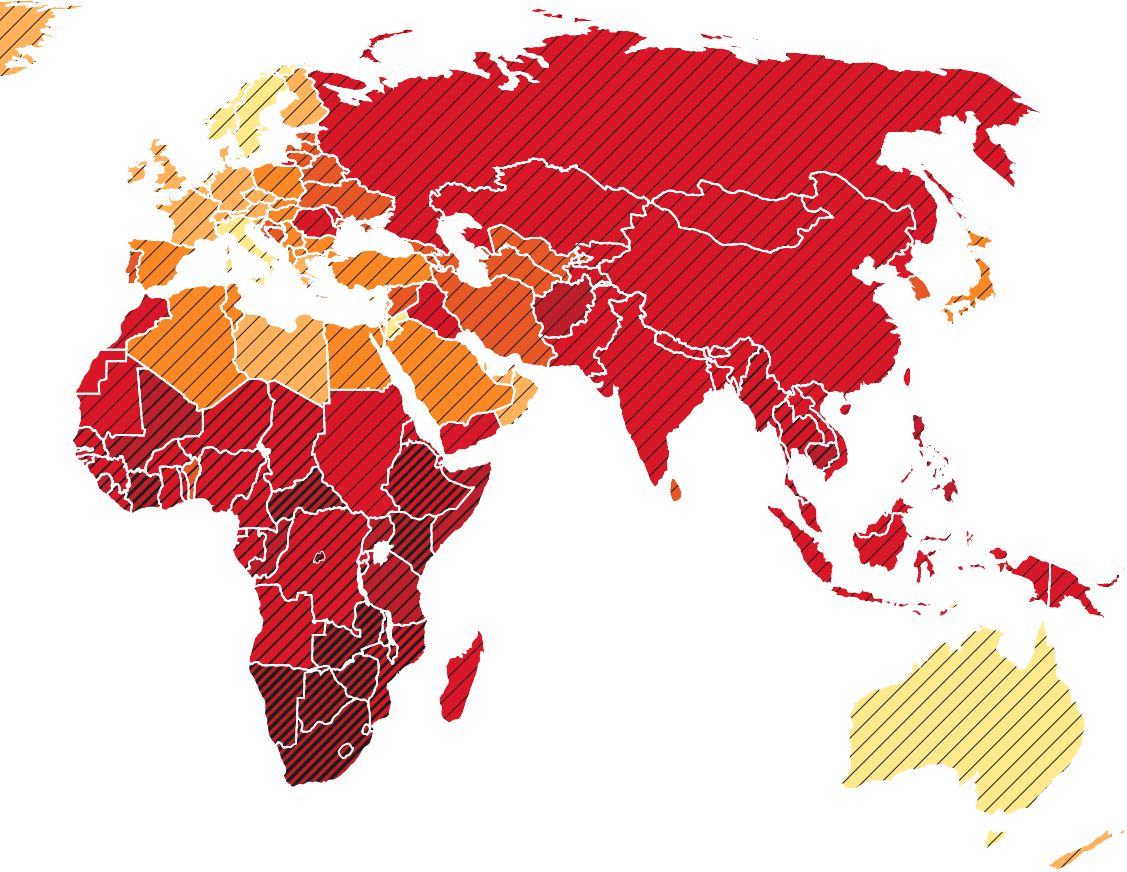
# TB infects over 2 billion people.



Source: Dye C. "Global epidemiology of HIV-related TB: Estimated burden and trends (Presentation)": World Health Organization (2002). (Data from 2000).

Tuberculosis kills one person every 15 seconds. Identified in human remains dating back 10,000 years, TB is the oldest known infection and has claimed over 1 billion lives. Explaining its historical persistence, the TB bacterium grows slowly and can survive for decades in its latent form in the human host. When the immune system is compromised, TB is "activated," and primarily attacks the lungs. Once symptomatic,

# *TB and HIV form a twin epidemic.*

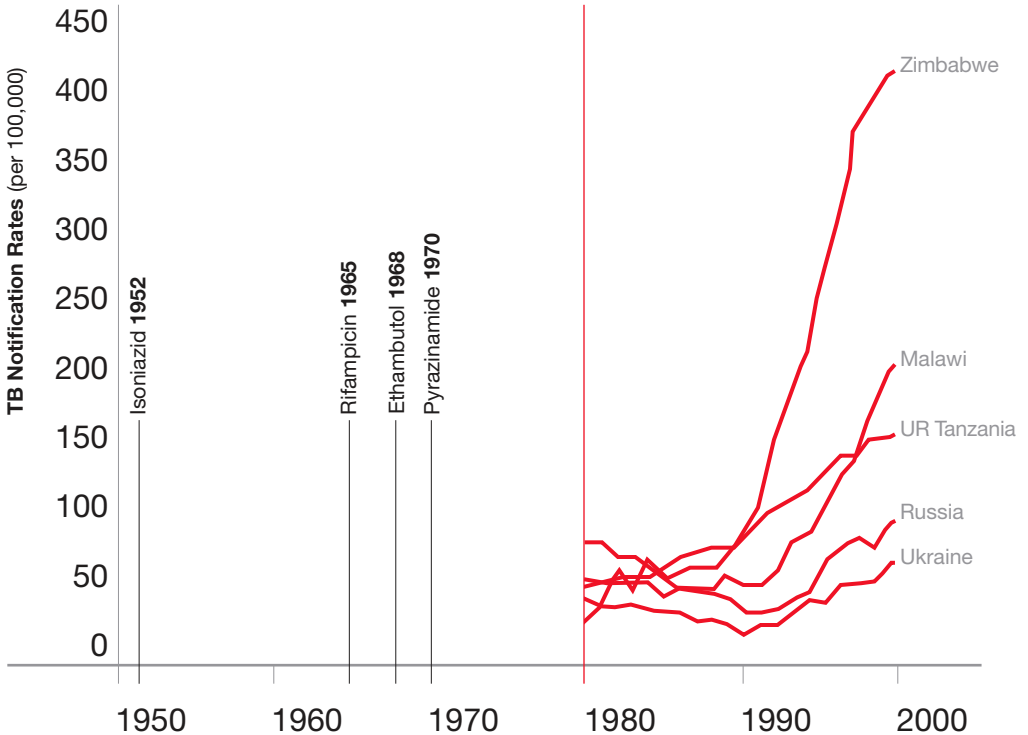


someone with active TB could infect up to 10–15 people, as the disease is transmitted by tiny infectious airborne particles.

Fifty years after the first TB drugs were introduced, close to 9 million people still develop the active and infectious form of TB and 2 million die every year. These alarming statistics belie the disease's full magnitude. The reservoir of latent TB cases numbers 2 billion, a third of the world's

population. 500 million infections are expected this decade. Fueled by this enormous reservoir, TB's rise over the last decade is associated with its symbiosis with HIV/AIDS. An individual with both HIV and latent TB is up to 50 times more likely to develop active, transmissible TB. Over the last decade, TB and HIV have merged into a twin epidemic.

# There have been no new TB drugs introduced in over 30 years.



— TB case rates in selected countries

Source for TB drugs: Duncan K. "Progress in TB Drug Development and What is Still Needed": *Tuberculosis* (2003) 83, 201-207.

Source for TB case rates: Raviglione M.C. "The TB epidemic from 1992 to 2002": *Tuberculosis* (2003) 83, 4-14.

Current TB treatment relies on four first-line drugs that were developed in the 1950s and 1960s. These old drugs impose a lengthy and complex regimen that lasts six to nine months and requires an army of healthcare workers to administer. With such constraints, only about a third of TB patients have access to today's

proper standard of care. Meanwhile, incomplete or improper treatment is fueling the alarming rise of deadly, multi-drug resistant (MDR-TB) strains. Each year, a majority of the 300,000 new cases of MDR-TB do not respond to three of the four first-line drugs, and few are effectively cured.



***Will there be a drug for her?***

Research and development efforts for TB drugs came to a virtual standstill after the 1960s, partly due to limited market incentives. As a result, the thinning pipeline failed to deliver new drugs that could shorten and improve treatment and limit resistance.

The Global Alliance for TB Drug Development (TB Alliance) was created to lead a collaborative effort between public and private players with a simple, shared goal: to accelerate and ensure the development of new, faster-acting and affordable TB drugs that will revolutionize TB control.





At the TB Alliance,  
we are trailblazing a new approach.

# here's how...

The TB Alliance is a new type of endeavor. In our search for faster-acting TB drugs, we convened leading experts to design a scientific blueprint and analyzed market forces to create new incentives for productive partnerships.

As we build our growing pipeline, we join unlikely partners and leverage intellectual capital across disciplines and countries. We push the

boundaries of science while using the best and highest standards. We invest in our own pipeline and support the initiatives of others. We fund open, shared technology platforms to lower the hurdles and streamline development.

