

## Cautionary Statement Regarding Forward-Looking Statements



In order to utilise the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, AstraZeneca is providing the following cautionary statement. This presentation contains forward-looking statements with respect to the financial condition, results of operations and businesses of AstraZeneca. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trade marks; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; and the risk of environmental liabilities.

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Seroquel™

Carolyn Fitzsimons

I never thought I could stay with a job this long

# Now I can


In schizophrenia and bipolar mania

**Seroquel**<sup>TM</sup>  
quetiapine

Help patients be their best

AstraZeneca  
NEUROSCIENCE

## Seroquel<sup>TM</sup> development programme submission plans



- 2006**
  - SR schizophrenia (US & EU)
  - Relapse prevention (US)
- 2007**
  - Bipolar maintenance (US & EU)
  - Bipolar depression (EU)
  - SR Generalised Anxiety Disorder (US)
  - SR Bipolar depression (US)
- 2008**
  - SR Major Depressive Disorder (US & EU)
  - SR Generalized Anxiety Disorder (EU)
  - SR Bipolar depression (EU)
  - SR Bipolar mania (US & EU)

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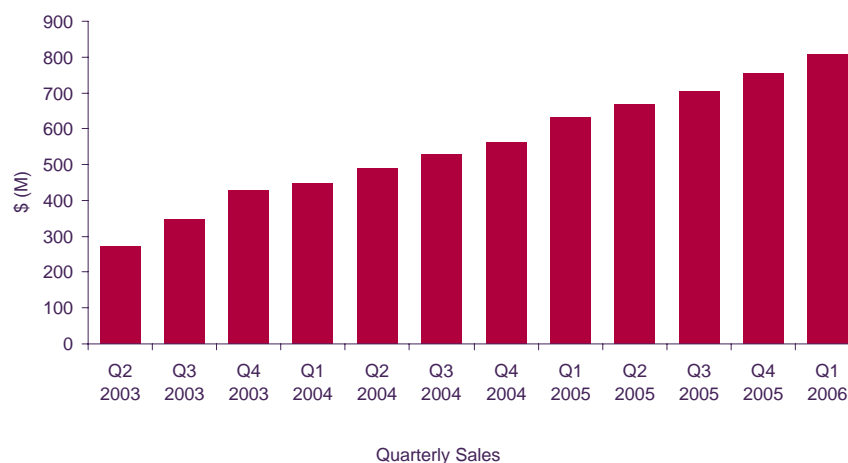
## Seroquel™ growth opportunities



- Short-term (<1 year)
  - Share growth
  - Capitalise on dynamic schizophrenia market
  - Differentiation in Bipolar Disorder
- Medium-term (1-3 years)
  - New SR Formulation
  - Enhanced patient care
- Long-term (> 3 years)
  - New indications

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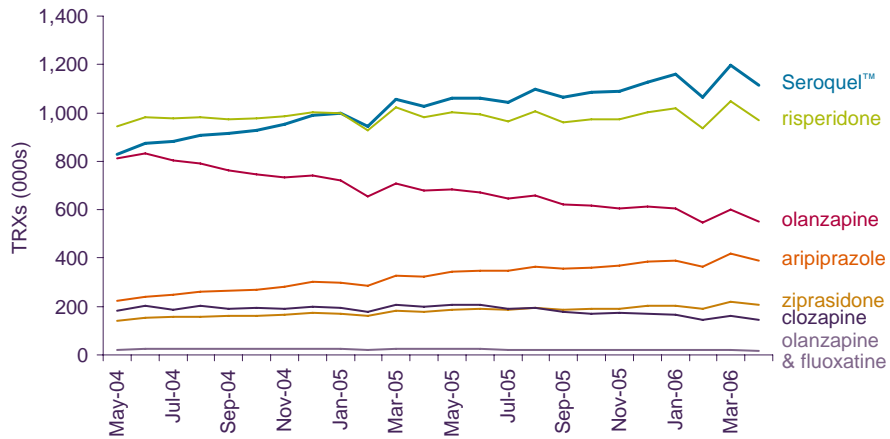
## Seroquel™ quarterly growth



