

A TRULY GLOBAL EPIDEMIC

TB RESPECTS NO BOUNDARIES.

1/3 OF HUMANITY IS INFECTED.

TB is a truly global disease, found in every country on earth. One third of humanity—over 2 billion people—carry the bacillus that causes TB, and each year 2 million people die of the disease. The devastation from TB is particularly severe in low-income countries, but the impact of TB is apparent worldwide. In our increasingly interconnected world, the burden of the disease is growing even worse, with both drug-sensitive and drug-resistant forms of TB spreading across the globe.

Now, more than ever, we need better, faster-acting TB drug regimens to combat a resurging TB pandemic.

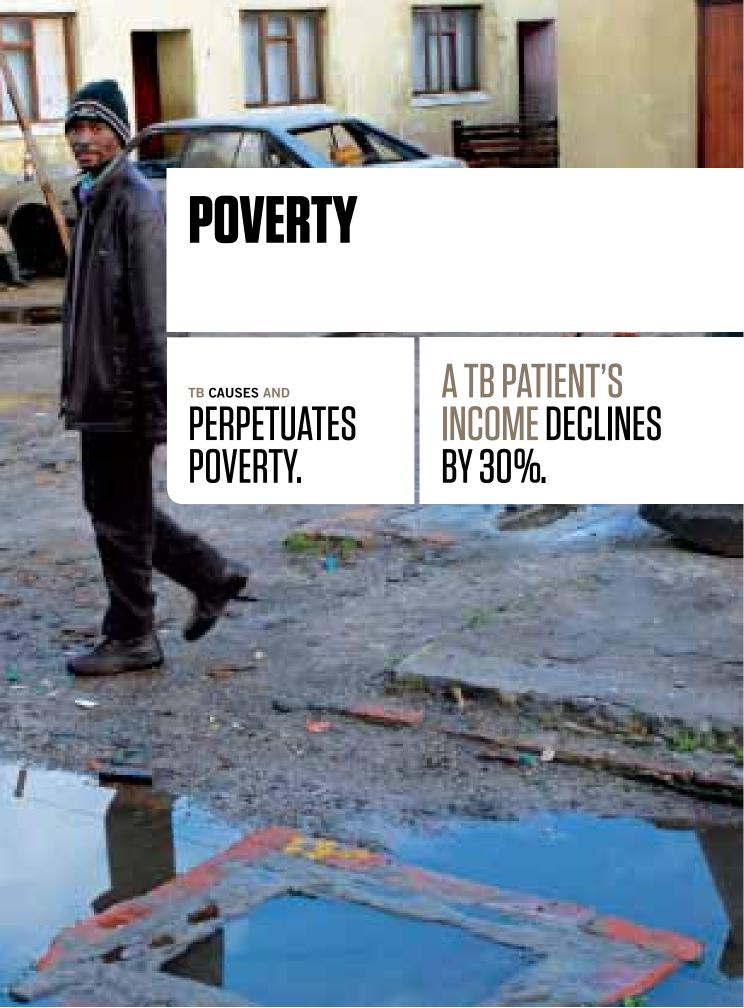


MORE THAN HEALTH

TB devastates fragile economies, draining nations of scarce resources and robbing people with TB of health, hope, and the ability to work and care for their families. TB attacks the most vulnerable among us, and is rampant among the poorest of the poor in all societies. It often strikes individuals in their most economically productive years and is expected to rob the world's most resource-limited nations of \$3 trillion over the next decade, thereby perpetuating the poverty cycle.

Our work to find and bring improved TB treatment regimens to millions is a critical component in alleviating a health-related cause of entrenched poverty.

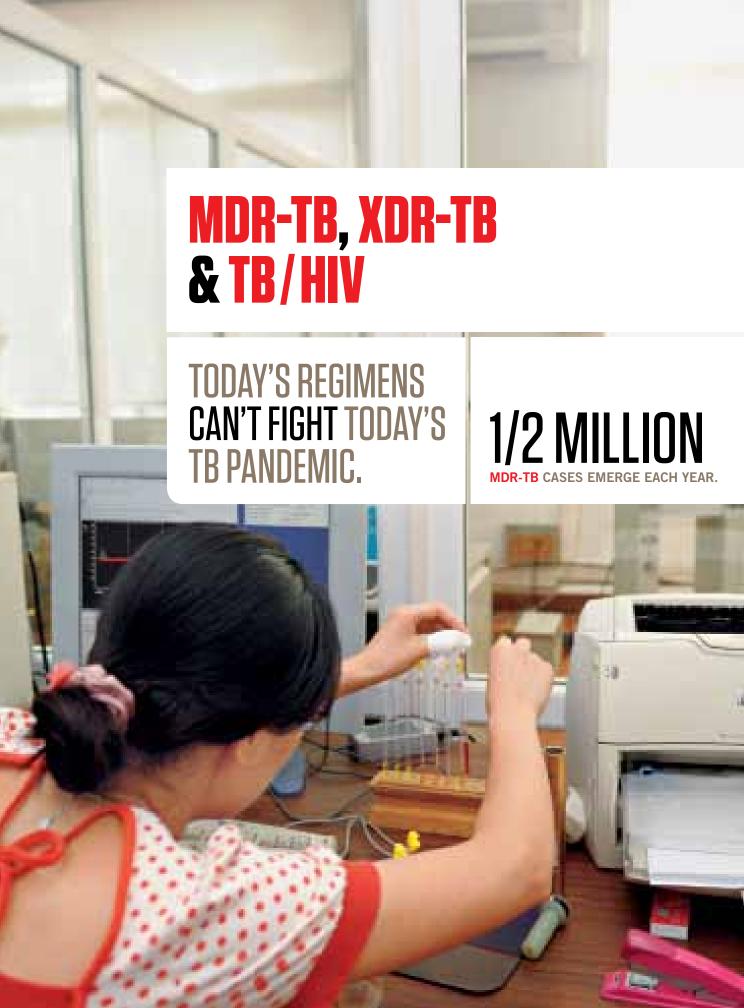
> Cape Town, South Africa Tuberculosis and poverty promote a vicious cycle, whereby TB perpetuates poverty, and poverty breeds TB.





MORE THAN TB

There have been no truly novel TB drugs in nearly 50 years, and the current treatments are inadequate to tackle today's TB pandemic. The first-line regimen must be taken for six to nine months; it is difficult for patients to adhere to and thereby has fueled the rise of drug-resistant TB. In addition, the past decade has seen rising rates of TB/HIV co-infection. Current TB regimens can be difficult to use with commonly administered HIV/AIDS medications and may take up to two years to treat multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). Simply put, people everywhere need faster, better, affordable cures that can tackle the complexity of a growing and evolving TB pandemic.



NEW DRUGS ARE NEEDED TO STOP MDR-TB AND XDR-TB FROM SPREADING AROUND THE WORLD

DRUG-RESISTANT TB

The complex and burdensome first-line TB treatment has led to the needless loss of millions of lives, but also has enabled TB to evolve into deadlier, more difficult, and costly to treat drug-resistant forms, which are spreading throughout the world.

