confronting TB

What It Takes

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

2008 Annual Report

Two billion people are infected—
1 out of every 3 people
on Earth.

Adherence is difficult, and
lengthy treatment burdens
patients and health services.

Every 20 seconds,
someone dies of TB.

Worldwide, TB is
the number one
infectious killer
of people living with HIV/AIDS.

Current TB regimens
take 6 to 24 months,
and require
frequent supervision.

Erratic and
incomplete treatments
have created the surge in
multidrug-resistant TB (MDR-TB) and, now,
extensively drug-resistant TB (XDR-TB).

XDR-TB has been reported in
at least 46 countries.

There have been
no new classes of
TB drugs in
40 years.

Every year, nearly half a million
MDR-TB cases emerge and more than
130,000 people die of MDR-TB.

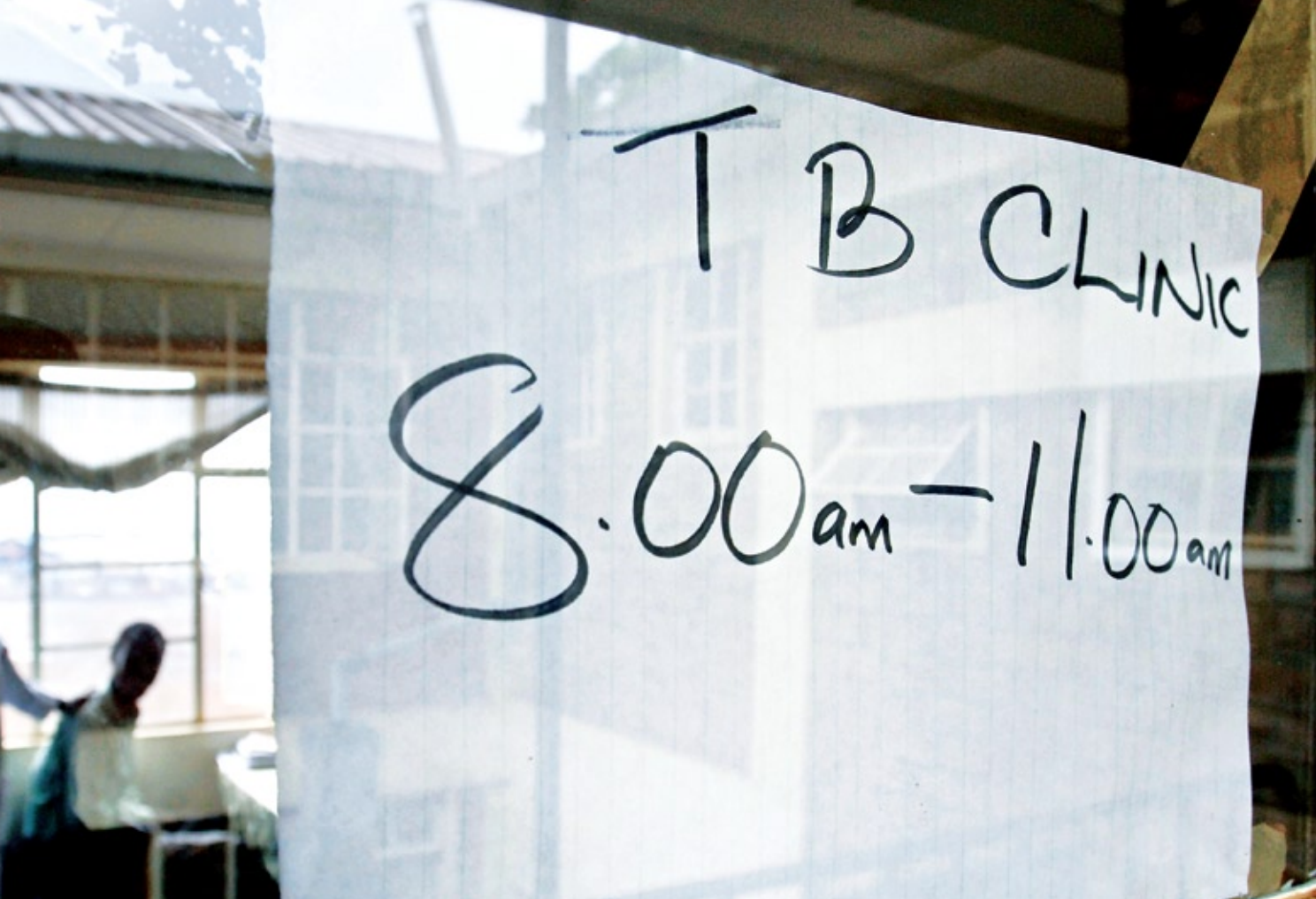
In some locations,
over 20% of new TB cases are now MDR-TB, and up to
10% of MDR-TB cases are XDR-TB.
These are the highest rates ever recorded.

fight

A scientific breakthrough
changes everything.
A faster, better cure is
imperative.

That's our job.

That's the battle
we intend to win.



| TOP |

KENYA

A sign hangs in the window of a one-room health clinic in Nairobi where patients come each morning for TB testing and treatment. Clinics like this serve many of the city's densely populated neighborhoods, where overcrowding and lack of adequate sanitation contribute to the spread of TB.

| BOTTOM |

INDIA

Global TB experts gather in Delhi for the two-day Open Forum, the third in a series of meetings aimed to raise and address key issues in TB drug development, with a special focus on regulatory affairs.

IDENTIFY IDEAS, ASSETS AND EXPERTISE, AND DRIVE THE EXPANSION OF THE WORLD'S LEADING TB DRUG PIPELINE.

create

a ground-breaking portfolio of TB drug candidates

A comprehensive effort is needed to find new TB drugs: we must traverse the long pathway from early discovery to ensuring that drugs are available to patients. The TB Alliance provides the leadership, brings together the best talents in the world, and coordinates their actions to create an efficient drug discovery and development engine.

OUR PROMISE IS TO REVOLUTIONIZE TB TREATMENT WITH SIMPLER, FASTER-ACTING CURES THAT WILL SAVE LIVES.

As a not-for-profit product development partnership (PDP), the TB Alliance can access a variety of funding sources and bridge gaps that usually impede drug development for neglected diseases. We operate as a virtual research and development (R&D) organization with no labs of our own, minimizing costs, and improving development efficiency.

The inputs for our programs come from many sources. In our quinolone program, for example, the pharmaceutical company Abbott (Abbott Park, Illinois, USA) has granted the TB Alliance freedom to operate with a proprietary chemical class. This provides the basis for an integrated chemistry program at Korea Research Institute of Chemical Technology (KRICT, Daejeon, Korea), leading to biological assays at Yonsei University (Seoul, Korea), and pharmacological and toxicological testing performed by contract research organizations.

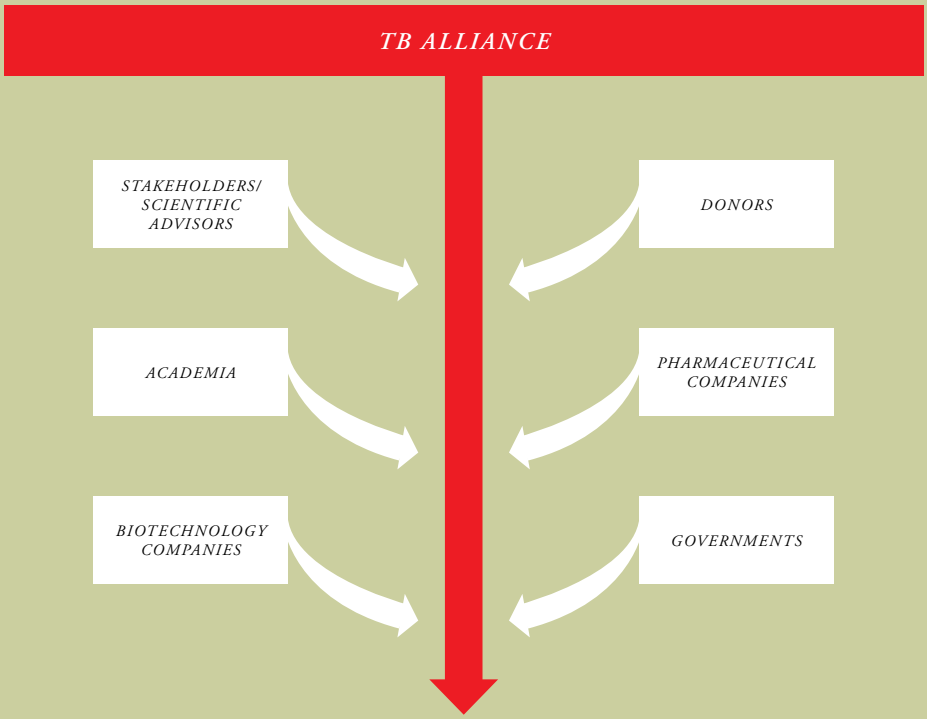
Our portfolio of TB drug discovery and development projects draws on both public and private sector sources, and is the result of numerous unique licensing agreements and partnerships. This year we renewed our research partnership with GlaxoSmithKline (GSK) and initiated a new five-year agreement with the Novartis Institute for Tropical Diseases (NITD). We continue to partner with nimble, talented groups at institutions—such as the Institute of Materia Medica in Beijing and the University of Auckland in New Zealand—that span the globe. All of these agreements provide TB Alliance scientists with access to world-renowned chemical libraries, laboratories and expertise.

