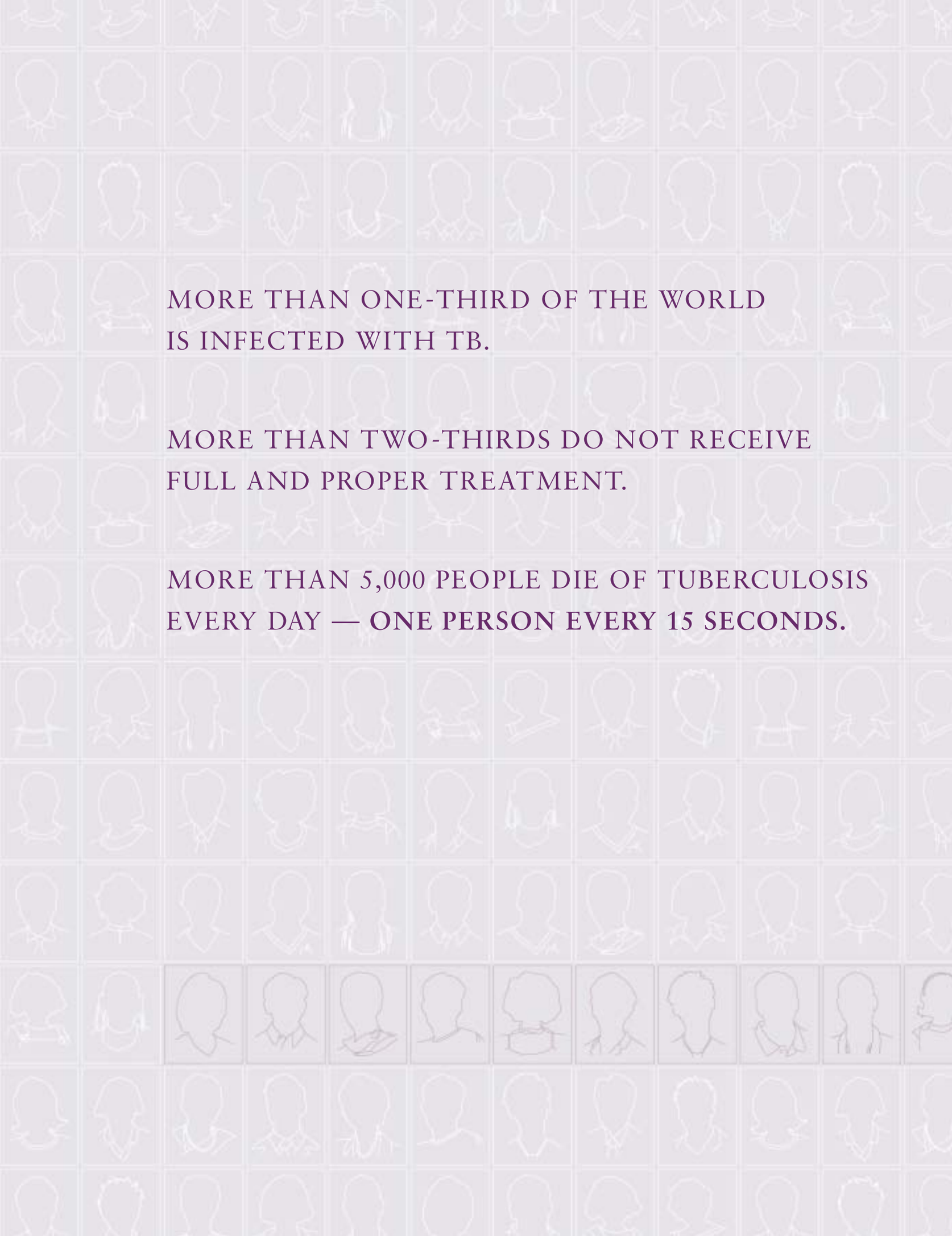
IT'S TIME FOR A FASTER CURE.

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

2001 – 2002 ANNUAL REPORT



MORE THAN ONE-THIRD OF THE WORLD
IS INFECTED WITH TB.

MORE THAN TWO-THIRDS DO NOT RECEIVE
FULL AND PROPER TREATMENT.

MORE THAN 5,000 PEOPLE DIE OF TUBERCULOSIS
EVERY DAY — **ONE PERSON EVERY 15 SECONDS.**

TUBERCULOSIS IS MORE THAN STATISTICS.

ELENA
RUSSIA
father died in prison from MDR-TB

TAE JOON
KOREA
does genomic research on TB

HELÈNE
FRANCE
met her first TB patient in a rural clinic

WAMBUI
KENYA
is coinfected with TB and HIV and advocates for access to medicines

MAURICIO
BRAZIL
screens thousands of molecules for TB activity

ANUSHA
INDIA
cares for her infected parent

SARAH
UNITED STATES
works for a biotechnology company

FOUAD
EGYPT
leads regional TB control activities

A FASTER CURE IS WITHIN OUR REACH.

The Global Alliance for TB Drug Development accelerates the discovery and development of faster-acting and affordable drugs to fight tuberculosis. By building a portfolio of promising drug candidates and forging innovative partnerships for their development, we maintain a laser-sharp goal of delivering a new anti-tuberculosis drug in a decade.

A not-for-profit enterprise, we enlist the best practices, science and resources of both the private and public sectors the world over in pursuit of an urgent public health need.

Through our stakeholders and other allies worldwide, our mission is to ensure equitable access to a faster tuberculosis cure that will advance global health and prosperity.

IT'S TIME TO

KEEP THE PROMISE OF SCIENCE.

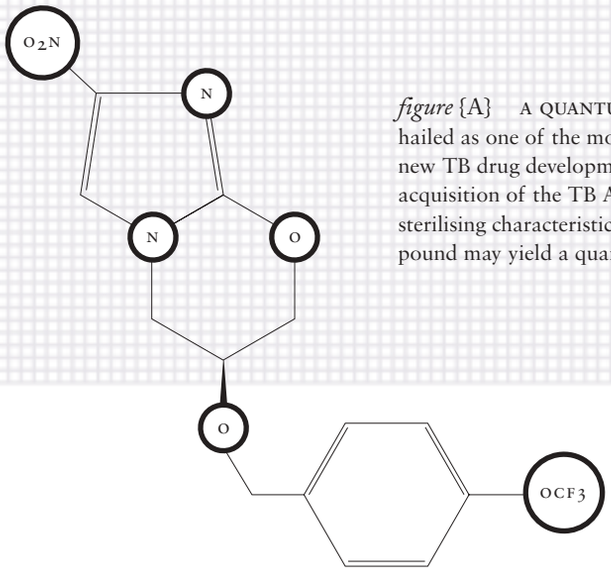


figure {A} A QUANTUM LEAP FORWARD — PA-824, hailed as one of the most promising lead compounds for new TB drug development in decades, is the first portfolio acquisition of the TB Alliance. With bactericidal and sterilising characteristics, this novel nitroimidazole compound may yield a quantum leap forward in new therapies.

