Avexa

“Changing market perceptions”

Company Presentation
June 2014

Disclaimer

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.

Company snapshot

- Focus
  - Infectious diseases & HIV and antibiotic-resistant bacterial infections
- Three drug compounds with the potential to treat resistant infections that are currently poorly treated
  - ATC - a very late stage therapy for the treatment of drug-resistant HIV infections
  - Integrase inhibitors – a series of discovery phase compounds for the treatment of integrase-inhibitor resistant infections
  - Antibiotic project – compounds with novel mode of action with activity against antibiotic resistant infections. Licensed to Valevia in Switzerland

Shares on issue	925.7m
Market capitalisation	$12.0m
Substantial shareholder	J Lim (15.6%)
Board & Management	2.1%

- ATC clinical trial funding strategy

Investment (30%) in the North Pratt coal mine in Alabama, USA. First coal production scheduled for Q4 2014.

AVX – significantly undervalued by any measure

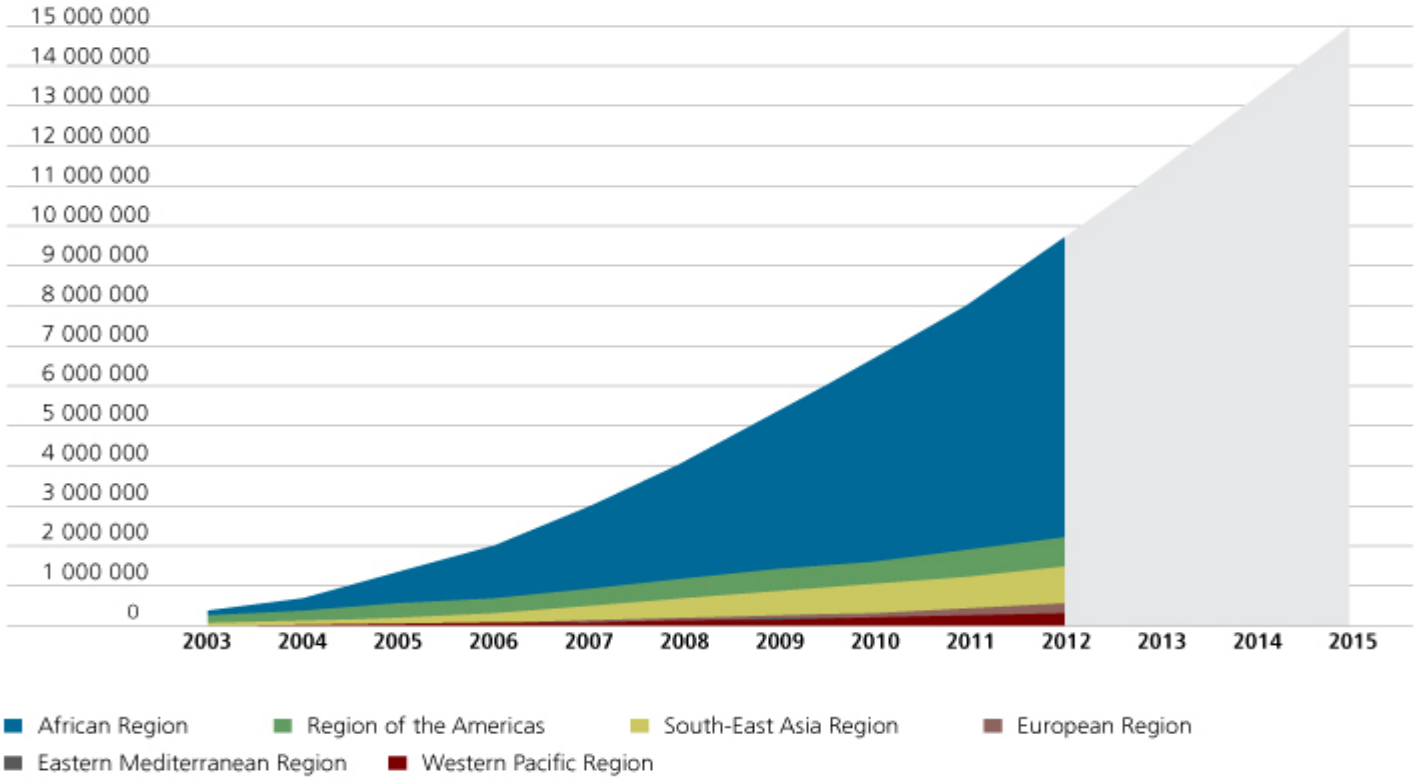
- Three drug assets with one, ATC, in Phase 3
- ATC has potential market sales of US$90 – 272m (USA alone)
- Manufacturing of ATC for clinical trials and special access schemes (Named Patient Scheme, NPS) has commenced
- NPS expected to commence Q4 2014
- Partnered with Link Healthcare – No.2 in HIV drug sales in South Africa
- 30% equity stake in US coal mine *(cash flows to fund trials)*
- Life-of-Mine cash-flow US$295m *(based on US$100/ton sales price)*
- Coal production expected to commence Q4, 2014
- Cash on hand post US coal investment $3.5m*