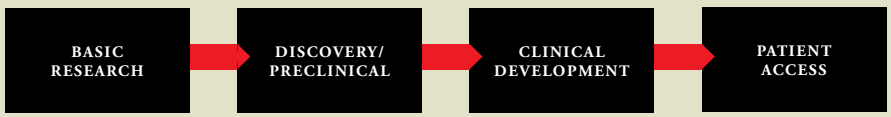
Although we still need many more drug candidates, we are, today, directing the largest new TB drug pipeline in history. Our promise is to revolutionize TB treatment with simpler, faster-acting cures that will save lives. Nothing less will suffice.

PRODUCT DEVELOPMENT PARTNERSHIP (PDP)

A product development partnership (PDP) is a not-for-profit organization that builds partnerships between the public, private, academic, and philanthropic sectors to drive the development of new products for underserved markets.

As the world's leading TB drug R&D institution, the TB Alliance has the influence and expertise to build a strong portfolio while mobilizing our peers. A focused discovery and development strategy led by a veteran team of scientists is the backbone of our collaborative operations.



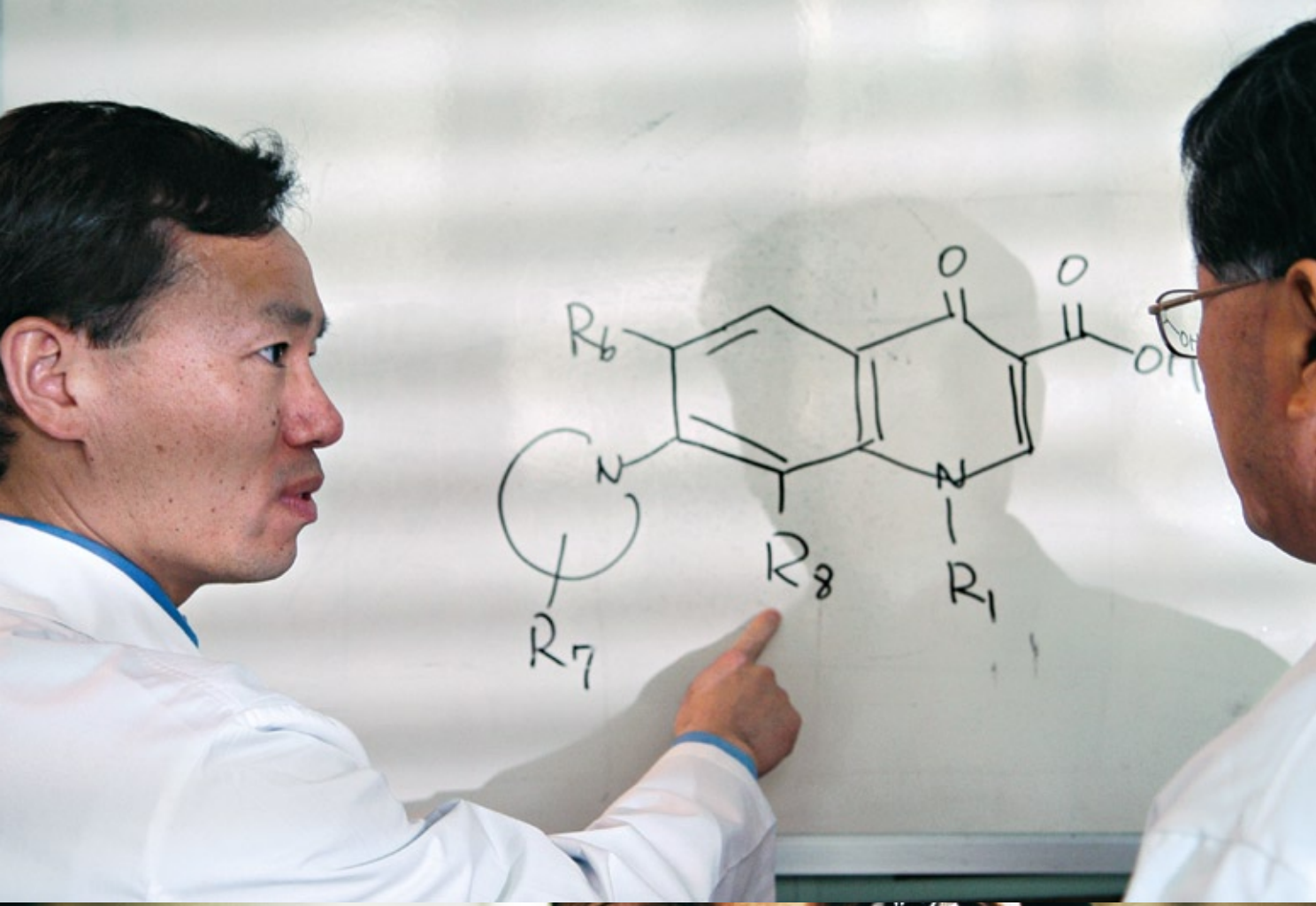


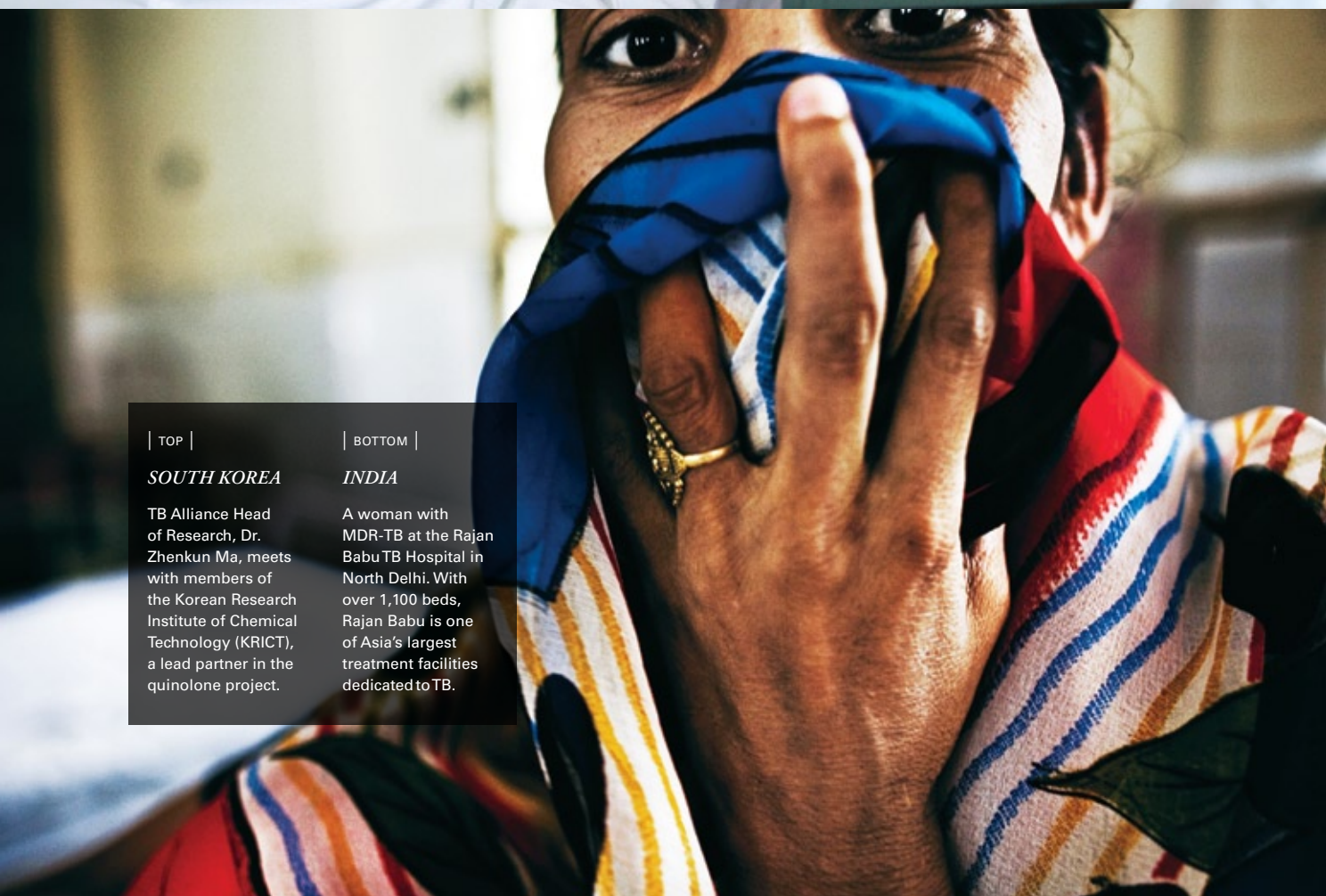
FASTER, SIMPLER TB TREATMENTS THAT ARE
AFFORDABLE, **ADOPTED** AND **AVAILABLE**

innovate

with novel approaches

Each of the new discovery projects added to the TB Alliance pipeline this year provides an exciting opportunity for enhancing the promise of our portfolio.