We leave no stone unturned to build the most robust pipeline possible for TB drugs, because it is time for a faster cure.

# We are realizing the first, most comprehensive TB drug pipeline since the 1960s.

## TB ALLIANCE PORTFOLIO 2004

## DISCOVERY

### Compounds and Drug Candidates

**Quinolones**  
(KRICT, YONSEI UNIVERSITY)

**Nitroimidazole Analogs**  
(NOVARTIS INSTITUTE FOR TROPICAL DISEASES, NIAID)

**Macrolides**  
(UNIVERSITY OF ILLINOIS AT CHICAGO)

**Carboxylates**  
(WELLESLEY COLLEGE)

**Methyltransferase inhibitors**  
(ANACOR PHARMACEUTICALS)

**New Target Projects**  
(PARTNERS TO BE ANNOUNCED)

**Novel Compounds**  
(PARTNERS TO BE ANNOUNCED)

**Rifalazil Analogs**  
(ACTIVBIOTICS)

**Alkaloids and Ascidiemins**  
(UNIVERSITY OF AUCKLAND)

### Platform Technologies


**Murine Model of TB**  
(JOHNS HOPKINS UNIVERSITY)

**Biomedical Information Resources/Database**  
(INTELLECTUALL LIMITED)

**Molecular Topology Model**  
(MEDISYN TECHNOLOGIES)

**Chemical-Biological and Related Technologies Database**

 TB Alliance portfolio

 TB Alliance in discussion/  
finalization stages

 TB Alliance terminated

Our goal is to stimulate, support, and ensure the reemergence of a global TB drug development pipeline. We build on industry's proven approach and leverage new expertise and capacity in emerging R&D centers. We catalyze TB drug research at large and engage public and private laboratories.

PRECLINICAL

CLINICAL TESTING

Quinolone, Non-Fluorinated  
(PROCTOR & GAMBLE)

Quinolone, Moxifloxacin  
(BAYER AG)

Nitroimidazole PA-824  
(CHIRON)

Pyrrole LL-3858  
(LUPIN LIMITED)

Quinolone KRQ-10018  
(KRICT, YONSEI UNIVERSITY)

Regulatory Guidance and Harmonization

Clinical Trials Infrastructure  
(IUATLD)

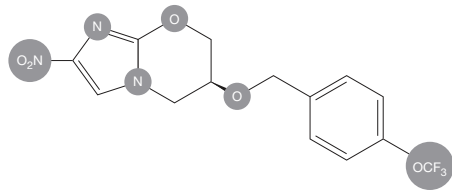
Clinical Trials Infrastructure  
(EDCTP)

The TB Alliance's portfolio is the first, most comprehensive TB drug pipeline since the 1960s. We actively scout the world for potential TB drugs and we take the lead where selected technology is needed to move forward and deliver on its promise. Our portfolio reflects a diversified strategy: we are developing derivatives of existing TB drugs; we

are researching antibiotics never yet tested for a TB indication; and we are exploring entirely novel compounds.

Several promising drug candidates are in, or are approaching, clinical development. The prospects of transforming TB treatment and helping reverse the epidemic are in sight.

# exploring novel drug classes



PA-824 STRUCTURE

## PA-824

WHO	PROJECT MANAGEMENT BY RESEARCH TRIANGLE,
	FIFTEEN CONTRACT RESEARCH ORGANIZATIONS,
	CHIRON CORPORATION, SUPPORT FROM NIAID
WHAT	TWO YEARS OF PRECLINICAL DEVELOPMENT
	PROGRESS: TOXICOLOGY, PHARMACOKINETIC,
	FORMULATION AND PRODUCTION ASSESSMENTS

The development plan for PA-824 follows the standard principles of drug development, streamlined to rapidly move the compound through critical go/no-go milestones and to minimize costs. With support from NIAID, Research Triangle Institute (RTI) and the TB Alliance manage the work of 15 external research groups. Since the TB Alliance does not have in-house laboratories, these Contract Research Organizations (CROs) have conducted the full range of preclinical, pharmacokinetic, toxicology, safety pharmacology and production assessments.

PA-824 is on track to complete all of its preclinical development milestones, with an investigational new drug (IND) submission planned for the second quarter of 2005, two years after the start of preclinical studies. The ongoing drug development program is geared to moving PA-824 to IND and Phase I trials, but also aims to set the groundwork for research that may lead to second-generation compounds with an even

greater utility and better drug profile than PA-824.

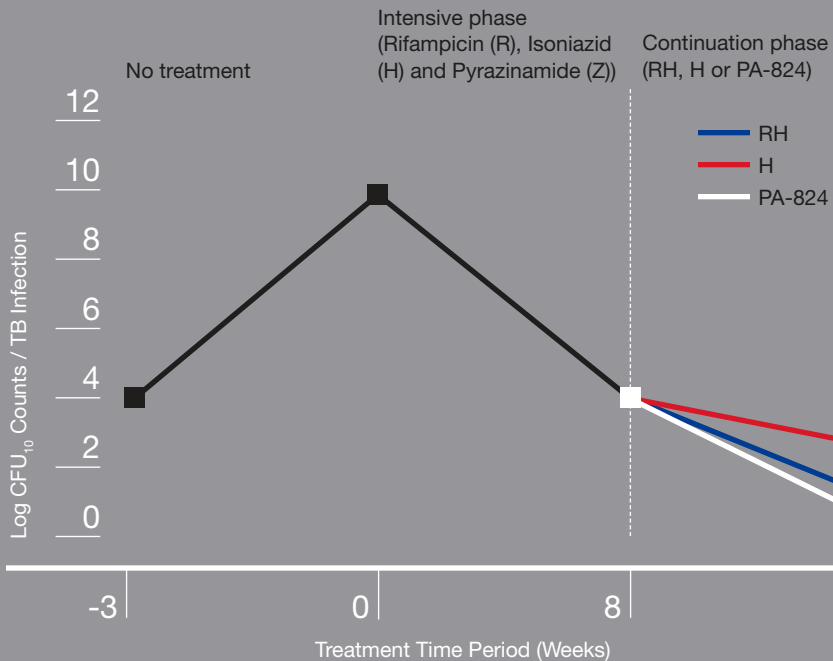
The preclinical phase of development has been evaluating PA-824's likely efficacy compared to, and in combination with, current TB drugs. Thus far, results are very positive. In animal models, PA-824 demonstrated excellent efficacy, rivaling that of isoniazid in its bactericidal properties and rifampicin as a sterilizing agent. These results and continuing studies will inform the design of optimal combination therapies for Phase II testing. In expanded *in vitro* studies, PA-824 was highly active against MDR-TB clinical isolates from diverse geographic sources.

Now nearly complete, the entire preclinical development program has already studied PA-824's non-clinical efficacy, pharmacokinetics, drug-drug interactions, safety/toxicity profile, formulation and synthesis optimization.

While more studies are ongoing, a very encouraging sign is PA-824's lack of any significant inhibition of the cytochrome P450 isozymes, supporting its potential for integration into TB-HIV treatment. Safety and toxicity tests have indicated a reasonable no adverse effects level; further safety tests are ongoing. An effective capsule formulation has been developed and a tablet option is being tested in the fourth quarter of 2004.

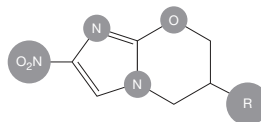
The first novel compound in the TB Alliance portfolio, PA-824 is a nitroimidazopyran with a mechanism of action distinct from known TB drugs. Recent efficacy tests in a murine model confirmed its potency against TB, showing it rivaled the sterilizing effects of rifampicin, a cornerstone drug of current treatment. Having passed major milestones, PA-824 is approaching clinical trials and a back-up program is underway.

### Promising results of PA-824 activity in TB Mouse Model



To evaluate its sterilizing activity, PA-824 was introduced after the standard intensive phase of treatment. PA-824 demonstrated excellent efficacy, rivaling that of isoniazid in its bactericidal properties and rifampicin as a sterilizing agent. (Jacques Grosset et al, 2004)





PA-824 ANALOG STRUCTURE

## PA-824 Analogs

WHO	NOVARTIS INSTITUTE FOR TROPICAL DISEASES,
	SINGAPORE; NATIONAL INSTITUTE OF ALLERGY AND
	INFECTIOUS DISEASES, US
WHAT	DEVELOPMENT OF BACK-UP & SECOND-GENERATION
	COMPOUNDS FOR PA-824

While pursuing PA-824's remaining development activities, the TB Alliance initiated a simultaneous back-up program to maximize the potential of this class of compounds. If PA-824 proves to be clinically useful, a second generation compound could be even better than PA-824. If PA-824 fails in its further development, a back-up program may provide superior compounds within the class with potential to overcome the issues that precluded PA-824's development.

