Brand Council I - 2003

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Answers That Matter.
WELCOME!
Introductions

- Name
- Area / Role

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Agenda Review

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Goal for Brand Council I

- Review Strategy
- Review Clinical Studies / Data
- Identify Gaps
- Fill Gaps wherever possible as a Brand Council

Success:
- Completed and prioritized grid of needs and group(s) responsible
What Stays the Same

- Strategic Intent: $6 by ‘06
- Brand Promise
- Brand Architecture
- Target Segments: Stabilize, Hope, Motivate
- CSFs (with the exception of Access)
Significant Changes

- Redacted
- Bipolar mania approval in EU
- Extremely positive SOHO results
- Exploration of new areas for schizophrenia: cognition, gray matter, prodromal, 1st episode
- Positive Geodon head-to-head
- Exploration (not funded at this point) of bipolar II, bipolar depot, schizoaffective, borderline and other opportunities
- No longer pursuing a dementia indication, high dose registration, or Zyprexa bipolar depression
- Delay in Depot study and RAIM
- Regulatory label changes
- Seroquel increasing as a competitive threat
“Of the ten best-selling drugs in 2002, the fastest-growing worldwide was Zyprexa, a schizophrenia and bipolar disorder treatment, with sales rising 21 percent year over year to $4.0 billion.”

## Leading Products in 2002 Global Pharmaceutical Sales

<table>
<thead>
<tr>
<th>Audited World Product Sales</th>
<th>2002 Sales (US$B)</th>
<th>Percentage Global Sales (US$)</th>
<th>Percentage Growth Year-over-Year (Constant dollar)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lipitor</td>
<td>$8.6</td>
<td>2%</td>
<td>+20%</td>
</tr>
<tr>
<td>2. Zocor</td>
<td>$6.2</td>
<td>2%</td>
<td>+13%</td>
</tr>
<tr>
<td>3. Losec/Prilosec</td>
<td>$5.2</td>
<td>1%</td>
<td>-19%</td>
</tr>
<tr>
<td>4. Zyprexa</td>
<td>$4.0</td>
<td>1%</td>
<td>+21%</td>
</tr>
<tr>
<td>5. Norvasc</td>
<td>$4.0</td>
<td>1%</td>
<td>+6%</td>
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<tr>
<td>6. Erypo</td>
<td>$3.8</td>
<td>1%</td>
<td>18%</td>
</tr>
<tr>
<td>7. O gast ro/Prevacid</td>
<td>$3.6</td>
<td>1%</td>
<td>+3%</td>
</tr>
<tr>
<td>8. Seroxat/Paxil</td>
<td>$3.3</td>
<td>1%</td>
<td>+13%</td>
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<tr>
<td>9. Celebrex</td>
<td>$3.1</td>
<td>1%</td>
<td>-1%</td>
</tr>
<tr>
<td>10. Zoloft</td>
<td>$2.9</td>
<td>1%</td>
<td>+12%</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>$44.7</strong></td>
<td><strong>11%</strong></td>
<td><strong>+11%</strong></td>
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</table>
Zyptexa 2003 Long Range Plan — Based on Affiliate Forecast Roll-Up

Zyptexa 2003 Long Range Plan by Line Extension (unprobablized)

- Zyptexa Depot, pTS=80%
- Zyptexa BPM, pTS=90%
- Zyptexa (Base, RAIM, Biploar Mania in EU)

Revenue ($000s)

- $9,000,000
- $8,000,000
- $7,000,000
- $6,000,000
- $5,000,000
- $4,000,000
- $3,000,000
- $2,000,000
- $1,000,000
- $0

Years: 2003 to 2015
Zytrexa Lifecycle Road Map

Q3/03 redacted
Q4/03 Zytrexa mania combination (US)
2003zytrexa RAIM launch

Bipolar Maintenance
(Q1/04 for US/EU)
Zytrexa depot launch
(Q1/07-Q3/07 US)
(Q3/07 EU)
Adolescent launch (Q3/07 US)
Oral Patent Expiration
Depot Patent Expiration