Source: Internal data OLAP/SCOUT  
Actual sales with actual RoX

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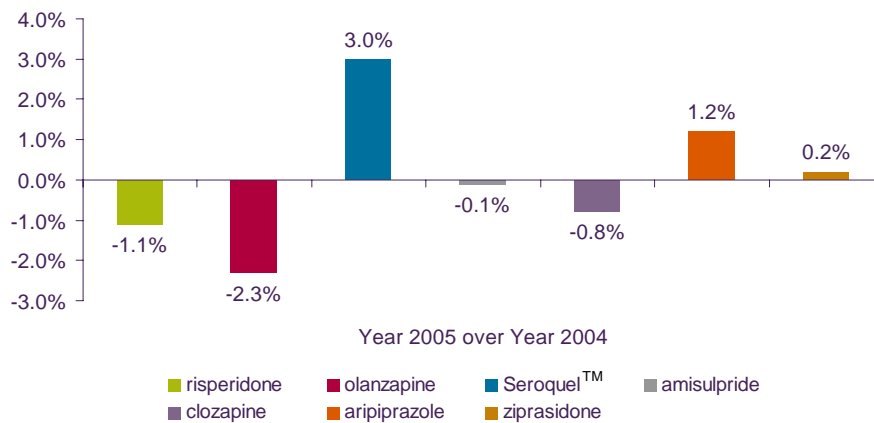
## Seroquel™: Most prescribed atypical



Source: IMS HEALTH, NPA, Monthly data, N5A1 plus Symbyax™  
US dispensed total prescriptions

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## Fastest global growth



Source: IMS Health, MIDAS, All Countries, Standard Units  
Market Share Change, Year 2005 vs Year 2004

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## Seroquel™ physician perceptions: Schizophrenia



- Comparable efficacy with other atypicals against positive and negative symptoms
- Effective in reducing anxiety and depressive symptoms
- Superior tolerability
  - Low rate of EPS (inc. akathisia)
  - Low rate of prolactin induction
  - Less weight gain than with olanzapine
- Overall favourable benefit/risk profile

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## Winning in the schizophrenia market



- Schizophrenia market is highly dynamic
  - 90% patients fail 1<sup>st</sup> line therapy
  - 55% fail 2<sup>nd</sup> line therapy
- US
  - Seroquel™ gains mainly from olanzapine (67%) and risperidone(26%)
  - olanzapine and risperidone both have net losses
- EU
  - Seroquel™ gains from olanzapine (40%) and risperidone (20%) and typicals (20%)

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## Seroquel™ physician perceptions: Bipolar



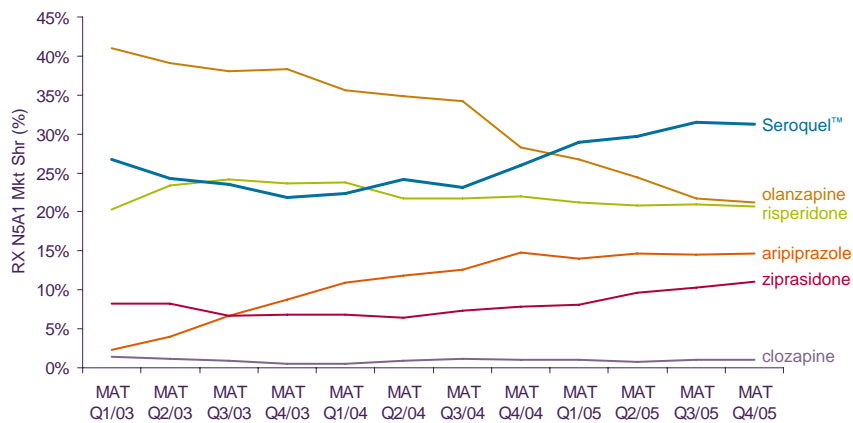
- Strong efficacy against mood symptoms
- Effective in reducing anxiety
- Superior tolerability
  - Low rate of EPS (inc. akathisia)
  - Low rate of prolactin induction
  - Less weight gain than with olanzapine
- Overall favourable benefit/risk profile

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## Market leader in Bipolar



US: Atypical market shares for Bipolar



Source: IMS Health, MIDAS, N5A1, US, All Bipolar, Written Prescription Share

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## Bipolar depression: Key dates



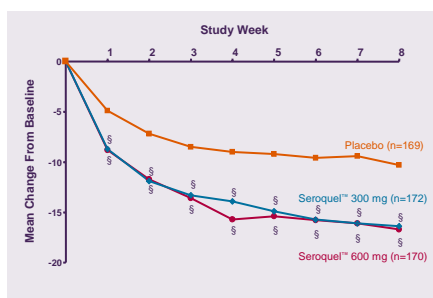
- sNDA filed in US December 2005
- PDUFA date October 30th 2006
- Filing in EU 1H 2007
  - Requires long-term data

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## Impact on Bipolar depression



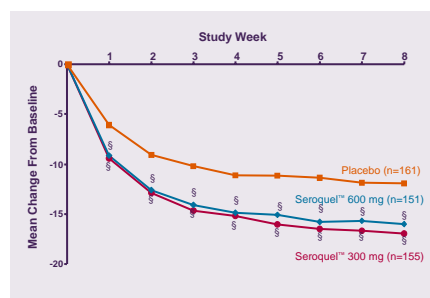
### BOLDER I



§P<0.001 vs placebo

Source: ITT, LOCF  
Calabrese et al (2005)