MDR-TB and XDR-TB arise when patients cannot complete their long course of treatment; the drug-resistant disease can then be spread to other people by coughing. Worse yet, treatment for drug-resistant disease, even when successful, can last up to two years or longer and involves daily injections and multiple other drugs with significant side effects and poor effectiveness.

MDR-TB and XDR-TB are especially difficult to control in resource-poor regions because the treatment itself is so long, complex, and expensive. Many communities are simply unequipped to deal with outbreaks. All together, as few as 1% of all MDR-TB patients receive the WHO-recommended treatment for MDR-TB.

A simpler, faster-acting, novel TB treatment regimen is needed to combat this global epidemic. An innovative treatment regimen would enable health workers to treat drug-sensitive *and* drug-resistant cases and has implications for reducing the need for drug susceptibility testing. It would also offer other important benefits, especially for MDR-TB, such as dramatically shortening the duration of therapy,

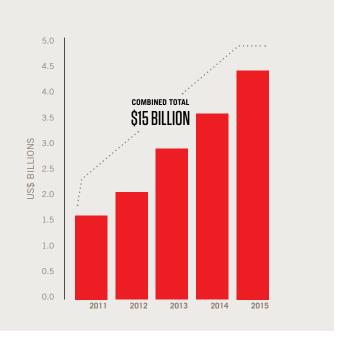
"We cannot win the battle against AIDS if we do not also fight TB. TB is too often a death sentence for people with AIDS."

Nelson Mandela

URGENT NEED: BETTER, MORE AFFORDABLE MDR-TB DRUGS

The World Health Organization has set a target to treat 80% of MDR-TB patients by 2015. The cost of scaling up to that target would cost roughly \$15 billion—more than the Global Fund has spent on treating AIDS, TB, and malaria over the last five years combined.

Investing in the development of new TB drugs will yield more affordable and better tools to fight the drug-resistant TB epidemic.



24% INCREASE

TB/HIV CASES.

TB IS THE #1 INFECTIOUS KILLER WORLDWIDE

markedly improving cure rates, and slashing the costs of procuring and administering the drugs. Overall, these new TB regimens will not only improve treatment of MDR-TB, but improve adherence rates for drug-sensitive TB patients, thereby preventing new MDR-TB and XDR-TB cases from emerging.

The TB Alliance pursues the development of novel TB drug candidates that exhibit the potential to be effective against both drugresistant and drug-sensitive disease, and is dedicated to overcoming the treatment challenges associated with fighting TB in all its forms.

TB/HIV: DEVELOPING DRUGS TO TACKLE THE DUAL EPIDEMIC

TB and AIDS are two deadly epidemics that attack as one. TB is the most common infectious cause of death among people with TB/HIV. Around the world, health officials continue to call for better integration of TB and HIV treatment to stop this deadly duo. However, the current standard treatment for TB interacts poorly with certain commonly administered antiretroviral HIV/AIDS medications, presenting challenges for a full pharmacological integration of treatments.

To achieve true harmonization of TB and HIV treatment, new TB drugs that don't interfere with HIV medications are needed. The TB Alliance's goals include discovering and developing treatment regimens that are compatible with commonly used HIV treatments. In 2010, additional data about clinical drug candidate PA-824 revealed no interaction with any of the cytochrome P450 enzymes commonly involved in the metabolism of many HIV drugs, indicating its promise to be given in conjunction with TB/HIV treatment.

TB/HIV ATTACK AS ONE

1 IN 4 TB DEATHS OCCUR IN HIV-POSITIVE PATIENTS. IN SUB-SAHARAN AFRICA, TB CAUSES UP TO HALF OF ALL AIDS DEATHS. IN SOUTH AFRICA,
70% OF NEW
TB CASES
OCCUR IN PEOPLE
LIVING WITH HIV/AIDS.

AT LEAST

ONE-THIRD

OF THE 42 MILLION
PEOPLE LIVING WITH
HIV WORLDWIDE ARE
INFECTED WITH TB.

PEOPLE WITH HIV ARE
20-30 TIMES
MORE LIKELY
TO DEVELOP TB
THAN THOSE
WITHOUT HIV.

Source: World Health Organization





Delhi, India

TB is one of humanity's oldest and most resilien plagues; combating it requires a partnered, integrated approach.

WORKING ON MULTIPLE FRONTS

Over the past decade, the TB Alliance and its partners have built the largest pipeline of TB drug candidates in history. Now, to bring these compounds through the final stages of testing and to people with TB who need them, we must continue working on many fronts:

WE ARE WORKING AS:

- A NOT-FOR-PROFIT DRUG DEVELOPER
- A HUMANITARIAN AGENCY FOCUSED ON ACCESS TO DRUGS FOR PATIENTS
- A REVOLUTIONARY FORCE IN INNOVATING CLINICAL TRIAL DESIGNS

- A CATALYST AND CONVENER, HELPING TO BUILD A GLOBAL TB DRUG DEVELOPMENT COMMUNITY
- A PARTNER TO COMMUNITIES, ESTABLISHING LOCAL CAPACITY AND INFRASTRUCTURE
- AN ADVOCATE FOR TB PATIENTS Around the World
- → The TB Alliance accelerates the discovery and development of faster-acting and affordable drugs to fight tuberculosis. Through innovative science and with partners around the globe, we aim to ensure equitable access to faster, better tuberculosis cures that will advance global health and prosperity.



MORE THAN PATIENTS

TB not only impacts individuals as patients, but as people. The long and onerous duration of treatment, combined with the stigma often associated with TB, can destroy families and communities, and erode society at large. TB is a leading cause of death in women, particularly in low- and middleincome countries. Active TB disease hampers a mother's ability to care for her family and robs hundreds of thousands of children of their mothers each year.





We are haunted yet inspired by the human face of this disease in all its diversity. TB is found wherever people are found.

Every person with TB has a right to health and hope. Each person has a unique experience. Here are stories from just a handful of the millions of TB patients who are forced to fight this disease despite inadequate treatment options.

Her friends call her Vuvu, and she has TB... again. Over the past decade, working in research as a patient recruiter, she's contracted the disease three times. "I know what I have to do to get better," she says, as she takes a fistful of medication in front of a DOTS worker in one long gulp.

For Vuvu, contracting TB not only impacts her today—but is robbing her of tomorrow. Beyond wrestling with the weakness, coughing, and other symptoms of the disease, she now needs to find a new line of work.

Vuvu is motivated to complete her drug regimen, but she can't help but despair at the prospect of finding a new job, and wonders how she will support herself. A new treatment regimen would not only improve the outcomes of patients like Vuvu, but might make it safe for her to work with patients again, engaging her passion and skills in the worldwide fight against healthrelated causes of poverty.

TB robs individuals of hope and perpetuates the poverty cycle by impacting individuals in their most economically productive years.



