Dear Colleagues: Over the past year at Aeras, thinking creatively about the science has been our primary goal as we seek to expand the global TB vaccine pipeline with a diversification of ideas and approaches necessary to advance the global effort to bring more effective vaccines to the fight against TB.

Working hand-in-hand with our research partners in 2013, we’ve incorporated lessons learned from past clinical trials to bring a more rational approach to decision-making about the pipeline of TB vaccine candidates; focused on issues ranging from antigen identification and selection; to go/no-go decisions on candidate advancement in the clinic; to experimental medicine trials; to refinements in animal models; and to the way we advocate for support to advance the pipeline.

At Aeras, we are striving to gain new scientific insights and clues in shorter timeframes that will inform us on what approaches are working and why. We are paying particular attention to using our resources appropriately and keeping the research process logical and streamlined. With better data in hand from novel animal studies and by obtaining clues from translational clinical trials, we will be more efficient and deliberate in our efforts moving forward.

To carry out studies in a faster and more economical manner, we are initiating two clinical trials with novel endpoints that require less than 1,000 subjects each. These relatively small studies will inform us as to the value of further development of the vaccine candidates studied by providing signals of clinically relevant biological activity and insights into the identification of biomarkers and potential correlates of protection.

Clearly, a vaccine that prevents not only disease but actual infection by Mycobacterium tuberculosis (Mtb) would have a major impact on the course of this global epidemic. Therefore, we are also taking a fresh look at the pipeline and BCG vaccine to assess their ability to prevent TB infection. This work is incorporated as part of an ongoing trial in South Africa, and also as a potential future study in healthcare or relief workers without a prior history of BCG vaccination.
We are moving forward with a talented array of research partners and funders, to whom we are deeply grateful. In this past year, we were fortunate to expand our collaborative efforts and join forces with researchers in Japan, Denmark, China and Canada, and at Dartmouth University. We also emphasized better communications efforts to engage new supporters and secure funding support from Australia, Japan and the UK. Aeras welcomed several leading experts to our senior leadership team and Board of Directors. Moving forward, we will continue efforts with European partners to coordinate resource mobilization and streamline joint decision-making processes on the global pipeline.

I look forward to continuing to advance tuberculosis vaccines in the coming years through novel scientific approaches and innovative partnerships. We will collectively pursue our goal to see this disease eliminated as a global threat through the ultimate protective measure of a new, effective TB vaccine. Thank you for supporting us and joining us in this mission.

Tom Evans, MD
CEO of Aeras
2013 Highlights

Tuberculosis remains a challenging evolutionary disease. As scientists, we seek to understand the most basic aspects of immunology so we can better design and advance vaccines with the highest chances of preventing infection and disease. Our data-driven portfolio management approach to TB vaccine development sets clear criteria for scientific advancement and resource allocation permitting us to gain greater understanding and apply this new knowledge to ultimately get us across the finish line.

Scientific Coordination, Evaluation and Review

To foster new ideas coming into the pipeline of candidates, Aeras experts solicit and review proposals from across the TB vaccine research field, searching for new vaccines that warrant further evaluation and support by Aeras and its partners.

- The Scientific Evaluation & Advisory Team was established in 2013 to solicit external proposals and make recommendations to our internal decision-making team, called the portfolio review committee. This team evaluates proposals for superiority to other like candidates, technical feasibility in development and scale up and expected safety.

- Over the past year, Aeras researchers also have participated in the Bill & Melinda Gates Foundation’s TB Accelerator Program, which is focused on finding and fueling promising new concepts for TB vaccines. This effort is focused on developing vaccines to prevent infection with *Mycobacterium tuberculosis* (*Mtb*), which causes TB, and developing preclinical animal models that more closely mimic the natural transmission of *Mtb*.
Pre-Clinical Approaches

At the pre-clinical stage of research, Aeras and its partners are pursuing a wide variety of new antigens, adjuvants and routes of delivery.

- One area of study is the aerosol, or inhaled, delivery of TB vaccines to enhance mucosal immunity. Aeras and GlaxoSmithKline (GSK) are collaborating on developing chimpanzee adenovirus-based TB vaccines, and are investigating aerosol delivery of these vaccines. Aeras, CREATE Vaccine Company, Ltd. and Japan’s National Institute of Biomedical Innovation (NIBIO), initiated collaboration on the development of new mucosal tuberculosis vaccines based on NIBIO’s human parainfluenza type-2 (rhPIV2) vector technology. Aeras has also supported researchers at the University of Pittsburgh and Wuhan University to conduct aerosol delivery to non-human primates that are showing promising early results. In April 2014, Aeras and NIAID convened a workshop on aerosol vaccines for TB, drawing expertise from Europe, China, Canada, South Africa and the United States.

