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Dear Colleagues,

Since its beginning, Aeras has dedicated itself to the idea that new, more effective tuberculosis vaccines will significantly alter the course of the global tuberculosis epidemic. When I took on the role of President and CEO earlier this year, I did it with confidence in the importance of our mission and a high level of enthusiasm for the scientific challenges that lay ahead.

We must delve deeper into understanding human immune response to TB, and rigorously work to diversify and advance a pipeline of next generation vaccine candidates.

These are critical steps to achieve the scientific breakthroughs we need to reach our goals, and this work can only be successful by working in close collaboration with a vast network of partners. Today, Aeras supports half of the vaccine candidates in the global pipeline. We are currently testing six vaccine candidates worldwide in nine clinical trials, and eight preclinical projects and platforms are in early stages of development.

In September, 2012, Aeras and our partners reached a major milestone when we concluded activities in the largest clinical trial to date, a late-stage trial of the TB vaccine candidate MVA85A as a booster vaccine for infants. The results, published in February, demonstrated that the vaccine candidate was safe, well tolerated and modestly immunogenic, but was not efficacious in preventing TB disease. While not the results we had hoped, the trial produced the most robust data generated in half-a-century and continues to provide crucial information in our efforts to advance the global portfolio.

Looking forward, we will continue to tackle scientific complexities in TB vaccine R&D by expanding our scientific collaborations and working in geographic regions where TB is endemic. This past year we joined with GlaxoSmithKline Vaccines to further the clinical development of one of the most advanced candidates in the global portfolio. In addition, the Bill & Melinda Gates Foundation reinforced its support of our vaccine manufacturing facilities, not only to push forward on TB vaccines, but also to assist other organizations in their efforts to develop vaccines for other neglected diseases. New, generous funding from the governments of Australia and the United Kingdom, announced in August, has also provided much needed global support for our efforts.

Our strategy moving forward will be to place greater emphasis on diversifying the pipeline of early-stage preclinical candidates and platforms, while we continue to scientifically advance candidates in the clinic. This approach, combined with a more rigorous global portfolio management system, aims to increase cost efficiencies and give us a greater chance at success.

I am looking forward to tackling these challenges with the Aeras team and our global partners. By hewing closely to these objectives and continuing to gather a broad base of international support and collaboration, we can fulfill our mission of advancing new tuberculosis vaccines for the world.

Here’s to another great year,

Tom Evans, MD · President & CEO
Historic Trial Results Lead to New Approach

The first new tuberculosis vaccine to be tested in infants at the proof-of-concept stage in 90 years did not produce any solutions to the TB epidemic, but it did prove that we have the capacity, the global cooperation and the dogged determination we need to find them. The large-scale clinical trial of the MVA85A vaccine candidate was conducted among nearly 2,800 infants in the Western Cape province of South Africa, a country that has been ravaged by this deadly disease. Organizations and scientists from all over the world partnered with the South African government and thousands of families to complete this groundbreaking Phase IIb trial at the highest international standards. While the vaccine did not boost the efficacy of BCG, the only vaccine currently used to prevent TB in children, researchers believe it has potential to protect adults from infection and to help those infected with HIV.

Partnerships Hold the Key

No single organization, country or researcher can solve the TB crisis alone. It’s going to take extensive global partnerships with a wide variety of stakeholders to drive both research and innovative financing.

Partnership highlights include:

- In 2012, Aeras joined forces with the TuBerculosis Vaccine Initiative (TBVI), European Commission and European Investment Bank to produce “TB Vaccine Research & Development: A Business Case for Investment.” This important document is based on a strategic market analysis and financial model that establishes TB vaccine research and development as a viable and attractive low-risk investment for industry partners and makes a case for public investment at the earlier, high-risk or “translational” stage of vaccine development.

- The TB Vaccine Acceleration Project is a joint effort with the Bill & Melinda Gates Foundation to test the role of antibodies in the prevention of infection, to explore novel immunogens, and to develop a more relevant animal model.

- Partnering with GlaxoSmithKline, a world leader in pharmaceuticals and health care, we will further develop a vaccine containing GSK’s proprietary M72/AS01e candidate. Together, we’ll provide the necessary resources to run a proof-of-concept clinical trial to test a vaccine candidate in healthy adults in Africa.
Global Forum Brings TB Scourge to the Forefront

The Third Global Forum on TB Vaccines brought more than 250 researchers, policymakers, donors and advocates from all over the world to Cape Town, South Africa, to discuss new findings, highlight the urgent need for more research and funding, and recognize the role of high-burden countries like South Africa in battling the disease.

One of the most important studies, presented by the London School of Hygiene & Tropical Medicine, suggests that new vaccines for adolescents and adults will be cost effective.

With limited resources available for vaccine R&D, the ability to prioritize which vaccines will have the most public health and economic impact is absolutely critical.

New Strategy Emphasizes Innovation and Diversity

One of the top priorities for the field is to strengthen and diversify the preclinical and clinical portfolio to facilitate a more rational, cost-effective and accelerated vaccine development process that replenishes the pipeline with new candidates from discovery and preclinical research.

Aeras and our R&D partners are also placing an increased emphasis on the early stages of vaccine development. For example, we are researching a standardized animal model that reflects the natural transmission of TB. Additionally, we will begin conducting clinical studies to assess vaccines that prevent infection rather than disease. By revamping trial design, we can significantly reduce their size, length and cost, allowing a better use of funds to develop a vaccine that is effective against TB.
EXPOSED Film Series Shows the Urgent Need for New TB Vaccines

In March, Aeras launched EXPOSED, a four-part series of short films on the deadly global TB epidemic. The series focuses on current efforts to halt this airborne disease, which is growing more difficult to address, as well as the urgent movement to develop new tools to prevent it. By telling the stories of four inspiring individuals, interspersed with expert commentary from some of the world’s top TB physicians, scientists, advocates and policymakers, EXPOSED brings viewers to the forefront of the race against tuberculosis.
Vaccine Research Programs

2012 Financials

Revenue

- Contributions from Foundations $40,776,763
- Government Grants $6,074,292
- Investment Income $207,115
- Other Revenue $893,761
- Total Revenue $47,951,931

Expenses - Vaccine Research Programs

- Vaccine Assessment $3,579,836
- Vaccine Discovery $3,557,267
- Technical Operations $13,265,329
- Clinical $20,376,995
- Total Vaccine Research Expenses $40,779,427
- External Affairs $3,071,274
- Total Program Services $43,850,701
- Management and Administrative $5,943,178
- Total Expenses $49,793,879

Net Assets

- Change in Net Assets $1,841,948
- Net Assets - Beginning of Year $38,210,209
- Net Assets - End of Year $36,368,261
Aeras Timeline

2013  Aeras receives a grant for AU$2.5 million from AusAID; data from first Phase Ib clinical trial for TB vaccines in infants, candidate MVA85A, is published in The Lancet; Aeras officially opens office in China, forming a partnership with China Center for Disease Control

2012  Aeras receives a grant from the Bill & Melinda Gates Foundation for up to $220 million; “TB Vaccines: A Strategic Blueprint for the Next Decade” is published in the journal Tuberculosis; Aeras partners with Tuberculosis Vaccine Initiative (TBVI), National Institute of Allergy and Infectious Diseases (NIAID), Infectious Disease Research Institute (IDRI), GlaxoSmithKline (GSK), and Chinese National Biotec Group (CNBG) – Aeras’ first partnership in China

2010  The United States government shows its support to Aeras through grants from the National Institutes of Health (NIH) and the Food and Drug Administration (FDA)

2009  Aeras receives a grant from DFID for £10.5 million; Aeras launches an expanded TB vaccine process development and manufacturing facility in Rockville, MD; Aeras and partners the South African Tuberculosis Vaccine Initiative (SATVI), Oxford-Emergent Tuberculosis Consortium, and Wellcome Trust begin the first Phase Ib proof of concept trial in infants in South Africa

2008  In April of 2008, Aeras opens an office in Cape Town, South Africa; along with partners, announces two new candidate trials – GSK M72 Phase II in South Africa in collaboration with SATVI, and Crucell Ad35/AERAS-402 Phase IIb in Kenya

2007  The Bill and Melinda Gates Foundation awards Aeras a $200 million five-year grant

2006  Aeras receives a grant from the Dutch government for €18.7 million; clinical trials begin for Crucell Ad35/AERAS-402

2005  Aeras joins in partnership with GSK and Statens Serum Institut; receives $4.5 million from Danida, the Danish development agency

2004  The Bill & Melinda Gates Foundation grants $82.9 million to Aeras to develop new TB vaccines; Aeras begins its collaboration with Crucell to jointly develop Crucell Ad35/AERAS-402

2003  On July 16, 2003, the Sequella TB Vaccine Foundation incorporates as Aeras Global TB Vaccine Foundation
Turberculosis
Contagious and Airborne

Today, more than 2 billion people—almost one third of the world’s population—are infected with TB, and 10 percent will become sick with the disease. Every year, 8.8 million people fall ill and 1.4 million die. Intensified efforts by the public health community to reduce disease burden have resulted in a more than 40 percent reduction in TB-related deaths over the past two decades. However, there are nearly a million more cases of TB in the world today than when the World Health Organization (WHO) declared TB a global emergency 20 years ago, with 7.8 million cases in 1990 and 8.7 million cases in 2011. Today, TB is second only to HIV/AIDS as the greatest killer worldwide due to a single infectious agent.

In addition, M. tuberculosis has evolved and become more challenging to cure, as evidenced by increasing cases of drug-resistant TB strains now present in almost all countries surveyed worldwide. While predominantly a disease of the poorest and most vulnerable, there is a clear risk of TB spreading even further internationally through migration and urbanization.

The costs of treating drug-resistant TB are staggering: more than $12,000 per multi-drug resistant (MDR-TB) patient in high-burden countries and as much as $500,000 in the United States. A recently released study found that in 2011, TB was costing the EU more than $700 million a year in treatment costs and another $7 billion a year in productivity losses.

New vaccines are essential to future TB elimination efforts.
Board of Directors

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Aeras and our global research and development partners play an integral role in developing approximately half of all TB vaccine candidates in clinical development around the world. There are also multiple collaborations underway for interesting leads at the preclinical stage of the pipeline.

**The Global Pipeline of TB Vaccine Candidates**

- **Viral Vector**
- **rBCG**
- **Immunotherapeutic**

**Protein / Adjuvant**
- Attenuated M.Tb
- AERAS Sponsored

**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:

- **Australian AID**
- **Bill and Melinda Gates Foundation**
- **Rijksoverheid**
- **UK aid**
- **GSK**
- **Crucell**
- **Sanofi Pasteur**
- **FDA**
- **National TB Partnership**
- **Wellcome Trust**
- **VPM 1002**
- **MVA85A / AERAS-485**
- **M. Vaccae**
- **Annui Longcom, China**