IN THE PURSUIT OF A FASTER CURE, THE TB ALLIANCE IS LEVERAGING THE LATEST SCIENTIFIC ADVANCES AND ENLISTING THE BEST PUBLIC AND PRIVATE LABORATORIES WORLDWIDE.

The objective of the Global Alliance for TB Drug Development (TB Alliance) is the development of new, affordable, faster-acting anti-tuberculosis medicines. This requires collaborating with the world's best scientists, leveraging scientific advances and catalysing research and development (R&D) worldwide.

Our priority is to ensure that new compounds move successfully through all stages of drug development, receive rapid and appropriate regulatory approval, and are promptly transferred into effective and accessible clinical use.

WHY NEW ANTI-TB THERAPIES

The standard anti-TB medicines reflect basic science that is up to half a century old. Since the introduction of an effective chemotherapy 50 years ago, the required duration has been halved and treatment simplified. Yet, the standard four- and two-drug dosage combinations must still be taken for six to nine months.

With such a lengthy regimen, the global health community is severely challenged in the face of today's triple threat: the rapid spread of tuberculosis infection, the rise of drug-resistant strains; and TB's dangerous interaction with the raging HIV epidemic.

The TB Alliance is hard at work developing new drugs to shorten or otherwise simplify TB treatment, to be effective against multi-drug resistant strains of TB (MDR-TB), and to improve the treatment of latent TB infection.

The target drug is an effective, novel, quick-acting sterilising agent that kills persisting TB bacilli not eliminated during the early period of standard treatment. Novel compounds can avoid cross-resistance with existing drugs, while addressing pressing medical needs. Medicines that radically shorten the course of treatment will lower toxic side effects, increase patient compliance and slow the spread of the disease and the development of MDR strains.

THE SCIENTIFIC CHALLENGES OF TB

Tuberculosis (TB) is one of the world's oldest infectious diseases, yet its causing agent, *Mycobacterium tuberculosis*, was only identified in 1882. Ever since, scientists have battled to understand this elusive adversary.

Unlike most bacteria, *M. tuberculosis* escapes detection by the immune system for a long time. Its unique cell wall — a waxy coating primarily composed of mycolic acids — disguises it from the host's immune system. Once inside a human lung, *M. tuberculosis* hides inside macrophages — the very cells designed to eliminate it — and reproduces slowly but steadily. Surviving dormant for up to many years, the mycobacterium makes its presence known only once it has launched its infectious attack.

The complex pathobiology of *M. tuberculosis* has made the search for full and fast-acting anti-TB treatment a great scientific challenge — one that for decades has attracted researchers, but dissuaded investors. Recent efforts to decipher the bacterium's unusual biology have been successful thanks to groundbreaking new scientific tools.

NEW HOPE FROM SCIENCE

Recent science may reveal the reasons for TB's persistence and virulence and what triggers a dormant bacterium to become a lethal attacker. The sequencing of the *M. tuberculosis* genome in 1998 has been a boon to finding better ways to tackle the bacillus' defences. In addition to simplifying and accelerating research, genomics gives scientists tools to identify the genes that are unique to the mycobacterium — and therefore essential to its survival. By clarifying the interactions between pathogen and infected host, this genomic information can lead to new targets and new drug candidates.

Moreover, a number of revolutionary tools, including microarray technology and combinatorial chemistry, have provided technical advances that are speeding discovery and innovation.

LEVERAGING EXISTING COMPOUNDS

Libraries of existing compounds may already contain novel, fast-acting therapies. Indeed, even during a 30-year standstill in anti-TB drug development, many potential compounds in a variety of families were discovered, but never nurtured towards drug development and registration.

Building on an initial analysis carried out with the Special Programme for Research and Training in Tropical Diseases (TDR), we carefully reviewed the most promising known families, listed below, to identify possible drug candidates:

- *Fluoroquinolones and quinolizine derivatives* that may hold the key to significantly shorter treatment regimens.
- *Longer-acting rifamycins* for more widely-spaced, intermittent treatment and potential for avoiding cross-resistance to other rifamycins and anti-retroviral drug interactions.

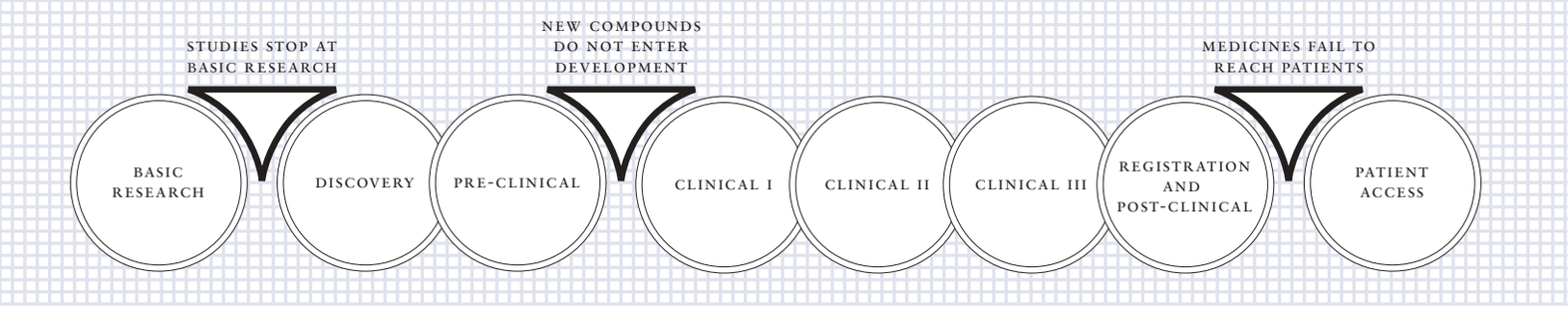


figure {B} BRIDGING GAPS IN R&D — For thirty years, precious few promising compounds have made their way off laboratory benches or shelves. The TB Alliance is seeking out both novel compounds and these "diamonds in the rough," and investing in their further development, while promoting a vital, reinvigorated R&D environment for researchers worldwide.