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SOUTH KOREA

TB Alliance Head of Research, Dr. Zhenkun Ma, meets with members of the Korean Research Institute of Chemical Technology (KRICT), a lead partner in the quinolone project.

| BOTTOM |

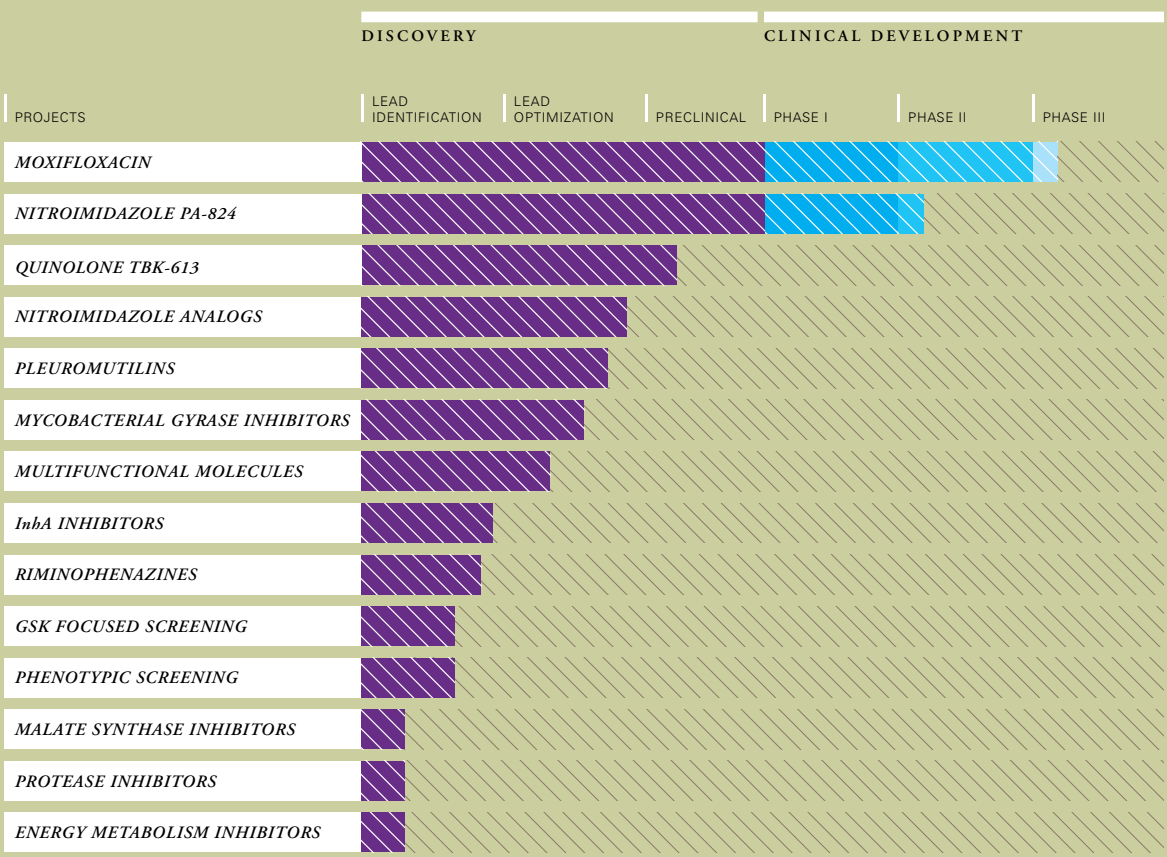
INDIA

A woman with MDR-TB at the Rajan Babu TB Hospital in North Delhi. With over 1,100 beds, Rajan Babu is one of Asia's largest treatment facilities dedicated to TB.

TB ALLIANCE PORTFOLIO

The TB Alliance, working with its public and private partners worldwide, is leading the development of the most comprehensive portfolio of TB drug candidates in history.

TB ALLIANCE PROGRAMS



NEW PROJECTS

The following programs were selected in 2008 during our active scouting of potential TB drug development approaches. A number of additional projects are in the final stages of consideration.

These projects are intended to cover novel targets, thus increasing the chances that a resulting drug candidate will be active against drug-sensitive and drug-resistant TB. The choice between these development strategies is made at the end of Phase IIa trials, when the risk-benefit equation for each strategy is clearer, although there are clear go/no-go criteria throughout the discovery and development process. At all stages, we work to ensure that any new drugs will be compatible with treatments for HIV/AIDS.

With this strengthened pipeline, we can fight the natural process of attrition and boost the chances of discovering the multiple new drugs needed to create a truly revolutionary new TB regimen.

PROTEASE INHIBITORS

In partnership with the Infectious Disease Research Institute (IDRI; Seattle, WA, USA)

Protease inhibitors are powerful components of current antiretroviral therapies against HIV/AIDS. However, the potential of inhibitors against a similar family of proteases from *Mycobacterium tuberculosis* (*M.tb*), the causative agent of TB, remains unexplored.

In partnership with IDRI, the TB Alliance is identifying which of the many proteases in *M.tb* might make the best targets for TB drugs. The program is off to a promising start: several proteases seem to be important for *M.tb* to stay alive under conditions commonly associated with persistent forms of *M.tb*.

ENERGY METABOLISM INHIBITORS

In partnership with the University of Pennsylvania School of Medicine and the University of Illinois at Chicago

Cutting off the energy supply for *M.tb* bacteria—using energy metabolism inhibitors—is the aim of a new project being conducted by the TB Alliance and teams at the University of Pennsylvania School of Medicine and the University of Illinois at Chicago. An entire metabolic pathway is the target of this effort, raising the chances of finding a drug that can kill persistent *M.tb* and thus shorten treatment time.