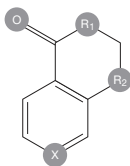
The PA-824 family of nitroimidazopyrans is one of the most promising opportunities for improving TB therapy. Studies completed so far demonstrate that PA-824 has multiple attractive characteristics as a potential drug: it has a novel mechanism of action; it is a proven bactericidal and sterilizing agent in mice; it shows activity against drug-resistant clinical isolates; it is not genotoxic, with no evidence of mutagenicity; and it shows no interactions with cytochrome P450, making it safe to use in joint TB-HIV treatment. Yet, it also has several aspects which should be addressed to improve its scientific or economic

prospects as a new drug, such as a relatively expensive synthetic route.

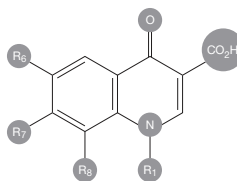
Given the odds of any drug development program, the goal of the PA-824 back-up program is to maximize the promising features of the class by identifying superior compounds and improving on PA-824's properties as a drug. In fact, there were signs during PA-824's discovery phase that other analogs had better *in vitro* activity than PA-824, but less activity *in vivo*. As the back-up program moves forward, scientists have already examined pharmacokinetic causes that could explain this discrepancy.

The TB Alliance has embarked on a joint program with the Novartis Institute for Tropical Diseases (NITD) in Singapore, which pledged to cooperate with the TB Alliance, and with Dr. Clifton Barry of the NIAID. The back-up program will also involve Dr. William Baker of Corus Pharma, a scientist with significant expertise in the nitroimidazopyran class, as he participated in PA-824's discovery. The back-up program, which was initiated in 2004, is to synthesize multiple compounds around the most promising areas for chemical modification of PA-824 and to determine the most viable lead compound by subjecting each to a systematic, comprehensive analysis.

# optimizing known TB compounds and...



ISONIAZID STRUCTURE



QUINOLONE STRUCTURE

## Carboxylates

WHO	WELLESLEY COLLEGE; TAACF; SUNY; JACOBUS PHARMACEUTICALS
WHAT	SYNTHESIS AND TESTING OF ISONIAZID DERIVATIVES, NOVEL CARBOXYLATES

Studying patterns of drug resistance against existing drugs may shed light on drug design approaches that minimize resistance. This project explores compounds in the carboxylate class, derivatives of isoniazid (INH), a mainstay of TB treatment since its 1952 introduction. The two-year project was designed to focus on the synthesis of novel compounds effective against MDR-TB, evaluate them for efficacy and selectivity, and confirm promising leads in animal models.

A lead compound, MJH-98-I-12, was identified based on *in vitro* characteristics. The compound can be easily synthesized, which would facilitate its manufacture in high-burden countries. Important common features among these compounds can be identified as optimizing activity in MDR-TB, fueling new drug design.

Researchers also investigated several acylated derivatives of INH. While these derivatives did not have the same efficacy as isoniazid, they were highly selective and active against strains of INH-resistant *M. tuberculosis*. These findings may serve as significant leads in antitubercular drug discovery.

## Quinolones

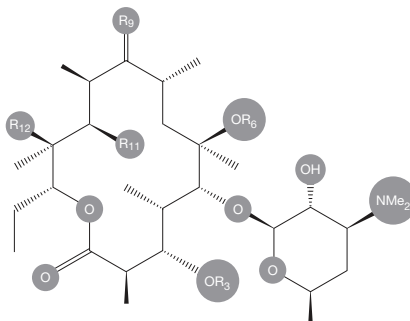
WHO	KOREAN RESEARCH INSTITUTE OF CHEMICAL TECHNOLOGY, YONSEI UNIVERSITY
WHAT	OPTIMIZING NOVEL QUINOLONES TO SHORTEN FIRST-LINE TREATMENT

This project aims to synthesize and evaluate novel quinolone compounds with improved ability to reach infected tissues and enhanced anti-tubercular potency. Especially attractive is the quinolizinone series of compounds, because they are highly active in general against mycobacteria and have enhanced solubility and pharmacokinetic properties.

In a project launched in 2003, KRICT has synthesized more than 200 new quinolones of the planned 500 quinolones and quinolizinones and transferred these to Yonsei University for biological testing. To date, 150 of these compounds have been evaluated and based on early indications from *in vitro* tests, a significant number of them have potential. Of the 500 quinolones evaluated for their *in vitro* anti-mycobacterial activity, some 20 of these compounds are planned for evaluation in short-term efficacy studies in mice. The three most promising of these compounds will then be tested in extended efficacy studies in mice. Compounds meeting pre-set potency, safety and pharmacokinetic profiles will advance to preclinical development.



# other antibiotics



MACROLIDE STRUCTURE

## Macrolides

WHO	INSTITUTE FOR TB RESEARCH, UNIVERSITY
	OF ILLINOIS; RAMATHIBODHI HOSPITAL,
	BANGKOK, THAILAND
WHAT	OPTIMIZATION OF ERYTHROMYCIN DERIVATIVES AS 3 <sup>rd</sup>
	GENERATION MACROLIDES FOR TB INDICATION

One way to fast-track the development of new TB drugs lies in exploring classes of existing antibiotics, which already possess desirable pharmacological properties, but do not yet include TB as an indication. Of these, the macrolides stand out as one of the most likely to yield a clinically useful TB drug, particularly because some already synthesized macrolides have been shown to have reasonable *in vitro* potency against *M. tuberculosis*.

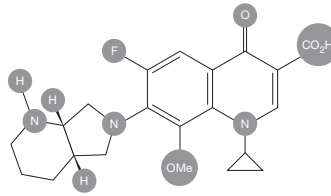
Erythromycin derivatives, in addition to anti-TB activity, possess desirable drug features, such as oral bioavailability, good distribution to the lungs, low toxicity, infrequent adverse reactions, extensive intracellular concentration, and anti-inflammatory properties. In addition, erythromycin is a relatively inexpensive starting material for semi-synthesis, indicating that a new TB drug arising from this class could be affordable.

The primary goal of this project is to optimize the anti-TB activity of the macrolide antibiotics through the synthesis of additional chemically

modified derivatives of erythromycin. Using classical design methodology and newer computer programming approaches, the derivatives have been designed by correlating the chemical structures of the existing compounds with their anti-TB activity and selectivity (the ability to selectively kill the tubercle bacillus but not a mammalian cell).

Using recent technological improvements, one hundred compounds will be prepared to test for superior activity and selectivity. After assessing them for human metabolism and anti-TB activity, the compounds will undergo biological testing for activity against MDR-TB strains at Ramathibodhi Hospital, Bangkok.

Compounds with a favorable therapeutic index, good activity and high selectivity will be further assessed to determine *in vivo* pharmacokinetics, including their ADME (absorption, distribution, metabolism, and excretion) properties. The compound(s) with the best overall profile in terms of anti-TB activity, pharmacokinetics and safety will advance to preclinical evaluation.



MOXIFLOXACIN STRUCTURE

## Moxifloxacin

WHO	BAYER AG
	EUROPEAN & DEVELOPING COUNTRIES
	CLINICAL TRIALS PARTNERSHIP (EDCTP)
WHAT	COLLABORATIVE CLINICAL DEVELOPMENT PROGRAM
	AIMED TOWARDS REGISTERING MOXIFLOXACIN AS
	AN ANTI-TB DRUG

Moxifloxacin has generated significant interest from the TB community for its potential to become the next major advance in TB therapy since the 1965 introduction of rifampicin. This interest stems from moxifloxacin's demonstrated *in vitro* potency, preclinical efficacy, and safety profile. In fact, of all the fluoroquinolones studied over the past 10 years, moxifloxacin appears to have the most potential to dramatically improve therapy in the near term.

Moxifloxacin has demonstrated *in vitro* and *in vivo* characteristics that hold promise in the treatment of TB, including demonstrated bactericidal activity similar to that of isoniazid against multiplying *M. tuberculosis* organisms, an activity that has been seen both *in vitro* and in a murine model of TB. Against persister organisms, moxifloxacin is more active than isoniazid and even has greater activity than other fluoroquinolones in a murine model.

Studies supported by the TB Alliance and conducted at Johns Hopkins University using an *in vivo* mouse model indicate that the substitution of moxifloxacin for isoniazid markedly shortens the duration of therapy needed to eradicate infection. These findings suggest that the substitution of moxifloxacin for isoniazid may shorten therapy from a total of six months to as little as three or four months.

Bayer AG (the makers of moxifloxacin), the TB Alliance and the European and Developing Countries Clinical Trials Partnership (EDCTP) are in discussion to formalize moxifloxacin's development as an anti-TB agent with a comprehensive clinical development program. As with all projects, the TB Alliance is involved with the goal of assuring that resulting therapies will be available to all patients in need. This program will build on a current Phase II trial, coordinated by the TB Trials Consortium at the US Centers for Disease Control and Prevention (CDC), which the TB Alliance helped facilitate.