- *Oxazolidinones,* broad-spectrum antimicrobials, which may have substantial anti-mycobacterial activity.
- *Nitroimidazoles,* a known family which includes PA-824, with potentially sterilising activity and effectiveness against MDR-TB.

We continue to identify possible drug candidates in these and other classes of compounds as critical elements of our portfolio. Experts worldwide have assisted us in evaluating the quinolone and rifamycin families. These consultations have helped shape the agenda for further research as well as identify the profile of promising new drug candidates.

CATALYSING TB DRUG DEVELOPMENT

The TB Alliance was created to reinvigorate a TB drug development process that, despite ongoing research, did not yield new classes of TB drugs for thirty years. There were two primary reasons. The market was not viewed as sufficiently lucrative and few recognised the unmet medical need arising from the lengthy treatment required by existing drugs.

The drug development strategy of the TB Alliance was designed with these realities in mind and based on a thorough analysis of the TB R&D environment, outlined in the *Scientific Blueprint for TB Drug Development*. The *Blueprint* identifies the disease's scientific challenges and recommends ways to fill the drug development gaps and meet the opportunities. It serves as a guide for the TB Alliance and researchers around the world by detailing the characteristics of desirable drug candidates and outlining how combined expertise can be leveraged to bring about a new TB drug within a prompt timeframe. It also recommends priorities of action in basic research, discovery, pre-clinical development, chemistry, clinical trials and technology transfer.

BUILDING A PORTFOLIO

The TB Alliance conducted a portfolio modeling exercise to establish selection criteria to maximise success. We are scaling up to an ongoing pipeline of five to seven hits and leads in the late discovery and pre-clinical stages, as well as pursuing aggressively the in-licensing of Phase I compounds. The first portfolio acquisition based on this strategy was completed in January 2002, and several others are imminent. (See chart on page 14.)

PA-824

The TB Alliance licensed PA-824 and related nitroimidazole compounds for development. Originally a by-product of 1990s cancer research at PathoGenesis Corporation (since acquired by Chiron Corporation), PA-824 has three key characteristics: it is novel, bactericidal and sterilising. The molecule is in the lead optimisation stage and, under our management, is moving through the R&D chain with outsourced support for chemical synthesis, formulation, toxicology and animal studies as first steps of its further development.

UPGRADING THE TOOLS AND THE ENVIRONMENT

The TB Alliance has funded and will continue to fund projects worldwide that expedite, support and lower hurdles in TB drug development.

Animal Models: The TB Alliance is funding the establishment of an animal facility at the Johns Hopkins University to evaluate new anti-TB drugs and drug regimens.

Clinical Trials: To improve capacity in endemic countries, the TB Alliance will support the development of multi-centre, randomised clinical trial expertise in national TB programs in Africa and Asia through the International Union Against Tuberculosis and Lung Disease (IUATLD).

Standardised Regulatory Frameworks: The TB Alliance will support an initiative to harmonise TB drug evaluation and approval worldwide.

TB Drug Database: Negotiations are underway for a web-accessible comprehensive data bank on each and every potential anti-TB compound.

Surrogate Markers: The TB Alliance is organising a consortium to conduct early bactericidal activity (EBA) and other surrogate markers studies.

GUIDED BY A BLUEPRINT AND THE LATEST SCIENCE, THE TB ALLIANCE BRIDGES GAPS IN R&D AND IS ASSEMBLING A PORTFOLIO OF PROMISING COMPOUNDS.

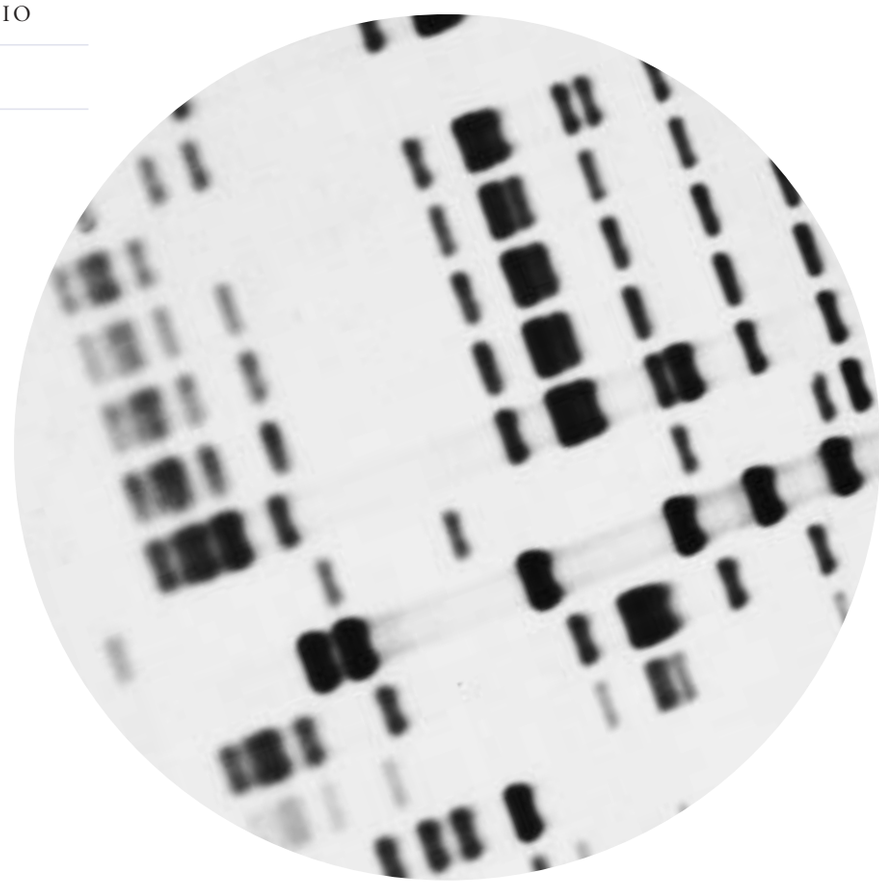


figure {C} TB GOES MOLECULAR — The DNA fingerprint shown at right, now used to identify and track TB infections on a global basis, is an example of the benefits gained from integrating molecular biology and epidemiology during the last decade. These rapid advancements, especially the sequencing of multiple *M. tuberculosis* genomes now underway, have led to increased optimism for improved TB control and are fueling further breakthroughs in drug discovery. (Image of DNA fingerprint taken from TB patients in New York City and analyzed at the Public Health Research Institute, Newark, New Jersey.)

