

ASX Announcement : 8 April 2013

## CEO on H1 Update and Company Outlook

**A V E X A**

Open Briefing interview with CEO Jonathan Coates and Chairman Iain Kirkwood

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In this Open Briefing<sup>®</sup>, Jonathan and Iain discuss:

- North Pratt Coal Mine update
- HIV Integrase development
- ATC distribution agreements

### Record of interview:

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Avexa Limited (ASX: AVX) had cash of \$11.88 million as at 31 December 2012, down from \$12.57 million six months earlier. Since then, you've sold your remaining holding in Allied Healthcare (ASX: AHZ) for about \$2 million, and substantially completed due diligence in relation to the North Pratt Coal Mine, which you expect to start investing in shortly. What is the expected investment in the mine this financial year and when do you expect first cash flow from the mine?

#### **Interim CEO Jonathan Coates**

The expected investment in the mine this financial year will be \$483,000 paid by way of an interest bearing facility (Promissory Note) over Coal Holding's assets (land). No further investment will be made until the mining permits have been issued which is expected by June. Barring any contingency, the expected cash flow is scheduled to start approximately six months after the mining permits have been issued.

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You reported net operating cash outflow of \$0.88 million for the first half ended 31 December 2012, versus outflow of \$1.23 million in the previous corresponding period. What is your expected operational cash burn for the full year?

#### **Interim CEO Jonathan Coates**

We estimate that it should be similar to last year at approximately \$2.0 million. Importantly, our overheads will reduce substantially with effect from July as the onerous lease on our current, large premises expires and we move to a much more appropriate new office.

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What progress is expected in your HIV Integrase programmes over the remainder of the year?

#### **Interim CEO Jonathan Coates**

Our HIV Integrase programme has made some remarkable progress this year with the discovery of compounds with physicochemical and biological properties that are indicative of a once-a-day dosed drug, with activity against wild-type and resistant virus. Even more exciting is that these predictions have been borne out in studies in rats and primates. This really hits our targets and industry targets for this programme, so we are currently having larger scale amounts of material synthesised to progress these compounds further.

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Avexa recently announced the signing of option agreements to market the HIV drug, apricitabine (ATC) with several companies covering specific regions, including one with Link Healthcare covering Australia, New Zealand and South Africa. What attracted Avexa to partner with Link, compared to the larger well known pharmaceutical distributors such as Sigma and API?

**Chairman Iain Kirkwood**

Firstly, Avexa was impressed by Link's proven ability to market specialist products in niche disease areas and to grow substantial sales for products that the larger pharmaceutical companies have overlooked. Secondly, their capabilities in South Africa and potentially the surrounding regions via their Equity Pharma subsidiary are also attractive, given the large and growing incidence of HIV in that area. Similarly, sales in parts of south east Asia would be an asset too.

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And what opportunity does Link see with ATC, given that larger pharmaceutical companies have not been attracted to license ATC?

**Chairman Iain Kirkwood**

Link was founded to focus on marketing niche therapeutic products that are of less interest to larger pharmaceutical companies. Indeed, Link's first products were pharmaceuticals that as a result of their low market size faced withdrawal in spite of patients and clinicians clear needs. Subsequently Link has built a portfolio of niche products in specialist areas which do not require the huge sales forces and infrastructure of larger companies, but which nonetheless generate good revenues. In Link's view, ATC fits perfectly into their business model - there is clearly demand from patients, as exemplified in the recent article on the HIV Haven website. In a nutshell, Link is confident there is a market that can be tapped into because, in this region, many of the first line therapies have been tried and have inevitably failed.

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Can you explain the significance of the recent merger between Link and Equity Pharma in South Africa?

**Chairman Iain Kirkwood**

South Africa's Equity Pharma has a similar focus to Link in providing specialist products. Equity also supports clinicians and patients with early access to important products in late stage development via the so called "Named Patient Schemes" which allow for the tightly controlled supply of medicines that are not yet registered but which are greatly needed by patients. Link and Equity's business models were very similar and while Equity Pharma were interested in getting their products into the Australian and New Zealand market, Link were likewise interested in the South African market. So with so much synergy a merger made good sense and has created a niche company with annual revenues approaching \$100 million and a focus on growing the business throughout the entire Asia-Pacific-African regions and beyond.