Additional considerations:
Risperdal patent expiration (2006)
Depakote patent expiration (2008)
## Competitive Landscape by Indications and Formulations

<table>
<thead>
<tr>
<th>Schizophrenia</th>
<th>ZYPREXA</th>
<th>Risperdal</th>
<th>Seroquel</th>
<th>Geodon</th>
<th>ABILIFY</th>
<th>DEPAKOTE</th>
<th>LAMICTAL</th>
<th>Others</th>
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<tbody>
<tr>
<td>Acute</td>
<td>X</td>
<td>X</td>
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<td>Suicide</td>
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<td>Dvlp</td>
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<td>Liquid</td>
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</table>

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Our Brand Promise

ZYPREXA is the Collaborative, Dedicated Leader that offers the dependable control to enable a more effective therapeutic alliance to help move lives forward and realize their individual potential.
Needs to Achieve $6B by ‘06

Further development of schizophrenia differentiation (delivery on brand promise)

• Further implementation differentiation from competitors
  - Continuous flow of data (non-registration studies) throughout the PLC
  - Continued emphasis on review and analysis of safety data (communicate reality, dispel competitively-generated perceptions)
  - Overall functional outcomes (Helps Move Lives Forward)
Ground Rules

- Broad participation – focus is on input from brand council members
- Move on in areas of agreement, discuss areas of meaningful disagreement for defined period then capture
- Stay within timeframe allotted for discussion
- Be ready for start times
- Please limit side conversations to minimum
- Keep pumping in the caffeine!
Strategy

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Summary of Key Themes

CSFs

- Need greater competitive differentiation in core business of bipolar and schizophrenia. Establish mood without diluting schizophrenia. Opportunity to redefine outcomes!

- Manage balance of side effect association / relevance

- $6B by ’06 attainable but need more “insurance” to increase probability

Brand Promise Differentiation
- 1st choice for patients with schizophrenia and the preferred foundational therapy for mood stabilization.

Brand Protection
- Physicians prescribing decisions are driven by a brands ability to deliver dependable control

Lifecycle Growth

Brand promise is the enabler
Global Marketing Objectives

Brand Differentiation
- Redefine “what’s possible for” schizophrenia and bipolar patient outcomes with scientific evidence supporting the brand promise.
- Achieve target ratings for selected brand equity measurements.
- Evolve branding to keep it relevant and fresh.

Brand Protection
- Achieve global alignment on competitor positioning and safety issues (Brand Equity targets).
- Achieve goals for data dissemination that support platforms for metabolic and cardiovascular issues.
- New competitors – Abilify, Lamictal, Risperdal Consta, Risperdal bipolar, Seroquel bipolar – are perceived as less dependable than Zyprexa.

Lifecycle Growth
- Prepare robust launch plans for Bipolar Maintenance, Depot, and prepare precommercialization plan for adolescent submission.
- Identify and develop areas of future differentiation to include cognition, gray matter, 1st episode and prodromal.
Our Overarching Strategy

Stabilize, Hope

No Control
Psychosis
Mania
Agitation
Florid

Insufficient Control
Schizophrenia
Bipolar
Early signs of breakthrough / Inadequate control
Zyprexa
Not Zyprexa

Motivate
“Sufficient” Control
Schizophrenia
Bipolar
In maintenance
Zyprexa
Not Zyprexa

Capture
Appropriate Dose
Consider Switch

Dependable Control
Therapeutic Alliance
Helps Move Lives Forward

Dependable Control
Therapeutic Alliance
Helps Move Lives Forward

Dependable Control
Therapeutic Alliance
Helps Move Lives Forward

Goal

Brand Promise Emphasis

Zyprexa MDL 1596: Confidential-Subject to Protective Order
Our Business

• Is comprised of four “buckets”
  ➢ What we control:
    – Schizophrenia
    – Bipolar
  ➢ What customers drive:
    – Other “mood” (depressive disorders)
    – Other uses (stuttering, dementia, PTSD, etc.)
Across the brand council countries, the proportion of Zyprexa DOT across disease states has remained relatively stable. However there are significant differences in the mix among BC countries.

