

# **Avexa AGM 2013**

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**Presentation by**

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**&**

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**KPMG House  
Collins St, Melbourne VIC  
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## 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.*



# Share Purchase Plan

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- The company had 8,376 shareholders at 8 October 2013
- Of these, there are some 6,000 shareholders with a non-marketable parcel of shares (i.e. < \$500)
- Directors concluded an SPP was the most effective way for shareholders with a small parcel of shares to top up their holdings to a marketable parcel or larger – free of brokerage and other transaction costs
- The SPP also offers all shareholders an opportunity to buy up to \$15,000 of shares at \$0.013 per share
- SPP closes 17 December 2013
- All shareholders encouraged to participate



# North Pratt coal investment (1)

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- Permits issued August
- Delay was a result of having to meet new, much more stringent EPA benchmarks
- Work commenced on site immediately to refurbish & clean out ponds, road access and site clearance
- These works now completed on schedule and budget



# North Pratt coal investment (2)



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# North Pratt coal investment (3)

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- Closing DD has validated capex and start up costs
- Some items of equipment will be leased where attractive
- First revenues expected Q3 2014
- Build up to full production during 2015
- Full production budgeted at 662,000 tons p/a
- EBITDA at budget US\$100 p/t = \$US31 million p/a
- AVX has 30% joint venture share
- Funds advanced to date – US\$1.2m (\$0.6 for bond)
- Remaining investment now held in US\$ (US\$ purchased ~mid 90's fx rate)
- No fx exposure during investment phase



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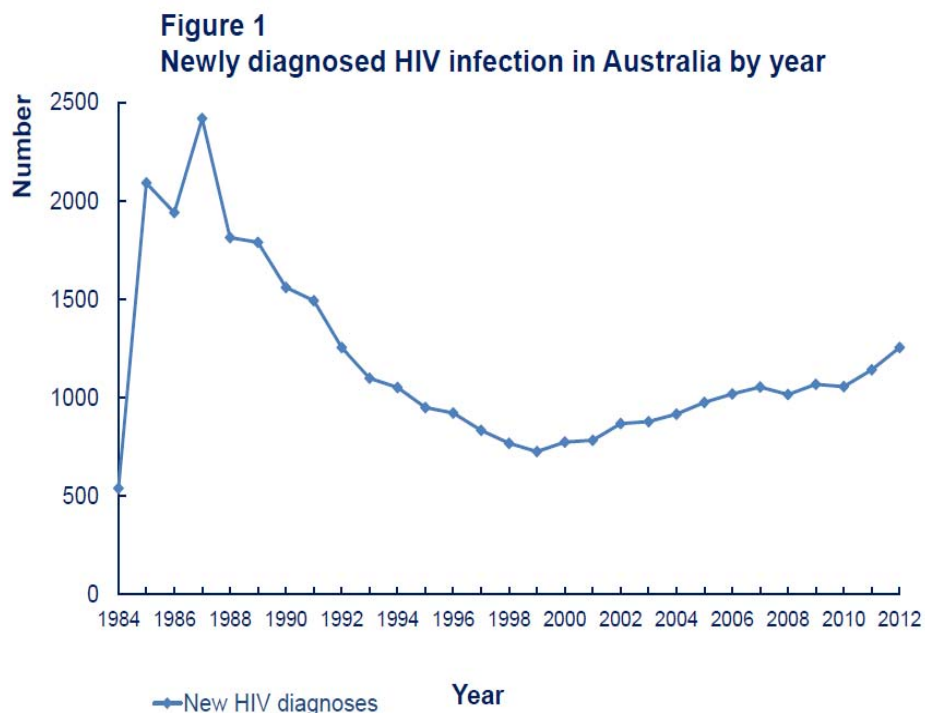
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# Jonathan Coates



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# There is a need for new anti-HIV drugs



- HIV infection steadily increasing in Australia for past ten years
- In Europe 80% of people with HIV are not fully suppressed
  - Not adequately treated
  - Risk of resistance
- 1.7 million deaths from AIDS worldwide (2011)
- Number of people with drug-resistant HIV in Europe has increased by 35% since 2003
- Most common form of resistance is to existing Nucleoside Reverse Transcriptase Inhibitors (NRTIs)



**AVEXA**



# Why Nucleoside Reverse Transcriptase Inhibitors (NRTIs)?

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- Resistance to NRTIs develops more slowly than other classes of HIV drugs
- Generally good safety and tolerability
  - Particularly cytidine analogues: 3TC and FTC
- Few interactions with other drugs
  - Easy to take with many other different drugs (other HIV drugs, diabetes, blood pressure, antibiotics, hepatitis etc)
- Unequalled efficacy
  - 7 clinical trials of regimens without NRTIs
  - All showed poorer outcomes (activity and safety/tolerability)
  - NRTI-free regimens continue to be shown to be less acceptable



# ATC ideally placed to fill the need

Issue	ATC
<i>Resistance to NRTIs develops more slowly than other classes of HIV drugs</i>	No resistance to ATC seen in the clinic out to and past 104 weeks therapy
<i>Generally good safety and tolerability</i>	No significant side effects seen in clinic for ATC
<i>Few interactions with other drugs</i>	<p>Very few significant drug-drug interactions seen with ATC</p> <ul style="list-style-type: none"> <li>• Doesn't interfere with the activity of other drugs</li> <li>• Therefore can be given with other drugs, because patients need other drugs too</li> </ul>
<i>Unequalled efficacy</i>	<p>ATC provided durable antiviral activity in combination with other drugs</p> <ul style="list-style-type: none"> <li>• Additional antiviral activity (0.4 log) over 3TC</li> <li>• Fewer rebounds</li> <li>• Increased CD4 cells</li> <li>• 73% achieved &lt;50 copies/mL at W48 compared to 64% in 3TC arm</li> </ul>



