

## AN AUDIENCE WITH...

## Victoria G. Hale



**Victoria G. Hale, Chief Executive Officer, Institute for OneWorld Health**

Victoria G. Hale is CEO of the Institute for OneWorld Health, a non-profit pharmaceutical company she founded in 2000 to tackle the lack of effective, safe and affordable drugs for tropical diseases. In addition to time spent in industry, Hale has gained valuable expertise in biopharmaceutical drug development at the FDA Center for Drug Evaluation and Research. By the end of 2005, the company will submit its dossier in India for its first drug, paromomycin, a treatment for the tropical parasitic disease visceral leishmaniasis.

*How was OneWorld Health first received by companies you approached?*

Initially there was a lot of scepticism. Companies asked why we needed to exist, what markets and diseases we would pursue and whether we would compete with them. But we made it clear that we're here to fill in the gaps and we need industry to work with us, to provide access to intellectual property (IP) that's not being pursued and scientists to help us on projects. Things began to accelerate after 3 years — we were in clinical trials, had our first significant funding from the Gates Foundation — and now we're friends with all the big companies and negotiating partnerships with the smaller ones.

*Where are your gaps in funding?*

Funding gaps currently exist around operations, so we're working now with several philanthropic organizations to help us build up our company. If we were intending to be a one-hit-wonder with paromomycin then we would have everything we need. But having put our energy into leishmaniasis for a while, we're moving onto bigger diseases such as malaria and diarrhoea, and some of these programmes could take 10 years. So we really need experienced executive staff, which requires larger salaries, and communications and human resources infrastructure. We've had interest from both retired individuals and others who are 10–15 years from retirement. So we're getting to know people, often as volunteers or consultants first, and are also discussing the possibilities of sabbaticals or executive-sharing programmes with some companies, which will enable us to deal with a very narrow or fixed issue using a focused executive team.

*OneWorld Health has so far focused on approving drugs for global diseases in individual countries. How will you translate this into a global strategy?*

It's the bottom third of the worldwide economic strata — two billion people — that no one is getting drugs to effectively. We have to be honest with ourselves about the magnitude of this issue, and when we choose our diseases we need to ask whether anyone has the will to distribute a particular drug if we developed it today. For instance, and it's painful to say this, we believe that developing a drug for sleeping sickness is just not an area on which we should spend our energy right now, because the countries where sleeping sickness is an issue are at civil war and aren't spending on public health. Sleeping sickness isn't always off our agenda. We revisit it every year to see if anything's changed, but we need to apply our limited resources on diseases where we can get products to people now. Going from national to global is addressed through an intelligent regulatory strategy and drug development plan. Although we work in a lead country, we talk to other countries to be sure we understand their needs.

*Will OneWorld Health always be non-profit?*

Yes. I think there's a need for a whole non-profit sector and I think that there will be other non-profit drug companies. There is a growing appreciation that a lot of IP exists that many people — the discoverers, the owners, the people in the world who are in need — all agree should be moved into the public domain, but there's nowhere for it to go. So, let's put it in this non-profit sector and see what happens. I feel very strongly that OneWorld Health should

remain non-profit. We have to continue to make our decisions about which drugs to pursue without profitability in mind and go for the opportunities that will benefit the poorest people. In India, Bangladesh, Sudan and Ethiopia, the people with visceral leishmaniasis are so poor that it's a case of getting the job done and not bringing in any revenue. But for some diseases, such as malaria and diarrhoea, which also affect the middle section of economic strata, we believe it is appropriate to tier pricing so that we have products that could bring back some revenue that we can apply to operations or to a new R&D programme. Once we prove we can do that, I believe we can attract a sector of society to invest in OneWorld Health, not with grants, but by providing low-interest loans — a form of social venture capital. So that's a future self-sustaining business step, but those products wouldn't be our whole portfolio, because we would always be looking to bring sleeping sickness, for example, back into our portfolio.

*How would the failure of paromomycin affect the R&D of your other drugs?*

If our first product were to fail, that would be a real problem, but we are fully aligned to the belief that it will succeed. Our worst-case scenario would be that regulators would want more clinical trial data; if so, we'll conduct more studies and come back again. Overall we diversify the portfolio and divide the risk. We've chosen as wisely as we can. Some of our projects are pretty high-risk. For example, our programme to synthesize artemisinin from *Escherichia coli* is a high-risk programme and we passionately believe in it, but it could fail. But the crisis with the shortage and high cost of artemisinin is so devastating that it's important for the world that someone tries. Five years at the FDA taught me one thing in particular: the success of a product depends primarily on the project team. The drug and its qualities are often secondary. There are a good number of average drugs on the market that succeeded because they had ace project teams, that overcame every obstacle. I'm convinced the key to our success is having the right people who will work on the programme and just not give up until it is done — and that's our philosophy.