PHENOTYPIC SCREENING

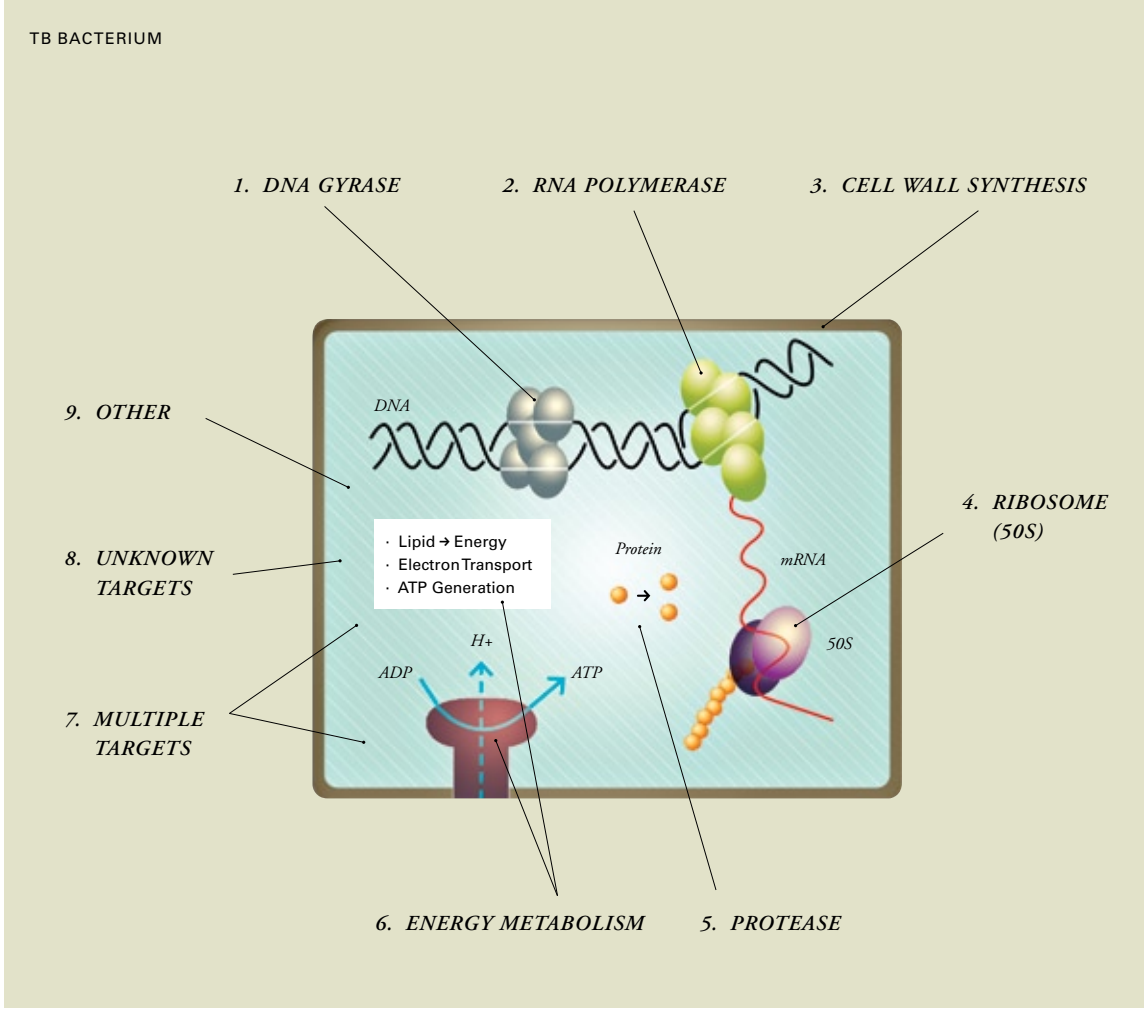
In partnership with the University of Illinois at Chicago

Phenotypic screening, a project being conducted in partnership with the University of Illinois at Chicago, puts the drug discovery process to work at the level of the whole organism. Antibiotic drugs work by inhibiting specific targets in a bacterial cell, but adding compounds to whole cells accesses every essential pathway and enzyme in the cell as a potential drug target.

The phenotypic screening has been conducted using libraries of chemicals—50,000 synthetic compounds with maximized diversity, and 1,500 derived from natural sources—and has already turned up some promising hits. The whole-cell method makes no assumptions about what will make the best drug target, and thus may turn up some welcome surprises.

MECHANISM OF ACTION DIAGRAM

The TB Alliance is exploring both new and known targets, and discovering and developing drug candidates that target *M.tb* in many different and better ways.



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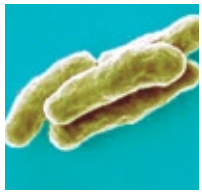
TB DRUG PROJECTS

LEGEND

- **TB ALLIANCE PROJECT**
  Recent achievements and current status
- DRUG USED IN CURRENT STANDARD FOUR-DRUG REGIMEN



1. *DNA GYRASE*

- **MOXIFLOXACIN**
  Patients are currently being enrolled in REMoxTB, a Phase III trial aimed at shortening TB treatment to four months.
- **QUINOLONE TBK-613**
  A preclinical candidate was recently selected and is progressing toward clinical trials.
- **MYCOBACTERIAL GYRASE INHIBITORS**
  Optimization has improved *in vitro* potency, *in vivo* efficacy, and pharmacokinetic and toxicological profiles.

2. *RNA POLYMERASE*

- RIFAMPIN

3. *CELL WALL SYNTHESIS*

- **InhA INHIBITORS**
  Identified leads are undergoing optimization.
- ETHAMBUTOL
- ISONIAZID

4. *RIBOSOME (50S)*

- **PLEUROMUTILINS**
  Lead compounds have been identified for *in vivo* testing.

5. *PROTEASE*

- **PROTEASE INHIBITORS**
  Target validation and assay development are ongoing.

6. *ENERGY METABOLISM*

- **MALATE SYNTHASE INHIBITORS**
  Promising hits have been identified.
- **RIMINOPHENAZINES**
  Novel analogs with improved activity and pharmacokinetics have been identified.
- **ENERGY METABOLISM INHIBITORS**
  Assays of the energy metabolism pathway are in development.
- PYRAZINAMIDE

7. *MULTIPLE TARGETS*

- **PA-824**
  A Phase IIa clinical trial has been completed. PA-824 was the first TB Alliance drug candidate to reach clinical development.
- **NITROIMIDAZOLES**
  New generation molecules, with improved efficacy and metabolic stability, have been identified and are approaching the selection of preclinical candidates.
- **MULTIFUNCTIONAL MOLECULES**
  The nitroimidazole-oxazolidinone class has been selected for further optimization.

8. *UNKNOWN TARGETS*

- **PHENOTYPIC SCREENING**
  Whole-cell screening was conducted under physiologically relevant conditions; hits were identified and are being followed up.

9. *OTHER*

- **GSK FOCUSED SCREENING**
  This incubator for new projects is being used to actively seek new opportunities.

| TOP |

INDIA

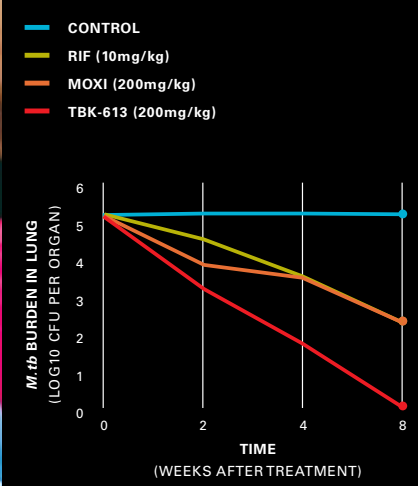
Community outreach workers go door to door with TB prevention and treatment information in a crowded Chennai neighborhood.

| BOTTOM |

AFGHANISTAN

Women wait with their children to receive medicines and treatment at a health clinic in Bamyan.

STERILIZING ABILITY OF TBK-613 IN MICE



MOVE MORE PROJECTS TOWARDS
AND THROUGH CLINICAL DEVELOPMENT.

bridge

from discovery to the clinic

The TB Alliance has the reach and scientific expertise to take compounds from early discovery, through clinical development, to registration. The outcome is a growing pipeline of clinical and preclinical candidates.

The two discovery projects that are furthest advanced—the nitroimidazoles and quinolones—are both approaching or entering preclinical development. This defined set of studies, guided by major regulatory authorities, is the final step before these drug candidates enter clinical trials where they are given to healthy human volunteers and, ultimately, to TB patients.

The *in vitro* and animal results with the lead quinolone, TBK-613, are particularly promising. This potent drug candidate can clear *M.tb* from the lungs of mice in a matter of weeks, raising the possibility of shortening treatment in humans.

For PA-824, which was originally in-licensed from Chiron (now Novartis), the first trial in patients was completed recently. This Phase IIa Early Bactericidal Activity (EBA) study yielded encouraging results that constituted an important proof-of-concept for this novel drug and indicated that the drug has promise at even lower doses than had been anticipated. In mice, the combination of PA-824, moxifloxacin and pyrazinamide was recently shown to cure faster than the current first-line regimen, further boosting the hopes for PA-824 as part of a fast and effective treatment for both drug-sensitive and MDR-TB.

However, some potential toxicity concerns have surfaced in animal studies and are being evaluated before any further clinical trials are conducted. If these issues can be satisfactorily resolved, the next human trial will likely be an EBA study of lower PA-824 doses. Lower doses would have the advantages of reducing both drug costs and the likelihood of any side effects for patients.

SOLVE THE CHALLENGES TO TB DRUG DEVELOPMENT SO THAT THE PATHWAY TO A CURE IS CLEAR.

overcome

clinical challenges

TB drug development is complex. Following are some of the challenges we face, and explanations of how the TB Alliance is responding.

1 *PROVIDING CLINICAL EVIDENCE FOR A SINGLE DRUG*

CHALLENGE How can we demonstrate that a single, new drug has anti-TB activity in patients when combination therapy is a clinical necessity?

RESPONSE Use of the Early Bactericidal Activity (EBA) study allows a single, new drug to be tested for 14 days as monotherapy. This establishes the single drug's bacteria-killing abilities in drug-sensitive patients, who immediately after the study are switched to a full course of standard combination therapy.

2 *PICKING THE RIGHT COMBINATIONS*

CHALLENGE Which of the existing first-line TB drugs should a new drug replace in a combination regimen? If there are multiple new drugs, the possibilities for combinations only multiply.