### BOLDER II



§P<0.001 vs placebo

Source: ITT, LOCF

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## Short-term opportunities



- Sustained share growth
- Enhance differentiation
- Market dynamics provide new opportunities

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## Mid-term opportunities

### Seroquel™ SR



## SR schizophrenia: Unique product profile



### Differentiating claims compared to IR

- Once daily
- Effective dose day two
- Faster titration
- Relapse prevention

### Additional data

- Simple switch (IR to SR)
- Well tolerated

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## SR vs Placebo PANSS Response Rate Day 42



Study 132 data on file

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## SR schizophrenia timings



- sNDA submission to FDA - July 2006
- EU submission – Q4 2006
- Patent expiry 2017

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## SR lifecycle plans



- Clinical programme for Bipolar mania and depression
- Key claims for Bipolar disorder
  - Mixed and rapid cyclers
  - Simple titration
  - Faster target dose
  - QD vs. BID

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## Mid-term opportunities



### New formulation

- Seroquel™ SR
  - An improved treatment option in schizophrenia and Bipolar disorder
- Enhanced patient care

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## Longer term opportunities

### Seroquel™: New indications



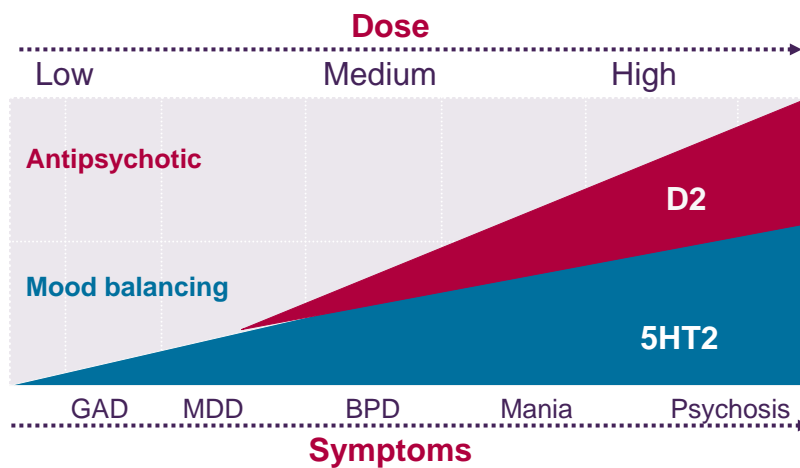
## Depression market opportunity



- Depression market 2005 global sales \$19bn
- 2005 growth -2%
- New product launches
  - Atypical antipsychotics
  - GABA analogues
  - Melatonin analogues

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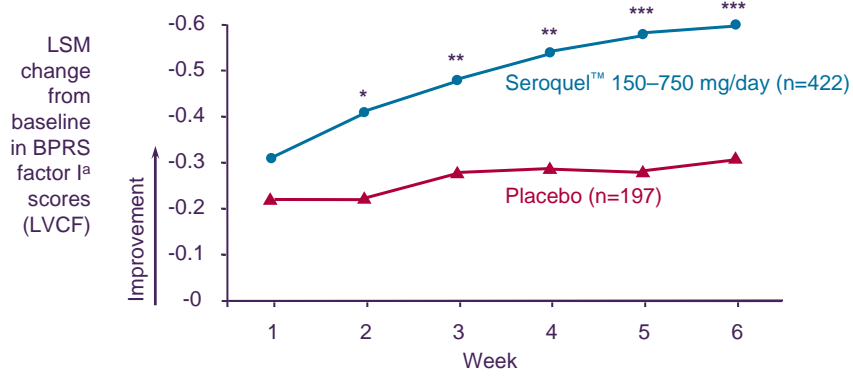
## Dose and effect



Seroquel™ is a mood stabilising agent and an effective antipsychotic at high dose

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## Improved mood symptoms in schizophrenia

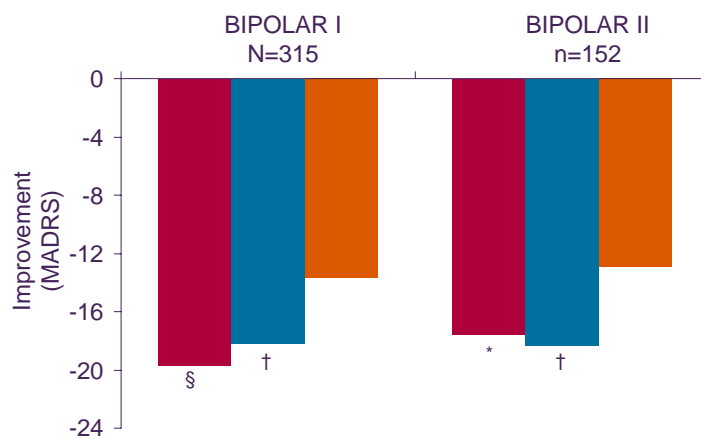


\* $p < 0.05$  \*\* $p < 0.01$  \*\*\* $p < 0.001$  vs placebo  
 Results from a meta-analysis of 3 randomised double-blind trials  
<sup>a</sup>anxiety, depression, guilt feeling, somatic concern

