AERAS[SM]

GLOBAL TB VACCINE FOUNDATION

2004 ANNUAL REPORT NEW TB VACCINES FOR THE WORLD

The Aeras Global TB Vaccine Foundation is dedicated to developing new tuberculosis vaccines and ensuring their availability to all who need them.

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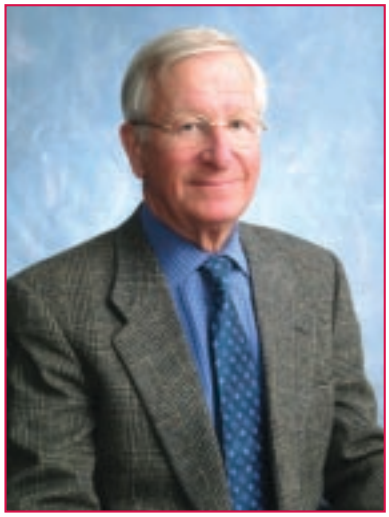
A WORLD FREE OF TUBERCULOSIS

It's an old scourge — dating from before recorded history — but a deadly one too. One-third of the world's population — 2 billion people — carry the TB bacterium. It is the leading cause of death in HIV-infected people; and 36 million people will die of the disease over the next 20 years, unless it is controlled.



These are unacceptable numbers. They are also the reason why Aeras Global TB Vaccine Foundation exists. We are the world's only nonprofit organization that works with scientists, industry, and governments in the United States, Europe, and the developing world to develop new, more effective TB vaccines and bring them to people around the world.

Helping Aeras is a dedicated Board of Directors committed to an operating model of vaccine development emphasizing accountability and transparency. My heartfelt thanks for dedicated service go to Richard Chaisson, who leaves the Board after serving since 2000. I also extend a warm welcome to Douglas Young who has just joined. Much appreciated for their assistance are the members of the technical advisory panels, listed on page 12, whose considerable expertise bolsters our scientific efforts. We are fortunate also in our knowledgeable and expert staff, which has grown remarkably fast — from 18 at the beginning of 2004 to 60 today.

Supporting our work is a most generous grant in the amount of $82.9 million from the Bill & Melinda Gates Foundation — the largest grant ever to support TB vaccine development. In 2004 Aeras also received a cooperative agreement from the U.S. Centers for Disease Control and Prevention to conduct epidemiologic studies in preparation for clinical trials of new TB vaccines in India, as more fully described later in this report.

Altogether, these impressive numbers — both in terms of funding and expertise — constitute a formidable arsenal of weapons that we are using to wage war on a modern scourge with ancient roots.

R. Gordon Douglas, Jr., MD
Chairman


CAUTION

IN THE BUSINESS OF SAVING LIVES

I come from the business world, and yet I run a nonprofit organization dedicated to making an effective TB vaccine accessible in every corner of the world. The two are not incompatible.

In the business world, the focus on product and profits can limit altruistic pursuits, while in the nonprofit world, the focus on altruistic pursuits can limit efficiency. At Aeras, we like to think we have married the best of these two worlds, using an industrial business model for a humanitarian purpose: to develop new TB vaccines as rapidly as possible and make them available to the world.

Although Aeras is a foundation in name, we are not a traditional grant-maker. We work with developers that have promising vaccine candidates, and we develop candidates ourselves in our laboratory. Time, risk, and resources are at the forefront of how we make decisions. From a scientific and technical viewpoint, the time is right to develop new TB vaccines. But with someone dying of TB every 15 seconds, we cannot afford to take a conservative approach.

Fortunately, the grant from the Bill & Melinda Gates Foundation, described more fully on page 4, has provided us with the resources to take the risks we must take if we are to achieve our mission — to develop better TB vaccines and make them available worldwide as quickly as possible.

Our work draws on 20 years of basic research in antigen identification and testing. That has helped narrow the choices for an improved vaccine to a "prime-boost" regimen that looks promising for prevention of TB: a prime injection at birth with the BCG (Bacille Calmette-Guérin) vaccine or a recombinant BCG or a live TB variant, followed by a boost at 10 or 14 weeks of age with a recombinant protein in adjuvant or a viral-vectored vaccine.