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# Stages to success

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- Clinical trial
- Regulatory approval
- Manufacturing
- Sales and marketing
  - LinkEquity Healthcare



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# Milestones to success

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- Funding for clinical trials and approval
  - North Pratt
    - Permit to mine approved
    - Expect mining to begin Q3 2014
    - Expect revenues to begin on Q3 2014
    - Timeline for beginning clinical trial planned to coincide with first revenues



# Affordable preparation underway

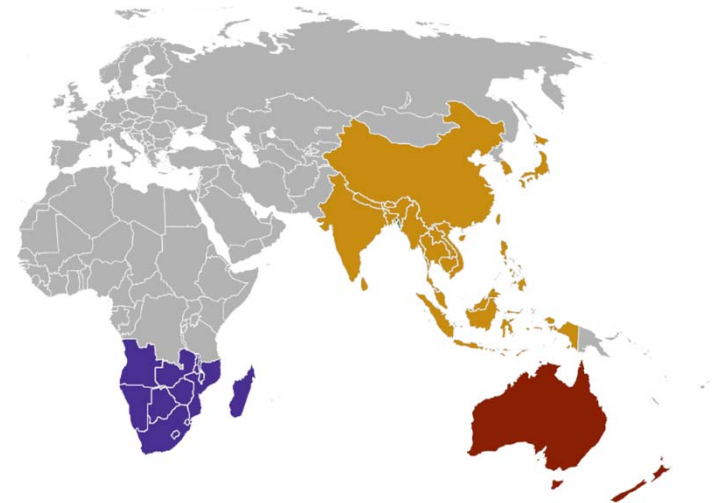
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- ATC active ingredient analysed and “in spec”
- Precursors sourced and ready for further ATC manufacture
- Study drug kit preparation sites “ready to go”
- Potential clinical trial sites approached
- Regulatory authority agreement for trial design



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PRETORIA – SYDNEY – SINGAPORE – AUCKLAND – TOKYO - HONG KONG



AFRICA, AUSTRALASIA, ASIA

## CORPORATE SUMMARY

*'medicine that matters'*

## Products...

- Gastroenterology
- Substance Abuse
- Allergy
- Cardiology
- Anaphylaxis
- Analgesia/Anaesthesia
- Anti-infective
- Endocrinology
- ENT
- Intensive care
- Metabolic disease
- Neurology
- Oncology
- Orphan Drugs
- Transplantation and Toxicology
- Advanced Wound Care



*'medicine that matters'*

*'medicine that matters'*



# Key Capabilities



100+ in-licensed or acquired registered and listed pharmaceuticals and medical devices:

- Specialist sales promotion (in-house sales teams)
- Regulatory maintenance: internal & external
- Production supervision
- Wholesale distribution with full cold chain capabilities
- Full Market support, Medical information and Pharmacovigilance

250+ Named Patient Products

- Early Access Program management
- Clinical trial supply

Supply chain management

- Named Patient Service: Named Patient Supply, Special Access Scheme (+250)
- Sophisticated direct distribution: direct to Hospital/Doctor
- Cold chain supply management throughout region
- Global access (the manufacturing source)
- Experienced import and export management
- Strong Government and Medical support

*'medicine that matters'*

*'medicine that matters'*



# HIV Integrase inhibitors: opportunity

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- 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

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- Series of second/third generation compounds
  - comprehensively protected by full length patents
- Active against both wild type and resistant virus
  - Multiple opportunities
- Two compounds have pharmacokinetic profiles indicative of once daily dosing in rats and primates
- Further analogues identified
  - Some with even higher potency
- Optimisation process underway (as funds allow)
  - Potency (wild type and resistant virus)
  - Pharmacokinetics (once daily)
  - Route of metabolism (co-formulation)
  - Likely daily dose



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# Urgent Crisis in Antibiotic Resistance

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- Two million serious antibiotic-resistant infections per year in the USA alone
  - 23 000 deaths
  - US\$20 billion in excess direct healthcare costs
- 250 000 hospitalisations in USA for *Clostridium difficile*
  - 14 000 deaths
  - US\$1 billion in excess medical costs
- 30% of enterococcus infections in USA are now vancomycin-resistant
  - 20 000 VRE infections
  - 1300 deaths
- Only one novel antibiotic developed in the last 50 years



# Avexa's antibiotic project

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- Programme licensed to Valevia
  - A Swiss-based biotech company
- Active against clinical isolates of
  - *Clostridium difficile*
  - multi-drug resistant *Staphylococcus aureus* (MRSA)
  - penicillin-resistant Streptococci
  - Vancomycin-resistant enterococci (VRE)
- Focusing on *Clostridium difficile* initially
- \$200K grant to Valevia (licensee) for preclinical studies
  - Preparation of material
  - Stability study
  - In vivo study
- Possibility for further grants



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**[www.avexa.com.au](http://www.avexa.com.au)**



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