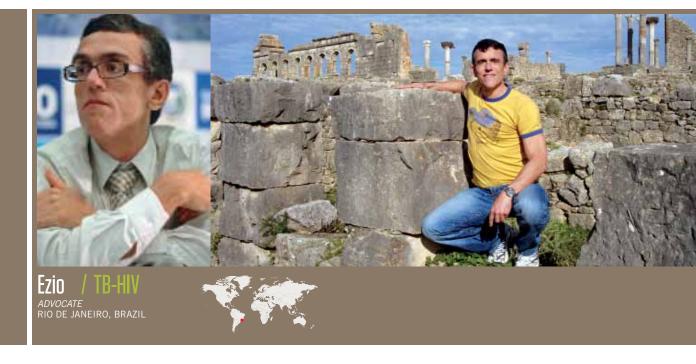
Christiaan was released from quarantine in late June 2010 but still suffers—not from the physical effects of TB, but from the side effects caused by inadequate MDR-TB treatment.

Better known as "The Fully Sick Rapper," Christiaan Van Vuuren contracted TB while traveling abroad from his native Sydney, Australia. Back home and highly infectious, Christiaan was placed in isolation. To pass the time, he wrote a song about his disease, made a video on his laptop computer, and uploaded it to YouTube. To his surprise, people all over the world tuned in and listened.

Christiaan was released from the hospital in January 2010, only to be quarantined again two weeks later when his tuberculosis proved to be resistant to medication. He spent the next six months in isolation, subject to incalculable side effects from the available MDR-TB treatment regimen. Lonely and bored, Christiaan continued to produce videos chronicling the significant flaws of the available treatment regimens and soon became a full-fledged YouTube sensation, his videos garnering millions of views.

Unfortunately, Christiaan's unexpected celebrity status is not the only legacy of his bout with MDR-TB. His doctors tell him that some of the side effects from his medication, like his hearing troubles, may persist long after treatment has been completed. Christiaan was released from quarantine in late June 2010 but still suffers—not from the physical effects of TB, but from the side effects caused by the inadequate MDR-TB

Optimized, novel treatment regimens could drastically reduce the side effects and shorten the time needed to cure tuberculosis and MDR-TB.



Ezio Távora dos Santos Filho, who lives with HIV/AIDS, was just one of the many staff members who contracted TB while coordinating a care program for HIV patients in Brazil. Soon, Ezio was bed-ridden and unable to work.

Ezio knew the importance of completing treatment for TB—at one point he had even served as a consultant to Brazil's National TB Treatment Program. But completing TB treatment was a harrowing physical challenge that, in and of itself, brought Ezio to the brink of death. He experienced dangerous reactions to treatment; once he had to be rushed to the hospital, narrowly escaping asphyxiation. Ezio's TB drug regimen was changed five times before a tolerable combination was discovered. But, even then, his problems were only beginning. Over the course of the next three years, Ezio spent 27 months on TB treatment, battling side effects and intermittently interrupting his HIV treatment.

Today, Ezio is active in the global fight against TB and TB/HIV. He has consulted for the Brazilian government, the Open Society Institute, and served on the Coordinating Board of the Stop TB Partnership.

Despite this unbelievable tale of suffering, Ezio says he is quite lucky. The repeated adjustment in regimens would simply not have been available to the tens of thousands of impoverished

Ezio's TB treatment regimen was changed five times before a tolerable combination was discovered. Even then, his problems were only beginning. Over the next three years, Ezio spent 27 months on TB treatment, battling side effects and intermittently interrupting his HIV treatment.

Brazilians infected with TB and battling TB/HIV. Ezio says, "I survived these experiences because I am privileged—I am employed, educated, and have private insurance, which gives me access to the best medical care." Unfortunately, the vast majority of TB patients have no such resources and opportunity.

New and improved TB regimens would result in better outcomes for all affected communities, rich and poor, HIVpositive and negative.





After three long years, Rachel Orduno, a school teacher from El Paso, Texas, finally received the proper TB diagnosis. It took another nine months to rid herself of the disease, much of which was spent wrestling with difficult side effects from the medication and in quarantine. Rachel said that the whole experience was difficult to handle. However, she says, the worst part was that during her long search for a proper diagnosis, she infected eight members of her family with TB, including her three-year-old niece. "It was bad enough that I was feeling the physical ailments of TB, but then there was the moral weight of having caused others around me to go through the same thing," she says.

Indeed, Rachel watched her niece, who had an extra-pulmonary form of the disease, undergo three operations and suffer each day from taking the treatment. Rachel suffered alongside her, feeling guilty as her niece struggled to swallow a bitter drink containing the crushed-up pills. But looking back on the situation, Rachel says that, at the very least, she was not alone. "Too often, patients that are affected by TB are shunned by their family, co-workers, friends," she says. "But my niece was so resilient... she showed me how to approach this disease."

Better TB drugs will reduce the burden TB places on families, including the quarter million children who battle TB each year. John* can't remember the names of all the medications he takes—there are just too many. In the morning, the nurses watch him swallow 10 pills and give him an injection, and in the evening, they stop by with another two tablets. The regimen is tiresome, says John, but he is sick and has no other options.

John is an MDR-TB patient at Kibo'ngoto National TB Hospital, one of the few places in Tanzania that is equipped to handle MDR-TB patients. Certainly, John is not alone—but he often feels like he is. In the isolation ward, MDR-TB patients are advised to keep some distance from other patients and to wear their masks at all times. John is only partially through his expected six-month stay at Kibo'ngoto, but even when John returns home, he will still have to continue taking daily treatment.

He misses his family. John says it's easy for patients to become depressed and despondent—and give up hope that they will ever get better. John counts on the nurses to keep him going through the tough treatment but he still longs to go home.

New TB drug regimens would restore health and hope to millions.

*name has been changed to protect the patient's privacy



MORE THAN DRUGS

Today, the TB Alliance is leading a movement to revolutionize TB drug development. With multiple compounds in clinical testing, it was possible to take the next step—moving from developing drugs to testing entire new regimens. This new approach can reduce the time needed to develop a new TB combination treatment from decades to years.



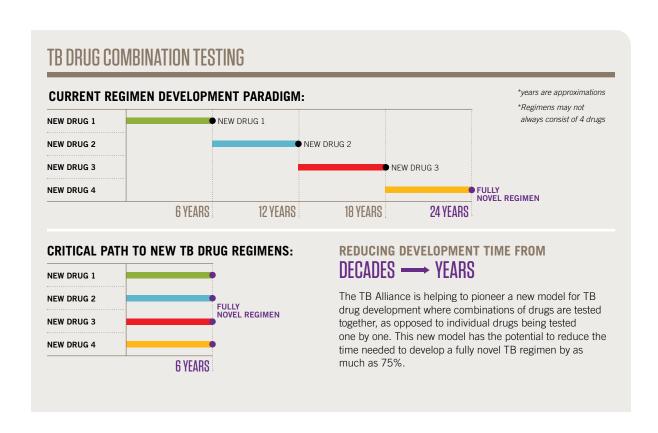
FROM DRUGS TO DRUG REGIMENS: COMBINATION DRUG TESTING

Critical Path to TB Drug Regimens launches, and the first clinical trial to test drugs in combination begins.