**As at end of May 2014*

Demand for Anti-Retroviral Therapy (ART) treatment is growing

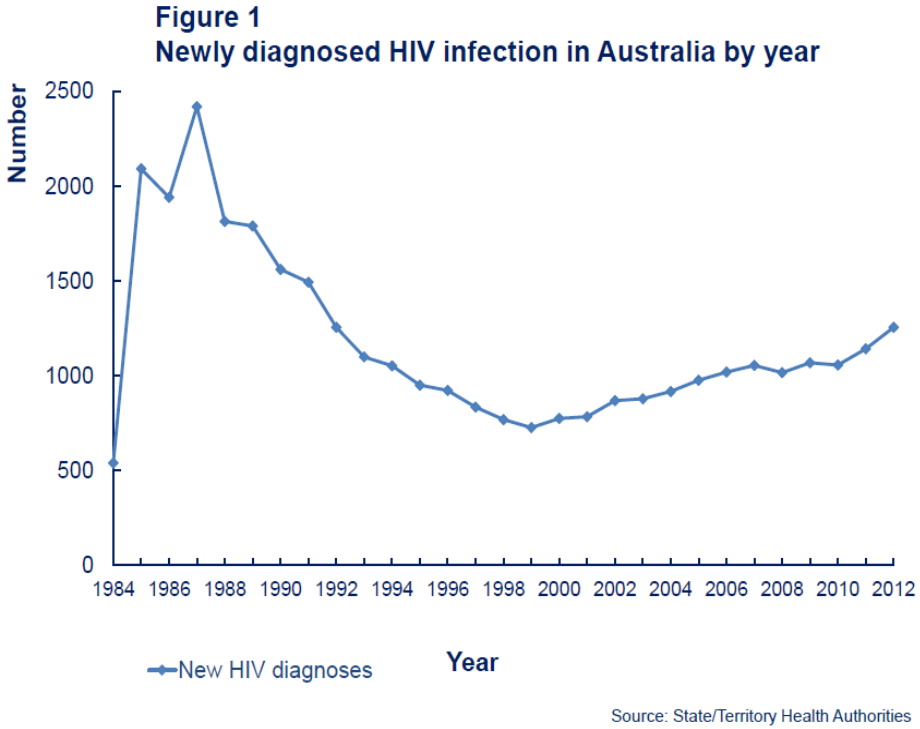
World Health Organization

Actual and projected number of people receiving antiretroviral therapy in low- and middle-income countries, by WHO region, 2003–2015



Source: 2013 Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS)

...so there remains a need for new anti-HIV drugs



- Most common form of resistance is to existing Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

- 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
- 18% of newly diagnosed young people in New York City are drug-resistant before therapy even starts

ATC overview

2005	ATC licensed from Shire (UK); ATC had completed Phase 2a
2009	ATC proved to be safe and effective in Phase 2b & Phase 3 trials > $100 million spent to date on trials / project
2010	Unable to secure funding /co-development deal with big pharma Project terminated and all ATC work stopped New board voted in to seek a different model to progress ATC Independent review confirms ATC has market potential
2011	USA & EU regulatory authorities agree to shorter and simpler, less costly, final Phase 3 clinical trial with a rapid (14 days) end-point for approval
2012	December AGM – shareholders approve investment in North Pratt coal mine as a vehicle to fund ATC development
2013	Collaboration with Link Healthcare on ATC Decision to make ATC available under special access/named patient schemes Manufacturing of ATC commences for clinical trials and special access
2014	Q4 – ATC expected to be available for special access ATC trials planned to commence as funding from coal cash flow allows