At the TB Alliance,  
we're defining a new bottom-line.

# here's how...

The TB Alliance is based on a new bottom-line. Besides engaging both public and private parties, we build partnerships that share risks and rewards.

The ultimate measure of our success is that the drugs we develop are affordable, adopted and accessible to patients who need

them most—the focus of our “AAA” strategy. We develop the best new medicines that science can deliver, and our bottom-line is access for all.

To navigate a new era, we tap the best minds embracing innovation. We merge public and private interests into a common and effective endeavor to ensure drugs reach patients.

# setting new standards



“What if a successful TB drug is too expensive? What if health practitioners do not use it or drugs do not reach patients? Beyond innovation, safety and efficacy, our bottom line is affordability, adoption and access. Only when all patients receive and take the new medicines, will we have a chance to reverse the epidemic.”

— Joelle Tanguy

Director of Advocacy and Public Affairs

## affordability

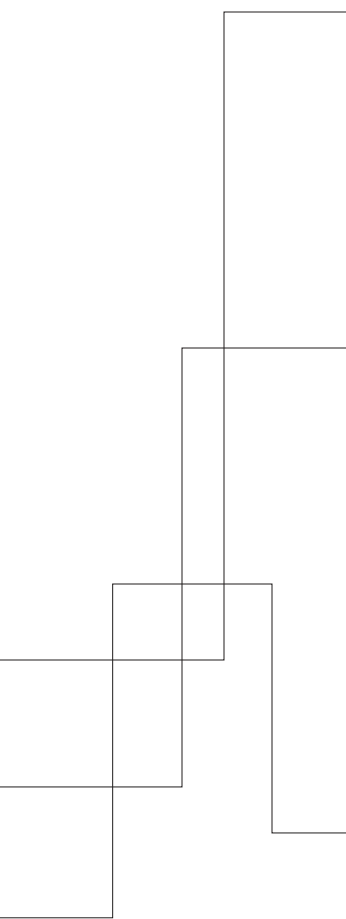
---

## adoption

---

## access

---



As we scout for potential drugs, we identify classes of compounds that can be developed, synthesized and manufactured in a cost-effective way to ensure the entire drug development process results in affordable drugs. We selectively leverage intellectual property rights (IPR), so that all our partnerships endorse affordability and therefore access to all.

Even at drug design stages, the TB Alliance consults with key stakeholders, experts and TB program managers of endemic countries to ensure early adoption. We established the characteristics of the target drug such as simple (oral) administration and compatibility with antiretroviral drugs. We also work closely with the World Health Organization (WHO), the Stop TB Partnership and the Global Fund for AIDS, TB and Malaria to lay the groundwork for the adoption and procurement of new drugs into existing treatment protocols.

Access is the culmination and final test of the AAA strategy, literally the stage when the drugs go into a patient's hands. Building on affordability and adoption, access also factors in the distribution channels including national TB programs, private providers, patient networks and community-based initiatives.

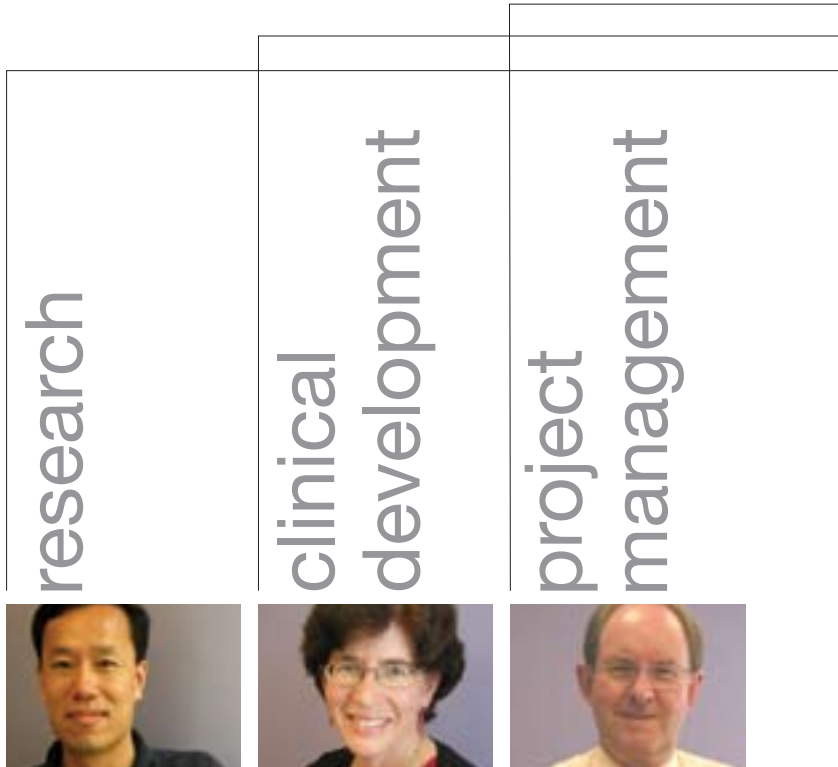
# tapping the best minds



“We’ve expanded the R&D team this year, bringing in-house the expertise necessary to expand the portfolio, move projects into the clinic and manage partnerships around the globe. Collectively this wealth of knowledge in medicinal chemistry, the science of tuberculosis, and project management represents a major asset in realizing the Alliance’s mission.”

—Dr. Mel Spigelman

Director of Research and Development







**Zhenkun Ma**

HEAD OF RESEARCH

The inventor on 40 patents and patent applications, Dr. Ma is intimately familiar with the challenges and rewards of drug discovery; he knows how to recognize promising lead compounds. A skilled medicinal chemist, Dr. Ma will leverage his first-hand knowledge of antibiotic drug development programs, which he directed at Abbott Laboratories and Cumbre Inc.

**Ann Ginsberg**

HEAD OF CLINICAL DEVELOPMENT

A widely respected TB expert, Dr. Ginsberg also brings industry and government experience to the TB Alliance. During her 15-year tenure at NIH, Dr. Ginsberg led the NIAID's TB and then respiratory disease program. Her expertise in global health and TB guides her work with stakeholders and partners, laying the groundwork for global clinical trial networks.

**Dean Haubrich**

HEAD OF PROJECT MANAGEMENT

A pharmaceutical industry veteran, Dr. Haubrich understands how to manage projects and partnerships to streamline the development timeline. Having led recent global partnership product launches for Bristol Myers Squibb, Dr. Haubrich will now oversee the coordination and progress of all TB Alliance portfolio project-related activities.

# navigating a new era

Since the last TB drugs were discovered in the 1960s, drug development has become more sophisticated, and our understanding of TB has expanded. The TB Alliance relies on the Scientific Advisory Committee (SAC) and other TB experts who have honed their knowledge of the bacterium and embraced innovation and apply lessons learned to the next generation of antibiotics for TB.



A chemist intrigued by patterns, **Dr. Chris Lipinski** formulated a simple algorithm in 1995 to help identify successful drugs. Ever since, the “Rule of Five,” centering around parameters containing a multiple of five, has become the baseline to weed out molecules with poor permeability, poor solubility or high toxicity. While there are occasional exceptions to the rule, Dr. Lipinski notes that the onus is on the investigator to demonstrate why a candidate will still work, if it does not fit the rule. The American Chemical Society recognized Dr. Lipinski for this landmark contribution with a 2004 award. The TB Alliance is applying Dr. Lipinski’s rule of thumb in its early stage projects.



An adviser to Indian pharmaceuticals, **Dr. Ramesh Panchagnula** is a principal investigator at National Institute of Pharmaceutical Education and Research (NIPER). Dr. Panchagnula and his colleagues have designed a “High-Throughput Pharmaceutics (HTP)” concept for new anti-TB drugs. By retrofitting these principals into molecular modeling, combinatorial chemistry and high-throughput screening, the paradigm aims to streamline and reduce the costs of drug development. Lending his expertise to PA-824’s development, Dr. Panchagnula designed studies to assess key physicochemical properties critical for synthesis and formulation.

## 2004 Scientific Advisory Committee

Dr. Clifton Barry, III  
National Institute of Allergy and Infectious Diseases,  
National Institutes of Health

Dr. Ken Duncan  
GlaxoSmithKline

Dr. Bernard Fourie, *Secretary*  
Medical Research Council of South Africa

Dr. Maria C. Freire  
Global Alliance for TB Drug Development

Dr. Jacques Grosset  
The Johns Hopkins University

Dr. Yoshiaki Kiso  
Kyoto Pharmaceutical University

Dr. Barbara Laughon, *Chair*  
National Institute of Allergy and Infectious Diseases,  
National Institutes of Health

Dr. Christopher Lipinski  
Pfizer Inc. (ret.)