IT'S TIME TO

INNOVATE TOGETHER.

figure {D} NIMBLE AND CONNECTED — The TB Alliance engages every relevant organisation with a stake in new TB drugs, and outsources R&D projects. By eliciting the best each one has to offer, partnerships allow risks and incentives to be shared, with health equity as the bottom line.

BY FORGING INNOVATIVE PARTNERSHIPS THAT GUARANTEE AFFORDABLE DRUGS, THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT ENLISTS SCIENCE AND MARKET INCENTIVES FOR THE PUBLIC GOOD.

Our strategy is built on partnerships where both risks and incentives are shared. Bringing together public and private parties that contribute scientific and financial resources, we leverage market forces while removing the barriers that deterred TB drug development for decades.

ECONOMICS OF TB DRUG DEVELOPMENT

To fine-tune our approach and inform investors, we enrolled experts worldwide and published a study on the *Economics of TB Drug Development*. This analysis, the first in over 30 years, put the TB drug market at $450 million a year in 2001 and estimated the cost of developing a lead compound through registration at just above $100 million.

The report shows that the market is growing rapidly and will reach $700 million by the end of the decade. While not inconsequential, this size — combined with other economic and geographic considerations — continues to dissuade industry players from pursuing the full development of an

anti-TB drug. The study underscores the importance of global partnerships, such as the TB Alliance, as a vital part of meeting the TB challenge.

GLOBAL ALLIANCES FOR RESULTS

Partnerships speed progress, reduce cost and diversify risk. The TB Alliance identifies prospective partners by scouting for the best, most cost-effective science and technology worldwide.

Outsourcing the development of drug candidates allows us to mobilise premier public, academic and private laboratories globally. While giving preference to joint ventures involving institutions in TB endemic countries, we can select players in any given field, based on their advantages at different points of the R&D chain:

- Academic research facilities excel in basic research from which drug discovery and new targets will arise;
- Government research institutions, as funders and researchers, offer a variety of discoveries, screening programs, clinical trials, etc.;
- Pharmaceutical and biotechnology companies can provide access to compound libraries, lend expertise in drug development and become co-development partners;
- Other commercial organisations provide support for novel chemistries, formulation, manufacturing, clinical research and trials; and
- Clinical networks and national TB programs are critical collaborators for scientific and clinical infrastructure.

By outsourcing deals with contractors and partners that establish clear, pre-defined milestones, specific evaluation criteria and go/no-go decision points, we maintain our laser-sharp focus on registering a new, affordable anti-TB drug by 2010.

WIN-WIN AGREEMENTS

The TB Alliance pursues intellectual property rights (IPR) to ensure the availability of novel technologies for public benefit. This approach allows us, at each stage of negotiations, to balance affordability and health equity with effective incentives for collaboration and win-win agreements.

We negotiate terms and conditions based on a variety of factors, including the public health impact of the technology, level of investment, stage of scientific and clinical development, pipeline requirements, timing and other business, economic and public health considerations.

A good illustration of this creative approach is our exclusive worldwide license to PA-824 and related compounds. In addition to other provisions, Chiron Corporation and the TB Alliance agreed that no royalties will be due for drugs marketed in less developed economies, including impoverished countries with a high burden of tuberculosis.

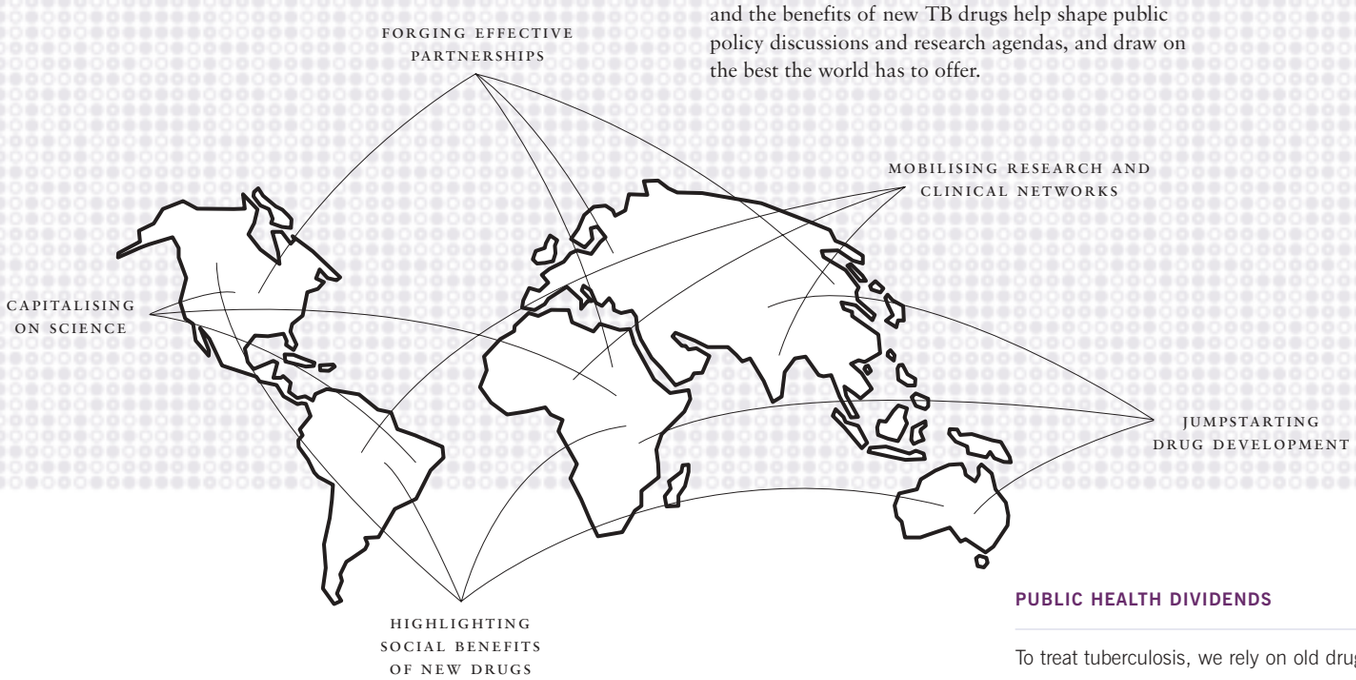
MOBILISING RESEARCHERS WORLDWIDE

The TB Alliance generates cross-pollination of scientific knowledge by working with national, regional and international R&D networks of researchers and scientists. Initial networks were formed in Brazil, France and Belgium, in addition to the Coalition of TB Research and Development Stakeholders from High-Burden Countries (The Coalition). The coordinating office of The Coalition is hosted in our Cape Town offices at the Medical Research Council facilities.