ATC funding strategy

- Remaining Phase 3 trial to cost circa $30 million
- New board needed to address
  - Insufficient cash reserves to recommence trials *($20m at Dec'12)*
  - Inability to raise cash from equity markets given recent circumstances
- Board looked "outside the box" and sought to break the "cap raise and cash burn" paradigm of most biotechnology companies
- Opportunity arose to invest in North Pratt coal mine *(Alabama, USA)*
- US$10m investment for 25% (now 30%) equity
- DD completed Q4 2012; shareholders approved at Dec'12 AGM
- Project commenced early 2013
- Permit delays in USA allowed AVX to negotiate better terms
  - Increase equity stake to 30%
  - Investment reduced to US$8m *(cost savings identified)*
  - High FX rate allowed AVX to fully hedge US$8m investment
- Named Patient Scheme (NPS) proceeds to be applied to ATC development

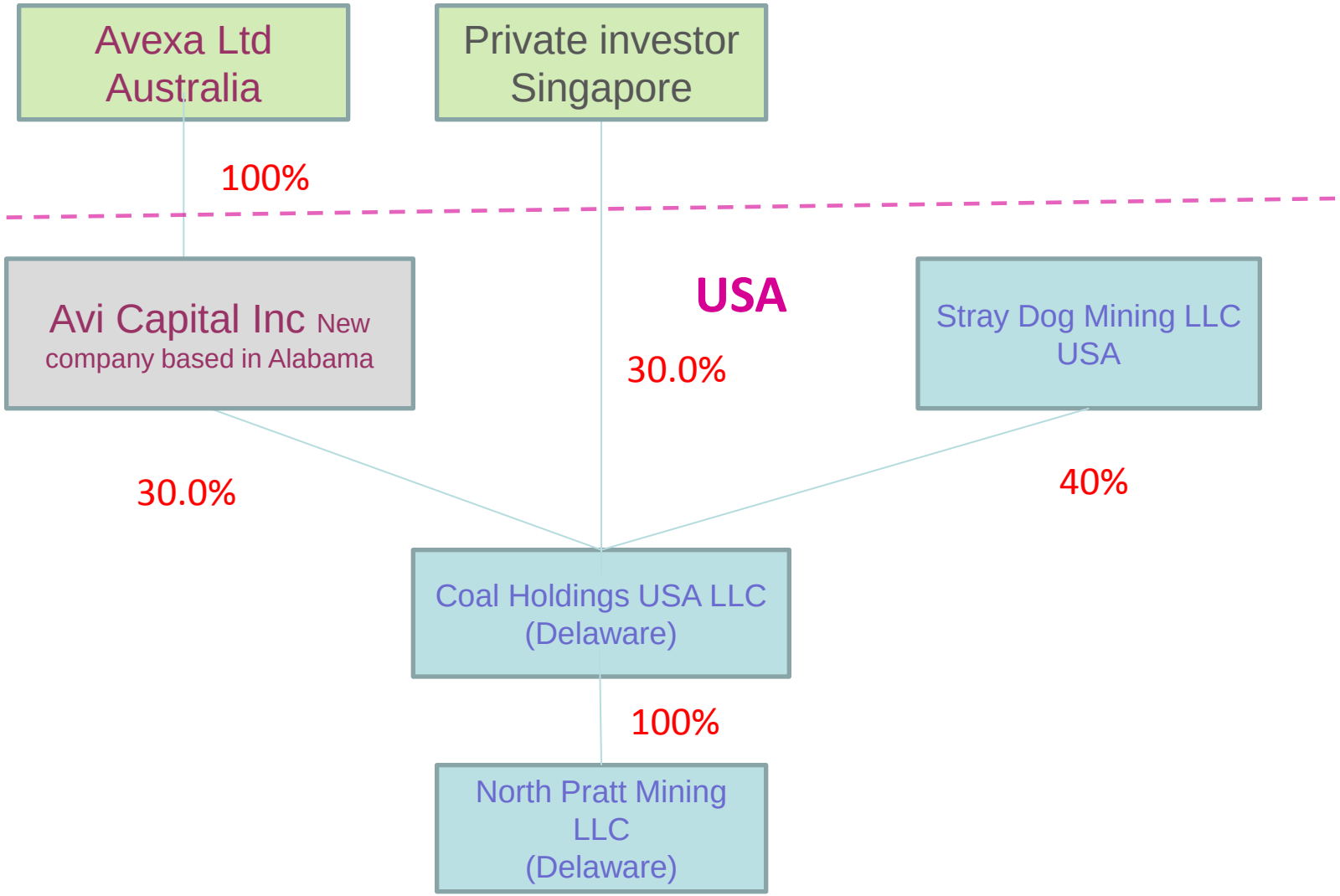
North Pratt coal mine investment

- North Pratt was a mothballed mine now being re-opened
- Metallurgical coal *(used to make steel)*
- US$8 million investment for 30% equity
- Expected to generate revenue of US$51m p/a gross based on US$100/ton sale price
- Allows AVX to allocate cash resources towards the final development of ATC
  - AVX-305 clinical trial - preparations already underway
- Revenue generating investment - flexibility

North Pratt – financial snapshot

- Projected Mine Life : 17 years
- Capital Investment : US$8m *(AVX share)*
- Saleable Coal Production Life of Mine (LOM) : 8.75m US short tons
- Average Coal Price : US$100 per ton *(budget)*
- Revenues : US$51m p/a; $875m Life of Mine
- EBITDA : US$344m LOM; US$19m p/a average
- Cash flow : LOM US$295M
- Return on Investment Before Taxes : 62%

North Pratt - corporate structure



ATC - stages to success: regulatory approval

- Final small clinical trial for approval
  - Only 300 patients
  - Primary endpoint at 14 days
  - Protocol developed in conjunction with FDA & EMA (European Medicines Agency)
  - Feasibility completed, sites identified
  - Existing ATC stocks
  - Preparations well advanced

ATC - stages to success: sales and marketing

- Evident that AVX was not going to secure big pharma assistance (either co-development or sales & marketing)
- Partnership with Link Healthcare was created in 2012/13
- No.2 seller of anti-HIV drugs in South Africa
- Expertise in marketing specialist products
- Highly experienced in pre-approval access