In May 2010, the Critical Path to TB Drug Regimens (CPTR) was launched by the Bill & Melinda Gates Foundation, the TB Alliance, and the Critical Path Institute. This group of partners joined with pharmaceutical and biotechnology companies, civil society organizations, and many others to tackle the challenges facing the search for novel, simpler, and faster-acting TB regimens, including the uptake of a regulatory and clinical model that can speed combination drug testing. In a keynote address at the launch of CPTR, U.S. Food and Drug Administration Commissioner, Dr. Margaret Hamburg,

applauded the initiative's partners for their commitment to innovation, and pledged the FDA's support to act as a "gateway" and not a barrier to the development of innovative, improved, and urgently needed TB regimens. Other regulators around the world have also shown their support.

In particular, CPTR provides a platform that will help pave the way forward for combination drug testing. For the past several years, the TB Alliance, in partnership with Johns Hopkins University and the University of Illinois at Chicago, has been testing promising combinations





"I applaud all the partners involved in this initiative for taking a risk and being innovative against a disease that has eluded us for far too long."

Dr. Margaret Hamburg COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION

of TB drugs in earlier stages of research. Now, a group of the world's leading drug developers has stepped up by making their TB drug candidates available for combination drug testing in the clinic. This will enable a new paradigm of drug development, where clinical trials can test combination drug regimens, offering the potential to slash the quarter century timeline previously needed to develop a completely novel TB treatment regimen.

The first of these trials is testing the combination of PA-824, moxifloxacin, and pyrazinamide, and began in fall 2010. This novel combination shows potential

to shorten the treatment time for both drug-sensitive and MDR-TB and simplify treatment by offering the world one tool capable of treating these two forms of the disease.

Combination drug testing is a platform supported by the initiative and may also serve as a model for other disease areas. CPTR's spirit of scientific collaboration and harmonization of research and regulation serves as an example for other fields where combination therapy is either standard or becoming routine. These include oncology, malaria, and hepatitis C, among others.

R**EUTERS: New Collaboration Aims to Speed TB Drugs to Market**-U.S. regulators, drug companies, philanthropis

Science Speaks:

18 March, 2010

Joining Forces Against TB

THE HINDU

CPTR To Speed Up Nod For Novel Therapies

Pharmaceutical Executive

March 18, 2010

A Critical Path to New TB Treatment

Bloomberg

J&J, SANOFI AND PFIZER SPEED **TESTING FOR TUBERCULOSIS DRUG** WALL STREET JOURNAL March 18, 2010

FDA IS EASING WAY FOR DRUG COCKTAILS

The Food and Drug Administration is devising guidelines that could accelerate testing and approval of multidrug regimens for some of the world's most deadly diseases.

At least two pharmaceutical consortia are poised to take advantage of the forthcoming policy: a group of 10 drug companies and several nonprofit organizations convened by the Bill and Melinda Gates Foundation.



MORE THAN SCIENCE

A decade ago, there was no clinical pipeline of TB drugs. With little commercial incentive, there were few prospects on the horizon for a better treatment for the millions who die each year from TB.

Today, the global TB drug pipeline is the most robust it has ever been, and a new sense of hope of a future with better treatments is sweeping communities affected by TB.

> Chennai, India Over the past decade, the TB Alliance has galvanized the global TB drug development

landscape.



2010 THE LARGEST TB DRUG PIPELINE IN HISTORY

Since the TB Alliance was established in 2000, we have built the largest TB pipeline in history. With the support of our donors and partners, the TB Alliance has catalyzed drug development by driving forward a new research paradigm of innovative regimen development. With three novel TB drug candidates in clinical trials and more than 25 projects in research and clinical development, the promise of a new TB drug regimen is closer than ever.

DISCOVERY

In 2010, the TB Alliance initiated the first-ever clinical trial to test a novel three-drug regimen for tuberculosis consisting of PA-824, moxifloxacin, and pyrazinamide. TB regimen development can dramatically speed development time of desperately needed innovative TB treatments. Recent advances in the pipeline have now enabled the paradigmatic switch from individual drugs to novel drug regimens. Compounds and drug combinations that show promise as building blocks for future regimens will be identified in earlier stages of testing and advanced with the goal of delivering better, faster-acting, novel regimens to patients in need.

Other combination drug testing using PA-824 and TMC207 also began, further establishing their value as important building blocks for tomorrow's regimens.

IMM/BTTTRI

PYRAZINAMIDE ANALOGS

TB ALLIANCE **PORTFOLIO**

TOPOISOMERASE I INHIBITORS GYRASE B INHIBITORS		RIMINOPHENAZINES	
TB DRUG DISCOVERY PORTFOLIO NITD		DIARYLQUINOLINES TIBOTEC/U. OF AUCKLAND	
PROTEASE INHIBITORS IDRI	MALATE SYNTHASE INHIBITORS GSK/TAMU	INHA INHIBITORS GSK	
NATURAL PRODUCTS IMCAS	WHOLE-CELL HIT TO LEAD PROGRAM GSK	MYCOBACTERIAL GYRASE INHIBITORS GSK	
TARGET OR CELL-BASED SCREENING	LEAD IDENTIFICATION	LEAD OPTIMIZATION	

AZ/NYMC FOLATE BIOSYNTHESIS INHIBITORS WHOLE-CELL HIT TO LEAD PROGRAM RNA POLYMERASE INHIBITORS A7/RUTGFRS **ENERGY METABOLISM INHIBITORS** AZ/U. PENN

PHENOTYPIC HIT TO LEAD PROGRAM U. III CHICAGO **MENAQUINONE BIOSYNTHESIS** INHIBITORS CSU

Novel TB regimen development

Current first-line TB treatment consists of Isoniazid (H) + rifampicin (R) + pyrazinamide (Z) + ethambutol (E)



These innovative regimens show promise for treating drug-sensitive and drug-resistant tuberculosis, and both drugs are being developed in parallel for these indications. Other studies continued to build the knowledge base around PA-824 and TMC207, shedding insight on proper dosing and scheduling, and yielding encouraging data regarding these two drug candidates' compatibility with HIV treatments. Additional clinical-stage compounds are in development by other sponsors, and the TB Alliance is working with these organizations to put into place the pieces of other novel TB treatment regimens.

Over the past year, the TB Alliance continued to move forward the Phase III clinical trial, REMox TB, where moxifloxacin is being tested for its ability to shorten treatment when substituted in the current first-line regimen

for ethambutol, and, in another arm of the study, isoniazid. REMox TB continues to add trial sites, increase enrollment, and build critically needed clinical development infrastructure. Moxifloxacin may prove to be one of the first new TB drugs registered in almost 50 years, but the legacy of the REMox TB trial will be even deeper, in the form of increased infrastructure for future research and enhanced capacity of local communities.

A decade ago, there was little hope for new TB drugs. Today, with this progress, we turn our attention not just to finding drugs, but also to speeding them through development in novel combinations as quickly as possible.