- An important preclinical study of a 9-antigen CMV vaccine study was completed in non-human primates in 2013 at Oregon Health Sciences University, and has shown great promise. Additionally, Aeras, INSERM, and the TuBerculosis Vaccine Initiative (TBVI) jointly advanced development of a novel adjuvanted recombinant protein candidate, heparin binding hemagglutinin antibody (HBHA), with a unique mechanism of action. The candidate will advance to additional preclinical testing in 2014.

- Aeras is pursuing a novel antigen selection strategy, identifying new antigen targets for potential inclusion in ongoing TB vaccine development.

The Global Clinical Pipeline of TB Vaccine Candidates

<table>
<thead>
<tr>
<th>PHASE I</th>
<th>PHASE IIa</th>
<th>PHASE IIb</th>
<th>PHASE III</th>
</tr>
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<tbody>
<tr>
<td>Ad5 Ag85A</td>
<td>VPM 1002</td>
<td>MVA85A/AERAS-485</td>
<td>M. Vaccae</td>
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<tr>
<td>McMaster CanSino</td>
<td>Max Planck, VPM, TBVI, SII</td>
<td>Oxford, Aeras</td>
<td>Anhui Zhifei Longcom, China</td>
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<tr>
<td>MTBvac</td>
<td>H1 + IC31</td>
<td>M72 + AS01E</td>
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<tr>
<td>TBVI, Zaragoza, Biofabri</td>
<td>SSI, TBVI, ECDCP, Intercell</td>
<td>GSK, Aeras</td>
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<tr>
<td>ID93 + GLA-SE</td>
<td>RUTI</td>
<td></td>
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</tr>
<tr>
<td>IDRI, Aeras</td>
<td>Archivel Farma, S.L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crucell Ad35/MVA85A</td>
<td>H4: IC31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crucell, Oxford, Aeras</td>
<td>SSI, Sanofi-Pasteur, Aeras, Intercell</td>
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</tr>
<tr>
<td>DAR-901</td>
<td>H56: IC31</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dartmouth, Aeras</td>
<td>SSI, Aeras, Intercell</td>
<td></td>
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<tr>
<td>TB/FLU-04L</td>
<td>Crucell Ad35/AERAS-402</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIBSP</td>
<td>Crucell, Aeras</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Viral Vector
Bacillus Calmette-Guérin (BCG)
Protein/Adjuvant
Attenuated M. Tuberculosis
Mycobacterial – Whole Cell or Extract
Clinical Development

Clinical trials are major undertakings that can be expensive and lengthy. With our partners we are focused on new ways to undertake clinical research that efficiently provides us with clear answers about TB biology and vaccinology, and about vaccine candidates' safety, immunogenicity and signals of clinical impact. In 2013, we focused on a variety of clinical trial designs including early experimental/translational medicine trials to answer focused, basic hypotheses about TB vaccine immune responses and delivery methods, and later stage proof-of-concept trial designs evaluating a variety of efficacy endpoints: prevention of \textit{Mtb} infection, prevention of TB disease recurrence in patients recently treated for TB, and prevention of TB disease in a latently-infected, healthy population. Careful sample collection is undertaken to allow further immunologic studies to define correlates of protection or correlates of risk. These proof-of-concept studies will assess, in a time- and cost-efficient way, whether various vaccine candidates have a meaningful biologic effect. Aeras is also helping to design and support researchers at McMaster University for a Phase I clinical trial of their TB vaccine candidate, Ad5Ag85A, to answer key questions about the immune response following two different routes of vaccine administration (aerosol and intra-muscular).

- **Experimental/Translational Medicine** – Aeras provided support to researchers at Dartmouth University’s Geisel School of Medicine for the process development and manufacture of DAR-901 and is now helping to support the first Phase I clinical trial of this vaccine. The trial will evaluate a range of doses and compare the immune response of DAR-901 to that of BCG. Phase I studies are designed to maximize knowledge gained using a wide variety of immunologic assays, including novel use of mRNA expressions and growth inhibition of \textit{Mtb}.

- **Prevention of Infection** – A Phase II prevention of infection study of H4:IC31 is now underway in South Africa, conducted by the South African Tuberculosis Vaccine Initiative (SATVI). The study will evaluate H4:IC31’s safety, immunogenicity, and ability to prevent infection by \textit{Mtb}, and will also evaluate BCG revaccination. The trial is designed to enroll 990 adolescents, who with adults bear the brunt of TB infection and disease. A vaccine for this age group could have a dramatic impact on the global TB epidemic, interrupting TB transmission and preventing tens of millions of cases and millions of deaths from the disease.

Aeras is partnering with Dartmouth and McMaster University on a novel vaccine platform.
Prevention of Recurrence – Plans are underway to initiate a Phase II clinical trial in South Africa in 2014 in collaboration with Staten Serum Institut (SSI) to study the safety of the candidate H56: IC31 in subjects treated for TB. Infectious Disease Research Institute (IDRI) will sponsor a similar study of their candidate ID93+GLA-SE. Both vaccines would then be evaluated in a collaborative Aeras-sponsored trial to investigate each candidate’s ability to prevent recurrence of TB in adults in the year after receiving effective standard treatment for active, drug-sensitive, pulmonary TB.

Prevention of Disease – The start of a large, multi-country Phase IIb clinical trial of GSK’s M72+AS01e vaccine candidate was delayed from a planned start in 2013 to include additional immunological endpoints and sample collection for biomarker discovery, and will now start in 2014 in several African countries.

Bacille Calmette-Guerin (BCG) Studies – Aeras is taking a second look at BCG to evaluate its potential to prevent infection in two studies. One, the Phase II prevention of infection study of H4: IC31, includes a study arm to evaluate BCG revaccination in adolescents who previously received BCG at birth. Another study in the early stages of development, in collaboration with researchers at the Harvard School of Public Health, will be designed to evaluate BCG’s ability to prevent Mtb infection among healthcare workers who have not previously been vaccinated with BCG.
New Collaborations Advancing Research

- Aeras continued to grow its contract manufacturing work in 2013, and further strengthened collaborations with other Product Development Partnerships (PDPs), including PATH, the International AIDS Vaccine Initiative (IAVI) and Sabin Vaccine Institute, as well as commercial biopharma partners. We also continue to use our process development capabilities to support our partners around the world in developing processes and analytical support utilizing innovative technology platforms focused on applications with TB and other priority diseases in global public health.

- Aeras officially opened its office in Beijing, China in August, 2013. Shortly after, Fudan University, with Aeras support, launched epidemiology studies in Wusheng County, Sichuan Province and Pingguo County, Guangxi Province, to estimate TB prevalence and evaluate the Xpert® MTB/RIF diagnostic system against more traditional TB diagnostic methods such as smear, culture and X-ray. These study activities contribute to local capacity-building for routine detection of TB disease and facilitate the planning and conduct of future TB incidence studies and vaccine trials in China. Also in 2013, Aeras signed a memorandum of understanding with the Chinese Center for Disease Control and Prevention (China CDC) to advance research and development of new TB vaccines. The new collaboration will accelerate research efforts for new vaccines by supporting studies that determine the incidence of TB infection, and will aim to strengthen the capacity within China to conduct future vaccine clinical trials.

- Aeras and the HIV Vaccine Trials Network (HVTN) have partnered to open Aeras’s South Africa Endpoint Assay Laboratory (SEAL). The lab (shown on opposite page), based in Cape Town, South Africa, allows clinical trial sample analysis to take place in South Africa, in addition to Aeras’s labs in Rockville. The establishment of the lab saves time and money and enhances the capacity of local scientists to perform standardized immunology assays at the highest levels of international standards of Good Clinical Laboratory Practices (GCLP).

- The Global Health Innovative Technology Fund (GHIT), a partnership advancing Japan’s contribution to global health, has awarded more than $6 million for work on a human parainfluenza type-2 (rhPIV2) vector technology co-developed by the Japan-based National Institute of Biomedical Innovation (NIBIO), Create Vaccine Co., Ltd and Aeras. Vaccines under development will be designed to target mucosal immunity to keep TB from establishing disease in the lungs.
Policy and Advocacy

In this past year, we found new ways to tell stories about TB, the need for new TB vaccines, and the groundbreaking work being done to advance TB vaccines around the world. We collaborated with European partners on novel financial mechanisms, ramped up US advocacy efforts by highlighting TB cases in the US, and featured voices of survivors and researchers in order to mobilize resources and political will around key populations. We also advocated for TB R&D to be included on the agenda to address the problem of tuberculosis in the African mining sector, which has one of the highest TB rates in the world.

- Aeras’s launch of the EXPOSED film series was widely received and reached much further than originally anticipated. By mid-2014, the films have been viewed over 100,000 times globally. The films won a PR Daily Digital PR Award, Silver Stevie American Business Association Award, and were nominated as a finalist for the Social Impact Media Awards.

- In an effort to highlight the important research efforts taking place in China, Aeras also created a film called Hope: Developing Safe and Effective Vaccines to Fight TB. This short documentary film explores the tuberculosis epidemic in China and around the world and highlights China’s innovative leadership and desire in solving the problem of TB. The film includes Chinese researchers who are leading the way in developing new vaccines to prevent tuberculosis. Featuring patients, doctors and top TB vaccine researchers in China, Hope illuminates China’s unique role in ending the global tuberculosis epidemic.

- Around World TB Day 2014, Aeras launched a TB Crisis Tracker. This map of the United States identifies recent TB cases in the news, with a focus on TB in specific institutional settings. We created the TB Crisis Tracker to bring more transparency and attention to the domestic TB crisis and help inform communities, policy makers and local NGOs.
Aeras began a campaign to raise awareness about tuberculosis in the mines of southern Africa, where 9 in 10 miners are infected with TB. Of the 2.3 million cases of TB in Africa, up to 760,000 may be connected to mining. Mining represents a huge portion of African economies. The reality is stark and the TB crisis in the mines of Southern Africa is becoming more acute and dangerous every year, threatening workers and industry. Aeras launched a petition urging the Southern African Development Community Nations (SADC) to prioritize TB R&D for new drugs, diagnostics and vaccines. The petition garnered nearly 5,000 signatures. Aeras also launched a short film called “Undermined,” exploring the problem of tuberculosis in southern Africa’s mines, and calling attention to the urgent need for TB R&D to benefit this industry, its workers and the world.

The Global TB Vaccine Partnership (GTBVP) is a governance framework that is being explored as a means to prioritize and accelerate the development of new TB vaccines. The partnership, with members from the European Commission, Bill & Melinda Gates Foundation, European Investment Bank, Aeras, the TuBerculosis Vaccine Initiative and the European and Developing Countries Clinical Trials Partnership, aims to improve the likelihood of successful TB vaccine development by identifying, prioritizing and monitoring a global portfolio of TB vaccine candidates, and will also promote and facilitate access to sustained financing. A draft governance framework is in development, and efforts to obtain input from a broader range of stakeholders and potential partners are ongoing.

“Undermined” has been viewed nearly 36,000 times online.

- 9 out of 10 gold miners are latently infected with TB
- Annual cost of TB on mining in South Africa is $1.2 Billion
  - Miners' lost wages
  - Treatment costs to government
  - Treatment costs to industry
  - Lost productivity & training costs
Major Donors and R&D Partners

Aeras is only successful through collaborations and partnerships that help support our TB vaccine development efforts. Aeras gratefully acknowledges these important donors and R&D partners, along with the numerous other collaborators not listed here, that help make our work possible:

<table>
<thead>
<tr>
<th>Academic Institutions</th>
<th>London School of Hygiene &amp; Tropical Medicine</th>
<th>Maastricht University</th>
<th>Universita Cattolica del Sacro Cuore</th>
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<tbody>
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<td>University of Alberta</td>
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<td>Huazhong Agricultural University</td>
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<tr>
<td>Imperial College London</td>
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<td>Wuhan University</td>
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<tr>
<td>Johns Hopkins University</td>
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# 2013 Financials

## Revenue

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<th>Source</th>
<th>Amount</th>
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<tbody>
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<td>Contributions from Foundations</td>
<td>$43,283,245</td>
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<tr>
<td>Government Grants</td>
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<td>Investment Income</td>
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<tr>
<td>Other Revenue</td>
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<td><strong>Total Revenue</strong></td>
<td><strong>$54,942,054</strong></td>
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## Expenses

### Vaccine Research Programs

- Vaccine Assessment and Optimization $3,043,223
- Vaccine Preclinical Assessment 2,998,417
- Technical Operations 14,402,364
- Clinical 18,071,116

**Total Vaccine Research Program Expenses** $38,515,120

### External Affairs

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<tr>
<td>External Affairs</td>
<td>$3,696,255</td>
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**Total Program Services** $42,211,375

### Management and Administrative

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<th>Source</th>
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<tbody>
<tr>
<td>Management and Administrative</td>
<td>$6,059,388</td>
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**Total Expenses** $48,270,763

## Net Assets

<table>
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<tr>
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<td>Net Assets, Beginning of Year</td>
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<tr>
<td><strong>Net Assets, End of Year</strong></td>
<td><strong>$43,039,552</strong></td>
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</tbody>
</table>

### Vaccine Research Programs

- Clinical 47%
- Pre-Clinical 16%
- Tech Ops 37%

**Total $38 Million**

### Total Expenses

- Management & Admin 13%
- External Affairs 8%
- Vaccine Research 79%

**Total $48 Million**
Board of Directors

Lota S. Zoth, CPA (Chair)
Former Senior VP and CFO of MedImmune, Inc.

Barry Bloom, PhD
Distinguished Service Professor at Harvard University

Jim Connolly
Former President & CEO of Aeras

Marja Esveld, MSc
Senior Advisor, Research and Innovation, Ministry of Health (The Netherlands)

Thomas G. Evans, MD
CEO of Aeras

Peter Barton Hutt
Senior Counsel, Covington & Burling, and Lecturer on Food and Drug Law, Harvard Law School

Marian Eslie Jacobs
Former Dean and Emeritus Professor of Paediatrics & Child Health Faculty of Sciences, University of Cape Town

Wayne F. Pisano
President and CEO of VaxInnate

Regina Rabinovich, MD, MPH
Exxon Mobil Malaria Scholar in Residence, Harvard School of Public Health

Gerd Zettlmeissl, PhD
Former CEO of Intercell AG
Senior Leadership Team

Thomas G. Evans, MD
Chief Executive Officer

Ann M. Ginsberg, MD, PhD
Chief Medical Officer

Rita Khanna, PhD, JD
General Counsel

Wendy Penry
Chief Human Resources Officer

Daniel Reznikov
Chief Financial Officer

Lewis Schrager, MD
Vice President, Scientific Affairs

Jacqueline E. Shea, PhD
Chief Operating Officer

Kevin Sly
Vice President,
Business & Corporate Development

Kari Stoever
Vice President, External Affairs

Barry Walker, PhD
Vice President,
Preclinical Development

Dereck Tait, MB, ChB
Director, Clinical Development
South Africa
Vaccine Advisory Committee

Aeras’s Vaccine Advisory Committee (VAC) provides external expert advice on criteria for vaccine candidate selection, preclinical stage-gating and priorities for advancing candidates in preclinical and clinical portfolios.

Ann M. Ginsberg, MD, PhD (Secretariat)
Chief Medical Officer
Aeras

Marcel Behr, MD
Professor of Medicine
Division of Infectious Diseases & Medical Microbiology

Ralf Clemens, MD, PhD
Head, Takeda Development
Takeda Pharmaceuticals

Patricia E. Fast, MD, PhD
Chief Medical Officer
IAVI

Barney S. Graham, MD, PhD
Senior Investigator
Chief Clinical Trials Core
Chief, Viral Pathogenesis Laboratory
Vaccine Research Center, NIAID, NIH

Peggy Johnston
HIV & TB Team
Bill & Melinda Gates Foundation

Rino Rappuoli, PhD
Global Head, Vaccines Research
Novartis Vaccines & Diagnostics

Robin Wood, MD DSC (Med)
Director, & Principal Investigator
Desmond Tutu HIV Centre Institute of Infectious Disease,
University of Cape Town

Douglas Young, MD
Fleming Professor of Medical Microbiology
Imperial College London
Head of Division of Mycobacterial Research (MRC)
National Institute for Medical Research

Barry Bloom, PhD – ex officio
Distinguished Service Professor at Harvard University

Gerd Zettmeissl, PhD – ex officio
Former CEO of Intercell AG
Biomarkers and Correlates Working Group

The Biomarkers and Correlates Working Group (BCWG) reviews progress in the field of correlates and biomarkers, including gaps and new developments in the field. The group also helps design Aeras studies and advises on funding needs.

JoAnne Flynn, PhD (Chair)
Associate Professor, Department of Molecular Genetics and Biochemistry
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania, USA

Alan Aderem, PhD
President; Full Professor
Seattle Biomedical Research Institute
Seattle, Washington, USA

Willem Hanekom, MBChB
Deputy Director, TB Vaccines
Bill & Melinda Gates Foundation
Seattle, Washington, USA

Professor Glyn Hewinson
Head, TB Research Group
Veterinary Laboratories Agency
Surrey, United Kingdom

Christopher Karp
Deputy Director, Global Health Discovery & Translational Sciences Program
Bill & Melinda Gates Foundation
Seattle, Washington, USA

Stefan H. E. Kaufmann, PhD
Director of the Department of Immunology
Max Planck Institute for Infection Biology
Berlin, Germany

Tom H. M. Ottenhoff, MD, PhD
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Head group Immunology and Immunogenetics of Bacterial Infectious Diseases
Dept. of Infectious Diseases
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Cape Town, South Africa

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National Institute of Allergy and Infectious Diseases (NIAID)
Bethesda, Maryland, USA

Christine Sizemore, PhD
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