



**A V E X A**

A biotechnology and research development company

# **Interim CEO & CSO Company Update**

# Avexa drug portfolio

## Avexa has three drugs

- Late stage/Phase III
  - ATC (apricitabine) – ready to start trials subject to funding
- Early stage/pre-clinical
  - HIV Integrase inhibitors (second generation) – two pre-clinical leads
  - Antibacterial program – exciting new data & ready to progress to formal preclinical studies



# ATC (apricitabine)

- Regulatory
  - Secured positive response from EMA – similar to FDA
  - Rapid route to approval both in EU & USA
- Development
  - AVX – 305 trial protocol developed
  - Feasibility study completed
  - Sites and investigators identified in 15 countries
  - Working with a CRO to undertake trial preparations
  - Low risk trial ready for rapid start
- Partnering
  - Co-marketing strategy working
  - Agreements in place with six companies to date



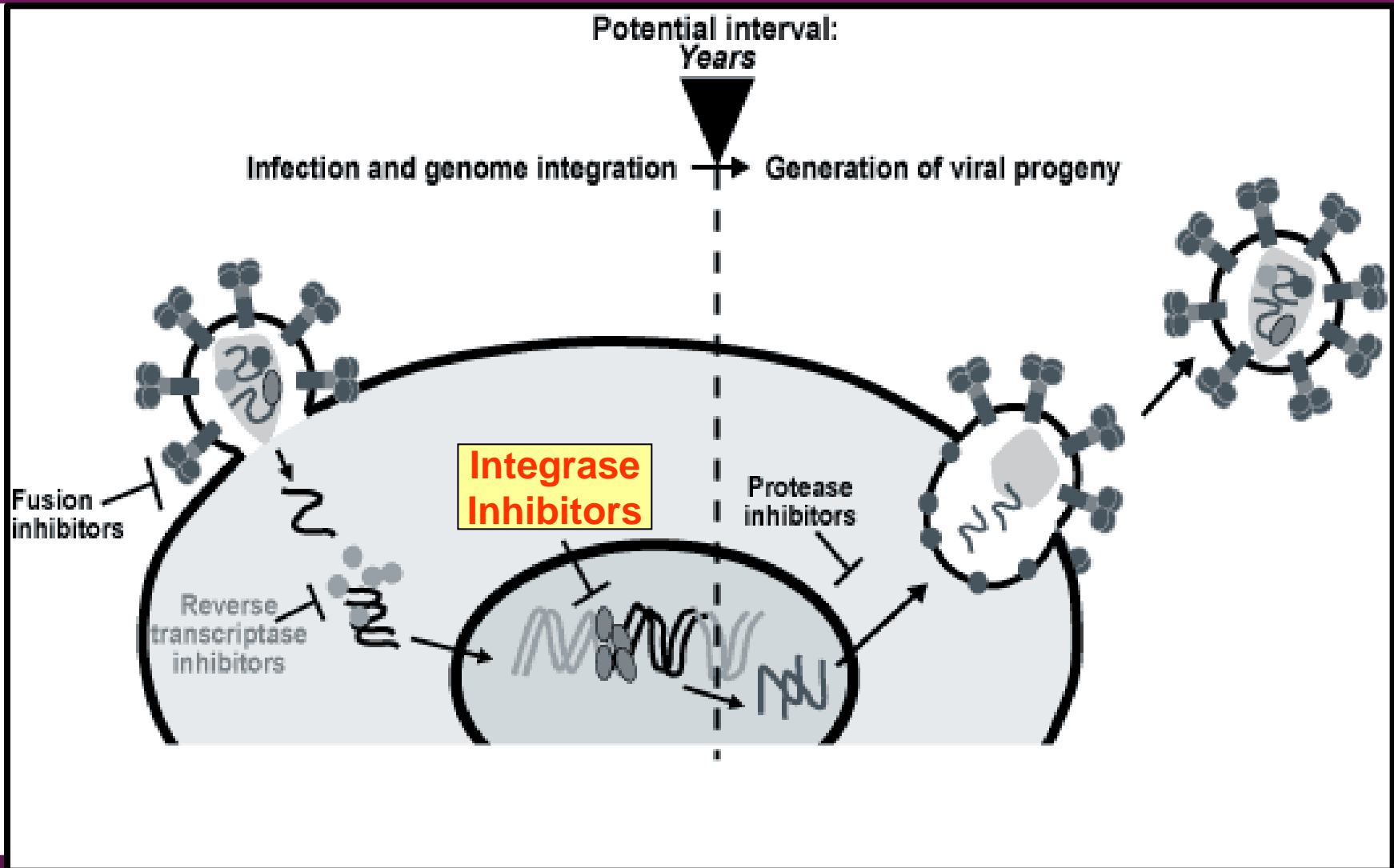
# Antibiotic Program

- Successful progress in moving the program towards pre-clinical development
  - Leveraging global anti-bacterial team
  - Exploring the new target of C. difficile
    - New exciting data
    - Currently \$25,000/day hospital costs for C. dif therapy
  - Unmet medical need
- Valevia anticipate clinical studies will commence in late 2013/ early 2014
- A number of European grants have been applied for



# HIV integrase in HIV Replication

an essential enzyme for viral replication



# HIV Integrase – competitive landscape

- Merck - raltegravir sales US\$1.4Bn in 2011
  - Twice daily
  - Resistance is common
- Gilead - elvitegravir recently approved for naïve patients
  - Once daily combination pill with a booster
  - Resistance pattern similar to raltegravir
- ViiV - dolutegravir in late development
  - Once daily for naïve patients but twice daily for resistant patients
  - Competes with Gilead's once daily
- Market Opportunity
  - Resistant patients
  - Patients who have failed first line integrase fixed combinations
  - Once daily preferred
  - Not necessarily in a fixed combination