PRECLINICAL DEVELOPMENT	CLINICAL DEVELOPMENT	CLINICAL DEVELOPMENT			
	CLINICAL PHASE I	CLINICAL PHAS	EII	CLINICAL PHASE III	
NITROIMIDAZOLES		PA-824		MOXIFLOXACIN (+ H, R, Z)	
U. OF AUCKLAND/U. ILL CHICA	GO	NOVARTIS		BAYER	
PRECLINICAL TB REGIMEN DEVELOPMENT JHU/U. ILL CHICA	GO	TMC207 TIBOTEC		MOXIFLOXACIN (+ R, Z, E) Bayer	
	PA-824/ PYRAZINAMIDE				
		TMC207/ PYRAZINAMIDE			
		PA-824/MOXIFLOXACIN/ PYRAZINAMIDE			
OUR R&D PARTNERS	— AstraZeneca (AZ)		New York Medie	cal College (NYMC)	
	 Bayer Healthcare AG (Bayer) 		— Novartis Institu	te for Tropical Diseases (NITD)	
		Beijing Tuberculosis and Thoracic Tumor		Novartis Pharmaceutical (Novartis)	
	Research Institute (BTTTRI) Colorado State University (CSU) GlaxoSmithKline (GSK) Infectious Disease Research Institute (IDRI) Institute of Materia Medica (IMM) Institute of Microbiology, Chinese Academy of Sciences (IMCAS) Johns Hopkins University (JHU)		 Rutgers: The State University of New Jersey (Rutgers) 		
			Texas A&M University (TAMU)		
			 University of Auckland (U. of Auckland) 		
			University of Illinois at Chicago (U. III Chicago)		
			 University of Pennsylvania School of Medicine (U. Penn) 		
			Yonsei University (Yonsei)		
	Johnson & Johnson/Tibotec (Tibo	tec)			



"This agreement shows the unparalleled collaborative powers and efficiency of organizations like DNDi and the TB Alliance and the benefits of these approaches within neglected disease research and development."

Bernard Pécoul EXECUTIVE DIRECTOR, DNDi

TB DISCOVERY INVESTMENTS "PAY OFF" FOR THE GREATER GOOD

The TB Alliance makes its research platform available to help the world get the cures it needs faster and more efficiently—and the impact extends beyond TB.

In July 2010, the TB Alliance announced a unique partnership with the Drugs for Neglected Diseases initiative (DNDi) that allows DNDi to freely access a class of novel compounds so that it can be tested for other diseases of poverty—and strengthen the impact of donors' global health investment dollars. Had DNDi attempted to repeat this research, it would have had to invest several years and millions of dollars.

Instead, through free access to the nitroimidazole class and the surrounding knowledge, which the TB Alliance has been developing since 2006 in partnership with the University of Auckland in New Zealand and the University of Illinois at Chicago, DNDi can more quickly identify development candidates for neglected diseases, in particular, human African trypanosomiasis (HAT), leishmaniasis, and Chagas' disease.

This partnership underscores the efficiency and synergy of product development partnerships (PDPs). With more than 150 active research programs among PDP portfolios, there are likely additional opportunities to leverage cross-disease partnerships. The TB Alliance is moving forward in several areas to investigate where its research can have a broader health impact and accelerate the pace of neglected disease drug development wherever possible.

In 2010, the TB Alliance also partnered with AstraZeneca to develop a joint TB drug research portfolio. The projects contributed by the TB Alliance were the fruits of ongoing collaborations with the University of Pennsylvania, Rutgers State University of New Jersey, and New York Medical College. The projects contributed by AstraZeneca originated in their TB research center in Bangalore, India.



BUILDING A FUTURE FOR ALL WHO SUFFER FROM TB →

The TB Alliance marks 10 years of innovation and significant progress in the development of new drugs to fight the TB pandemic. Difficult challenges, including a critical need for additional funding, remain. However, after a decade of working with our committed partners and donors, there is more than hope in the pipeline—there is a reason to believe there will be a future for all those who suffer from TB.

Co-founded the Critical Path to TB Drug Regimens (CPTR) initiative and

LAUNCHED A NEW PARADIGM OF DRUG DEVELOPMENT.

Successfully advocated for the inclusion of TB and TB R&D in policies outlining and earmarking funding for strategic philanthropic investments.

Mapped drug delivery and policy pathways, and engaged regulators to harmonize regulatory guidances and

SPEED THE ADOPTION

of new products.

Initiated the first-ever

LEL TB DRUG

of a TB drug candidate for drug-sensitive and drug-resistant indications (with Tibotec).

Raised \$250,000,000 **Established** COMMUNITY ADVISORY BOARDS (CABs) for TB drug trials.

Assembled and manage the

of potential new TB drugs

Mapped the global capacity to

and helped to develop global research infrastructure, including many sites in endemic countries.

ESTABLISHED PARTNERSHIPS

with most of the world's major pharmaceutical companies.

REINVIGORATED DRUG DEVELOPMENT.



⇒ 2000

Cape Town, South Africa Ten years ago, the TB Alliance was established to develop new TB drugs.

→ The TB Alliance was conceived at a February 2000 meeting in Cape Town, South Africa, where 120 representatives from academia, industry, governments, WHO, non-governmental organizations, and donors gathered to discuss the problems of TB treatment. Participants stressed the need for new TB drugs, highlighting the unprecedented scientific opportunities and the economic rationale for developing new medicines. The resulting "Declaration of Cape Town" provided a road map for TB drug development and outlined the need for the creation of the TB Alliance. Cape Town signatory institutions formed the original Stakeholders Association for the nascent organization.

TB ALLIANCE OPENS ITS DOORS

With seed money from the Rockefeller Foundation, and an early and generous grant from the Bill & Melinda Gates Foundation (BMGF), the TB Alliance formally began pursuing its mission to reinvigorate the TB drug development landscape.

NOVEMBER 2000

TB Alliance initiates search of industrycompound libraries







⇒ 2001

TOTAL PROJECTS

⇒ 2003 TOTAL PROJECTS TOTAL PROJECTS

FEBRUARY 2001

FIRST PRESIDENT OF THE STAKEHOLDERS ASSOCIATION FLECTED

OCTOBER 2004



United States government commits \$8.000.000

to the TB Alliance

APRIL 2005



Government of the **United Kingdom commits**

F6.5 MILLION

to the TB Alliance

ACQUISITION OF PA-824

From Chiron (now Novartis), the TB Alliance receives the exclusive worldwide license to PA-824 and related compounds for the development of a new drug to treat tuberculosis. PA-824 is currently undergoing latestage combination testing along with moxifloxacin and pyrazinamide.

PA-824 BEGINS CLINICAL-STAGE DEVELOPMENT

The first TB drug candidate to undergo development by a not-for-profit organization enters clinical trials.

DECEMBER 2005

INAUGURAL OPEN FORUM



In 2005, in Washington DC, Open Forum is held. This is the first in a series of conferences designed to bring TB researchers, regulators, National Treatment Program managers, and others together to inform and

harmonize regulatory practices. Since 2005, there have been three additional Open Forum events held in London (2006), New Delhi (2008), and Addis Ababa (2010), each with a regional focus.

OCTOBER 2005

TB ALLIANCE **PARTNERS** WITH BAYER

The TB Alliance and Bayer Healthcare AG sign an agreement to study whether the quinolone antibiotic, moxifloxacin, can reduce treatment times for tuberculosis.

This is the first joint TB clinical development venture between an international pharmaceutical company and a productdevelopment partnership.



"We are witnessing an historic moment in global health. Today, we stand with Bayer, embarking on a major clinical trial program to see if this excellent antibiotic can significantly improve TB therapy."