* Australia not available

Source: Medical Dynamics
Other Levers of Business: Length of Therapy and Therapeutic Dose

Length of Therapy:
• In 2001, Zyprexa LOT in Schizophrenia ranged from 33 weeks in the UK to 55 weeks in Australia – on par with competitors, but suboptimal treatment for chronic patients.

• In 2001, Zyprexa LOT in Bipolar ranged from 14 weeks in Spain to 42 weeks in Canada. Traditional mood stabilizers have fared far better – especially Lithium, with a mean LOT of 157 weeks. Depakote averaged approx. 55 weeks of therapy. **exception Italy

Dose (mg/day):
• In 2001, across Schizophrenia and Bipolar disorder, the average mg/day for Zyprexa was 10mg. Studies show that for many Schizophrenic patients the appropriate dose is 15 -20mg and for many Bipolar patients the appropriate dose is 10-15mg.
State of the Business

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Brand Equity Review: The Most Important Measurement of our Success

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Equity Takeaways

• Overall, very little change since wave 1

• The positioning and strategy is still right, which is evidenced by high relevance on key factors

• However, clear opportunity exists to improve implementation of strategy
  ➢ Continue to stay focused with simple message
  ➢ Therapeutic alliance/Helping Move Lives Forward are still untapped
  ➢ **MISS:** The opportunity demonstrated in our brand promise has not been realized
Across the 4 affiliates, general alignment on most relevant factors.

**Brand Promise**

- **U.S.:** Therapeutic Alliance / Helping Move Lives Forward
  - Mood
  - Dependent Use
  - Psychosis
  - Corporate / Brand Identity
  - Metabolic Side Effects
  - Unpredictable Side Effects
  - Dosing/Efficacy Concerns

- **France:** Therapeutic Alliance / Helping Move Lives Forward
  - Mood
  - Psychosis & Broad Use
  - Corporate / Brand Identity
  - Metabolic Side Effects
  - Unpredictable Side Effects

- **Canada:** Therapeutic Alliance / Helping Move Lives Forward
  - Mood
  - Psychosis & Broad Use
  - Corporate / Brand Identity
  - Metabolic Side Effects
  - Other Side Effect Concerns
  - Dosing / Efficacy Concerns

- **Italy:** Therapeutic Alliance / Helping Move Lives Forward
  - Mood
  - Psychosis & Broad Use
  - Corporate / Brand Identity
  - Side Effects Concerns

Note: Dosing concerns is a new factor for the US. France and Canada have not been “re-factored” yet. This was Italy’s first wave.
Wave 2

Therapeutic alliance/HMLF: the most important factor for each affiliate.
  - Risperdal is the main competition and is at parity on most elements.

Dependable control (psychosis/mood) are key factors.
  - Some differentiation for Zyprexa especially on “wide range of symptoms and patients”.
  - Competition is either Risperdal or a MS.

Metabolic side effects
  - Differentially associated with Zyprexa but are not correlated to brand loyalty –physicians universally believe Zyprexa causes weight gain and related issues, yet it is not a barrier to choice.

- Triglycerides, Switching patients off of Zyprexa once symptoms controlled are barriers to use of Zyprexa in some affiliates.
Affiliate-Specific Highlights: 2003 Equity

- **US**
  - Positive movement on DC-Mood factor
  - Physicians switching patients once they are stabilized
- **Canada**
  - At parity with Risperdal on DC-Psychosis elements, more distance vs. atypicals on DC-Mood
  - Concern over triglycerides is impacting brand loyalty
- **France**
  - Changed competitive set, Solian out, Depakote in, explaining much of Zyprexa and Risperdal’s positive movement
  - Side effects still not impacting brand loyalty
- **Italy**
  - Neurologists have much better opinion of Zyprexa than psychiatrists
  - Zyprexa has little or no association with side effects factor elements, concern over weight gain does not load with ANY factor
Recommendations