IT'S TIME FOR

A HEALTHIER WORLD.

figure {E} CATALYST FOR CHANGE — As a global organisation, we reach out to every continent to educate, inform and mobilise, so that the urgency of TB control and the benefits of new TB drugs help shape public policy discussions and research agendas, and draw on the best the world has to offer.



WE NOW HAVE THE MEANS AND THE RESPONSIBILITY TO DEVELOP A FASTER CURE. BY WORKING WITH OTHER STOP TB PARTNERS, THE TB ALLIANCE CAN HELP TURN THE TIDE ON THE BIGGEST COMEBACK INFECTIOUS DISEASE IN HISTORY.

PUBLIC HEALTH DIVIDENDS

To treat tuberculosis, we rely on old drugs with a lengthy regimen. This dependency is resulting in much greater costs in public health and economic well-being than the investment required to deliver a better cure.

To improve adherence to the lengthy regimen imposed by existing TB medicines, a practice was instituted a decade ago whereby healthcare workers directly observe patients taking their medications. This is part of the Directly Observed Treatment Short course (DOTS) strategy promoted by the World Health Organization.

DOTS is extremely effective, but it only reaches 27 percent of the world's TB patients. TB remains the number two infectious cause of adult mortality in the world after AIDS; and a third of AIDS patients die of TB.

Much of the problem rests with today's six to nine month regimen. The length of regimen handicaps TB control programs — particularly in the poorer, endemic countries — fuels resistance, and impedes effective prevention. More people continue to be infected and incidence rates are increasing.

The promise of TB control efforts will only be fully met when healthcare workers are given the best tools that modern science can deliver. A shorter TB drug regimen will radically improve treatment and compliance, accelerate the reach of DOTS and allow more patients to be treated cost-effectively. Cost-savings may be redirected to detection and treatment of patients, thus accelerating the control of the epidemic.

STEMMING THE RISE OF DEADLY RESISTANT STRAINS

Adding to the TB conundrum is the rising tide of MDR-TB, caused by poor compliance to lengthy therapies and lack of access to proper treatment. Incomplete therapy can lead to resistance to existing drugs. Some estimate MDR-TB's global spread at 400,000 cases a year, and note it is as likely to break out in London as it is in Lima.

The costs of curing MDR-TB are staggering, entailing up to 2 years of treatment with other, so-called "second-line" drugs that are often toxic and ineffective. Many MDR-TB cases defy a cure. A new drug with demonstrated activity against MDR strains is desperately needed.

TACKLING THE HIDDEN THREAT: LATENT TB

The latent form of *M. tuberculosis* presents further hurdles to better TB control since its undetected presence accounts for high disease incidence. Latent TB can trigger active disease transmission at any time, particularly in those with weaker or compromised immune systems — children, the elderly and people with HIV.

Not surprisingly, tuberculosis is now the biggest AIDS-related killer in the world. Indeed, no two diseases are so closely interconnected, taking an enormous collective toll on individuals and their families. HIV patients are at least 30 to 50 times more likely to convert latent TB into the active, transmissible form. In turn, TB speeds up the progression of the AIDS virus. A faster TB medicine would defuse much of the impact of the dual infection.

SOCIO-ECONOMIC BENEFITS

TB is more than a disease — it is also a marker of poverty and threatens economic development. New medicines give us a chance to slow down this vicious cycle. When a TB patient ceases work because of a lengthy treatment, families absorb myriad costs and, if the patient dies, can lose up to 15 years of income. Children often stop attending school to tend an afflicted parent and may never return — in India alone that number exceeds 300,000.

Healthcare savings from a shorter TB treatment will have a direct impact on whole economies, especially in nations that carry the brunt of the TB burden. Shorter treatments could save up to 65 percent of the cost of curing a case of tuberculosis. Since a majority of the costs for TB treatment are non-drug related, a shorter therapy would eliminate many such costs and redirect spending to basic health expenses.

Giving ourselves the proper means to fight tuberculosis must be more than an aspiration; it is a global imperative. Making TB a problem of the past is long overdue — and we can do something about it now.

WE’RE DOING SOMETHING ABOUT IT.

Dear Friends and Stakeholders,

We find ourselves at a unique time in history when scientific advances, unmet medical needs, and support from public and private sectors have converged. This unusual nexus of forces created a novel engine for tuberculosis drug development, the Global Alliance for TB Drug Development (TB Alliance). It is the irrefutable need for new and affordable medicines that drives this public-private partnership resolutely forward.

We are pleased to share with you the first report on the activities of the TB Alliance.

TB ALLIANCE MILESTONES

OCT 2000
TB Alliance launched

NOV 2000
Call for proposals issued

Search of industry compound libraries initiated

DEC 2000
Inventory of 35 existing compounds with TDR

JAN 2001
21 of 103 proposals from RFP selected for review

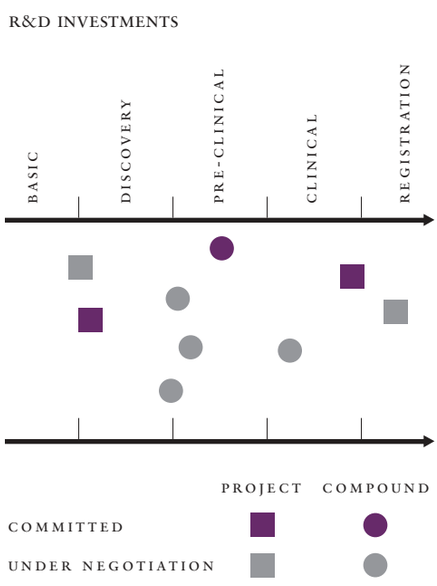


figure {F} Last year, the TB Alliance evaluated in-depth some 30 projects and potential compounds to help build a robust portfolio and ensure a vital R&D environment. Of those, agreements were concluded for the in-licensing of one compound at the pre-clinical stage, and for projects to support animal model research and clinical trials capacity in high endemic countries. These, plus other compounds and projects currently under review or negotiation, promise a rich and diverse portfolio.