Dr. Maria C. Freire FORMER PRESIDENT AND CEO



MAY 2006

ASSESSMENT OF GLOBAL CAPACITY TO PERFORM CLINICAL-STAGE TB RESEARCH BEGINS

SEPTEMBER 2006

Government of Ireland commits

£9 MII I INN

to the TB Alliance

NOVEMBER 2006



Dutch government pledges €8 MILLION to the TB Alliance, building on its previous support of €6 MILLION from 2002–2005

BMGF REINVESTS IN TB ALLIANCE **WITH A \$104 MILLION GRANT**

MAY 2007

Pathways to Patients Published



The TB Alliance publishes Pathway to Patients, which reveals the variability and complexities of the global market for first-line TB drugs. The findings reaffirm the market-based reasons for why TB drug development lagged for so many years, and thus the critical need for the existence of the Alliance itself.

SEPTEMBER 2007

IN VITRO **COMBINATION TESTING** PROGRAM BEGINS FEBRUARY 2008

FIRST CAB **FSTARLISHED**



In concert with the REMox TB trial, the TB Alliance establishes its first community engagement program. These programs proactively gather feedback and involve and educate communities about research.

APRIL 2008

In vivo combination testing program begins. This program establishes the basis for subsequent regimen-based drug development strategies.

NOVEMBER 2007

CLINICAL-STAGE MILESTONES ARE MET

Both moxifloxacin and PA-824 reach the next stage of their respective development programs. Moxifloxacin begins a large-scale, international, pivotal Phase III clinical trial, known as REMox TB. PA-824 enters Phase II development.







⇒ 2009 /

OCTOBER 2008



United States government pledges up to \$40 MILLION to the TB Alliance

JANUARY 2009



Government of the **United Kingdom commits** £18.000.000 to the TB Alliance

JUNE 2009

PARALLEL DEVELOPMENT OF TMC207

The TB Alliance and Tibotec launch a landmark collaboration to jointly develop the promising clinical-stage TB drug candidate, TMC207. The partnership includes a plan to develop TMC207, in parallel, for both drug-sensitive and drug-resistant TB. This is the first time a TB drug candidate has ever undergone parallel track development for drug-sensitive and drug-resistant TB.



Mel Spigelman, M.D. PRESIDENT AND CEO. TB ALLIANCE

"We see tremendous potential in the future of TMC207 as part of a critically needed new TB regimen. Tibotec is an essential long-term partner in our fight to end one of the greatest epidemics of our time."

AUGUST 2009



Defining the value proposition of new TB drug regimens

What Countries Want explores, for the first time, how decision makers and patients prioritize various attributes when considering adoption of new TB regimens.

 \mathbf{R} New Projects

MARCH 2010

LAUNCH OF THE CRITICAL PATH TO TB DRUG REGIMENS (CPTR)



In March 2010. CPTR was launched by the TB Alliance, the Bill & Melinda Gates Foundation, and the Critical Path Institute. This comprehensive initiative for tackling TB drug development establishes a clinical and regulatory framework by which new

TB regimens can be developed in a matter of years. The TB Alliance leads the Drugs Coalition arm of the initiative.

NOVEMBER 2010

NEW DEVELOPMENT PARADIGM LAUNCHED

NC001 tests PA-824, moxifloxacin, and pyrazinamide, which is the first regimen to be tested in a novel TB drug development paradigm in humans. This regimen has the potential to improve treatment for drug-sensitive TB and reduce the cost and shorten treatment duration for MDR-TB

JULY 2010

DNDi collaboration

The TB Alliance grants the Drugs for Neglected Diseases initiative rights to develop a class of compounds that show significant promise for treating other neglected diseases that largely affect the world's poor. This unique first-of-its-kind license agreement highlights the efficiency and synergy of PDPs.

OCTOBER 2010



United States Food and Drug Administration issues two grants to fund TB Alliance research that will benefit the field at large

10 YEARS OF INNOVATION

MORE THAN EVER, we are on the brink of conquering one of humanity's oldest and most resilient plagues. Faster, better, and simpler TB cures are not just a hope, but an imminent life-saving reality.

The TB Alliance vaults into our next decade of innovation with even greater knowledge and experience, and our widest and most diverse network of partners and staff yet. Over the next decade and beyond, we will continue to be a force of innovation in creating and fostering the development of new tools to fight tuberculosis everywhere.

A SPECIAL THANK YOU TO OUR DONORS

Special recognition should be given to our donors that, over the past decade, invested in creating the new and better tools needed to impact the TB epidemic.

- Bill & Melinda Gates Foundation
- European Union
- Irish Aid
- The Netherlands Ministry of Foreign Affairs
- Rockefeller Foundation
- United Kingdom Department for International Development
- United States Agency for International Development
- United States Food and Drug Administration





MORE THAN RESEARCH

Building the necessary social and physical infrastructure is crucial for mounting a long-term solution to TB.

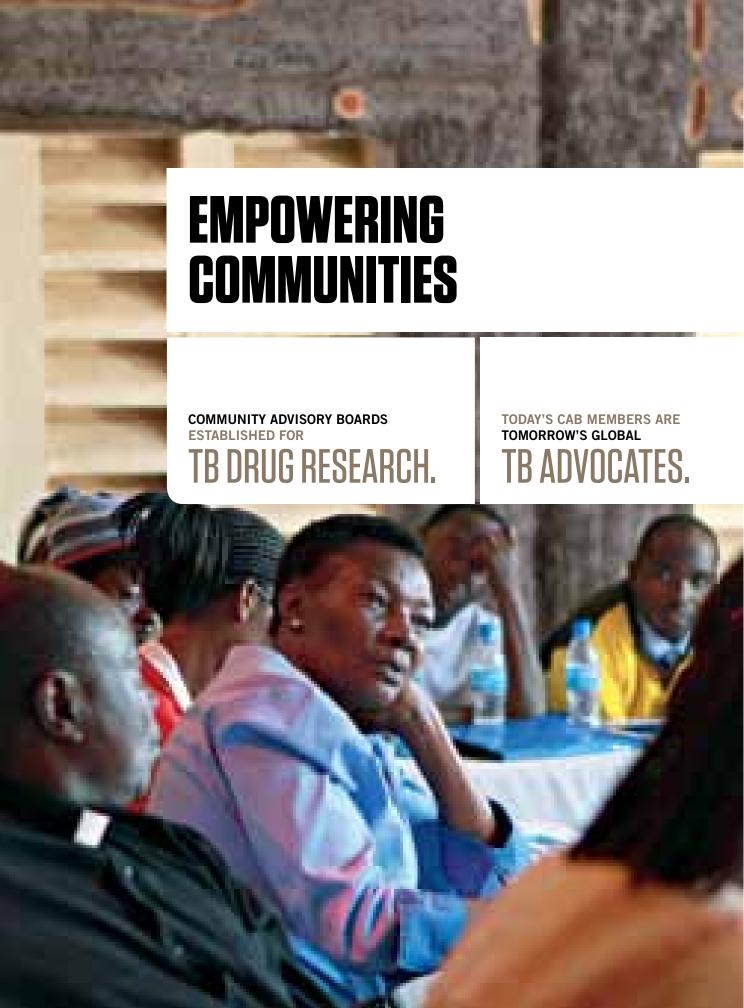
The TB Alliance is building the local capacity of communities to combat tuberculosis by supporting the establishment of community engagement programs at clinical trial sites. Run by Community Advisory Boards (CABs), these groups help promote open dialogue between researchers and the communities in which they work. The HIV/AIDS research field set a standard for community participation in clinical trials, and the TB Alliance is working to ensure community engagement in TB drug development as well. Our Phase III clinical trial, REMox TB, is operating at multiple sites around the world, each of which have active or planned community engagement programs.