Dr. Dennis Mitchison  
St. George's Hospital Medical School

Dr. Richard O'Brien  
Foundation for Innovative New Diagnostics

Dr. Ramesh Panchagnula  
Indian National Institute of Pharmaceutical  
Education and Research

Dr. Philippe Prokocimer  
Johnson & Johnson

Dr. Christine Sizemore  
National Institute of Allergy and Infectious Diseases,  
National Institutes of Health

Dr. Mel Spigelman  
Global Alliance for TB Drug Development

Dr. C. Kendall Stover  
Pfizer Inc.

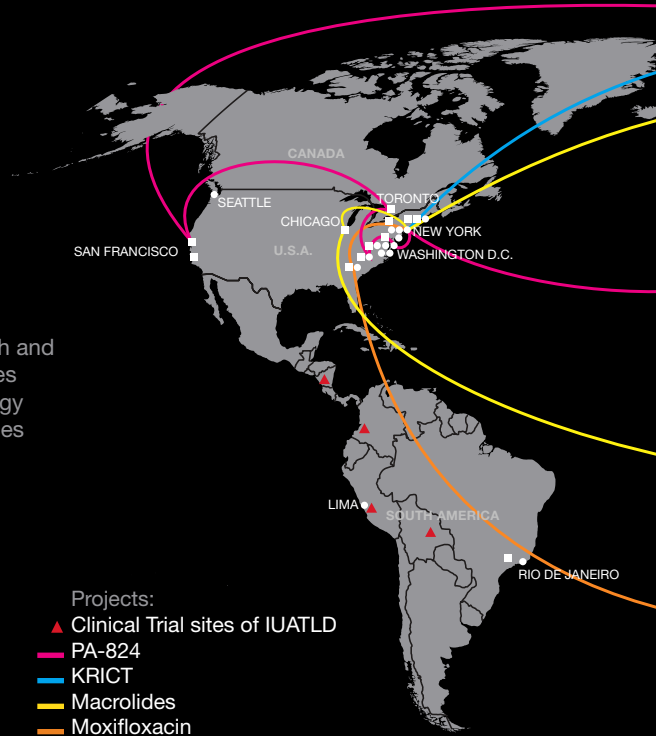


Professor **Dennis Mitchison**'s career is marked by milestone advances in TB treatment. The proof for today's TB treatment—six-month combination therapy—came from British Medical Research Council (BMRC) studies that Prof. Mitchison led with his colleague, Dr. Wallace Fox. Crucial to that breakthrough was the addition of rifampicin and pyrazinamide. Prof. Mitchison is also noted for making the distinction between sterilizing and bactericidal activity of TB drugs. Prof. Mitchison is now championing the use of early bactericidal activity (EBA) studies and serial sputum CFU counts (SSCC) to assess and predict the efficacy of new TB drugs at St. George's Hospital Medical School in London.



**Dr. Scott Franzblau** believes in the value of a fresh perspective on an old problem. A microbiologist at University of Illinois's College of Pharmacy, Dr. Franzblau built his TB expertise on successful clinical trials in leprosy. Treating leprosy with clarithromycin convinced him that the macrolide class could also become a new TB therapeutic. He developed a new TB drug susceptibility assay for high-throughput screening and low-tech assays in developing countries, which he tested in Thailand. Armed with a TB Alliance grant to investigate third generation macrolides for TB, Dr. Franzblau says he can now devote the full resources necessary to translate a hunch into a lead after over a decade's wait.

# transforming the way the world works



TB Alliance partners include both the health and technology sectors of high-burden countries as well as pharmaceutical and biotechnology companies with relevant expertise, resources and capacity to contribute.

## Partners:

- Scientific Collaborators and Related Parties
- Stakeholders and Associated Institutions

### Brazil

- Oswaldo Cruz Foundation (FioCruz)
- Rede-TB

### Canada

- MDS Pharma

### European Institutions

- European & Developing Countries Clinical Trials Partnership (EDCTP)
- European Commission

### France

- ● International Union Against Tuberculosis and Lung Disease (IUATLD)

### Germany

- Bayer AG

### India

- Indian Council of Scientific and Industrial Research (CSIR)
- International Centre for Genetic Engineering & Biotechnology (ICGEB)
- ● National Institute of Pharmaceutical Education and Research (NIPER)
- ● Lupin Laboratories
- Novartis India, Ltd

## Projects:

- ▲ Clinical Trial sites of IUATLD
- PA-824
- KRICT
- Macrolides
- Moxifloxacin

### Japan

- Research Institute of Tuberculosis, Japan Anti-TB Association (RIT/JATA)

### Korea

- Korea Research Institute of Chemical Technology (KRICT)
- Yonsei University

### Netherlands

- Netherlands Ministry for Development Cooperation
- Royal Netherlands Tuberculosis Association (KNCV)

### New Zealand

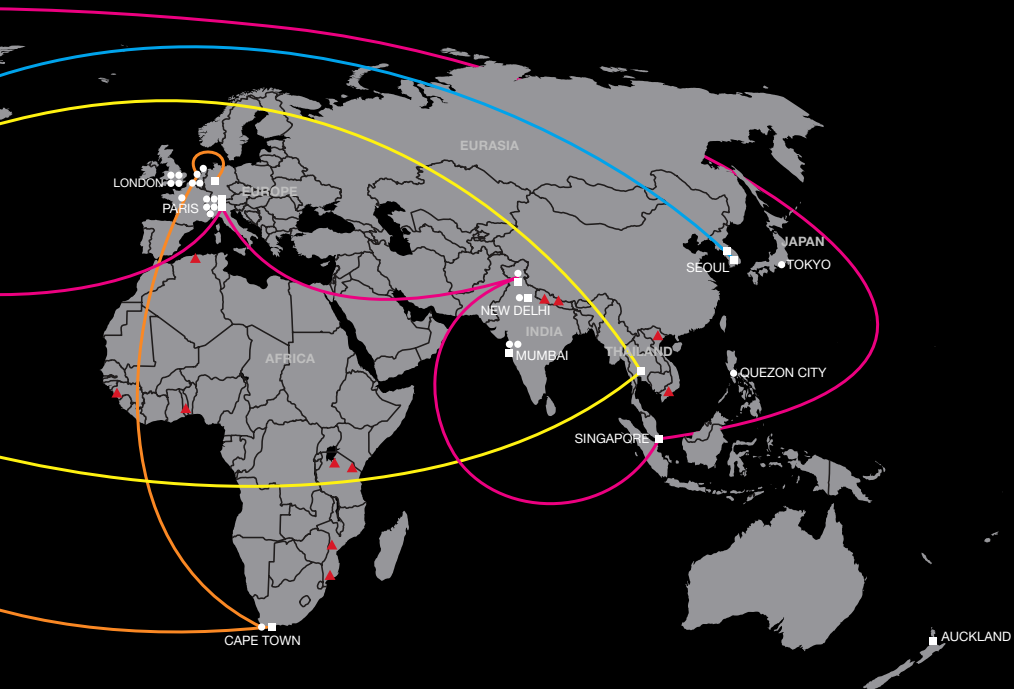
- University of Auckland

### Peru

- Ministry of Health of the Government of Peru

### Philippines

- Philippines Coalition Against Tuberculosis (PHILCAT)



Singapore

- Novartis Institute for Tropical Diseases (NITD)

South Africa

- ● Medical Research Council of South Africa

Switzerland

- EMS Dottikon
- Global Forum for Health Research
- Médecins Sans Frontières – Doctors Without Borders (MSF)
- Novartis International AG
- World Health Organization (WHO)
- Stop TB Partnership
- UN Programme for Research and Training in Tropical Diseases (TDR)

United Kingdom

- Association of the British Pharmaceutical Industry (ABPI)
- Department for International Development (DFID)
- TB Alert
- Wellcome Trust

United States

- ActivBiotics
- Agency For International Development (USAID)

- American Lung Association (ALA)
- American Society for Tuberculosis Education and Research (ASTER)
- American Thoracic Society (ATS)
- Anacor Pharmaceuticals
- Bill and Melinda Gates Foundation
- ● Centers for Disease Control and Prevention (CDC)
- Chiron Corporation
- Johns Hopkins University
- ● National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIAID/NIH)
- New Jersey Medical School National Tuberculosis Center
- Partners In Health
- Rockefeller Foundation
- ● Research Triangle Institute (RTI)
- Results
- Sequella Global Tuberculosis Foundation
- State University of New York
- University of Illinois at Chicago
- Wellesley College
- World Bank

Let's put science to work and  
deliver a faster cure.