In our first full year of operation, we've done more than bench research and animal testing of candidate vaccines. We've conducted clinical studies in the United States and South Africa and begun developing a new site for clinical studies in India, as explained in greater detail on page 8. All of that takes expertise, which is the primary reason why Aeras has grown from a staff of 18 to 60 in just a year. We now have the kind of expertise at every level that could rival any private-sector biotechnology company.

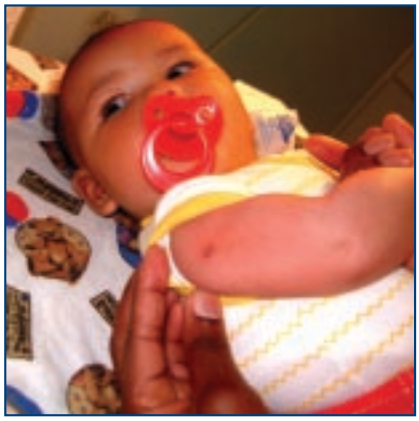
Our advances in research and clinical studies have occurred at the same time that we've been hiring new staff and developing our laboratory facilities, prompting some to liken our situation to "sailing the ship while building it." But that's just the way we want it.

A big pharmaceutical company that loses a year in meeting its production schedule risks losing sales. For a nonprofit like Aeras, if we don't push forward as hard and as fast as we are capable of doing, countless lives will be lost. With the backing of a generous donor and the commitment and expertise of our Board and staff, we will ultimately meet our bottom line: reduction in the global burden of TB and millions of lives saved.

Jerald C. Sadoff, MD, President and Chief Executive Officer

2004 IN REVIEW

SUPPORTING DEVELOPMENT OF NEW TB VACCINES



Two billion people—one out of every three people on Earth—are infected with the tuberculosis pathogen. TB is the leading killer of people infected with HIV. TB disease, fueled by the HIV/AIDS epidemic, is increasing in the developing world, and 36 million people could die of TB over the next 20 years unless the pandemic is brought under control. Fortunately, the Bill & Melinda Gates Foundation has decided to fight these grim numbers with more positive ones.

In February 2004, the Foundation made the largest grant ever to support TB vaccine development when it provided $82.9 million over five years to Aeras for development, regulatory approval, and manufacturing of one or more new TB vaccines.

The existing TB vaccine, Bacille Calmette-Guérin — or BCG — has been in use since the early 1900s. Administered to millions of newborns around the world (although not in the United States), BCG appears to reduce the risk of serious childhood forms of tuberculosis. However, the high incidence of TB in those developing countries where BCG immunization is widely practiced indicates that it is not effective over the many years that people are at risk.