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Could ATC be provided to the market by this kind of delivery mechanism, given the need?

**Chairman Iain Kirkwood**

Yes, the potential to explore this avenue is another good reason to explore the synergies between Link and Avexa. Link has a great deal of regulatory expertise in this area so it's clearly worth consideration.

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During the 1H 2012 you announced the signing of option agreements to market your HIV drug apricitabine (ATC) with five companies covering specific regions. How did you choose

these particular partners and what do they offer as ATC co-marketing partners in their respective territories?

#### **Interim CEO Jonathan Coates**

Egamid, a brokering company which specialises in the in-out licensing of pharmaceuticals products in the international healthcare sector with operations in Europe, USA, Japan and other countries, was appointed by Avexa in May 2012. The first step was to generate a list of appropriate target companies so, in collaboration with Avexa, a fairly long 'shortlist' of over 200 companies was drawn up. These were companies identified with the appropriate expertise, interest, territorial reach, and track record to be able to market ATC to greatest advantage a fairly complex process as you can imagine.

Next, in June/July 2012, we developed a concise information brief (often referred to as a flyer), which provided the targeted companies with initial highly detailed but non-confidential information about ATC. At the same time these companies were given information on the search process and were invited to continue discussion. As you might imagine this detailed information pack was the catalyst for a considerable number of interactions with potential partners who sought to understand the product (ATC) and the advantages of ATC and the rights that may be on offer. By August we were able to select over 30 companies who wanted to receive confidential information on ATC and who were prepared to sign a Confidentiality Disclosure Agreement (CDA).

Having reviewed the confidential information provided on ATC, the next step for the remaining 30 companies was to move to full due diligence. This is a process wherein a company should examine every relevant piece of information about a project at every level, to assure them that the project and all the assumptions provided satisfy their own, in-house technical and investment criteria. This is an extensive process which involves examining many hundreds of documents and reports running to thousands of pages. Avexa set up a large, secure website in October solely for this purpose. This is no small undertaking and because of the time and effort involved, companies entering a due diligence process only do so where there is a very high level of interest in the project, We have been delighted that the feedback from this has so far been excellent which would indicate the thoroughness and quality of the data that we hold on ATC. To date we have disclosed potential partners for Middle Eastern markets, Turkish and surrounding regions, Korea and other international regions, the markets of Australia, New Zealand and South Africa, Latin American regions and Taiwan.

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Avexa has yet to sign ATC marketing agreements for major markets such as the US and Europe. What interest have you had from pharmaceuticals companies or distributors in these markets and why is it taking longer to find partners there?

#### **Interim CEO Jonathan Coates**

This process is well underway but given the size and importance of these markets and the number of interested parties, the process is somewhat more complicated. For example in Europe there are a number of companies whose territorial interests overlap. We conclude that it is preferable to have a small number of partners to deal with, so the selection criteria become more important to tie down to the best deal with the best people. We are still sensing an appetite to sell ATC in this very large market. We want to get this right rather than fast.

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You've recently highlighted the support for the development of ATC from among the HIV patient population, citing an article on the HIV Haven website calling for US federal government funding of Phase III ATC trials. Is there any potential to find external funding for the Phase III trials given growing numbers of drug-resistant HIV patients?

**Interim CEO Jonathan Coates**

This is only one of a number of such pieces that have been written extolling the potential benefits that ATC has for patients. In fact, just published very recently is a letter to members of the US legislature seeking support for the development of Nucleoside Reverse Transcriptase inhibitors, and specifically citing ATC as a prime candidate for such funding. The link to that article is [www.ipetitions.com/petition/atc-for-salvage-therapy](http://www.ipetitions.com/petition/atc-for-salvage-therapy).

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Thank you Jonathan and Iain.

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

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