• Identify ways to improve/accelerate implementation of the Brand Promise: *stay on course*. *Each BC affiliate needs to identify goals for 2003, 2004, 2005.*

• Reinforce association with key differentiating elements for Zyprexa, “wide range of patients” and “wide range of symptoms”

• Focus resources on demonstrating TA/HMLF elements to gain differentiation

• Catch mood stabilizers in DC-Mood
  ➢ Beat Risperdal/Seroquel to key associations

• Put side effect concerns in perspective
  ➢ Positive associations still prevail over negative associations
  ➢ Bothersome side effects can be managed (weight gain) versus serious side effects that must be avoided (EPS, QTc, activation, etc.,)
Competitive and Issues Tracker Global Comparison

Results for US, Japan, Australia, Spain, France

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Summary of Findings
US, Japan, Australia, Spain, France

• Zyprexa has high association as a first line schizophrenia agent: first episode and relapse
  ➢ But so does Risperdal – need to differentiate!

• Zyprexa obtains “foundation of treatment” status in bipolar in the US
  ➢ Only vs. AP’s
  ➢ Australia also has perceptions of effectiveness in bipolar
  ➢ Takeaway: significant gains possible in short time period

• Zyprexa liabilities rank highest among psychiatrists, leading to discontinuation of Zyprexa.
  ➢ While we need to continue addressing liabilities to prevent switching, it is more important we strengthen execution of the brand promise
% of Psychs that indicated Zyprexa was the most commonly prescribed for Schizophrenia

<table>
<thead>
<tr>
<th></th>
<th>First Episode</th>
<th>Relapse</th>
<th>Refractory</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) US</td>
<td>37</td>
<td>37</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>(b) AUS</td>
<td>39</td>
<td>60</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>(c) Japan</td>
<td>6</td>
<td>2</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>(d) France</td>
<td>42</td>
<td>24</td>
<td>5</td>
<td>39</td>
</tr>
<tr>
<td>(e) Spain</td>
<td>19</td>
<td>25</td>
<td>83</td>
<td>86</td>
</tr>
</tbody>
</table>

Zyprexa is considered first line use in US, Australia and France, while use in both refractory and side effect patients in Spain and Japan indicate second line use.
% of Psychs that indicated Zyprexa was the most commonly prescribed for Bipolar Disorder

<table>
<thead>
<tr>
<th></th>
<th>Mania %</th>
<th>Bipolar Depression %</th>
<th>Rapid Cyclers %</th>
<th>Side Effects %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) US</td>
<td>18</td>
<td>9</td>
<td>5</td>
<td>20</td>
</tr>
<tr>
<td>(b) AUS</td>
<td>20</td>
<td>1</td>
<td>1</td>
<td>7</td>
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<td>(c) Japan</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>4</td>
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<tr>
<td>(d) France</td>
<td>7</td>
<td>7</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>(e) Spain</td>
<td>13</td>
<td>1</td>
<td>4</td>
<td>11</td>
</tr>
</tbody>
</table>

Only in the US is Zyprexa used more broadly across the range of bipolar disorder patients.
% of Psychiatrists that indicated that Zyprexa is used as their foundation of treatment in Bipolar

<table>
<thead>
<tr>
<th></th>
<th>Zyprexa</th>
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<tbody>
<tr>
<td>(a)</td>
<td>US</td>
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<td>(b)</td>
<td>AUS</td>
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<td>(c)</td>
<td>Japan</td>
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<td>(d)</td>
<td>France</td>
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<tr>
<td>(e)</td>
<td>Spain</td>
</tr>
</tbody>
</table>

The US is the only country where Zyprexa is perceived as a foundational medication for Bipolar as compared to other atypicals.
Effective in Schizophrenia for Zyprexa vs. AP Competitors

% of Psychiatrists that feel Zyprexa is effective in Schizophrenia

<table>
<thead>
<tr>
<th></th>
<th>US</th>
<th>Australia</th>
<th>Japan</th>
<th>France</th>
<th>Spain</th>
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<tr>
<td></td>
<td></td>
<td>Risp, Hald</td>
<td>Risp</td>
<td>Risp, Hald</td>
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</table>