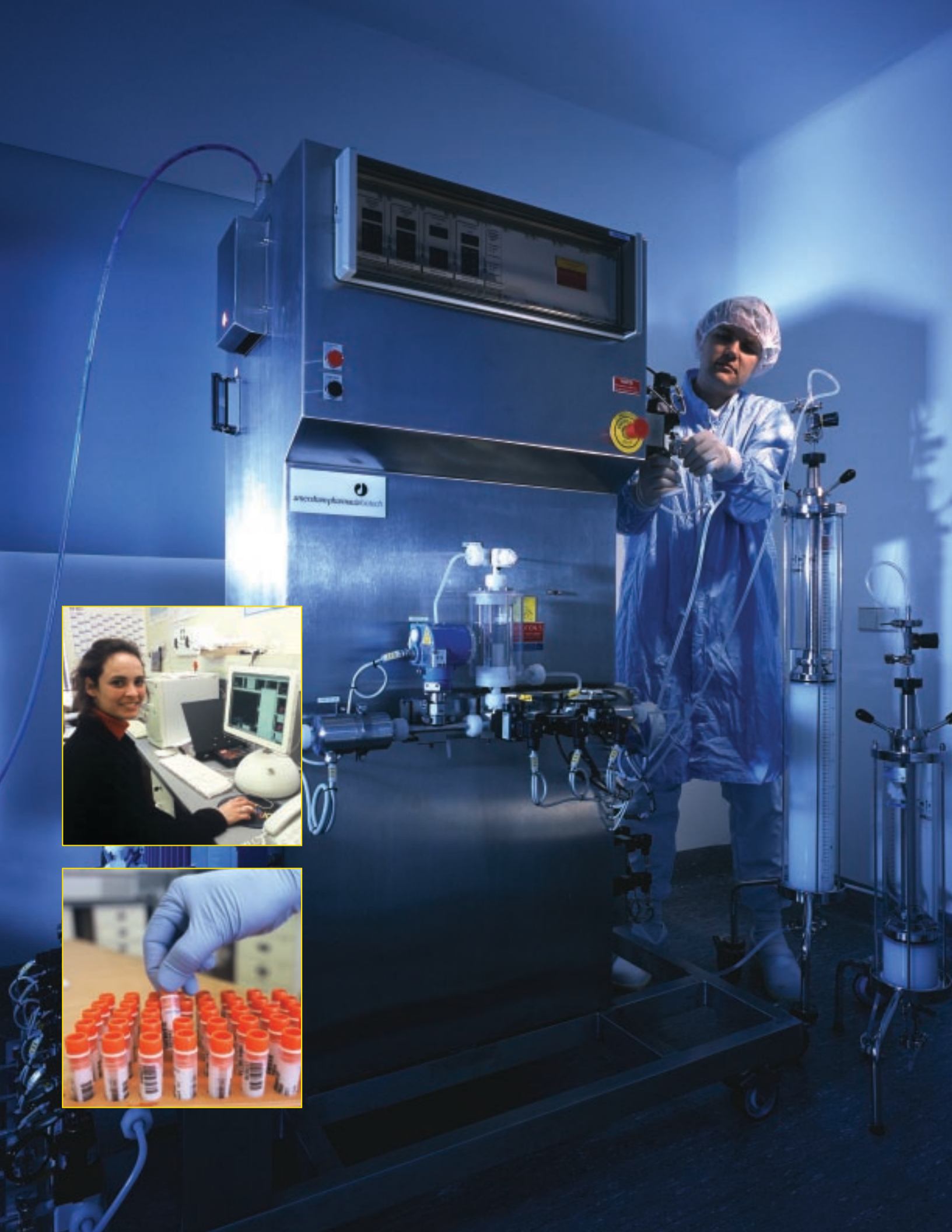
To help Aeras meet its goal of delivering a more effective vaccine within 10 years, the Gates Foundation grant is supporting work in three major areas:

VACCINE TRIALS: Clinical trials of prime-boost regimens that use promising TB candidate vaccines. Leading candidates include recombinant BCG strains being prepared in the Aeras laboratories, recombinant TB antigen fusion-protein formulations, and recombinant viral vector-based vaccines.

IMPROVED ANIMAL MODELS: Studies of the ability of animal models to predict vaccine effectiveness in humans. Finding such predictive models will greatly accelerate future TB vaccine research.

NEXT-GENERATION VACCINES: Early research on the next generation of TB vaccines. Researchers will construct and evaluate several new vaccine candidates and prepare the most promising ones for human trials.

"Through accelerated research and development, a new vaccine could permanently change the trajectory of the epidemic and save millions of lives every year," said Dr. Richard Klausner, executive director of the Gates Foundation's Global Health Program, in announcing the grant to Aeras. The Gates grant to Aeras will more than double the amount spent annually on TB vaccine development worldwide.



STAFFING UP FOR THE CHALLENGE

In February 2004, Aeras moved to new headquarters in Bethesda, Maryland, and picked a location in nearby Rockville where a new laboratory and manufacturing facility is now under construction and slated for completion in 2005.