This document highlights the key milestones and achievements of this new organisation in setting and implementing the strategy to attain an ambitious yet critical goal — the delivery of a faster-acting, affordable tuberculosis medicine by 2010. With the invaluable support from the Board of Directors, Scientific Advisory Committee and Stakeholders, the TB Alliance has articulated a clear vision, outlined a workable plan and built a solid foundation in a short period of time.

The major scientific and R&D milestones described in this report constitute the cornerstone and early validation of our business model at work. Over the past 18 months, we have carried out an in-depth analysis of the R&D environment and strategy tailored to TB drug development in the *Scientific Blueprint for TB Drug Development*, analysed the TB drug market in the *Economics of TB Drug Development*, and invested in drug candidates and infrastructure projects, thereby cementing our strategy. These and future investments bode well for a rich, diverse portfolio.

Maintaining a crisp pace of drug development goes hand-in-hand with thoughtful policy decisions that frame our public health mission. We have articulated clear policies — including one that outlines how intellectual property strategies can balance incentives and health equity. We also have helped shape policy discussions as they unfold worldwide. Our first portfolio acquisition, PA-824, contributed to an emerging global dialogue about access and intellectual property rights, and is proof of evolving approaches to the bottom line. The provisions in that agreement represent our views of intellectual property as a strategic tool to facilitate and ensure the availability of novel technologies for public benefit.

The Stakeholders of the TB Alliance inform, guide and shape our mobilisation efforts. From patient groups to multilaterals, from TB scientists to development agencies, our global base of Stakeholders represents the diverse constituencies and reinforces the strong mandate of the TB Alliance. It is due to each member's institutional strengths and histories that we make decisions in the context of an informed, stimulated and newly mobilised community of public health experts, scientists and drug researchers worldwide. Their involvement is essential to our efforts to educate opinion makers around the world on the threat of tuberculosis, the imperative of new drugs and the promise of public-private partnerships in accelerating R&D for global health. In the years to come, our Stakeholders will also be instrumental to our efforts as we work with others to ensure broad access to the medicines we produce.

Further, a solid infrastructure ensures that programmatic and policy activities thrive. In addition to putting effective administrative and communications structures in place, we have assembled a core team of diverse, talented and motivated individuals. With recruiting efforts for remaining functions in full swing, we are poised for efficient and integrated operations in the New York, Brussels and Cape Town offices. While ensuring our global outlook, this operational network will be managed to promote creative thinking, synergies and savings.

The TB Alliance's early successes could not have occurred without the generosity of our founding donors, principally the Bill and Melinda Gates and Rockefeller Foundations, and the steadfast support of institutions such as the Stop TB Partnership, the U.S. National Institutes of Health, and the Special Programme for Research and Training in Tropical Diseases (TDR). Furthermore, our progress is the direct result of the devoted efforts of many individuals all over the world who have given generously of their time and

FEB 2001 First R&D Coalition meeting, Cape Town, South Africa

MAR 2001 Creation of R&D networks in Belgium & France

APR 2001 Workshop on fluoroquinolones

Scientific Blueprint published

MAY 2001 Asian Conference of TB R&D Coalition

JUNE 2001 Board approves 11 projects for investment

STREAMLINING THE R&D TIMELINE

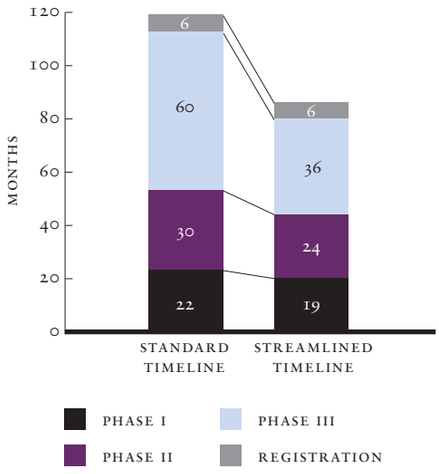


figure {G} The *Scientific Blueprint* established a streamlined timeline from Phase I trials to regulatory approval that significantly reduces the time typically required — a process that can take up to 10 years. The streamlined timeline is reached by obtaining regulatory fast-track status, conducting clinical trials where the necessary volume of patients already resides, and using an efficient and proactive management process.

expertise. We are most grateful to all of them. We have been fortunate to count on Dr. Carlos Morel, who not only shepherded the TB Alliance during its formative months as chairman of the Board, but also oversaw the successful negotiations for the first portfolio acquisition, PA-824. We owe a debt of gratitude to Dr. Richard O'Brien, whose skillful and thoughtful stewardship of the Scientific Advisory Committee provides us with a solid TB drug development programme that addresses the public health need, and Dr. James Orbinski for his leadership of the Stakeholders Association during a critical time of our development. And, this report would be incomplete if we did not recognize the efforts of our staff and consultants, and in particular the expertise and dedication of Dr. Giorgio Roscigno, without whom the TB Alliance would not be where it is today.

Looking ahead, the success of our mission will depend on the commitment — financial and otherwise — of governments around the world: they provide funding and critical in-kind support. Through international organisations, such as the World Health Organization and the Global Fund for AIDS, TB and Malaria, the public sector also holds the key to our ultimate goal — access to public health systems that will guarantee swift and equitable patient treatment. We are encouraged that the European Parliament, the U.S. Congress and several governments are stepping up their commitment to fight TB and have pledged publicly to express their support of the TB Alliance. Of equal significance, we were pleased to establish the groundwork for productive partnerships with representatives of countries with high TB incidence, such as Brazil, South Africa and India. We look forward to cementing these and other relationships as these countries implement their commitment to stop TB.

The TB Alliance values the know-how and expertise of the private sector in the area of drug development. We are encouraged that industry is increasingly open to creative approaches that serve our public mission. The involvement of companies worldwide, large and small, that support our efforts is built into the unique design of the TB Alliance business model. While aware of the real complexities of drug development, we plan on leveraging the full range of opportunities of this modest-sized market through partnerships. So, by sharing technical knowledge, inventions and development experience, the private sector is helping us achieve success.

In the coming year, we will continue the fast-paced growth as we are galvanized into action by the stark urgency of the TB epidemic, the promise of science and the commitment of all of those who, like us, believe that we can and will achieve an ambitious goal. We will maintain our focused approach to programmatic investments, seek novel compounds for the pipeline, and enlist the widest circle of allies to accelerate TB R&D activities, as we give testimony to our global commitment with strategic investments and activities around the world.

We are proud of the progress we have made in a relatively short time, and we are excited about the future. We invite you to participate in this unique and important enterprise, confident that together we can profoundly improve the lives of millions worldwide.