Zyprexa is at parity with the competitors in US, Aus, and France, while losing to Risperdal in Japan and Spain on perceptions of its effect in treating patients with Schizophrenia.
Effective in Bipolar: Zyprexa vs. AP Competitors

% of Psychiatrists that feel Zyprexa is effective in Bipolar

<table>
<thead>
<tr>
<th></th>
<th>US</th>
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<tbody>
<tr>
<td></td>
<td>Australia</td>
<td>Zyprexa win over competiton</td>
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<td>Japan</td>
<td>Zyprexa parity w/ competition</td>
</tr>
<tr>
<td></td>
<td>France</td>
<td>Zyprexa loss over competition</td>
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<td></td>
<td>Spain</td>
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<tr>
<td></td>
<td></td>
<td>Risp, Hald</td>
</tr>
</tbody>
</table>

Zyprexa wins in treating patients with bipolar in US and Australia. While Zyprexa is at parity with competitors in France and Spain, it loses to Haldol in Japan.
## Brand Association with Side Effects

*(Summary of Top 2 Box)*

**Among Psychiatrists**

<table>
<thead>
<tr>
<th></th>
<th>Zyprexa (75)</th>
<th>Risperdal (75)</th>
<th>Seroquel (74)</th>
<th>Clozaril/ Clopine (70)</th>
<th>Haldol (75)</th>
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<tbody>
<tr>
<td>Weight gain</td>
<td></td>
<td>95&lt;sup&gt;bcde&lt;/sup&gt;</td>
<td>9</td>
<td>4</td>
<td>8</td>
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<tr>
<td>Activation</td>
<td>11</td>
<td>15</td>
<td>12</td>
<td>17</td>
<td>9</td>
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<tr>
<td>Is associated with cardiac complications</td>
<td>7&lt;sup&gt;bc&lt;/sup&gt;</td>
<td>1</td>
<td>--</td>
<td>59&lt;sup&gt;abce&lt;/sup&gt;</td>
<td>7&lt;sup&gt;bc&lt;/sup&gt;</td>
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<tr>
<td>Unpredictable efficacy</td>
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<td>7</td>
<td>31&lt;sup&gt;abde&lt;/sup&gt;</td>
<td>3</td>
<td>8</td>
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<tr>
<td>Prolactin elevation</td>
<td>5</td>
<td>64&lt;sup&gt;abcde&lt;/sup&gt;</td>
<td>3</td>
<td>17&lt;sup&gt;ac&lt;/sup&gt;</td>
<td>46&lt;sup&gt;abd&lt;/sup&gt;</td>
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<tr>
<td>Limited efficacy due to an EPS dose ceiling</td>
<td>3</td>
<td>33&lt;sup&gt;abcd&lt;/sup&gt;</td>
<td>3</td>
<td>1</td>
<td>85&lt;sup&gt;abcd&lt;/sup&gt;</td>
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<tr>
<td>Complicated titration</td>
<td>3</td>
<td>8</td>
<td>27&lt;sup&gt;abe&lt;/sup&gt;</td>
<td>47&lt;sup&gt;abce&lt;/sup&gt;</td>
<td>11&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Prolongation of the QTc wave</td>
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<td>5</td>
<td>4</td>
<td>24&lt;sup&gt;abce&lt;/sup&gt;</td>
<td>13&lt;sup&gt;abc&lt;/sup&gt;</td>
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<td>EPS (extra pyramidal side effects)</td>
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<td>20&lt;sup&gt;abcd&lt;/sup&gt;</td>
<td>--</td>
<td>1</td>
<td>97&lt;sup&gt;abcd&lt;/sup&gt;</td>
</tr>
<tr>
<td>Inferior relapse prevention</td>
<td>1</td>
<td>3</td>
<td>15&lt;sup&gt;abc&lt;/sup&gt;</td>
<td>3</td>
<td>19&lt;sup&gt;abd&lt;/sup&gt;</td>
</tr>
<tr>
<td>Is associated with nausea and/or vomiting</td>
<td>--</td>
<td>1</td>
<td>--</td>
<td>10&lt;sup&gt;abc&lt;/sup&gt;</td>
<td>5&lt;sup&gt;ac&lt;/sup&gt;</td>
</tr>
<tr>
<td>Worsening of psychosis</td>
<td>--</td>
<td>--</td>
<td>7&lt;sup&gt;abc&lt;/sup&gt;</td>
<td>--</td>
<td>3</td>
</tr>
</tbody>
</table>

Q. 24. Now, using a five-point scale where "5" means describes extremely well, "4" means describes very well, "3" means describes somewhat well, "2" means does not describe very well, and "1" means does not describe at all, please indicate how much do you associate each one of the following attributes with the following medications. Base Ever prescribed medication.
Competitive / Issues Tracker Takeaways

• Zyprexa is established as first line for schizophrenia in many affiliates
  - Opportunity to increase conversion rate in Europe
  - Opportunity to further differentiate via Brand Promise in high conversion

• Zyprexa obtains “foundation of treatment” status in bipolar in the US
  - Zyprexa can and must drive perceptions to fulfill Brand Promise
  - Mood Stabilizers own perceptions with some Atypicals following us closely

• Zyprexa liabilities rank highest in side effect concerns. These concerns lead psychiatrists to switching and discontinuation of Zyprexa.
  - We must continue to address liabilities to prevent switching
Summary of Key Themes

- Need greater competitive differentiation in core business of bipolar and schizophrenia. Establish mood without diluting schizophrenia. Opportunity to redefine outcomes!

- Manage balance of side effect association / relevance

Brand promise is the enabler
The Rest of Today

• BRIEF strategy overviews
  ➢ Schizophrenia
  ➢ Bipolar
  ➢ Issues
  ➢ Competition

• Small group break-outs to identify GAPs in the Scientific Evidence Supporting our Lifecycle
  ➢ Registration (label) studies
  ➢ Non-registration studies
  ➢ Data (including health outcomes)
  ➢ Publications
  ➢ Programs

• Debrief to summarize GAPS
• Prioritize/Agree Action Plans
This document is for strategy and evaluation purposes only and does not represent definitive plans for implementation.
30 Minute Overview

- Overarching strategy
- Phased approach for strategy
- Data and Indications
- Areas of exploration
- Summary
- What’s Missing?
Key Takeaways

• Schizophrenia is core global business with lots of up-side
• Achieving $6B by ’06 can only come from delivery on schizophrenia and bipolar objectives
• Phased approach is critical to achieve goals
• Significant HO data available
• Exciting new imaging and outcomes data becoming available, gray matter and cognition
• Focus on enabling an effective therapeutic alliance to help move lives forward is next step in Brand evolution
Zy prexa Strategy in Schizophrenia

Internal Goal:
• Zy prexa is the first-choice treatment for patients with psychosis.

Reason to believe:
• Zy prexa helps move lives forward because it makes the goal of reaching individual potential attainable by providing dependable control and removing barriers to an effective therapeutic alliance.

What we want our customers to remember:
• Target patient (symptoms) + brand promise
  ➢ WHO AND WHY

Where the business comes from in ’03-’05:
• Increase capture through differentiation from Typicals and Atypicals at therapeutic dose and retain patients in the Motivate segment
In order to own Helping Move Lives Forward, Brand must demonstrate ability to…

- Demonstrate immediate and enduring Dependable Control – ANTE
- Enable an effective therapeutic alliance by removing barriers to engagement – DIFFERENTIATE
- Help patients achieve individual potential
  - Physician’s agree that “potential” is a very individual notion
  - There are stages of patient progress. Although many physicians have aspirational aims for their patients, in order to be relevant to physicians, the brand must address the emotional benefit derived from basic improvements in patients, a large share of physician experiences.
# An evolution of focus, not message

<table>
<thead>
<tr>
<th>Brand Equity Dependent</th>
<th>PHASE I: DC-TA-HMLF</th>
<th>PHASE II: DC-TA-HMLF</th>
<th>PHASE III: DC-TA-HMLF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT TYPE</strong></td>
<td>First break and acutely symptomatic relapsed patients (Stabilize, Hope, Motivate)</td>
<td>Expand: Capture target does not change, new equity fuels prescriber loyalty (Stabilize, Hope, Motivate)</td>
<td>Expand: Capture target does not change, new equity fuels prescriber loyalty (Stabilize, Hope, Motivate)</td>
</tr>
<tr>
<td><strong>WHERE BUSINESS COMES FROM</strong></td>
<td>Conversion Displace typical agents, known for gold standard efficacy for positive symptoms.</td>
<td>Atypical Differentiation First choice treatment for patients in need of dependable control and an effective therapeutic alliance.</td>
<td>Redefining outcomes Zyprexa is the first-choice treatment for patients with psychosis.</td>
</tr>
</tbody>
</table>
## Phased Approach for Growth

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>FOCUS FOR FIELD</strong></td>
<td><strong>FOCUS FOR FIELD</strong></td>
<td><strong>FOCUS FOR FIELD</strong></td>
</tr>
<tr>
<td>• Effective in wide range of patients</td>
<td>Remove barriers to Therapeutic Alliance</td>
<td>• Superior functional outcomes</td>
</tr>
<tr>
<td>• Effective in wide range of symptoms</td>
<td>• Mood (depressive symptoms)</td>
<td></td>
</tr>
<tr>
<td>• Breadth of Zyprexa Franchise</td>
<td>• Thinking more clearly</td>
<td></td>
</tr>
<tr>
<td>• Rapid and Dependable control of dangerous and inappropriate behaviors</td>
<td>• Negative symptoms</td>
<td></td>
</tr>
<tr>
<td>• Zyprexa provides enduring efficacy and relapse prevention</td>
<td>• Attention</td>
<td></td>
</tr>
<tr>
<td>• Known and manageable side effect profile</td>
<td>• Lack of support system</td>
<td></td>
</tr>
<tr>
<td>• Helps Move Lives Forward by addressing patient needs</td>
<td>• Stigma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Fear of relapse</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lack of trust</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Helps patients achieve individual potential</td>
<td></td>
</tr>
</tbody>
</table>
Strategy Focus

- Know your market, don’t let competitive threats and competitors focus on issues derail your focus from the benefits of Zyprexa

- Continue to own Dependable Control in both acute and maintenance phases of treatment – it is the ante and all else is irrelevant in its absence

- Shift focus to Zyprexa as the remover of obstacles to the Therapeutic Alliance
  - Use clinical data to identify barriers and Zyprexa’s effect on them
  - Message more emotional in nature, include success stories
  - Remove non-clinical barriers to the Therapeutic Alliance – provide resources to treatment teams (services, informational resources) to inform families/care-givers of their role in an effective Therapeutic Alliance
  - Leverage above through other channels to be recognized for efforts (build equity)

- Begin to redefine expectations by communicating functional outcomes made possible by Zyprexa

- Generate appropriate excitement internally to prevent complete shift of focus to new indications and launches
Regulatory Priorities – ’03-’06

- Expected US IM Launch Q3 ‘03
- Expected OUS IM Launch Q4 ‘03
- Depot Submission US ’05
- Depot Submission EU ’06
- Japan Zydis Submission ’05
- Japan RAIM submission ’06
- Adolescent Schizophrenia Indication (US) submission ’06

2003
RAIM US Launch

2004
RAIM OUS Launch

2005
Zydis Submission Japan
Depot Submission (US)
RAIM Submission Japan
Depot Submission (EU)
Adolescent Schizophrenia Submission (US)
PLC Opportunities – Investigating but not funded

- Schizoaffective Indication
  - No other drug has indication
  - Bridge between bipolar and schizophrenia
  - Do we already get that business anyways?