RESPONSE The TB Alliance is conducting an *in vivo* animal study of many different potential drug combinations. This is the first time such a large set of TB drug combinations, comprising current and potential new drugs, is being tested comprehensively in an animal model of TB.

3 *SIZE OF PHASE III TRIALS*

CHALLENGE We must demonstrate that a new, shorter TB regimen is just as effective as the current first-line regimen. This requires many patients, because the current regimen's main defect is not its efficacy (relapse levels are low) but its length.

RESPONSE REMoxTB, the current Phase III trial being directed by the TB Alliance with its partners, is large enough to compare with confidence the current regimen and two new, shorter regimens. The TB Alliance has assembled a diverse, global team to execute and manage the complex task of running such large, modern, registration-grade TB trials. We are a pioneer in these efforts.

4 *DURATION OF PHASE III TRIALS*

CHALLENGE TB trials take a long time. After patients are recruited, the treatment is 6 months (or more for drug-resistant TB), and then results are only clear after one or more additional years of follow-up.

RESPONSE The TB Alliance is searching for biomarkers—molecular signposts of the body's response—that would give an earlier and easier indication of treatment success, and a good sense of the appropriate dose and dose regimen before starting a large Phase III trial.

5 *CLINICAL TRIAL CAPACITY*

CHALLENGE Few clinical trials for TB have been conducted in the past 40 years, and almost none have been conducted to modern regulatory registration standards. Infrastructure for conducting these trials is typically lacking in resource-limited settings where the majority of TB cases are found.

RESPONSE The TB Alliance has conducted a wide-ranging assessment of TB clinical trial site capacity. Individual assessments have been used to identify issues that need to be addressed and to select sites for participation in REMoxTB and other Phase III trials.

6 *REGULATORY EXPERIENCE*

CHALLENGE For 40 years, no new classes of TB drugs have been registered. Little regulatory guidance exists for those testing TB drugs, and modern guidelines are needed.

RESPONSE The TB Alliance has initiated a dialogue with regulatory agencies to develop guidances on major issues that are specific to TB drug development and registration. A key element in this approach has been the Open Forums on key issues in TB drug development, which have been convened by the TB Alliance and its partners. In 2008, the European Medicines Agency (EMEA) issued a concept paper proposing draft TB guidances for the first time.

Our job at the TB Alliance is to change the way the world treats TB—through better, faster combinations that save more lives and reach every patient in need. This requires resolve, even stubbornness, and a stepwise approach to achieving the best possible new combinations, while developing the best possible new compounds. My only objective is to improve the outcome for TB patients.

My passion for this work knows no bounds. This is a position that requires me to apply everything I have learned over the last 30 years of drug development and business development, and I am privileged to assume this role.

As part of my first year at the TB Alliance, I will drive an expansion and intensification of our efforts. I am confident this will lead to our success.

Step-by-step, we will work toward a new treatment reality, one that offers patients and health workers better tools and greater hope. With today's science, and with your help, we can build a better future.

Thank you for your support,

Jerome Premmereur, M.D.

| TOP |

RUSSIA

TB patients are treated by a nurse at a hospital in the Siberian town of Tomsk.

| BOTTOM |

USA

Global health experts gather on World TB Day for a panel discussion at Columbia University in New York City.

ENSURE A DISCIPLINED FOCUS ON THE REQUIRED OUTCOME.

inspire

through experience

Our mission demands top-notch leadership and a management team that can meet the challenges of drug development at every stage.

In early 2008, the TB Alliance Board of Directors appointed veteran pharmaceutical executive and medical doctor Jerome Premmereur as President and Chief Executive Officer. Dr. Premmereur has spent nearly two decades leading scientists through the intricate late stages of drug development and global registration at sanofi-aventis. His leadership and decades of drug development experience will be critical as we work to advance projects through clinical development and to ensure drugs reach patients.

The TB Alliance brings together the best from all fields to create an innovative business model. Our academic partners provide unique insights into the bacterium that causes TB—both its biology and how it can best be attacked. Many of our experts have wide-ranging experience in drug R&D, where they have built careers working to improve or save lives through medicine. This is what we need. Patients are waiting for new drugs.

INCREASE THE SCALE AND IMPACT OF CURRENT AND FUTURE TB CLINICAL TRIALS.

expand

clinical trial possibilities

Conducting a global, registration-quality Phase III clinical trial for drug-sensitive TB is like assembling a jigsaw puzzle. Principal investigators, sponsors, contract research organizations and thousands of patients across multiple countries and continents must all adhere to a single protocol and contribute to a single, definitive result.

| TOP |

SOUTH AFRICA

A mother and her child visit a health clinic in Cape Town's Langa Township, where TB and HIV are common infections.

| BOTTOM |

MYANMAR

A young girl is held by her father on the bank of the Yangon River. In 2006, there were an estimated 80,000 new cases of TB in Myanmar.

The TB Alliance is working to bring all of these pieces together as a key driver of the REMoxTB Phase III clinical trial, which is conducted in close partnership with Bayer HealthCare AG, University College London (the trial sponsor), and the British Medical Research Council. REMoxTB is designed to test whether a moxifloxacin-containing combination regimen of just four months can result in cure and relapse rates that are non-inferior to those achieved with the standard six-month TB regimen.

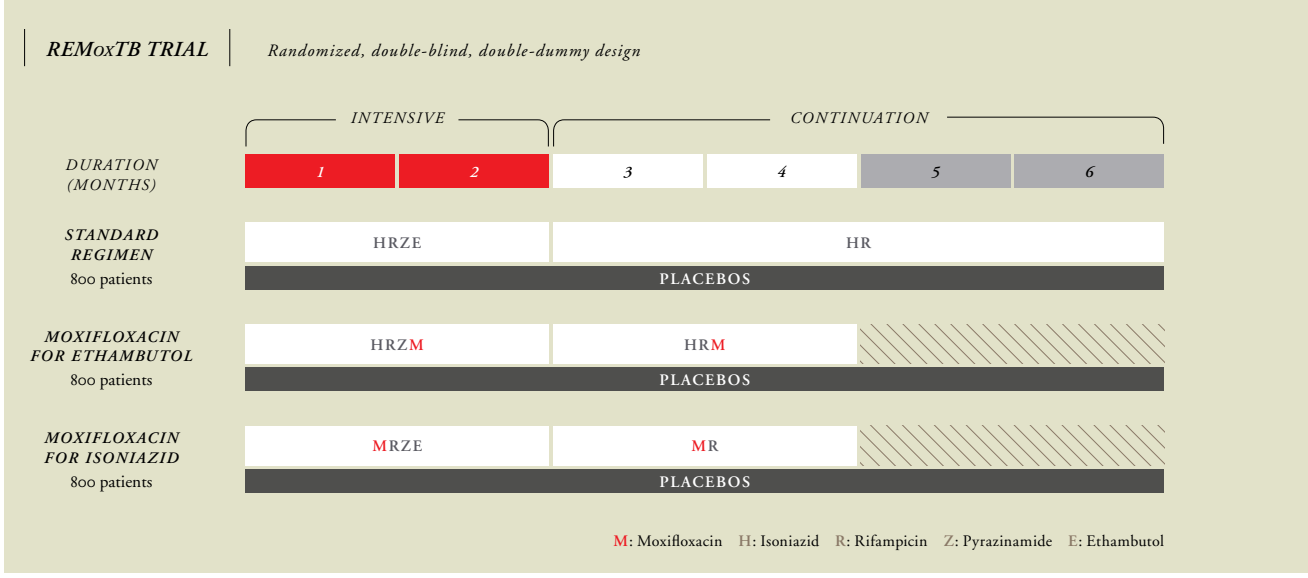
A critical piece of the puzzle fell decisively into place in January 2008 with the enrollment, in Zambia, of the first REMoxTB patient. From there, the trial has accelerated to include patients at three additional clinical trial sites in Africa. More sites are expected by the end of 2008, including a variety of locations in Asia.

The TB Alliance has worked with regulators to expand what was originally a smaller, Phase II study into a pivotal Phase III trial—a trial that meets the requirements of modern regulatory standards and has the geographic reach to support global registration. From four sites on one continent we are expanding to 20–30 sites on three continents.

REMoxTB IS HELPING TO BUILD A MODERN TB CLINICAL TRIALS INFRASTRUCTURE.

Assembling this network of sites has required a mammoth effort to assess the readiness and capabilities of TB clinical trial sites worldwide—with a total of 77 sites in 34 countries on 5 continents assessed thus far. This network will be critical as more compounds progress through the global TB drug R&D pipeline. We need an infrastructure capable of supporting multiple, concurrent, large-scale TB drug trials.