Maria C. Freire
CHIEF EXECUTIVE OFFICER

Seán P. Lance
CHAIRMAN OF THE BOARD

SEPT 2001
Dr. Maria C. Freire appointed as CEO

NOV 2001
Release of *Economics of TB Drug Development*

TB Alliance meeting on surrogate markers

JAN 2002
Landmark deal for PA-824 signed with Chiron

TB conference co-hosted with AstraZeneca Foundation in India

MAR 2002
Seán Lance succeeds Dr. Carlos Morel as Chairman of the Board

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors of
The Global Alliance for TB Drug Development, Inc.:

In our opinion, the accompanying balance sheet and the related statement of activities and cash flows present fairly, in all material respects, the financial position of The Global Alliance for TB Drug Development, Inc. (the "Alliance") at December 31, 2001 and 2000, and the changes in net assets and cash flows for the year ended December 31, 2001 and for the period July 24, 2000, formation of the Alliance, to December 31, 2000, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Alliance's management; our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

June 14, 2002
Melville, NY 11747

BALANCE SHEETS

December 31, 2001 and 2000

	2001	2000
ASSETS		
Cash and cash equivalents	$ 17,031,287	$ 3,769,362
Restricted cash	119,888	—
Investments, at market value	—	8,609,280
Property and equipment, net	208,260	60,818
Other assets	147,712	3,100
Total assets	**$ 17,507,147**	**$ 12,442,560**
LIABILITIES AND NET ASSETS		
LIABILITIES		
Accounts payable and accrued expenses	$ 320,801	$ 318,031
Obligation under capital lease	112,074	—
Advance support	1,875,000	2,250,000
Total liabilities	**2,307,875**	**2,568,031**
NET ASSETS		
Unrestricted	15,199,272	9,874,529
Total net assets	**15,199,272**	**9,874,529**
Total liabilities and net assets	**$ 17,507,147**	**$ 12,442,560**

 THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS.

STATEMENT OF ACTIVITIES

For the year ended December 31, 2001 and for the period
July 24, 2000, formation of the Alliance, to December 31, 2000

	Unrestricted	
	2001	2000
Support and other revenue:		
Contributions	$ 7,000,000	$ 10,150,000
Contributed consulting services	598,738	130,000
Investment income	473,935	105,692
Total revenue	**8,072,673**	**10,385,692**
Expenses:		
Program services		
Advocacy	727,066	11,168
Research and development	1,012,526	33,503
Business and organisational development	53,616	67,007
Total program services	**1,793,208**	**111,678**
Management and general	880,309	399,485
Fund raising expenses	74,413	—
Total expenses	**2,747,930**	**511,163**
Change in net assets	**5,324,743**	**9,874,529**
Net assets, beginning of year	9,874,529	—
Net assets, end of year	$ 15,199,272	$ 9,874,529

STATEMENTS OF CASH FLOWS

For the year ended December 31, 2001 and for the period
July 24, 2000, formation of the Alliance, to December 31, 2000

	2001	2000
Cash flows from operating activities:		
Change in net assets	$ 5,324,743	$ 9,874,529
Adjustments to reconcile change in net assets to net cash provided by operating activities:		
Net realized gain on sale of investments	(306,240)	(70,276)
Change in unrealized appreciation of investments	9,456	(9,456)
Depreciation expense	34,553	—
Changes in assets and liabilities:		
Increase in restricted cash	(119,888)	—
Increase in other assets	(144,612)	(63,918)
Increase in accounts payable and accrued expenses	2,770	318,031
(Decrease) increase in advance support	(375,000)	2,250,000
Net cash provided by operating activities	**4,425,782**	**12,298,910**
Cash flows from investing activities:		
Purchase of investments	(10,250,072)	(24,654,548)
Proceeds from sales and maturities of investments	19,156,136	16,125,000
Purchase of property and equipment	(58,998)	—
Net cash provided by (used in) investing activities	**8,847,066**	**(8,529,548)**
Cash flows from financing activities:		
Repayment of capital lease obligation	(10,923)	—
Net cash used in financing activities	**(10,923)**	—
Net increase in cash and cash equivalents	13,261,925	3,769,362
Cash and cash equivalents, beginning of period	3,769,362	—
Cash and cash equivalents, end of year	$ 17,031,287	$ 3,769,362
Supplemental disclosure of cash flow information and noncash investing and financing activities:		
Interest paid	$ 6,407	$ —
Noncash items:		
Acquisition of equipment through capital lease obligations	$ 122,997	$ —

1. ORGANIZATION

The Global Alliance for TB Drug Development, Inc. (the "TB Alliance") is a non-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, Cape Town and New York.

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation
The TB Alliance's financial statements have been prepared on the accrual basis of accounting. Resources are reported for accounting purposes into separate classes of net assets based on the existence or absence of donor-imposed restrictions. In the accompanying financial statements net assets that have similar characteristics have been combined into similar categories as follows:

Unrestricted – Net assets that are not subject to donor imposed stipulations and for which the TB Alliance has full discretion as to use. Unrestricted net assets can be utilized to carry out any of the purposes of the TB Alliance.

Cash and Cash Equivalents
Cash and cash equivalents consist of cash and short term investments purchased with original maturities of three months or less. Cash balances are maintained in operating accounts, money market accounts and Certificate of Deposit accounts at a major money center institution, which at times may exceed federally insured limits.

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

Property and Equipment
Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the lesser of the estimated useful lives of the related assets, generally ranging from three to five years, or the shorter lease term if applicable.

Investments
Investments are carried at fair value. All changes in fair value are reflected in the statement of activities.

Income Taxes
The IRS has determined the TB Alliance is exempt from Federal income taxes under section 501(a) of the Internal Revenue Code (the "Code") as an organisation described in section 501(c)(3).

The IRS has made a determination that the TB Alliance can be treated as a publicly supported organisation described in code sections 509(a)(1), and 170 (b)(1)(a)(vi) during an advance ruling period beginning on July 24, 2000 and ending December 31, 2004. After the advance ruling period the IRS will make a final determination of the TB Alliance's public charity status.

Use of Estimates
The preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of revenues and expenses during the reporting period. Significant estimates relate to fixed assets. Actual results could differ from these estimates.

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 No. 116 "Accounting for Contributions Received or Contributions Made."

Program Services

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

Research and Development
The Global Alliance for TB Drug Development 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 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.

Business and Organizational Development
The Global Alliance for TB Drug Development negotiates, implements and manages agreements with public and private organisations worldwide and does so by adhering to sound business practices while ensuring the public good. Specifically, the 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.

