

DR. CAMERON DURRANT

KALOBIOS PHARMACEUTICALS CHAIRMAN & CEO

Interview by Kamran Rafiq (ISNTD Communications Director)

Dr. Cameron Durrant is Chairman and CEO at KaloBios Pharmaceuticals, which is based in California, and he has gained wide-ranging experience and recognition in pharma and biotech as an operating executive at several blue-chip pharmaceutical companies and as CEO and/or chairman of several companies, with a focus on turnarounds. In this exclusive ISNTD interview, Dr. Durrant talks about the adoption of a new pricing model that will guide KaloBios' strategy and operations, and explains how this framework will help to define and develop transparent and responsible pricing for products as well as positively address the concerns that drug pricing raises for all stakeholders in healthcare.

WHO estimates between 6 and 7 million people are infected with *Trypanosoma cruzi* the parasite responsible for causing Chagas disease – how is KaloBios involved in combating this?

Some credible sources state that 8-10 million people globally are living with Chagas disease. There is also an increase in cases presenting in countries such as the US, Canada, Japan and Australia, as well as in the European Union. Our strategy is to bring an approved Chagas treatment to the US and then branch out from there to help combat the disease however we can.

KaloBios is working on developing a version of benznidazole, the current gold standard treatment for Chagas disease, for approval in the US. If we

get FDA approval, we would make the product available in the US and potentially elsewhere. In the US, up to 300,000 people are infected, according to the Centers for Disease Control and Prevention (CDC). Right now, physicians can only get the drug through an investigational protocol with the CDC. It can be a cumbersome, lengthy and confusing process for patients and physicians. Some of the physicians we have spoken with have mentioned losing patients to follow up due to the length of the process and frustration with the diagnostic tests required. And CDC apparently faces shortages of supply sometimes. So to start, we are working to bring a commercially available, efficacious treatment to patients in the US. Upon getting FDA approval, we could then offer a quality alternative stable supply

source of a valuable medicine to other parts of the world to help ease the burden of this silent killer.

The new KaloBios strategy is to focus on bringing medicines to patients with neglected and rare diseases. Chagas disease is a perfect opportunity to anchor that strategy.

KaloBios started to emerge from a tumultuous period by indicating a new direction based on a novel pricing model. How will this work and how will it affect the disease burden?

First, we are working very hard to exit bankruptcy as soon as we can. It is an incredibly complex process. But we're pretty confident we can see light at the end of the tunnel. As things stand now, we expect to emerge from bankruptcy as a new company with a new direction, investors, board and management sometime this summer.

Emerging from bankruptcy is an opportunity to rebuild this company, starting with a blank sheet of paper. KaloBios's history, with Martin Shkreli's brief, near-disastrous, less than four-week involvement with the company, of course adds to the challenge. So we see this tumultuous period as an extraordinary

opportunity to be a transformative leader in the industry – to try some things many people don't expect, or perhaps even don't believe is possible, at a biopharma company.

We wanted to set the foundation of our company and strategy by announcing our Responsible Pricing Model early on in this turnaround. This is to make clear how KaloBios will act and operate ahead. The key tenets in our model are transparency, affordability, earning a reasonable return, working well with stakeholders and supporting vital access programs.

We plan to use this as the basis for how we price products in the future. Our Responsible Pricing Model spells this out in as much detail as we have today. For instance, we commit to pricing benznidazole, at cost plus a modest margin. The price will be transparent – that means that we will publicly share the elements that go into it. We also commit to making sure patients can get the drug, irrespective of their ability to pay, which is obviously very important for Chagas.

As to how it will affect the disease burden, we think the Responsible Pricing Model can help in direct and indirect ways. We would hope that more patients, particularly those in poor and marginalized settings, would be able to access treatment. And indirectly, we want the model to help lead a new kind of conversation between industry and stakeholders that spurs more treatments at responsible prices for neglected diseases and beyond.

This new pricing model has wider implications and so what are your plans outside of the Chagas disease setting?

This model will apply to all of our future products in our determined focus to bring medicines to patients with neglected or rare diseases. We intend to have an open dialogue about what would constitute a reasonable profit margin for future products beyond benznidazole.

More broadly, the conversation about industry models and drug pricing needs fresh ideas. Given the strain on healthcare resources globally, these are needed in a concrete and practical form, rather than endless debate that only leads to ossified positions and disparate positions being maintained. In other words, no progress.

We believe the Responsible Pricing Model shows leadership in some transformational ways. There are features in it that address some blind spots in the current pricing environment and discussion.

Transparency is at the heart of this. When we know the elements that make up any of our product prices we will share them. Again, a key feature is for collective input on what would constitute responsible pricing. Another feature is to limit any annual price increases – if taking any at all – to the Consumer Price Index, or the level of inflation, and to explicitly not take arbitrary or predatory price increases. We think all of these have wider implications and can catalyze debate that leads to actual concrete change.

Our motto here at the ISNTD is 'Progress through Partnership' - what types of partnerships and collaborations are you looking to pursue and develop?

We are setting a course to demonstrate transformational thinking and operating models in pharma and biotech. One way to think about our approach is: the right model for these kinds of diseases for the right (responsible) price. For us, partnerships and collaborations are at the heart of the innovative models we are espousing. The more 'outside the box' the new operating model partnership is, the more interesting it potentially could

be to us.

Let me give you some specific examples of what transformation could look like:

- We are seeking new ways of developing products.
 For instance, one way could be for public-private partnerships with capable drug development organizations.
- We are seeking new ways of making products available commercially.
 One way, for example, could be through collaborations with NGOs, advocacy groups or a coalition of interested stakeholders.
- 3. We are seeking new ways of capitalizing and funding R&D. This could be done, for example, through investment and additional support from socially responsible institutional 'impact' investing groups. This not only expands our shareholder universe, but aligns with our overarching strategy.

In addition, we see collaboration as a fundamental part of the Responsible Pricing Model. We want, and will seek, stakeholder input on what would constitute a reasonable return, particularly where an R&D innovation premium is deserved.

In terms of affordability of medicines - what steps or commitments are you willing to make to those who are unfortunately unable to afford medication? Are you concerned with access only in the US, or beyond that?

The commitment is clearly stated in our Responsible Pricing Model. First, we want to tackle the affordability challenge as best we can. We plan to make our products affordable for patient and payers. We will not take egregious price increases. We will work with stakeholders to establish prices and be held accountable to those.

Second, we are well aware that our focus on neglected and rare diseases will come with a responsibility to create ways to get our future medicines to patients who do not have the means to pay for them. We will support and engage partners for access programs and patient assistance opportunities wherever we are able to see our products commercialized. For benznidazole, this would be in the US to start.

However, we also clearly state in our pricing model that we plan to make benznidazole available in developing countries at, or near, cost by working with partners to supply it to patients in need.

What do your investors think of all this?

When asked about our Responsible Pricing Model and investors, the assumption is that the investment community would be a barrier. Our experience is exactly the opposite. Our investors are very supportive, and they all, along with our Board, had input into our model. They fully support our strategy and plan to develop our key programs, and see opportunity in helping turnaround this company.

We strongly believe that our Responsible Pricing model will aid in our capital-raising efforts. If you notice, recently some investors have been called to testify before US Congress over their involvement in companies that had pricing practices questioned. We see future investors attracted to the new KaloBios with a sustainable, transparent pricing commitment and innovative business models. Investors come in all shapes and sizes. We believe that there are plentiful investors outside of our current base with whom our philosophy resonates.

What other interest in neglected diseases do you have?

We are interested in a wide array of neglected diseases, both long-known and emerging threats. KaloBios is actively exploring deals, partnerships and other opportunities for compounds to develop for treating neglected diseases. Even though we are still working to exit bankruptcy, we see real opportunity ahead and are committed to focusing on neglected and rare diseases.

How can a small company make a difference?

Smaller companies have always had the opportunity to be the agents of change. They can take risks and explore models and product ideas that established companies might not consider desirable. The status quo can be less important for a new, small company. With the right incentives, small companies can follow new ideas that could lead to impact inversely proportional to their size. This is sometimes forgotten in the pharmaceutical world that increasingly sees small companies only as asset innovators/incubators and not operational innovators. Every pharma company was a small company at some stage.

What is your message for the NTD community?

We are committed to helping shape transformational change in the pharma/biotech space. We see our Responsible Pricing Model as just the beginning. We plan to share more and more on how we are implementing it, as soon as we can. We expect to be held accountable to our actions measuring up to the words in this model. And we want to lead by example. We also have clear, concrete ideas that begin to tackle endemic issues related to R&D, commercial and financing in biopharma.

Emerging from bankruptcy, we want to build momentum as a brand new company. We are focused on neglected and rare diseases and want to operate with an innovative, transparent spirit to help make us a partner of choice. Finally, we seek to encourage and engage in openminded dialogue with other stake-holders in this space.

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