Breathing new life into clinical trial site capacity for TB drugs is a process that benefits the entire field. By initiating this task, the TB Alliance reinforces its role as a leader in accelerating TB drug development for all sponsors.



CLINICAL TRIAL SITES AND LABORATORIES ASSESSED TO DATE

77

SITES ASSESSED

THE AMERICAS

ARGENTINA	2
BRAZIL	5
CANADA	2
COLOMBIA	1
MEXICO	1
PERU	4
UNITED STATES	5

EUROPE

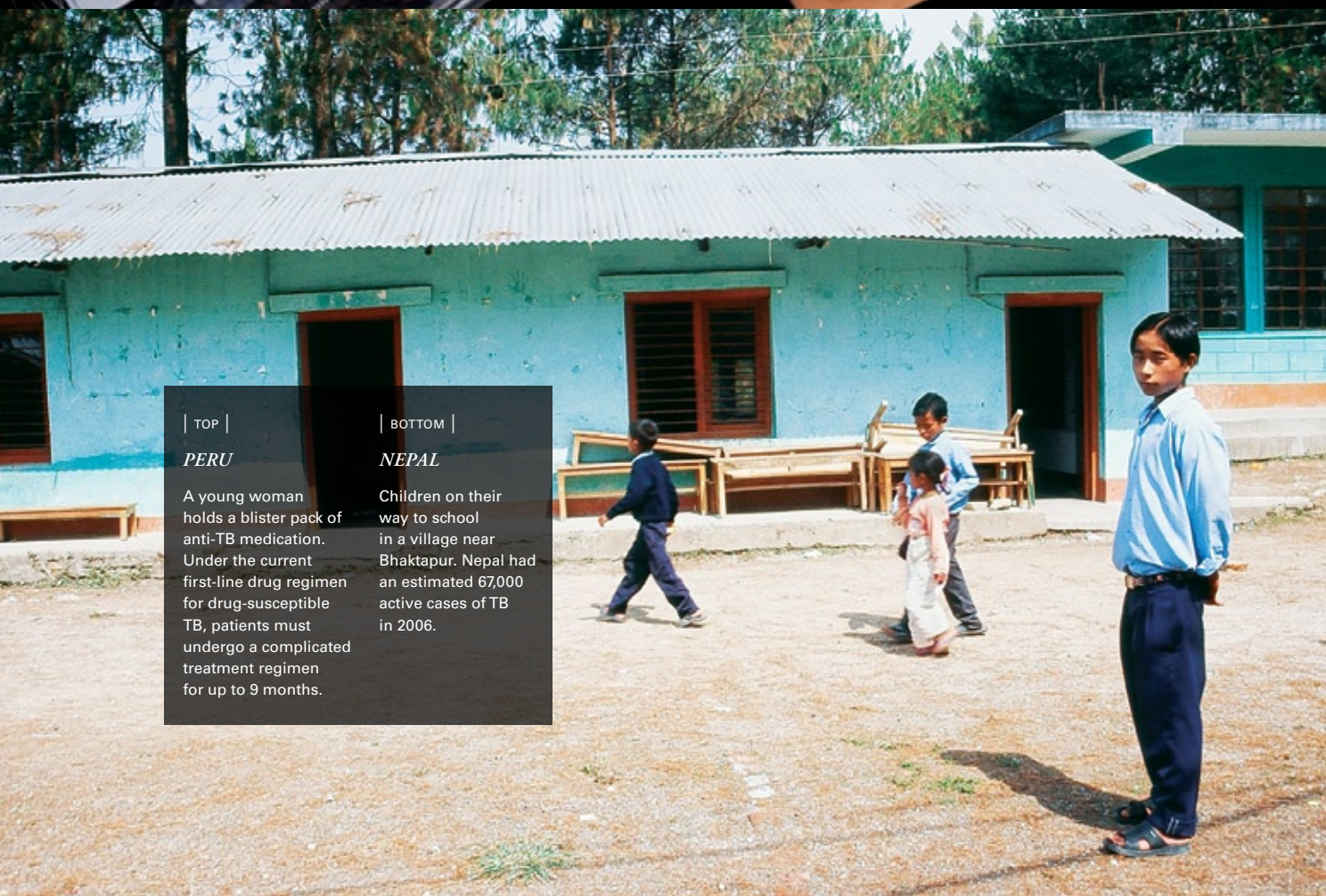
LATVIA	1
MOLDOVA	2
ROMANIA	1
RUSSIA	4
SPAIN	1
TURKEY	1
UNITED KINGDOM	1

AFRICA

BENIN	1
ETHIOPIA	1
THE GAMBIA	1
GUINEA	1
KENYA	1
MOZAMBIQUE	1
SOUTH AFRICA	11
TANZANIA	4
UGANDA	3
ZAMBIA	2

ASIA PACIFIC

CHINA	3
HONG KONG	1
INDIA	3
INDONESIA	2
SOUTH KOREA	2
MALAYSIA	2
PHILIPPINES	1
TAIWAN	1
THAILAND	3
VIETNAM	2



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PERU

A young woman holds a blister pack of anti-TB medication. Under the current first-line drug regimen for drug-susceptible TB, patients must undergo a complicated treatment regimen for up to 9 months.

| BOTTOM |

NEPAL

Children on their way to school in a village near Bhaktapur. Nepal had an estimated 67,000 active cases of TB in 2006.

UNDERSTAND AND STRENGTHEN THE PATHWAY FROM TB DRUG DEVELOPMENT TO PATIENTS IN HIGH BURDEN COUNTRIES.

connect

to the field

A new drug—no matter how potent—does no good in a drug developer's storeroom. The TB Alliance is committed to ensuring that new drug combinations get into the hands of patients, and we realize that preparation for this task must begin now.

The first step in preparing for adoption is to understand, at the country and global levels, what patients, TB experts and national TB programs (NTPs) want from a new TB drug regimen. To assess these issues, the TB Alliance conducted a study in Brazil, China, India, Kenya and South Africa—five countries that together represent over 50% of the global burden of TB.

Based on 172 interviews, it became clear that shorter regimens would be welcomed. There were, however, some caveats: countries that use fixed-dose combinations (in which two or more drugs are combined in one tablet) would request similar combination tablets in order to implement a new, shorter regimen; certain countries would require data from clinical trials conducted in their own country; and data on patients co-infected with HIV were seen as critical for areas such as sub-Saharan Africa. Endorsement by the World Health Organization was thought to be necessary but not sufficient.

As a next step, the TB Alliance is conducting a Country Introduction Study to understand the pathways for new regimen introduction in each of the 22 high burden countries for TB. This study is gathering past experiences with TB regimen change, and determining whether mechanisms exist for countries to assess and implement future regimen change. Based on interviews, we are analyzing the many possible opportunities for and barriers to new regimen introduction in each country. This study will provide the basis for a logical roll-out strategy that targets the issues that are most salient in a given location.

While responding to these findings, the TB Alliance is also working to ensure that there will be manufacturing and distribution capacity to make new drugs available to high burden markets at a price that is affordable.

A continued connection to local stakeholders and an understanding of local conditions will be critical to the rapid and broad dissemination of new treatment combinations. The TB Alliance is committed to a robust dialogue with the people who confront the TB crisis on the ground every day, so that the introduction of a new regimen can be as rapid and effective as possible.

THE TB ALLIANCE MISSION INCLUDES AN EXPLICIT COMMITMENT TO "AAA": AFFORDABILITY, ADOPTION, AND AVAILABILITY.

lead

Dear friends, donors and stakeholders: In the last year, there has been encouraging progress and some notable change here at the TB Alliance.

With numerous new projects entering the pipeline and a maturing clinical portfolio, the TB Alliance and its collaborators are closer each day to improving the treatment paradigm for the millions affected by TB. At the same time, the TB Alliance is growing in its size and commitments and is moving closer to registering and launching its first new drug for TB. Our organization is cementing its reputation as the formidable, full-scale R&D institution that our founding stakeholders envisioned.

| LEFT |
Dr. Jerome Premmereur
CEO and President

| RIGHT |
Dr. Gijs Elzinga
Chairman of the Board

Earlier this year, we bid farewell to Dr. Maria C. Freire, whose six years of tireless leadership stewarded so many of our achievements to date. We wish Dr. Freire and the Albert and Mary Lasker Foundation, which she now heads, great success as they work to advance world-class scientific achievement for many years to come. At the TB Alliance, we build upon the foundation established by Dr. Freire as we provide ongoing leadership for a growing organization.