- Named Patient Scheme (NPS)
  - Enables provision of life-saving new drugs prior to regulatory approval
  - Provides greater access to ATC than a small clinical trial
    - Clinical trial not run in all countries
  - Builds familiarity
  - Driven by demand
  - Volumes of products delivered through NPS can be significant
- NPS net revenues to contribute to cash flow

Link Healthcare – a fast growing specialty pharma

- +250 NPS Products
- >60+ in-licensed or acquired registered & listed pharmaceuticals and medical devices:
  - Regulatory maintenance: internal & external
  - Production supervision
  - Wholesale distribution
  - Full market support/medical info
  - Specialist sales promotion (in-house sales teams)
- Supply chain management
  - Named Patient Service: Special Access Schemes (>100)
  - Sophisticated direct distribution: direct to Hospital/Doctor
  - Cold chain supply management throughout region
  - Global access
  - Experienced import management
  - Strong Government and medical support

Why ATC?

- Active in all classes of drug resistant patients
  - NRTI, NNRTI, protease, integrase, CCR5 and fusion inhibitors
- Extremely low development of resistance
  - No resistance to ATC up to 144 weeks of treatment
- Excellent safety and tolerability
  - More than three years of treatment
- Very few interactions with other drugs
  - other HIV drugs, diabetes, blood pressure, antibiotics, hepatitis etc
- Proven efficacy
  - 48 week study (AVX-301) and 144 week study (AVX-201E)
  - Both studies fully reviewed by FDA
- NRTI regimens continue to be shown to be the gold standard
  - 7 clinical trials of regimens without NRTIs
  - All showed poorer outcomes (activity and safety/tolerability)

HIV Integrase inhibitors

- 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

- 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

Urgent Crisis in Antibiotic Resistance

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

Avexa's antibiotic project

- Programme licensed to Valevia *(Swiss 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

Board & Management

Mr Iain Kirkwood *MA (Hons) Oxon, FCPA, CA, MAICD*
Independent Non-Executive Chairman

Mr Bruce Hewett *BAppSc. (Pharmacy), GAICD*
Independent Non-Executive Director

Mr Allan Tan *LLB (Hons), Barrister-at-Law (Gray's Inn) MA*
Independent Non-Executive Director

Dr Jonathan Coates *PhD*
CSO & Interim CEO

Mr Lee Mitchell *BA LLB*
Company Secretary

www.avexa.com.au