Source: Data on file (S128) - AstraZeneca

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## Alleviating depression in Bipolar I and II patients



\* $P < 0.05$ ; † $P < 0.01$ ; § $P < 0.001$  vs placebo

Week 8, MMRM  
 Source: Calabrese et al 2005;  
 In-house data, AstraZeneca Pharmaceutical, LP. December, 2005

■ Seroquel™ 300 mg (n=155)  
 ■ Seroquel™ 600 mg (n=151)  
 ■ Placebo (n=161)

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## Unmet needs in depression



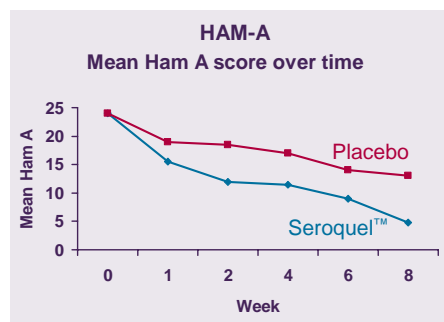
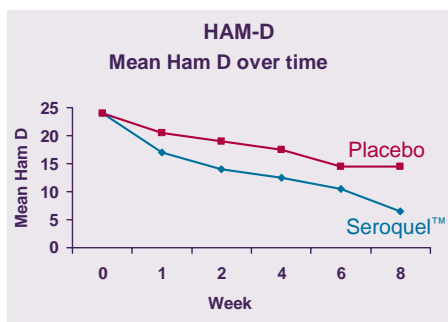
- Efficacy
  - More effective than antidepressants alone when used in combination
  - Early onset of action
- Well tolerated
- Effective and well tolerated in co-morbid anxiety and depression
- Effective in patients with co-morbid sleep disturbance

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## Growing evidence in depression and anxiety (results from McIntyre, August, 2005)



Statistically significant separation from placebo at every time point including week 1

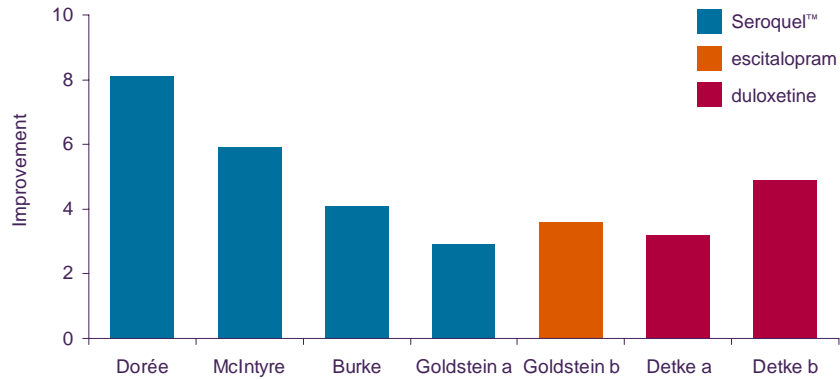


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## Potential vs leading antidepressants



Indirect comparison between the Seroquel™ studies and pivotal trials for escitalopram and duloxetine that have used HAM-D



Source: Dorée et al. 2004, Poster APA (lithium, not placebo); McIntyre. 2005, Manuscript; Am J Psychiatry; Burke et al., 2002, J Clin Psychiatry; Goldstein et al. 2002 J Clin Psychiatry; Goldstein et al. 2004, J Clin Psychopharmacol; Detke et al. 2002. Journal of Psychiatric Research; Detke et al. 2002 J Clin Psychiatry, (MMRM, not LOCF)

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## Long-term opportunities



### New indications

#### ■ MDD and GAD

- Growth driven by real patient benefits

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## Antipsychotics: Viewed as highly differentiated



- Antipsychotics are viewed as a highly differentiated class
  - Physicians
  - Payors
- Recognition that no single treatment will suit all patients
- CATIE reconfirmed need for treatment choice

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## Seroquel™ development programme



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Now we can...



I've always wanted to be part of a team

**Now I can**

**Seroquel**  
quetiapine

Help patients be their best

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