**Dr. Maria C. Freire**  
*President and CEO*



**Dr. Gijs Elzinga**  
*Chairman of the Board*

## Dear Stakeholders, Donors and Friends,

A decade ago, developing affordable drugs for a disease with an unattractive commercial market was a pipe dream. Today, new and better treatments for TB are coming within our reach, thanks to innovative approaches and committed partners and stakeholders. Our bold initiative to catalyze the development of affordable TB drugs is well underway, and, with your help, holds the promise to turn the tide on tuberculosis.

In four years, the TB Alliance has established the first, most comprehensive portfolio of potential TB drugs since the 1960s. Reflecting a diversified approach, this pipeline encompasses entirely novel classes of compounds as well as next generation analogs of current antibiotics. Moreover, through investments in platform technologies and in-kind support, we have helped reinvigorate the field of TB drug development and enlisted new players.

### BOARD OF DIRECTORS

**Dr. Gijs Elzinga**  
*Chairman of the Board*

Deputy Director-General,  
Netherlands' National  
Institute of Public Health  
and the Environment

**Dr. Carlos Morel**  
*Vice Chair*

Scientific Coordinator,  
Oswaldo Cruz  
Foundation

**Dr. Ariel Pablos-Méndez**  
*Secretary*

Director, Knowledge  
Management and Sharing  
World Health Organization

**Mr. Charles Kaye**  
*Treasurer*

Co-President,  
Warburg Pincus

Our multifaceted strategy has elicited the support of industry, catalyzed new projects and accelerated promising drug candidates towards registration. Importantly, all this has been accomplished while affirming the guiding principles of our AAA strategy: affordability and access of the medicine to those in need through its adoption in the field.

Now is the time to scale up the pipeline and accelerate clinical trials to deliver on the promise of this emerging portfolio. This depends on the support of the public and private sectors worldwide. We are grateful that so many organizations have already participated in significant ways, either financially or in-kind to our efforts. In particular, we want to acknowledge the commitment of the first high-burden countries to facilitate and foster partnerships with their biotechnology and pharmaceutical companies, health care providers, governmental organizations and academic institutions.

As the global health community knows well, oftentimes the leadership of a few courageous individuals makes all the difference. The TB Alliance has lived up to this tradition. We are especially indebted to Mr. Seán Lance, whose four-year tenure on the Board of Directors and inspired chairmanship for two years accounts for our rapid progress and clarity of mission.

Our level of motivation is in proportion to the scope of the problem TB has become. An epidemic that kills someone every 15 seconds and has outwitted us for centuries continues to spread, despite the hard work of everyone on the front lines. Current tools are woefully inadequate and serve as poor weapons against new complexities that demand a faster cure limited to weeks, not months of treatment.

Multi-drug resistant tuberculosis strains defy a dwindling drug arsenal and are the seeds of a potential global catastrophe. TB is a leading cause of death of AIDS patients, which underscores the urgency

Dr. Maria C. Freire  
*President and  
Chief Executive Officer*  
Global Alliance for  
TB Drug Development

Dr. Gail Cassell  
Vice President,  
*Scientific Affairs,*  
Eli Lilly and Company

Dr. Paul Herrling  
Head of Corporate  
Research, Novartis  
International AG

Mr. Seán Lance  
Chairman of the Board,  
Chiron Corporation  
(Emeritus)



“Developing anti-TB medicines is both a health and a moral imperative. The impact will be profound, not only in those countries hardest hit, but wherever the possibility of TB exists—and that is everywhere.”

for TB therapies that are faster-acting and compatible with antiretrovirals. Highlighting this stark reality at the July International AIDS Society meeting in Bangkok, Nelson Mandela said: “We cannot win the battle against AIDS if we do not also fight TB. TB is too often a death sentence for people with AIDS. It does not have to be this way.”

Until we register new medicines for tuberculosis, it may too often be this way. And Mr. Mandela is right to invite us to change our thinking and overcome boundaries. This same vision is core to the effort at hand: to leverage technology and science for new avenues in disease control that will reverse the deadly trends and help meet the Millennium Development Goals.

Developing anti-TB medicines is both a health and a moral imperative. The impact will be profound, not only in those countries hardest hit, but wherever the possibility of TB exists—and that is everywhere. No doubt, this is not an easy or a small task. But, over the last four years, we have

moved from vision to possibility and we laid the groundwork for the steps ahead. We thank the organizations and individuals who have contributed to this effort, and we invite all to join us.



Dr. Maria C. Freire  
President and Chief Executive Officer



Dr. Gijs Elzinga  
Chairman of the Board

Dr. John La Montagne  
Deputy Director, U.S.  
National Institute of  
Allergy and Infectious  
Diseases, National  
Institutes of Health

Dr. Lee Reichman  
*President*, TB Alliance  
Stakeholders' Association  
Executive Director,  
New Jersey Medical  
School National  
Tuberculosis Center

Sir David Weatherall  
Founding Director  
Emeritus, Weatherall  
Institute of Molecular  
Medicine, University  
of Oxford

# Financials

# independent auditors' report

**Board of Directors of  
The Global Alliance for TB Drug Development, Inc.**

We have audited the accompanying statement of financial position of The Global Alliance for TB Drug Development, Inc. as of December 31, 2003, and the related statements of activities, functional expenses and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall

financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of The Global Alliance for TB Drug Development, Inc. as of December 31, 2003, and the changes in its net assets and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Information for the year ended December 31, 2002 is presented for comparative purposes only and was extracted from the financial statements of The Global Alliance for TB Drug Development, Inc. for that year, on which we expressed an unqualified opinion, dated June 9, 2003.



April 7, 2004

# statement of financial position

(with comparative totals for 2002)

Year Ended December 31,	2003	2002
<b>Assets</b>		
Cash and cash equivalents (Note 2)	\$ 21,004,225	\$ 22,367,458
Cash - restricted (Notes 2 and 6)	125,087	125,087
Other assets	228,404	165,434
Property and equipment, net (Notes 2 and 4)	136,989	134,958
	<b>\$ 21,494,705</b>	<b>\$ 22,792,937</b>
<b>Liabilities and Net Assets</b>		
		-
<b>Liabilities:</b>		
Accounts payable and other liabilities	\$ 632,607	\$ 210,954
Accrued payroll and payroll related liabilities	91,959	29,968
Capital lease obligation (Note 6)	65,089	88,581
Deferred revenue	-	1,800,000
<b>Total liabilities</b>	<b>789,655</b>	<b>2,129,503</b>
Commitments (Note 7)		
<b>Net assets:</b>		
Unrestricted net assets (Note 2)	20,705,050	20,663,434
	<b>\$ 21,494,705</b>	<b>\$ 22,792,937</b>

See accompanying notes to financial statements.

# statement of activities

(with comparative totals for 2002)

Year Ended December 31,	2003	2002
<b>Public support and other revenue:</b>		
Contributions	\$ 4,741,143	\$ 8,441,731
Contributed services (Note 3)	487,628	268,460
Interest and dividend income	231,082	308,055
Miscellaneous income	3,182	227
<b>Total public support and other revenue</b>	<b>5,463,035</b>	<b>9,018,473</b>
<b>Expenses:</b>		-
Program services:		
Research and development	3,319,207	1,510,522
Business development	276,038	333,817
Advocacy	888,055	826,805
<b>Total program services</b>	<b>4,483,300</b>	<b>2,671,144</b>
Supporting services:		
Management and general	1,055,814	839,169
Fundraising	119,136	116,472
<b>Total supporting services</b>	<b>1,174,950</b>	<b>955,641</b>
<b>Total expenses</b>	<b>5,658,250</b>	<b>3,626,785</b>
<b>Change in net assets before foreign translation gain</b>	<b>(195,215)</b>	<b>5,391,688</b>
<b>Foreign translation gain (Note 2)</b>	<b>236,831</b>	<b>72,474</b>
<b>Change in net assets</b>	<b>41,616</b>	<b>5,464,162</b>
<b>Net assets, beginning of year</b>	<b>20,663,434</b>	<b>15,199,272</b>
<b>Net assets, end of year</b>	<b>\$ 20,705,050</b>	<b>\$ 20,663,434</b>

See accompanying notes to financial statements.

# statement of cash flows

(with comparative totals for 2002)

Year Ended December 31,	2003	2002
<b>Cash flows from operating activities:</b>		
Change in net assets	\$ 41,616	\$ 5,464,162
Adjustments to reconcile change in net assets to net cash provided by (used in) operating activities:		
Depreciation and amortization	59,294	100,176
Increase in assets:		
Restricted cash	-	(5,199)
Security deposits and other receivables	(62,970)	(17,722)
Increase (decrease) in liabilities:		
Accounts payable and other liabilities	421,653	(109,847)
Accrued payroll and related liabilities	61,991	29,968
Deferred revenue	(1,800,000)	(75,000)
<b>Net cash provided by (used in) operating activities</b>	<b>(1,278,416)</b>	<b>5,386,538</b>
<b>Cash flows from investing activities:</b>		
Additions to property and equipment	(61,325)	(26,874)
<b>Cash flows from financing activities:</b>		
Repayments of capital lease obligation	(23,492)	(23,493)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(1,363,233)</b>	<b>5,336,171</b>
<b>Cash and cash equivalents, beginning of year</b>	<b>22,367,458</b>	<b>17,031,287</b>
<b>Cash and cash equivalents, end of year</b>	<b>\$ 21,004,225</b>	<b>\$ 22,367,458</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 6,203	\$ 6,200

See accompanying notes to financial statements.