Growth and change at the TB Alliance come at a pivotal time for both the organization and the condition of TB control worldwide. The past year has, once again, seen TB in the global spotlight. Substandard drug quality and inadequate or inappropriate treatment of drug-susceptible TB has caused a dramatic rise in the global incidence of drug-resistant TB. Cases of drug-resistant TB are surfacing in every corner of the world, and more and more lives are being lost.

The deadly synergy of TB and HIV/AIDS is also exacting a devastating toll. In June 2008, global leaders, including United Nations Secretary-General Ban Ki-moon and former US President Bill Clinton, gathered at the UN headquarters in New York to discuss the TB-HIV co-infection emergency. Director General of the World Health Organization Dr. Margaret Chan urged participants to address the need for better tools through enhanced support for research.

Today's standard TB drug regimen is difficult to administer effectively with certain common antiretrovirals used to treat HIV/AIDS. Now, more than ever before, we stand by our commitment to ensure new drug combinations are effective in all patients, including those with HIV/AIDS.

The impact of TB today is clear. Without new, faster drug combinations that are effective against all forms of the disease in all patients, TB's global threat will intensify. For the first time in nearly a half-century, we have a growing pipeline of potential new drugs in preclinical and clinical development, making novel therapies and drastically better combinations a realistic possibility.

Patients are in desperate need and time is short. We thank you for your continued loyalty and support as we work to bring new hope to millions in need of a better cure.

Dr. Jerome Premmereur
CEO and President

Dr. Gijs Elzinga
Chairman of the Board

financials

INDEPENDENT AUDITOR'S 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. ("TB Alliance") as of December 31, 2007, and the related statements of activities, functional expenses and cash flows for the year then ended. These financial statements are the responsibility of the TB Alliance'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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the TB Alliance's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, 2007, 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, 2006 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 5, 2007.

BDO Seidman, LLP

BDO Seidman, LLP
July 9, 2008

STATEMENT OF FINANCIAL POSITION

(with comparative totals for 2006)

DECEMBER 31,	2007	2006
ASSETS		
Cash and cash equivalents (Notes 2 and 3)	$ 30,267,411	$ 18,147,261
Assets limited to use (Note 2)	873,478	–
Investments at fair value (Note 3)	21,458,570	18,671,671
Accounts receivable	584,666	867,145
Security deposits	142,618	142,618
Other assets	150,461	72,894
Fixed assets, net (Notes 2 and 5)	474,164	228,310
	$ 53,951,368	$ 38,129,899
LIABILITIES AND NET ASSETS		
Liabilities:		
Accounts payable and other liabilities	$ 4,207,638	$ 1,962,768
Accrued payroll and payroll related liabilities	179,021	141,354
Deferred revenue (Note 6)	20,689,391	11,059,140
Deferred rent	384,508	163,513
Total liabilities	25,460,558	13,326,775
Commitments (Note 7)		
Net assets:		
Unrestricted net assets (Note 2)	28,490,810	24,803,124
	$ 53,951,368	$ 38,129,899

See accompanying Notes to Financial Statements.

STATEMENT OF ACTIVITIES

(with comparative totals for 2006)

YEAR ENDED DECEMBER 31,	2007	2006
Public support and other revenue (Unrestricted):		
Contributions	$ 24,697,671	$ 18,519,930
Grants	4,221,636	5,230,535
Contributed services (Note 4)	–	25,088
Interest and dividend income	1,319,699	983,865
Net realized and unrealized gains on investments	584,420	222,092
Miscellaneous income	26,493	5,209
Total public support and other revenue	30,849,919	24,986,719
Expenses:		
Program services:		
Research and development	22,624,182	14,808,362
Business development	324,081	322,652
Public affairs and policy	2,404,032	2,858,293
Total program services	25,352,295	17,989,307
Supporting services:		
Management and general	1,842,489	1,872,104
Fundraising	180,527	227,572
Total supporting services	2,023,016	2,099,676
Total expenses	27,375,311	20,088,983
Change in net assets before foreign translation gain	3,474,608	4,897,736
Foreign translation gain (Note 2)	213,078	193,639
Change in net assets	3,687,686	5,091,375
Net assets, beginning of year	24,803,124	19,711,749
Net assets, end of year	$ 28,490,810	$ 24,803,124

See accompanying Notes to Financial Statements.

STATEMENT OF CASH FLOWS

(with comparative totals for 2006)

YEAR ENDED DECEMBER 31,	2007	2006
Cash flows from operating activities:		
Change in net assets	$ 3,687,686	$ 5,091,375
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Depreciation and amortization	86,187	101,838
Realized gain on sales of investments at fair value, net	(578,444)	(50,478)
Unrealized gains on investments at fair value	(5,976)	(171,614)
(Increase) decrease in assets:		
Assets limited to use	(873,478)	142,150
Accounts receivable	282,479	(162,177)
Security deposits	–	1,896
Other assets	(77,567)	(20,227)
Increase in liabilities:		
Accounts payable and other liabilities	2,244,870	934,574
Accrued payroll and related liabilities	37,667	15,009
Deferred revenue	9,630,251	8,780,975
Deferred rent	220,995	10,879
Net cash provided by operating activities	14,654,670	14,674,200
Cash flows from investing activities:		
Purchase of investments	(34,115,479)	(14,849,579)
Proceeds from sale of investments	31,913,000	3,175,000
Purchase of fixed assets	(332,041)	(67,903)
Net cash used in investing activities	(2,534,520)	(11,742,482)
Cash flows from financing activities:		
Repayments of capital lease obligation	–	(12,130)
Net increase in cash and cash equivalents	12,120,150	2,919,588
Cash and cash equivalents, beginning of year	18,147,261	15,227,673
Cash and cash equivalents, end of year	$ 30,267,411	$ 18,147,261
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ –	$ 242

See accompanying Notes to Financial Statements.

1. ORGANIZATION

The Global Alliance for TB Drug Development, Inc. ("TB Alliance") is a not-for-profit 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, Belgium; Pretoria, South Africa; and New York, New York.

The TB Alliance was formed to accelerate the development of effective new combinations of 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 MDR-TB strains and improve treatment of latent infection.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of Presentation
The financial statements of the TB Alliance have been prepared on the accrual basis and the presentation follows the requirements of the Financial Accounting Standards Board in its Statement of Financial Accounting Standards ("SFAS") No. 117, "Financial Statements of Not-for-Profit Organizations." Under SFAS No. 117, the TB Alliance is required to report information regarding its financial position and activities according to three classes of net assets: unrestricted net assets, temporarily restricted net assets and permanently restricted net assets.

(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 the 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 the TB Alliance.

(ii) Temporarily Restricted
Net assets resulting from contributions and other inflows of assets whose use by the TB Alliance is limited by donor-imposed stipulations that either expire by passage of time or can be fulfilled and removed by actions of the 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
The TB Alliance considers short-term investments with original maturities of three months or less to be cash equivalents.

(d) Assets Limited to Use
Assets limited to use consist of cash and cash equivalents held by banks providing collateral for certain leases held by the TB Alliance.

(e) Investments at Fair Value
Investments in equity securities with readily determinable fair values and all investments in debt securities are stated at their fair values in the statement of financial position. Net realized gains and losses and net change in unrealized gains and losses for the period are shown in the statement of activities.

(f) Investments in Auction Rate Securities
The TB Alliance has invested in certain Auction Rate Preferred Shares ("the Securities") issued by several closed-end mutual funds ("the Funds"). The Securities generally entitle the TB Alliance to receive interest or dividends at a rate that is reset periodically to the rate produced in an auction that is governed by a set of auction procedures established by the Funds and their auction agents. The frequency of the periodic auctions varies. The Securities are not listed on an exchange, but are instead bought or sold via participation in auctions arranged through the auction agent and the Funds, or through secondary markets. The Securities are senior to the common shares issued by the Funds and benefit from a liquidation preference in the event of dissolution of the Funds entitling the TB Alliance to receive both the face value invested and any accumulated but unpaid dividends.

The Securities are subject to redemption at the option of the issuing Funds; however, the Funds' ability to redeem the Securities is generally limited by securities regulations. The Securities are mandatorily redeemable upon liquidation of the issuing fund. It is the policy of the TB Alliance to hold the Securities to maturity.

(g) 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

(h) Income Taxes
The 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. In addition, the TB Alliance has been determined by the Internal Revenue Service not to be a "private foundation" within the meaning of Section 509(a) of the Code. There was no unrelated business income for 2007.

(i) Contributions and Grants
Contributions received are recorded as unrestricted, temporarily restricted or permanently restricted support, depending on the existence and/or nature of any donor restrictions. Contributions with purpose or time restrictions (defined by management as unrestricted amounts due in more than one year) are reported as increases in temporarily restricted net assets. When a donor restriction expires, that is, when a time restriction ends or purpose restriction

is fulfilled, temporarily restricted net assets are reclassified to unrestricted net assets and reported in the statement of activities as net assets released from restrictions. Restricted gifts and grants, received and utilized in the current year, are reflected in the statement of activities in the unrestricted class of net assets.