Meeting the challenge of developing new TB vaccines also required ramping up staff expertise in numerous areas — vaccine construction, manufacturing, regulatory compliance, development of assays and analyses, preclinical work with animals, clinical testing, ethics and legal rights, and other areas. In less than a year, Aeras has increased its staff from 18 to 60.

By actively pursuing collaborations with researchers around the world, the foundation intends to bring forward 20 years' worth of TB vaccine research and apply that body of knowledge to developing and manufacturing new, more effective vaccines. At the close of the year, Aeras had begun working collaboratively with UCLA, Crucell NV, and the Statens Serum Institut, and was actively pursuing collaborations with a number of other researchers and organizations.

PHASE I VACCINE TRIAL

In February, Aeras and the David Geffen School of Medicine at UCLA began the first clinical trial of a live recombinant TB vaccine in the United States. Volunteers were inoculated with the new vaccine, known as rBCG30, at the Center for Vaccine Development at St. Louis University in Missouri, and at Piedmont Medical Research Associates in Winston-Salem, North Carolina.

Altogether, the clinical trial enrolled 35 healthy adults to test the safety of the vaccine and the immune response that it provokes. Preliminary results from the trial indicate that the vaccine candidate did not result in any serious adverse events and was well tolerated by the volunteers.

STUDIES IN SOUTH AFRICA

In 2001, in partnership with South African investigators at the University of Cape Town, Aeras launched a randomized, controlled trial of two different routes of administering the existing BCG vaccine to infants. The trial study area was in the Boland-Overberg region of Western Cape Province. Enrollment of nearly 12,000 infants in the trial was completed in July 2004, and follow-up will continue for approximately 2 more years.

In the same region, Aeras also sponsored a survey of the prevalence of TB infection in adults. Conducted by the University of Cape Town, this study enrolled and tested 367 volunteers to determine the incidence of TB infection using the tuberculin skin test and the new QuantiFERON® test. The study was designed to provide information for Phase I studies of new candidate vaccines in this population.

Longitudinal infant and adolescent cohort studies were also designed and are slated to be implemented in 2005. Conducting these studies will generate the estimated sample size numbers for projected Phase III field trials.

NEW FIELD SITE IN INDIA

Early in 2004, Aeras defined requirements for a new clinical trials site in India, and by June a site in southern Andhra Pradesh had been selected. The collaborating institution is St. John's National Academy of Health in Bangalore. Planning for laboratory and other infrastructure improvements took place toward the end of 2004 to prepare for epidemiological studies in the site area that will launch in 2005.

In September 2004, Aeras received a three-year cooperative agreement from the U.S. Centers for Disease Control and Prevention to develop the Andhra Pradesh site. The cooperative agreement marks the first government contribution to Aeras, and will help create a professional development program for project staff in India, develop laboratory capacity for TB diagnosis and referral systems for patients, and study TB incidence among infants and teenagers in the study area.