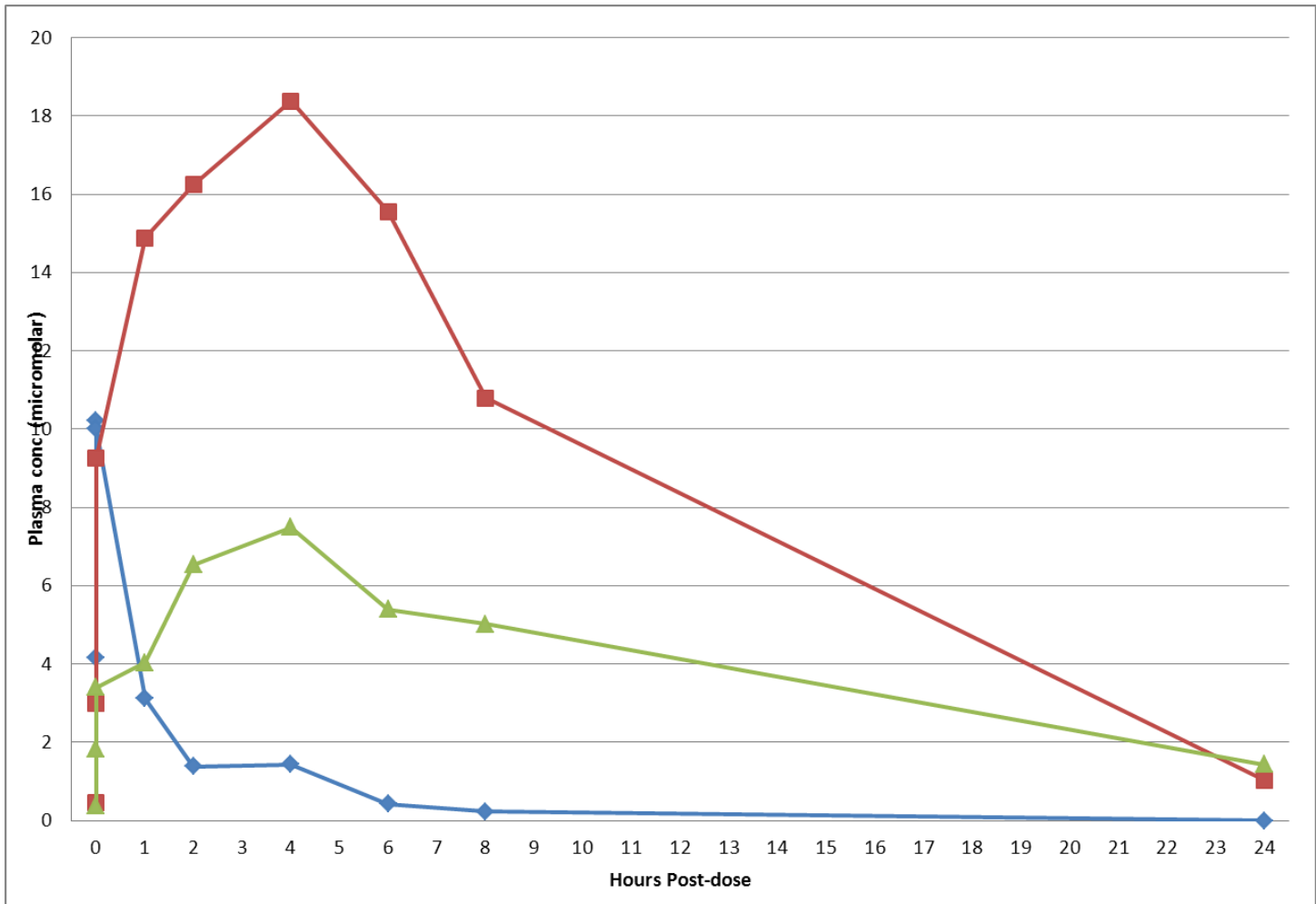
# Avexa's HIV Integrase – the problem

- Series of compounds discovered with highly potent activity against sensitive and resistant HIV strains
- Short half life after oral administration
  - Suggested twice daily dosing
- Undertook optimisation programme to improve PK parameters
  - Gave compounds with improved PK
  - Indicative of once daily dosing
  - Retains excellent antiviral activity



# HIV integrase inhibitors

## – PK after oral dosing





# Avexa's HIV Integrase

- Highly potent inhibitors
- Active against resistant virus
- PK parameters indicate once daily dosing
- Future development milestones:
  - Pre-clinical programme and IND filing (12-18mths)
  - Phase 1/2 clinical study (12-18mths)
  - Relatively low cost – so can be completed with cash on hand even after proposed Alabama investment
  - High level of experience
  - Highly attractive licensing point after Phase 1/2





# AVEXA

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AVEXA

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# Supplementary material

# ATC: EMA response positive

- EMA regulates approval of medicines in 30 European countries
- Traditionally more conservative than the FDA
  - Can be difficult to get consensus
- Secured a positive response
  - Broadly similar to that of FDA regarding requirements to complete ATC development and obtain approval
- Supportive of ATC's potential role in HIV treatment
- Acknowledgement of the unmet need in resistant HIV patients and ATC's potential to meet that need
- Secured a rapid route to approval in both EU and USA
  - Low cost
  - Low risk



# ATC Partnering Strategy

- Co-marketing vs Co-Development
  - ATC not attractive to large Pharma
  - ATC attractive to patients and clinicians
    - Marketable asset
- Seek Marketing Partners
  - 250+ target companies
  - Non-confidential dossier
  - CDA
  - Confidential dossier
  - Due diligence
  - Marketing agreements



# ATC: Co-marketing partnering strategy working

- Announced marketing agreements with:
  - Dem Ilac
  - Dong Wha
  - Link Health
  - Sanfer
  - Shiner