Public grants from government agencies are recorded based on the terms of the grantor allotment, which generally provides that revenue is earned when the allowable costs or units of services of specific grant provisions have been incurred or provided.

(j) Reclassifications
Certain reclassifications have been made to the 2006 amounts to conform with the 2007 presentation. Such reclassifications have no impact on changes in net assets.

(k) Promises to Give
Unconditional promises to give are recognized as contribution revenue in the period received and as assets, decreases of liabilities, or expenses depending on the form of the benefits received, and are classified as either unrestricted, temporarily restricted, or permanently restricted support. Promises to give are recorded at net realizable value if expected to be collected in one year. Unconditional promises to give that are expected to be collected in the future years are recorded at the present value of these estimated future cash flows.

Conditional promises to give are not recognized until they become unconditional, that is, when the conditions on which they depend are substantially met. Contributions of assets other than cash are recorded at the estimated fair value.

(l) 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."

(m) Program Services

(i) Research and Development
The 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, the 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
The 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, the 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) Public Affairs and Policy
The TB Alliance manages critical alliances with public and private organizations to raise awareness about 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.

(n) 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.

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

(p) Comparative Financial Information
The financial statements include certain prior year summarized comparative information. Accordingly, such information should be read in conjunction with the prior year financial statements from which the summarized information was derived. With respect to the statement of functional expenses, the prior year expenses by expense classification are presented in total rather than by 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.

(q) Foreign Currency Translation
All elements of the financial statements reflecting the TB Alliance's operations in Brussels are translated into US dollars using applicable exchange rates. For assets and liabilities, this is the rate in effect at the statement of financial position date, with the exception of property and equipment, which is measured at the historical rate. For revenue and expense items, translation is performed monthly using the average rate for the month. The exchange rate as of December 31, 2007 was 1.47290 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 the 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, 2007	
Cumulative translation gain adjustment, beginning of year	$ 381,956
Translation adjustment	213,078
Cumulative translation gain adjustment, end of year	$ 595,034

The cumulative translation gain is included in unrestricted net assets.

3. INVESTMENTS AT FAIR VALUE

The TB Alliance's cost and fair value of investments are summarized as follows:

DECEMBER 31, 2007	FAIR VALUE	COST
Auction rate securities	$ 4,675,000	$ 4,675,044
Government bonds	8,783,570	8,605,936
Market linked deposits	8,000,000	8,000,000
	$ 21,458,570	$ 21,280,980

Investment earnings are comprised of the following:

DECEMBER 31, 2007	
Interest and dividend income	$ 1,319,699
Net realized and unrealized gains on investments	584,420
	$ 1,904,119

In addition to the above investments, the portfolio included $23,987,700 of cash and cash equivalents at December 31, 2007. Subsequent to December 31, 2007, $2,050,000 of the auction rate securities have been recalled.

4. CONTRIBUTED SERVICES

Included in the TB Alliance's statement of activities is approximately $-0- and $25,088 for the years ended December 31, 2007 and 2006, respectively, of in-kind contributions, which were related to project management costs.

5. FIXED ASSETS, NET

Fixed assets, net, stated at cost, consists of the following:

DECEMBER 31, 2007	
Computer equipment	$ 328,503
Furniture and equipment	227,311
Leasehold improvements	417,289
Total fixed assets	973,103
Less: Accumulated depreciation and amortization	(498,939)
Fixed assets, net	$ 474,164

6. DEFERRED REVENUE

In November 2006, the Department of Development of the Netherlands Ministry of Foreign Affairs ("DDC") approved an 8,000,000 EUR three-year grant for the period from 2006 to 2009 for research and development to optimize tuberculosis drug therapy. The contract stipulates that any unused funds be returned to the DDC at the expiration of the grant term. As of December 31, 2007, the TB Alliance received $5,124,516 related to this grant. The remaining unspent funds of $2,548,621 are recorded as deferred revenue as of December 31, 2007.

In May 2006, the TB Alliance received a conditional promise-to-give award from the Bill & Melinda Gates Foundation in the amount of $104,403,823 for the period of May 1, 2006 to May 1, 2011. To date, the TB Alliance has received $44,348,366 of the award. As of December 31, 2007, the TB Alliance recognized $26,207,626 income on the grant for project milestones achieved and has included $18,140,740 in deferred revenue. The remaining amount of $60,055,457 has not been recognized in the financial statements.

7. COMMITMENTS

The TB Alliance has operating lease agreements for office space in New York, New York; Brussels, Belgium; and Pretoria, South Africa. The TB Alliance New York office lease expires in December 2017, the Brussels lease agreement expires in November 2009 and the Pretoria lease expires in October 2009.

The following is a schedule of future minimum rental payments under the Brussels, Pretoria and New York operating leases as of December 31, 2007:

YEAR ENDED DECEMBER 31,	
2008	$ 1,049,539
2009	1,373,150
2010	1,369,000
2011	1,409,286
2012	1,414,476
Thereafter	6,330,702
	$ 12,946,153

The TB Alliance terminated the lease at 80 Broad Street in New York, New York, on April 30, 2008. According to the terms of the lease agreement a cancellation fee of $100,000 was paid and $1,727,689 was removed from commitments.

The 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, 2007.

The following is a schedule of future minimum research and development payments under the above agreements as of December 31, 2007:

YEAR ENDED DECEMBER 31,	
2008	$ 10,311,111
2009	5,542,463
2010	500,000
2011	500,000
2012	500,000
Thereafter (per year)	500,000

8. PENSION PLAN

The TB Alliance has a 401(k) plan that covers all employees who are age 21 and older. Employees may contribute up to 15% of their pay each pay period. Catchup deferral of up to $5,000 in 2007 is available for eligible employees 50 years old or older during the plan year. The TB Alliance matches 50% of the first 3% of the pay contributed through the employee's salary deferral. Discretionary and qualified non-elective contributions are also made to the plan. Pension expense was $164,103 for the year ended December 31, 2007. In January 2006, the TB Alliance converted into a 401(k) Safe Harbor Plan.

STAKEHOLDERS

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

American Lung Association

American Thoracic Society

Association of the British Pharmaceutical Industry

Bangladesh Rural Advancement Committee

Bill & Melinda Gates Foundation

Eli Lilly and Company

European Commission

Global Business Coalition on HIV/AIDS, TB and Malaria

Global Forum for Health Research

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

Médecins Sans Frontières–Doctors Without Borders

Medical Research Council of South Africa

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

RTI International

RESULTS

Rockefeller Foundation

Sequella, Inc.

SHA Patient Representative, Pervaiz Tufail

Stop TB Partnership

TB Alert

Treatment Action Group

Tropical Disease Foundation

UK Department for International Development

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

US Agency for International Development

US Centers for Disease Control and Prevention

US National Institute of Allergy and Infectious Diseases, National Institutes of Health

Wellcome Trust

World Bank

World Health Organization

SCIENTIFIC ADVISORY COMMITTEE

Members of the Scientific Advisory Committee provide the TB Alliance with invaluable scientific expertise.

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RECOGNITION OF SUPPORT

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Bill & Melinda Gates Foundation

Irish Aid

The Netherlands Ministry of Foreign Affairs

Rockefeller Foundation

United Kingdom Department for International Development

United States Agency for International Development

Bayer HealthCare AG

GlaxoSmithKline

RTI International

Stop TB Partnership

United States Centers for Disease Control and Prevention

United States National Institute of Allergy and Infectious Diseases, National Institutes of Health

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ABOUT THE TB ALLIANCE

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; 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.

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Ideas On Purpose New York, NY
www.ideasonpurpose.com

PHOTOGRAPHY

Cover, **Paul Weinberg**; inside front cover, pages 4 (bottom), 9 (bottom), 17 (1, 5, 6), inside back cover, **Zackary Canepari**; page 4 (top), **Sven Torfinn**; pages 6, 11, 14 (top), 17 (4), 22 (top and bottom), back cover, **Atul Loke**; page 9 (top), **Seokyong Lee**; pages 14 (bottom), 21 (bottom), **Patrick Andrade**; pages 17 (2, 3), 20 (top), 26 (bottom), **Eric Miller**; page 18 (top), **Jon Spaull**; page 18 (inset and bottom), **John-Michael Maas**; page 24 (top), **Vera Lentz/ Black Star**; pages 24 (bottom), 27, 29 (left), **Cuyler Mayer**; page 26 (top), **Douglas Engle**

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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.

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT