CEO on Integrase Developments

Open Briefing interview with Interim CEO and Chief Scientific Officer Jonathan Coates

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In this Open Briefing®, Jonathan discusses:

- New generation integrase compounds active against sensitive and drug-resistant HIV in laboratory
- Potential market in first-line and second-line HIV treatment
- Promising marketing interest in ATC

Record of interview:

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Avexa Limited (ASX: AVX) recently announced that laboratory tests had shown its second generation HIV integrase inhibitors are active against not only wild type HIV but also against HIV with mutations that reduce the activity of the integrase inhibitors currently available. How do your integrase inhibitors differ from those currently on the market and what are the implications of the laboratory result for their potential market?

Interim CEO Jonathan Coates
The integrase inhibitors currently on the market have been very successful in the initial treatment of HIV but after a while resistance develops, characterised by a particular set of well known HIV mutations. The drugs now available become less active once the mutations develop. Our integrase inhibitors differ in that they retain activity even with these mutations.

One obvious potential market for our compounds is the treatment of patients who've become resistant to the current drugs. But they've also got potential as a first-line treatment, especially as the initial data shows they could be simpler and easy to dose.

There are two integrase inhibitors currently available on the market: raltegravir, which is made by Merck; and elvitegravir, made by Gilead. In 2011 raltegravir had sales of approximately US$1.4 billion. There's no sales data available for elvitegravir as it's only recently been approved.

Both drugs are used as first-line treatments. They are cross-resistant, so patients are prescribed one or the other. Once the treatment fails and patients become resistant, there isn't currently a second-line integrase treatment available. So that market would potentially be available for our compounds. Almost all first-line patients become second-line patients at some point.

That said, our compounds may also be able to compete as a first-line treatment given the early data shows the potential for once daily dosing without a boosting agent, something that isn't available at the moment. Raltegravir requires twice daily dosing, while elvitegravir requires the use of a pharmacological boosting agent.

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You've indicated that two lead compounds had been selected for further pre-clinical development. What tests remain to be done before the compounds could progress to clinical testing and what is the expected time line for this?

Interim CEO Jonathan Coates
Pre-clinical development will involve optimising the synthesis of the compounds so we can make larger amounts to conduct the safety and animal studies that will characterise the dosing, safety and metabolism of the compounds. As you'd expect, there are stringent tests required before patients can be dosed with any new drug, and these normally take 18 months to two years to complete.

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What level of patent protection do you have for the integrase inhibitors internationally?

Interim CEO Jonathan Coates
The series of compounds from which our leads come are thoroughly protected by patents we've filed over the last two years in all the major markets. The first of these were granted recently in the US; we therefore have the maximum length of patent to run.

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What are your intentions with regard to the development and/or licensing of the integrase inhibitors? Given Avexa's cash on hand was $12.6 million as at 30 June, are you adequately funded to progress the integrase programme to clinical stage?

Interim CEO Jonathan Coates
Our intentions are to develop these compounds to the point where the maximum commercial return can be extracted. We believe that point would be reached when we demonstrate a clear benefit over the competitor compounds in the clinic, ideally in a Phase I/II clinical trial. Our current cash in hand is more than adequate to progress these compounds to that point. Notwithstanding that, we could consider augmenting our funds through a capital raising or from returns from investments that we may make as or when the opportunity may arise.

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You've indicated that your search for a co-marketing partner for your HIV drug apricitabine (ATC) is progressing well. What has been the response to date and what processes have to be completed before a deal can be struck?

Interim CEO Jonathan Coates
We've been very pleased with the response. We've had a large number of companies wanting to enter detailed discussions on licensing to market ATC. Some of these are global companies while others are smaller companies that specialise in marketing in particular regions. We're evaluating each of these very carefully: we want to be sure we negotiate the very best outcome for our shareholders.

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What is your level of confidence that finalising a marketing partnership deal for ATC will enable Avexa to raise the funding for the 300-patient Phase III trial agreed with both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for ATC's regulatory approval?

Interim CEO Jonathan Coates
We believe it's achievable, although we recognise that the current condition of financial markets globally could be a hurdle. We're looking at a few different avenues to raise the funding. The business proposition is simple – the trial we need to complete for approval is a low risk, rapid one, and with committed partners to sell the drug this makes for a good business model. We're confident this will have commercial appeal.

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Thank you Jonathan.

For more information about Avexa, visit www.avexa.com.au or call Jonathan Coates on (+61 3) 9208 4300.

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