Each site's community engagement program is unique, and designed and developed by the local community. Through these

programs, CABs educate their communities about TB disease, the best means of control, and proper treatment compliance. The TB Alliance also works with CABs to build research literacy and training skills so that these groups can educate their fellow community members about TB drug research.

While the REMox TB trial is modernizing research facilities to help expedite the development of new tools, the corresponding community engagement programs help develop communities' understanding of research and build their social capital by empowering them as educators, advocates, and more informed trial participants with a voice in TB Alliance research to develop new TB drugs.

> Moshi, Tanzania Community members participate in an educational workshop on TB.





MORE THAN APPROVAL

New TB drug regimens will only have their intended major public health impact when they reach the millions of patients in need. That is why, as a core part of its mission, the TB Alliance is committed to the "AAA Mandate": We pledge that any TB drugs we develop will be affordable, adopted, and available to those patients around the world who need them.

> Cape Town, South Africa In addition to regulatory challenges, practical obstacles also act as barriers to accessing treatment, especially for patients in resourcepoor settings.



Over the past 10 years, the TB Alliance has built a formidable understanding of the existing treatment landscape—from the drug volumes, dosages, and manufacturers in both public and private markets, to stakeholder preferences surrounding new treatments, to regimen change procedures in high-burden countries. Lessons from our access work inform the criteria not only for advancing or terminating projects (to ensure new TB treatments are developed with the needs of patients and local programs in mind), but also for selecting future partners in manufacturing and delivery of new TB regimens.



As the date for the introduction of new TB drugs approaches, the TB Alliance is focusing on the practical requirements for new regimen delivery. These include regulatory approval, WHO guideline changes, and manufacturing and demonstration projects. Preparation for these steps and pursuit of these goals in parallel will ensure that new, lifesaving treatments reach patients as soon as possible. A key step is engaging regulators to speed the introduction of new treatments. To that end, in August 2010,

the TB Alliance held the fourth meeting in its Open Forum series. Convened in Addis Ababa, Ethiopia, and co-sponsored by the Ethiopian Ministry of Health and other organizations, Open Forum 4 was dedicated to facilitating discussion between researchers, regulators, and National TB Program managers, with a specific focus on the challenges facing Africa. It was the first Open Forum meeting since the launch of the Critical Path to TB Drug Regimens initiative, and regulators were keen to engage around this new development paradigm.

1) Dr. Hind Satti, Partners in Health; 2) Dr. Akihiro Seita, World Health Organization; 3) Dr. Mel Spigelman, TB Alliance; 4) Dr. Mark Goldberger, Abbott and Dr. Margareth Sigonda, New Partnership for Africa's Development; 5) Mandisa Hela, Medicine Control Council, South Africa; 6) Representatives from various National Treatment Programs; 7) Dr. Haileyesus Getahun, World Health Organization.

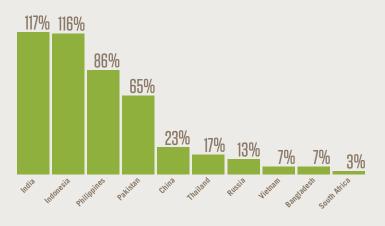


FOCUS ON: THE PRIVATE MARKET

TB is considered primarily a public health, public sector disease. But in a recent study, the TB Alliance found that enormous volumes of TB drugs are being sold in the private sectors of some high-burden countriesenough drugs, in some cases, to treat every new TB patient with a full daily 6- to 8-month regimen. Treatment default is common in the private sector, where patients are paying for their own drugs. This first-of-a-kind research uncovers the global dynamics of access and is critically important to mapping the pathway from pipeline to patients.

PRIVATE SECTOR DRUG VOLUMES AND NATIONAL TB BURDEN

(y-axis) % incident cases covered by private sector TB drugs





MORE THAN FUNDING

Thanks to the compassion, vision, and generosity of our donors and in-kind contributors, the TB Alliance is changing the future for all those with TB. To advance promising regimens through the final stages of testing and to patients, more than ever, we need your help.

In the next decade, we hope to unleash the promise in our pipeline, by developing new TB drug regimens to save millions of lives. However, the large-scale clinical trials needed to bring promising new regimens through the last, but most expensive, phases of testing require more support.

Since our inception, the TB Alliance has been productive and efficient, developing the largest pipeline of TB drugs ever by leveraging efforts around the world through partnerships. We've negotiated to ensure the maximum impact of our precious resources. On average, every dollar invested in the TB Alliance yields a 166% return of services procured. That means we are forming strong and value-added collaborations that allow us to leverage in-kind contributions that benefit the global health community at large.

Looking ahead, the challenges today—and tomorrow—are not only scientific and regulatory. Instead, the ability to develop the new TB drugs the world so desperately needs will come down to the availability of funding.

Now, more than ever, the donor community must mount a response to the TB pandemic by scaling up funding to bring promising TB cures through their final stages of testing and to the patients who need them. Support is needed for the work of the TB Alliance, whose pipeline represents hope for health, prosperity, and empowerment for individuals and communities around the world.

South Korea

To leverage the hope in the pipeline, more funding is needed for late-stage clinical trials.



TO OUR FRIENDS, DONORS, STAKEHOLDERS, PARTNERS, AND PATIENTS:

A decade ago, against the backdrop of a global tuberculosis epidemic spiraling out of control, a group of individuals and organizations who were committed to a vision of a world without TB met in Cape Town, South Africa. The resulting "Declaration of Cape Town" sketched a road map for the formation of the TB Alliance and gave spark to the fight for a future free of tuberculosis.

The mission of the TB Alliance is to fill a desperate need—to discover and develop a new and improved arsenal of drugs to stop the growing tuberculosis pandemic. Ten years ago, it seemed like an almost impossible challenge. There had been no new TB drugs for nearly 50 years, and the world's pipeline was virtually bare.







Dr. Bruce Carter Chairman of the Board

Since then, with the investment of our donors and support of our global partners, we're proud to report many key accomplishments. We have:

- assembled and now manage the largest TB portfolio in history, including several promising innovative TB drug regimens, three new drugs in regimen development, and more than 25 projects in the portfolio.
- helped reinvigorate the broader field of TB drug development by lowering the barriers for pharmaceutical companies and others to participate in TB drug research and development. There are now 10 TB drug candidates in clinical development in the global portfolio.
- led the development of an innovative new paradigm. of TB drug testing that could dramatically shorten the time needed to develop a fully novel TB regimen. The regulatory and other changes that will be needed to support combination drug testing will be championed through the Critical Path to TB Drug Regimens initiative.
- invested in building the necessary infrastructure in high-burden countries that allows rapid testing of promising new therapies.

