

# Avexa AGM 2014

**Presentation by**

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**&**

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**A V E X A**

## Forward-looking Statements

*This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Avexa to be materially different from the statements in this presentation.*

*Actual results could differ materially depending on factors such as the availability of resources, the results of pre-clinical proof-of-concept studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection.*

*Additional information regarding risks and uncertainties is available from Avexa on request.*





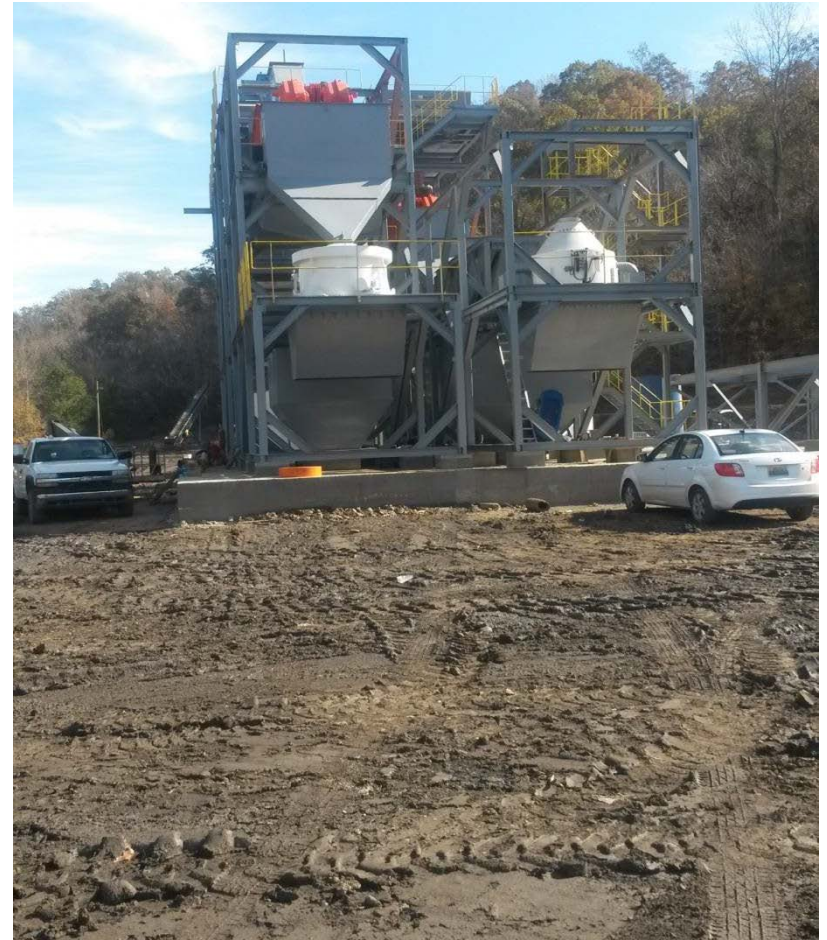
# 2014 highlights

- ❁ Income producing investment (Nth Pratt coal mine, AL, USA)
  - ✓ Completed US\$9 million investment
  - ✓ Capex incl. wash plant completed (end November)
  - ✓ First coal production in December
  
- ❁ Apricitabine (ATC)
  - ✓ Manufacturing successfully completed
  - ✓ Product shipped to (LINK) warehouse in Singapore
  - ✓ Worldwide distribution established
  - ✓ NPS access commenced December
  - ✓ World AIDS Conference (Melbourne) highlights ATC as a promising new AIDS drug





# Nth Pratt wash plant (mid November)



# Jonathan Coates



# Critical role of cytidine analogues in treatment of HIV

- Many different drugs are available to treat HIV
  - Protease inhibitors, integrase inhibitors, entry inhibitors and others
- Three separate fully powered clinical studies discussed at the 20<sup>th</sup> International AIDS Conference in Melbourne
- Compared treatment based on cytidine analogues to treatment based on other drugs
  - Integrase inhibitor
  - Entry inhibitor
  - Non-cytidine nucleoside analogues
- Treatment with cytidine analogues more beneficial in each case
- It is now apparent how important cytidine analogues are in second line treatment



# What are cytidine analogues?

- Analogues of the natural cytidine nucleoside found in viral genome
- Act as chain terminators of viral replication
- 3TC and FTC are the only two approved cytidine analogues
- Very effective drugs
- Very safe drugs
- Very (indeed most) important part of HIV treatment
- BUT easily thwarted by development of the common M184V mutation