PRODUCT DEVELOPMENT COLLABORATIONS

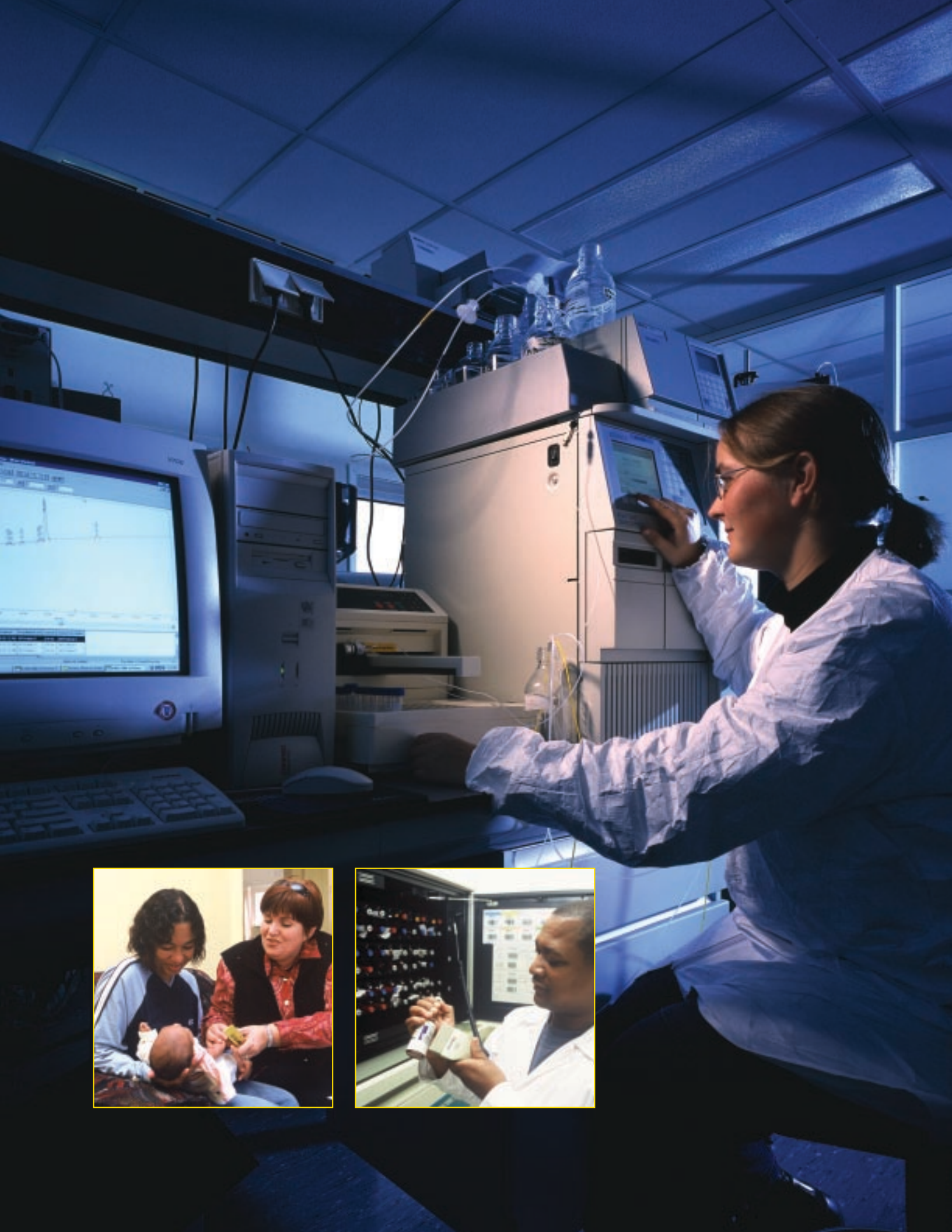
In March, Aeras and Crucell NV, Leiden, The Netherlands, announced that the two organizations would be collaborating on the pre-clinical and clinical development of candidate TB vaccines. Crucell is a leader in the development of adeno-vectored vaccines. The Aeras-Crucell program focuses on construction and testing of Adeno35 vectored vaccines as boosters to an improved BCG vaccine using Crucell's proprietary PER.C6™ and AdVac™ technologies. By the end of the year, a lead candidate vaccine had been developed and tested in animals and was ready for production of clinical lots.

Aeras also began working with the Statens Serum Institut (SSI), Copenhagen, Denmark, which has an outstanding record of TB antigen discovery and early vaccine evaluation work. Aeras and SSI initiated collaborative preclinical studies of promising SSI recombinant hybrid protein and adjuvant combinations for boosting BCG. The goal of the Aeras-SSI partnership is to bring the most promising SSI TB vaccine candidate through preclinical and process development stages to initial clinical evaluation.

SHARING RESEARCH MATERIALS

During 2004, Aeras scientists supported preparation of standardized BCG positive control and Mtb challenge stocks for animal immunogenicity and challenge studies. These stocks, which are infectious materials for use in animal studies, were made available for distribution by the U.S. Food and Drug Administration and the World Health Organization. Characterization and use of these reagents are currently in progress in multiple laboratories around the world.

Going forward, Aeras plans to share data, reagents, protocols, and other information that can help researchers accelerate their work to develop and test new TB vaccines.



FINANCIAL OVERVIEW

FUNDING. In 2004, Aeras Global TB Vaccine Foundation's revenues totaled $27.8 million, with more than 95 percent of the support coming from the Bill & Melinda Gates Foundation, which awarded Aeras a five-year grant of $82.9 million in February 2004. Two grants from the National Institutes of Health and a new cooperative agreement with the Centers for Disease Control and Prevention awarded in September 2004 provided the majority of the remaining support, with the balance coming from interest income.

PROGRAMS. Aeras Global TB Vaccine Foundation's programs in 2004 were primarily focused on initiating efforts to develop new vaccines against tuberculosis. Program expenses totaled $8.3 million, with $7.2 million (86 percent) devoted to TB vaccine research and development, including preclinical and clinical development of candidate vaccines, establishment of field sites for vaccine trials, epidemiology studies, and staff expansion and infrastructure development at Aeras headquarters. The remaining expenses supported other vaccine research initiatives.

SUPPORTING SERVICES. General and administrative expenses, which support Aeras's mission, totaled approximately 30 percent of expenses for the year.

Aeras Board of Directors. From left to right: Vijay Samant, R. Gordon Douglas, Jr., Ann M. Ginsberg, David McMurray, Michel Greco, Douglas B. Young, Kenneth H. Silverberg, Jerald C. Sadoff.

AERAS GLOBAL TB VACCINE FOUNDATION

STATEMENT OF ACTIVITIES

FOR THE YEAR ENDED DECEMBER 31, 2004

Revenue	
Contributions from foundations	$ 26,664,075
U.S. Government grants	476,615
Interest	210,790
Other	7,623
Prior year's revenues used for 2004 activities	397,843
Total public support and revenue	**27,756,946**
Expenses	
VACCINE RESEARCH PROGRAMS	
Tuberculosis vaccine research and development	7,187,542
Other vaccine reseach activities	1,146,616
Total program expense	8,334,158
SUPPORT SERVICES	
Fund raising	272,050
Management and general	3,395,733
Total support services expense	3,667,783
Total program and support service expense	**12,001,941**
Change in net assets before other charges	15,768,450
Foreign currency translation loss	(13,445)
Prior year's revenues used for 2004 activities	(397,843)
Change in net assets	**15,357,162**
Net assets, beginning of year	397,843
Net assets, end of year	**$ 15,755,005**

Copies of Aeras Global TB Vaccine Foundation's complete audited financial statements are available upon request.

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**Scott J. Thaler was Chief Medical Officer until his death in September 2004. J. Bruce McClain assumed the position in November 2004.*

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IN MEMORIAM

Scott J. Thaler, MD (1962-2004)

On August 27, 2004, Aeras Foundation lost its chief medical officer, Scott Thaler, to melanoma. He was an attending physician at Brigham and Women's Hospital and the Dana-Farber Cancer Institute and an instructor at Harvard University. Before joining Aeras, he was a clinical researcher at Merck Research Laboratories, where he worked on vaccines for pediatric diseases and HIV. A man of few words, but great brilliance and warmth, Scott's scientific, academic, and clinical development achievements are dwarfed by the genuine affection and love for him that was held by all of those who knew him. In his honor, Aeras created the Scott J. Thaler Lecture Series. The first lecture, by Dr. Douglas Kernodle of Vanderbilt University, was held November 15, 2004.

Antonio Ruiz (1956-2005)

On February 15, 2005, Aeras lost another colleague, Antonio Ruiz, a scientist in the Immunology Group, to colon cancer. Antonio was born and raised in Puerto Rico, coming to the United States in 1982. He taught school, served at Walter Reed Army Institute of Research, received his MS degree from Johns Hopkins University, and worked as a scientist at MedImmune, Inc. and EntreMed, Inc. before joining Aeras in 2004. Antonio's integrity and dedication, optimism and humor, and insightfulness and balance inspired everyone who knew him. He was greatly loved by his colleagues and will be greatly missed.

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