- mapped and strengthened the global capacity to conduct TB clinical trials, and established Community Advisory Boards at trial sites, which create important links between the researchers and the community.

While these achievements were necessary steps, we remain focused on the future. The scientific and, especially, the financial challenges that face the TB Alliance and TB drug development more broadly are not to be underestimated. We have no doubt, however, that with the continued support of our dedicated workforce, donors, partners, stakeholders, and friends, we will develop the technologies the world so desperately needs.

A decade ago, this progress was difficult to even conceive of—today, however, we are in the process of reshaping reality for those who suffer from TB. Please join us so that together we can have a brighter, TB-free tomorrow.

Sincerely.

Nul Spigelin

Dr. Mel Spigelman President and CEO, TB Alliance Chairman of the Board

Dr. Bruce Carter





FINANCIALS AND **ACKNOWLEDGEMENTS**

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Scientific Advisory Committee

Recognition of Support

Board of Directors

TB Alliance Leadership

TB Alliance Team

STATEMENT OF FINANCIAL POSITION

STATEMENT OF ACTIVITIES

YEAR ENDED DEC	EMBER 31, 2009
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Fixed assets, net	2,703,153
Other assets	337,449
Contributions receivable	1,439,551
Accounts receivable	813,499
Investments at fair value	3,000,000
Assets limited to use	913,224
ASSETS Cash and cash equivalents	\$ 45,021,624

LIABILITIES AND NET ASSETS

Liabilities:

	\$ 54,228,500
Unrestricted net assets	30,563,654
Net assets:	
Commitments	
Total liabilities	 23,664,846
Deferred rent	1,018,689
Deferred revenue (Note 6)	 13,097,138
Accrued payroll and payroll-related liabilities	 923,784
Accounts payable and other liabilities	\$ 8,625,235

VEAR ENDED DECEMBER 31 2009

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Unrestricted 35,910,717

Comprehensive 2009 TB Alliance financial statements are available at: www.tballiance.org/newscenter/publications.php

STATEMENT OF CASH FLOWS

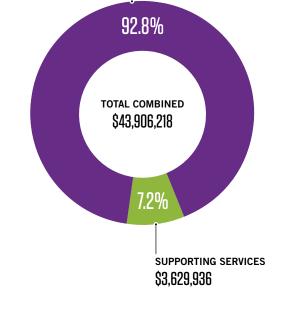
PROGRAM SERVICES VS. SUPPORTING SERVICES

PROGRAM SERVICES

\$40,276,282

YEAR ENDED DECEMBER 31, 2009

Net cash provided by operating activities		(2,300,454)
Deferred rent		(83,611)
Deferred revenue		(11,458,414)
Accrued payroll and related liabilities		(191,322)
Accounts payable and other liabilities		6,246,183
Increase (decrease) in liabilities:		
Other assets		(142,750)
Pledges receivable		1,366,970
Accounts receivable		1,340,538
Assets limited to use		(13,266)
(Increase) decrease in assets:		
Unrealized losses (gains) on investments at fair value		(60,450)
Realized gain on sales of investments at fair value, net		81,750
Loss on disposal of fixed assets		
Depreciation and amortization		423,971
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
CASH FLOWS FROM OPERATING ACTIVITIES: Change in net assets	\$	189,947
	Φ.	100.0



CASH FLOWS FROM INVESTING ACTIVITIES:

Purchase of investments		(20,019,670)
Proceeds from sales of investments		51,002,820
Purchase of fixed assets		(110,785)
Net cash used in investing activities		30,872,365
Net increase in cash and cash equivalents Cash and cash equivalents, beginning of year		28,571,911 16,449,713

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

Cash paid for interest

\$

THE STAKEHOLDERS ASSOCIATION

American Lung Association

American Thoracic Society

Association of the British Pharmaceutical Industry

Bill & Melinda Gates Foundation

Eli Lilly and Company

European Commission

Global Business Coalition on HIV/AIDS, TB and Malaria

Global Fund to Fight AIDS, TB and Malaria

Infectious Diseases Society of America

International Union Against Tuberculosis and Lung Disease

JATA Research Institute of **Tuberculosis**

KNCV Tuberculosis Foundation

Lupin Laboratories

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National Institute of Pharmaceutical Education and Research, India

New Jersey Medical School Global Tuberculosis Institute

Novartis India, Ltd.

Oswaldo Cruz Foundation

Partners in Health

Philippines Coalition Against Tuberculosis

RESULTS

RTI International

Sequella, Inc.

Community Representative, Francis Apina

South African Medical Research Council

Stop TB Partnership

TB Alert

Treatment Action Group

Tropical Disease Foundation

U.K. Department for International Development

U.S. Agency for International Development

U.S. Centers for Disease Control and Prevention

UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases

Wellcome Trust

World Health Organization

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Project Director, The Tuberculosis Coalition for Technical Assistance (TBCTA), KNCV Tuberculosis Foundation

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William Wells, M.I.A., Ph.D.

Skyelar Yaffie

The Global Alliance for TB Drug Development is a notfor-profit, tax-exempt organization recognized under section 501(c)3 of the United States Internal Revenue Code; 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: info@tballiance.org Global Alliance for TB Drug Development 40 Wall Street. 24th Floor New York, NY 10005

Concept and Design

Ideas On Purpose New York, NY ideasonpurpose.com

Photography

Cover, inside cover (1, 3, 4, 5–10, 13), 2 (right), 8–9, 10 (left), 11, 12, 15, 16 (left), 17, 23 (right), 25 (second from bottom), 27 (top), 29 (top), 30 (top row), 31, 33, 34 (center, right), 38 (center, right), 42-43, 50, inside back cover, John-Michael Maas; Inside cover (2, 11), 2 (left), 16 (center), Jad Davenport (World Lung Foundation); inside cover (5, 12), 5, 25 (top), Yijie Zhan; 2 (right), 3, 4 (right), 10 (center), 23 (center), 35 Eric Miller (Panos); 4 (left), Virginia Arnold (World Lung Foundation); 10 (left), 20 (center), 23 (left), **Douglas Engle**; 10 (right), Jan Van den Hombergh (World Lung Foundation); 13, Christiaan Van Vuuren; 14 (right), Ezio Tavora dos Santos Filho; 16 (right), 20 (left), 28, 39, Seokyong Lee; 19, 31 (middle right), Global Health Strategies; 20 (right), 21, 27 (bottom), 30 (left), 34, 38 (left), **Atul Loke**; 24, **DNDi**; 25 (second from top), 37, Richard Lord; 28 (bottom), TB Alliance; 29 (left), 32 (left), William Wells; 32 (right), Stephanie Seidel; 36–37, Abate Damte; 40 (left), George Koroneos; 40 (right), Yuen Lui

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The TB Alliance accelerates the discovery and development of fasteracting and affordable drugs to fight tuberculosis. Through innovative science and with partners around the globe, we aim to ensure equitable access to faster, better tuberculosis cures that will advance global health and prosperity.

