

27 November 2018

Chairman's Address

Since our listing in 2016, our goal has been to resurrect a valuable drug called Bisantrene.

One of the ways that we planned to create value with Bisantrene was to complete the clinical and regulatory work needed to get it approved in the US, the most important pharmaceutical market in the world. In that regard, we have made a lot of progress.

We also planned to generate early revenues by making Bisantrene available on a Named Patient basis outside the US, especially in Europe. In that regard, we have yet to see real progress.

I am pleased to say that we have an outstanding medical affairs expert on the ground in Europe – Dr Samar Al-Behaisi – and a few weeks ago, I had the opportunity to spend two days with her, in Zurich, to discuss all aspects of our named patient program.

Since she started in May, Samar has built positive relationships with AML doctors in Europe and created real awareness of Bisantrene. Along the way, we have learned a lot about the barriers to contemporary NPP use, especially for an older drug like Bisantrene, and I have to say, candidly, that those barriers are significant.

The most significant is the competition that we face from clinical trials. It is clear that, while doctors see a genuine role for Bisantrene in treating AML, they would prefer to direct their relapsed/refractory AML patients into any one of the many clinical trials for newer AML drugs, where the drug is provided free-of-charge, rather than ask their hospital to pay for a drug like Bisantrene.

We will continue to pursue NPP revenues wherever feasible, but we believe the potential revenues will be modest, at best. In parallel, we will work to get doctors using Bisantrene in a clinical trial setting, where our drug is provided at no cost, and particularly to build interest in paediatric use of Bisantrene, where we know it has already saved the lives of two French girls, who are still alive today.

While the lack of NPP sales has been a disappointment, on the positive side of the ledger, we had an unexpected and valuable surprise in the form of the award of a Rare Paediatric Disease designation by the FDA in July. The RPD designation opens the door to a Priority Review Voucher or 'PRV'.



The PRV system was introduced by the US FDA about 10 years ago as a way to incentivise pharmaceutical and biotech companies to develop drugs for rare diseases. The FDA recognised that such diseases would be unlikely to generate profitable returns, so to compensate companies, they created a voucher system, where companies received a voucher to an accelerated 6-month review on their drug at registration. Importantly, the voucher can be sold to other companies for use on a different drug. For a large company with a blockbuster drug, an accelerated review is extremely valuable and since 2016, PRVs have sold for between US\$80 million and US\$130 million.

In Race's case, the designation was awarded for childhood AML, which is considered a rare disease. To obtain the PRV, Race will now need to complete a relatively modest study in childhood AML.

Given the unrealised value of the PRV and the fact that Bisantrone is on the cusp of Phase 3 trials next year, we believe that Race is seriously undervalued at present.

Your board continues to wholeheartedly believe in the value of Bisantrone, and our goal has not wavered from delivering on that value and producing a substantial return for our shareholders in the process.

In fact, we are impatient to do so. To that end, we recently engaged Biosynergy in New York, represented by Race director Dr John Cullity, to immediately pursue licensing partners for Bisantrone. Our goal is to crystallise the value of Bisantrone and to gain non-dilutive funding to support the costs of the adult and paediatric clinical trials.

We have already started the process of engaging with potential partners and have been reassured by the responsiveness of parties as they evaluate the potential that is presented by Bisantrone. We will continue to report on developments on this important new project for value realisation for Race.

Thank you for your continued support.