# Why apricitabine (ATC)?

- ATC is a new cytidine analogue
- Similar excellent safety and tolerability to 3TC/FTC
- BUT still active against the M184V mutation
- Advanced development
  - One further simplified trial required
    - Rapid endpoint
    - Relatively small
- ATC has an important role in second line treatment
  - Article in A&U magazine
  - Expert panel discussion





# Focus on ATC

- Funding
  - North Pratt
- Early Access Programme / Named Patient Scheme
  - LINK Healthcare (“LINK”)



# Early Access Programme - what is it?

- Special regulations that allow access to lifesaving investigational drugs prior to commercial approval
- Several different names such as:-
  - “Named Patient Scheme”;
  - “Treatment IND”;
  - “Autorisations Temporaires d’Utilisation” (ATU);
  - “Early Access Program” (EAP)
- Only for patients in significant medical need, and only for drugs with solid clinical evidence of safety and efficacy
- Cost recovery possible
- LINK are highly experienced



# Early Access Programme 'EAP' (1)

- Manufacture and supply of ATC substance
  - Existing stocks re-qualified
  - Plans for continued manufacture
  - Improvements in synthetic methods
  - Reduction in cost of goods
- Manufacture and supply of ATC product
  - Encapsulation and bottling
  - Use of existing stocks of ATC
- Sufficient stocks of ATC to service the Phase III trial
- Established the mechanisms for servicing an EAP with LINK



# Early Access Programme (2)

- Stocks of ATC to be held by LINK Healthcare in Singapore warehouse
- System in place for global distribution of ATC
- Provision of ATC to patients who have very few options for therapy remaining
- Revenues
  - Price will be in line with similar therapeutic agents



# HIV Integrase inhibitors: opportunity

- First generation integrase inhibitors now recommended as first line therapy
  - Raltegravir (Merck) twice daily
  - Elvitegravir (Gilead) once daily only with boosting agent
  - Both fragile to resistance development
- Dolutegravir (ViiV) recently approved
  - Once daily combination pill in naïve patients, otherwise twice daily
  - Retains some activity against integrase resistant virus (but twice daily)
  - US wholesale price \$14K/year if once daily
- Increasing use of integrase inhibitors in first line therapy = increasing integrase resistance when first line therapy fails
- No once daily integrase inhibitor active against resistant virus for use after first line



# Avexa's integrase project

- Cash spend - priority on ATC
- Maintaining a strong IP position
  - Long patent lives
  - Strong protection
  - Global coverage
  - Leeway to “catch up”
- Comparing our leads with latest innovations
  - Once daily like dolutegravir
  - Once monthly, in the pipeline



# Urgent Crisis in Antibiotic Resistance

- The World Health Organisation's (WHO) first worldwide report into antimicrobial resistance (2014) says as well as superbugs in hospitals, everyday infections such as pneumonia and urinary tract infections are becoming harder to treat.
- Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections (2013).
- *C. difficile* causes diarrhea linked to at least 14,000 American deaths each year.
- Methicillin-resistant *Staphylococcus aureus* (MRSA) is a bacteria that is resistant to many antibiotics and can cause life-threatening bloodstream infections, pneumonia and surgical site infections.



# Avexa's antibiotic project – work in progress

- Programme licensed to Valevia
  - A Swiss-based biotech company
- Active against clinical isolates of
  - *Clostridium difficile*
  - multi-drug resistant *Staphylococcus aureus* (MRSA)
- \$200K grant in 2013 to Valevia (licensee) for preclinical studies
  - Preparation of material
  - Stability study
  - In vivo study
- Focusing on ***potential for oral activity*** initially
  - Unsuccessful in attempts to make the drug orally active
- Possibility for further grants in the topical arena







## 2015 outlook

### ⊗ Investment

- ✓ Expected recovery in met coal prices
- ✓ Loan repayments commence
- ✓ Look for opportunities to sell investment

### ⊗ Apricitabine (ATC)

- ✓ Full year of EAP
- ✓ Final Ph.III trial expected to commence

### ⊗ Share Purchase Plan offer

- ✓ Opportunity for all shareholders to acquire up to \$15k worth of shares without brokerage costs
- ✓ \$250k underwritten



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