



# REACHING FURTHER

## Message from the CEO



**“We now have the audacity to envision a world where all TB patients can be treated for a few months with the same regimen, with excellent results.”**

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# Dear Stakeholders, Partners and Patients,

For TB Alliance, 2015 was a milestone year marked by tremendous accomplishments, including reaching some of the most vulnerable and neglected patients with TB.

A major achievement was our first introduction of TB Alliance sponsored products. Working alongside key partners, including the [World Health Organization](#) and [UNITAID](#), we were able to bring to market the first [appropriately dosed and formulated child-friendly TB medicines](#). Historically, children with TB have been neglected, without access to appropriate medicines. Today, because of these new medicines, there is an incredible opportunity to improve treatment for the 1 million children around the world with TB and save countless lives.

Without an effective treatment, XDR-TB is a veritable death sentence for most patients. Over the past year, TB Alliance began the so-called [Nix-TB](#) clinical trial to test a new paradigm for developing novel, impactful regimens while simultaneously providing hope for patients with highly-resistant TB. The trial is progressing well, with the number of patients enrolled in 2015 tripling our expectations. The first set of study participants have completed the 6 month all-oral [regimen](#) and have been able to return home to their families. They will now be monitored for an additional two years to see if they have been cured of XDR-TB.

Over the past year, we've also completed the phase 2b trial of the [BPaZ \(bedaquiline, pretomanid and pyrazinamide\) regimen](#), which is predicted to be the fastest-acting TB cure currently in clinical development. The regimen shows potential to treat virtually all patients with drug-sensitive TB as well as approximately half of all MDR-TB cases. The results of that trial are expected in 2016. If those results are positive, BPaZ could progress to Phase 3 registration trial.

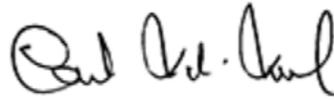
In the area of early research and discovery, TB Alliance progressed more compounds than ever before, adding projects and partners in a variety of new geographies. We also became a formal member of the Bill & Melinda Gates Foundation sponsored [TB Drug Accelerator Program](#). These efforts should expand the strength of the global TB portfolio and help ensure a critical mass of new compounds advancing into the clinic over the next few years.

Despite this tremendous progress in 2015, we also faced some setbacks. The [STAND](#) trial remains on partial clinical hold and the program for TBA-354, a Phase 1 candidate, was discontinued. This highlights to us that the work we're doing is still fraught with risk, emphasizing the reality that even though we have the largest single TB drug pipeline ever assembled, we need more investment to build a sufficiently robust pipeline.

However, we also need to focus on the potential that lies ahead with the current development programs. We now have, for the first time ever, a totally novel regimen for which we've already seen patients benefit. As an organization and as a community, that should give us the audacity to reach into the future and envision a world where all TB patients can be treated for a few months with the [same regimen](#), with excellent results.

I would like to thank all of our partners — the donors, collaborators, and most especially the TB patients who have participated in our clinical trials. It is only through their commitment that progress has been made towards saving the lives of millions of TB patients around the world.

Sincerely,



## **Dr. Mel Spigelman**

President and CEO,  
TB Alliance



## **Dr. Carlos Morel**

Chairman of the Board,  
TB Alliance