# notes to financial statements

## 1. Organization

The Global Alliance for TB Drug Development, Inc. (“TB Alliance”) is a nonprofit organization incorporated on July 24, 2000 under the General Corporation Law of Delaware and authorized to conduct business in New York under the Not-for-Profit Corporation Law of New York. It operates as a not-for-profit, with offices in Brussels, Cape Town and New York.

The TB Alliance was formed to accelerate the development of effective new medicines to treat tuberculosis and ensure their affordability and availability in high-endemic countries.

Advocating for a worldwide mobilization against the TB epidemic through innovative research into new therapeutics, the TB Alliance develops innovative partnerships and involves scientists and researchers globally. It builds a portfolio of promising drug candidates and outsources research and development projects to public and private labs to develop affordable new drugs that will shorten the treatment of tuberculosis, be effective against multi-drug resistant strains and improve treatment of latent infection.

## 2. Summary of Significant Accounting Policies

### (a) Basis of Presentation

The financial statements have been prepared on the accrual basis.

### (b) Financial Statement Presentation

The classification of a not-for-profit organization’s net assets and its support, revenue and expenses is based on the existence or absence of donor-imposed restrictions. It requires that the amounts for each of three classes of net assets, permanently restricted, temporarily restricted, and unrestricted, be displayed in a statement of financial position and that the amounts of change in each of those classes of net assets be displayed in a statement of activities.

Income from investment gains and losses, including unrealized gains and losses, dividends, interest and other investments should be reported as increases (or decreases) in unrestricted net assets unless the use of the income received is limited by donor-imposed restrictions.

These classes are defined as follows:

(i) **Permanently Restricted** — Net assets resulting from contributions and other inflows of assets whose use by TB Alliance is limited by donor-imposed stipulations that neither expire by passage of time nor can be fulfilled or otherwise removed by actions of TB Alliance.

(ii) **Temporarily Restricted** — Net assets resulting from contributions and other inflows of assets whose use by TB Alliance is limited by donor-imposed stipulations that either expire by passage of time or can be fulfilled and removed by actions of TB Alliance pursuant to those stipulations. When such stipulations end or are fulfilled, such temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statement of activities.

(iii) **Unrestricted** — The part of net assets that is neither permanently nor temporarily restricted by donor-imposed stipulations.

### (c) Cash and Cash Equivalents

TB Alliance considers short-term investments with original maturities of three months or less to be cash equivalents.

### (d) Restricted Cash

Restricted cash consists of cash held by banks providing collateral for TB Alliance’s leased equipment.

### (e) Investments

Investments are valued at fair value in the statement of financial position. Unrealized gains and losses are included in the statement of activities.

### (f) Depreciation and Amortization

The cost of property and equipment is depreciated over the estimated useful lives of the assets using the straight-line method. Leasehold improvements are amortized over the lesser of the life of the lease or asset. The estimated useful lives of the assets are as follows:

Computer equipment	3–5 years
Furniture and equipment	3–5 years
Leasehold improvements	5–10 years

### **(g) Income Taxes**

TB Alliance is exempt from Federal and state income taxes under Section 501(c)(3) of the Internal Revenue Code (the "Code") and therefore has made no provision for income taxes in the accompanying financial statements. The Internal Revenue Service (the "IRS") has made a determination that TB Alliance can be treated as a publicly supported organization described in Code Sections 509(a)(1) and 170(b)(1)(a)(vi) during an advance ruling period beginning on July 24, 2000 and ending December 31, 2004. After the advance ruling period, the IRS will make a final determination of TB Alliance's public charity status. There was no unrelated business income for 2003.

### **(h) Contributions and Promises to Give**

Contributions and promises to give are recorded as revenue when either unsolicited cash is received or when donors make a promise to give. Contributions and promises to give are classified as either unrestricted, temporarily restricted, or permanently restricted support.

### **(i) Contributed Goods and Services**

Contributed goods and services are recognized as revenue and expenses if such goods and services meet the criteria for recognition as stated in Statement of Financial Accounting Standards ("SFAS") No. 116, "Accounting for Contributions Received or Contributions Made."

### **(j) Program Services**

**(i) Research and Development** — TB Alliance creates and manages a portfolio of new anti-TB drug candidates by identifying, evaluating and acquiring promising molecules from scientific laboratories worldwide and outsourcing their development to appropriate public and private partners. Further, TB Alliance invests in infrastructure research projects that accelerate anti-TB drug development and analyzes existing scientific gaps to address these as part of the overall development strategy.

**(ii) Business Development** — TB Alliance negotiates, implements and manages agreements with public and private organizations worldwide and does so by adhering to sound business practices while ensuring the public good. Specifically, TB Alliance negotiates terms that support the development and access of new affordable anti-TB drugs equitably to those areas most in need while encouraging the private sector to help develop new medicines for TB indications.

**(iii) Advocacy** — TB Alliance manages critical alliances with public and private organizations to raise awareness about tuberculosis ("TB") and advocate for public and private involvement in research for new anti-TB medicines. It develops landmark studies to support policy developments seeking to accelerate anti-TB drug research and mobilizes networks of researchers and investigators worldwide to focus on the development of these medicines.

### **(k) Use of Estimates**

In preparing financial statements in conformity with generally accepted accounting principles, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the financial statements and revenues and expenses during the reported period. Actual results could differ from those estimates.

### **(l) Comparative Financial Information**

The financial statements include certain prior year summarized comparative information. With respect to the statement of activities, the prior year information is presented in total, not by net asset class. With respect to the statement of functional expenses, the prior year expenses are presented by expense classification in total rather than functional category. Such information does not include sufficient detail to constitute a presentation in conformity with accounting principles generally accepted in the United States of America. Accordingly, such information should be read in conjunction with the TB Alliance's financial statements for the year ended December 31, 2002, from which the summarized information was derived.

### **(m) Concentration of Credit Risk**

Financial instruments which potentially subject TB Alliance to concentration of credit risk consist primarily of temporary cash investments. At various times during the year, TB Alliance had cash deposits at financial institutions which exceeded the FDIC insurance limit.

### **(n) Foreign Currency Translation**

All elements of the financial statements reflecting TB Alliance's operations in Brussels are translated into U.S. dollars using applicable exchange rates. For assets and liabilities, this is the rate in effect at the statement of financial position date. For revenue and expense items, translation is performed monthly using the average rate for the month. The exchange rate as of December 31, 2003 was 1.2557 EUR/USD.



Foreign currency is translated in accordance with the provisions of SFAS No. 52, "Foreign Currency Translation". Under the provisions of SFAS No. 52, the local currency used in TB Alliance's foreign operations is considered to be the functional currency of these operations. Translation of the financial statements of these operations resulted in a translation gain as follows:

December 31, 2003	
Cumulative translation gain adjustment, beginning of period	\$ 59,006
Translation adjustment	236,831
Cumulative translation gain adjustment, end of period	\$ 295,837

The cumulative translation gain is included in unrestricted net assets.

### 3. Contributed Services

Included in TB Alliance's statement of activities is approximately \$490,000 and \$270,000 for the years ended December 31, 2003 and 2002, respectively, of in-kind contributions.

The amounts recognized during the year ended December 31, 2002 were related to project management costs.

### 4. Property and Equipment, Net

Property and equipment, net, stated at cost, consists of the following:

December 31, 2003	
Computer equipment	\$ 33,023
Furniture and equipment	100,720
Leasehold improvements	136,979
Total property and equipment	270,722
Less: Accumulated depreciation and amortization	(133,733)
Property and equipment, net	\$ 136,989

### 5. Support

On September 8, 2000, the Bill and Melinda Gates Foundation approved a five-year unrestricted grant to TB Alliance in the amount of \$25,000,000 for use in furtherance of its overall charitable purpose and mission to improve the supply of anti-TB drugs for national TB control efforts and to develop a collaboration for TB drug development. The remaining balance of \$5,000,000 is a conditional grant expected to be paid to TB Alliance in one annual payment in January 2005, upon the achievement of certain milestones and the use of past contributions received.

On November 30, 2001, the Rockefeller Foundation announced a general support grant to TB Alliance for up to \$3,500,000 for the one-year period beginning August 1, 2002 with any unused funds reverting back to the Foundation at the end of the grant period. The Rockefeller Foundation had made two separate payments of \$1,750,000 each to TB Alliance in both 2003 and 2002.

On October 9, 2002, the World Health Organization approved a general support grant to TB Alliance for up to 2,007,876 Euros for the two-year period beginning January 1, 2002 with any unused funds reverting back to the World Health Organization at the end of the grant period. As of December 31, 2003, the World Health Organization had paid TB Alliance the sum of 1,003,938 Euros of the 2,007,876 Euros which was equivalent to \$1,175,230 at the funds received date.

### 6. Capital Lease Obligation

At December 31, 2003, capital lease obligation consisted of the following:

<p>TB Alliance financed the cost of certain equipment with a lease obligation in various monthly installments of \$ 2,475 until May 2006, including interest at 7.96%; secured by restricted cash accounts totaling \$ 125,087</p>	\$ 65,089
Less: Current maturities	25,430
	\$ 39,659

Future minimum lease payments due under these capital lease obligations at December 31, 2003 are as follows:

Year ending December 31,	
2004	\$ 25,430
2005	27,529
2006	12,130
	\$ 65,089

## 7. Commitments

TB Alliance has operating lease agreements for office space in New York, Brussels and Cape Town. TB Alliance moved its New York office in March 2004. The prior lease results in a final three month commitment of rental payments of \$42,421. The Brussels lease agreement expires in November 2009. The Cape Town lease expired in January 2004 and has not yet been renewed.

The following is a schedule of future minimum rental payments under the Brussels and Cape Town operating leases as of December 31, 2003:

Year ending December 31,	
2004	\$ 24,532
2005	23,500
2006	23,500
2007	23,500
2008	23,500
Thereafter	70,501
	\$ 189,033

TB Alliance has research and development agreements with several research institutions to fund various research and development contracts useful for treatment of TB. The agreements' expiration dates are undeterminable as of December 31, 2003.

The following is a schedule of future minimum research and development payments under the above agreements as of December 31, 2003:

Year ending December 31,	
2004	\$ 1,441,561
2005	575,000
2006	500,000
2007	500,000
2008	500,000
Thereafter	500,000 per year

## 8 Subsequent Events

In January 2004, TB Alliance entered into a new 10-year lease agreement at 80 Broad Street, New York, NY and moved into the new office in March 2004.

The following is a schedule of future minimum rental payments under the new operating lease.

Year ending December 31,	
2004	\$ 161,721
2005	219,671
2006	224,339
2007	228,826
2008	250,653
Thereafter	1,330,496
	\$ 2,415,706

## 9. Related Parties

A member of the Board of Directors of TB Alliance is an employee of the Rockefeller Foundation, a grantor of TB Alliance.

Another member of the Board of Directors of TB Alliance is affiliated with Chiron Corporation, a company from whom the TB Alliance has licensed rights to a family of compounds.

# staff and consultants

**Maria C. Freire, Ph.D.**  
President and Chief Executive Officer

**Mel Spigelman, M.D.**  
Director, Research and Development

**Joelle Tanguy**  
Director, Advocacy and Public Affairs

**Bradley Jensen**  
Director, Finance and Administration

**Serdar Elmali**  
Information Technology and  
Networking Consultant

**Sarah Ee**  
Public Affairs Fellow

**Beatrice M. Evangelista**  
Officer, Public Affairs

**Janean Jeffries**  
Executive Assistant to President and CEO

**Ann Ginsberg, M.D., Ph.D.**  
Head of Clinical Development

**Dean Haubrich, Ph.D.**  
Head of Project Management

**Heather Ignatius**  
Policy Fellow

**Zhenkun Ma, Ph.D.**  
Head of Research

**Gwynne Oosterbaan**  
Assistant Director, Public Affairs

**Doris Rouse, Ph.D.**  
Portfolio Project Manager

**Muntaha Sabah Lazim**  
Administrative Manager - Europe

**Gerald J. Siuta, Ph.D.**  
Consultant, Business Development

**Ethan Wilensky-Lanford**  
Assistant, Advocacy and Public Affairs

**Karen Wright**  
Senior Advisor

# stakeholders

The following institutions formally pledged to accelerate the development of TB drugs. They advise, guide and support the efforts of the Global Alliance for TB Drug Development:

American Lung Association (ALA)	New Jersey Medical School National Tuberculosis Center
American Society for Tuberculosis Education and Research (ASTER)	Novartis India, Ltd
American Thoracic Society (ATS)	Partners in Health
Association of the British Pharmaceutical Industry (ABPI)	Philippines Coalition Against Tuberculosis (PHILCAT)
Bill and Melinda Gates Foundation	Research Institute of Tuberculosis, Japan Anti-TB Association (RIT/JATA)
Centers for Disease Control and Prevention (CDC)	Research Triangle Institute (RTI)
European Commission	Rockefeller Foundation
Global Forum for Health Research	Royal Netherlands Tuberculosis Association (KNCV)
International Union Against Tuberculosis and Lung Disease (IUATLD)	Sequella Global Tuberculosis Foundation
Lupin Laboratories	Stop TB Partnership
Médecins Sans Frontières-Doctors Without Borders (MSF)	U.K. Department for International Development (DFID)
Medical Research Council of South Africa (MRC)	U.N. Programme for Research and Training in Tropical Diseases (TDR)
National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIAID/NIH)	U.S. Agency for International Development (USAID)
National Institute of Pharmaceutical Education and Research, India (NIPER)	Wellcome Trust
	World Bank
	World Health Organization

# acknowledgments

The Global Alliance for TB Drug Development gratefully acknowledges the generosity of the following institutions that provide key funding or in-kind support and expertise:

Bill and Melinda Gates Foundation

Rockefeller Foundation

Netherlands Ministry for Development Cooperation

United States Agency for International Development

World Health Organization/Stop TB Partnership

U.S. National Institute of Allergy and Infectious Diseases, National Institutes of Health

Centers for Disease Control and Prevention

Research Triangle Institute

The Global Alliance for TB Drug Development gratefully acknowledges the leadership of the following institutions which executed Memoranda of Understanding to formalize collaboration and advance research and development for new TB drugs:

Ministry of Health, Government of Peru

Oswaldo Cruz Foundation (FioCruz), Government of Brazil

Council of Industrial and Scientific Research (CSIR), Government of India

Medical Research Council (MRC), Government of South Africa

European and Developing Countries Clinical Trials Partnership (EDCTP)

The Global Alliance for TB Drug Development is a not-for-profit, tax-exempt organization recognized under section 501(c)(3) of the United States Revenue Code; and contributions are tax-deductible in the United States. Its Belgium branch office was also registered in the Annex of the Belgian State Gazette for non-profit organizations on February 28, 2002.

For inquiries, please contact the New York office: Global Alliance for TB Drug Development, 80 Broad Street, 31st Floor, New York, NY 10004

# board of directors

Dr. Gijs Elzinga

*Chairman of the Board*

Netherlands' National Institute of Public Health  
and the Environment

Dr. Carlos Morel

*Vice Chair*

Oswaldo Cruz Foundation

Dr. Ariel Pablos-Méndez

*Secretary*

World Health Organization

Mr. Charles Kaye

*Treasurer*

Warburg Pincus

Dr. Maria C. Freire

*President and*

*Chief Executive Officer*

Global Alliance for TB Drug Development

Dr. Gail Cassell

Eli Lilly and Company

Dr. Paul Herrling

Novartis International AG

Mr. Seán Lance

Chiron Corporation (Emeritus)

Dr. John La Montagne

U.S. National Institute of Allergy and Infectious  
Diseases, National Institutes of Health

Dr. Lee Reichman

New Jersey Medical School National  
Tuberculosis Center

Sir David Weatherall

Weatherall Institute of Molecular Medicine,  
University of Oxford

Photography credits: Inside front cover, WHO/STB/*Colors Magazine*/Rajesh Vora; pages 5, 12, 17, 24,  
John-Michael Maas; pages 6, 8-9, Juliana Thomas; page 17, WHO/STB/*Colors Magazine*/James Mollison;  
page 18, Gary Hampton; Inside back cover, WHO/TBP/Jad Davenport

Design: Ideas On Purpose, New York, NY [www.ideasonpurpose.com](http://www.ideasonpurpose.com)

A photograph of a pregnant woman and a young child. The woman is wearing a light blue t-shirt and a dark jacket, and is holding her belly. The child is wearing a striped shirt and suspenders. The background is blurred, showing other people in a public setting.

*A faster cure will  
make all the difference.*



# TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

The TB Alliance accelerates the discovery and development of faster-acting and affordable drugs to fight tuberculosis, a disease now infecting one in three people worldwide. Through innovative science and with partners around the globe, we aim to ensure equitable access to a faster tuberculosis cure that will advance global health and prosperity.

[www.tballiance.org](http://www.tballiance.org)