Reclassifications
Certain prior year amounts were reclassified to conform to the current year presentation.

3. IN KIND SERVICES

Included in the TB Alliance's statement of activities is approximately $600,000 and $130,000 for the years ended December 31, 2001 and 2000, respectively, of in-kind contributions.

The amounts recognized during the year ended December 31, 2001 were related to the TB Alliance's research, development, publication and distribution of a scientific study, the *Scientific Blueprint for TB Drug Developmen*t and a market research and costs study titled *Economics of TB Drug Development*. The amounts recognized in 2000 were consulting services for the initial organisation of the TB Alliance.

4. INVESTMENTS AND INVESTMENT INCOME

In July 2001 the TB Alliance sold all its positions in fixed income securities.

The market value and cost of investments at December 31, 2000 are as follows:

	Market Value	Cost
Fixed income security	$ 8,609,280	$ 8,599,824

Investment income consists of the following for the years ended December 31, 2001 and 2000:

Years ended December 31,	2001	2000
Interest income	$ 177,151	$ 25,960
Realized gain on investments, net	306,240	70,276
Change in unrealized appreciation	(9,456)	9,456
	$ 473,935	$ 105,692

 THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS.

5. PROPERTY AND EQUIPMENT

At December 31, 2001 and 2000, property and equipment was comprised of the following:

Years ended December 31,	2001	2000
Computer equipment and software	$ 98,053	$ 60,818
Furniture, fixtures and office equipment	136,060	—
Leashold improvements	8,700	—
	242,813	60,818
Less accumulated depreciation	34,553	—
Property and equipment, net	$ 208,260	$ 60,818

Included in property and equipment at December 31, 2001 and 2000 are assets, primarily furniture, office and computer equipment, held under capital lease of approximately $123,000 and $0, respectively.

Depreciation and amortization expense was approximately $35,000 and $0 in 2001 and 2000, respectively.

6. SUPPORT

On September 8, 2000, the Bill and Melinda Gates Foundation approved a five-year unrestricted grant to the TB Alliance in the amount of $25,000,000 for use in furtherance of its overall charitable purpose and mission to improve the supply of antituberculosis drugs for national tuberculosis control efforts and to develop a collaboration for tuberculosis drug development. The Statement of Activities includes $5,000,000 and $10,000,000 as unrestricted contributions for years ended December 31, 2001 and 2000, respectively, for funds received. The remaining $10,000,000 is a conditional grant expected to be paid to the TB Alliance in two future annual payments of $5,000,000 upon the achievement of certain milestones.

On October 23, 2000, the Bristol-Myers Squibb Foundation, Inc. contributed a general support grant of $150,000 which is included in the Statement of Activities as unrestricted contributions for the year ended December 31, 2000.

On December 22, 2000, the Rockefeller Foundation approved a general support grant to the TB Alliance of up to $4,500,000 for 2001, for which an extension was granted in November 2001 to extend the period of availability to December 31, 2002 with any unused grant funds reverting back to the Foundation. As of December 31, 2001, the Rockefeller Foundation had advanced the TB Alliance the sum of $3,875,000 of the $4,500,000. The Alliance anticipates expending the entire grant by December 31, 2002.

On November 30, 2001, the Rockefeller Foundation announced a second general support grant in 2002 to the TB Alliance for up to $3,500,000 for the one-year period beginning August 1, 2002 with any unused funds reverting back to the Foundation at the end of the grant period. Payment is scheduled for 2002.

7. COMMITMENTS & CONTINGENCIES

The TB Alliance has operating lease agreements for office space in New York, Brussels and Cape Town for various terms expiring in November, 2009. The future remaining cash payments under these agreements are as follows:

Year ending December 31,	
2002	$ 347,258
2003	350,629
2004	340,404
2005	339,372
2006	212,108
Thereafter	108,313
	$ 1,698,084

Total rent expense amounted to approximately $174,000 and $8,000 for the years ended December 31, 2001 and 2000.

In June 2001, the TB Alliance entered into a five-year non-cancelable capital lease for certain property and equipment. The future minimum lease payments for the capital lease obligation are as follows:

Year ending December 31,	
2002	$ 29,695
2003	29,695
2004	29,695
2005	29,695
2006	18,447
Total minimum lease payments	137,227
Less: Amount representing interest at an average rate of 9%	25,153
Present value of minimum lease payments	$ 112,074

During 2001, the TB Alliance finalized research and development commitments resulting in an additional program expense of $100,000 included in accounts payable and accrued expenses as of December 31, 2001. In addition, the TB Alliance is committed for aggregate payments associated with research and development of $1,400,000 over the next four years.

8. RELATED PARTIES

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

STAKEHOLDERS

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

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

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The Bill and Melinda Gates Foundation

The Rockefeller Foundation

The Netherlands Ministry for Development and Cooperation

The Stop TB Partnership

The Special Programme for Research and Training in Tropical Diseases (TDR)

The United States Centers for Disease Control and Prevention (CDC)

The United States National Institute of Allergy and Infectious Diseases (NIAID)

The Research Triangle Institute (RTI)

The Bristol Myers Squibb Foundation

The Medical Research Council of South Africa

The Global Alliance for TB Drug Development also recognises gifts from the following:

Janice M Hughes, Donald Morrow, Judith Egner, and donations in Memory of Dorothy Hughes Snyder

The following lent invaluable intellectual support and commitment of time:

Dr. Barbara Laughon, Dr. Carlos Morel, Dr. Richard O'Brien, Dr. James Orbinski, Dr. Ariel Pablos-Mendez, Ms. Nancy Pekar, Dr. Doris J. Rouse, Dr. Bernard Fourie, the Tuberculosis R&D Coalition, and the numerous contributors to the *Scientific Blueprint for TB Drug Development* and the report on the *Economics for TB Drug Development*.

The Global Alliance for TB Drug Development is a non-profit, tax-exempt organisation recognized under section 501(c)(3) of the United States Revenue Code; and contributions are tax-deductible in the United States. Its Belgium branch office was also registered in the Annex of the Belgian State Gazette for non-profit organisations on February 28, 2002.

IT'S TIME TO FIND A FASTER CURE FOR TUBERCULOSIS.

DONATE • VOLUNTEER • PARTICIPATE

Join this novel partnership where the talents of every individual, organisation and nation will help make tuberculosis a thing of the past.

VISIT WWW.TBALLIANCE.ORG TO LEARN MORE.

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