- Neuroprotection (??)
  - What can Zyprexa claim?

- Additional exploratory imaging studies
Data to Support Message Evolution

Existing

**Phase I**
- Olz superior to clz, ris, hal in treatment resistant schiz and schizoaffective patients as measured by PANSS total score, Volavka, 2000
- IM Zyp superior to IM hal in PANSS EC reduction at 15 minutes, Wright, 2001
- Zydis rapidly reduces psychopathology and improves compliance, Kinon, 2000
- Rapid Initial Dose Escalation allows for acute control of agitation in schizophrenia, Baker, 2001
- Suicide attempts 2.5x less per year with olz than hal, Glazer, 1998
- Olz superior time maintaining response vs. hal, Tran 99, vs. risp, Tran 97

**Phase II**
- Superior reduction in depressive cluster of BPRS in schiz treatment vs hal at 6 wks, Tollefson, 1998
- Olz superior change in cognition score vs hal, risp (overall, new learning, attention, motor, executive, non-verbal), Purdon, 1999
- Olz superior to hal meta-analysis on PANSS total score (neg sx, pos sx, disorganized thought, impulsivity/hostility, anxiety/depression) Davis, Chen, 2001.
Data to Support Message Evolution
Existing

Phase II

- Olz superior to hal in intrapsychic foundation score over 52 wks (sense of purpose, motivation, curiosity, anhedonia, aimless inactivity, empathy, emotional interaction), Revicki, 1999
- Olz superior to hal in perceived health status at 6 wks (SF-36 subscale)Tunis, 1999
- Olz superior to risp on 40, 50, 60% improvements on Interpersonal relations (QLS interpersonal), Zhao, 2002
- Patients switched to olz (70% from typicals, 30% from risp) experience overall improvements in cognitive functioning, Stip, submitted J Clin Psychopharm
- Significant predictors of relapse:(focus- depressive symptoms, executive function, parkinsonism)-all differentiating points for Zyprexa and barriers to TA, Robinson, in press

Phase III

- Olz patients significantly more likely to work part or full time at 52 wks vs hal, Hamilton, 1999
- Olz patients experienced significant improvements in social outcomes at 52 wks vs hal, Hamilton, 1999
Schizophrenia - Zyprexa Lifecycle Map

**Areas of Interest**

**Indications**

Adolescent Schizophrenia

**Other studies**

**PRIME - Prodrome**
- HGGF Placebo, 2yr, n=60, LPV Q203
- Study completed - HGDH hal, 2yr, n=263
- Study completed - LOBU pk + tolerability, 20days, n=37

**First Episode**

**High Dose – pilot study**

**EU SOHO**

**Competitive**
- Ziprasidone v Zyprexa
- Aripiprazole v Zyprexa

**Issues**

Insulin Sensitivity

**2003**
- Q1
- Q2
- Q3
- Q4

**2004**
- Q1
- Q2
- Q3
- Q4

**2005**
- Q1
- Q2
- Q3
- Q4

**2006**
- Q1
- Q2
- Q3
- Q4

**2007**

**2008**

**2009**

**2010**

HGIN
- Placebo, 32 wks, FPV Q402

Funded Trial Code
- With Start and End Date
- Proposed Trial
- Include LAUNCH, if appropriate

EU - SOHO
- 3 yr data lock Q105

Study completed - HGHJ
- n=538

HGLB
- FPV Q3 03

S014
- Zyprexa vs. Risperdal

9/1/2004
File name/location

Company Confidential
Copyright © 2000 Eli Lilly and Company

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Schizophrenia- Zyprexa Lifecycle Map

Areas of Interest

Formulations

Depot US registration study

Depot EU registration study

Comparator study

Switching study

Conversion – oral to depot

RAIM pk pilot Japan submission

RAIM dose finding Japan submission

2003 2004 2005 2006 2007 2008 2009 2010
Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

HGJZ

HGKA

Depot US launch Q1/07-Q3/07
Depot EU launch Q3/07

HG??

HG??

HG??

RA01

RA02

Funded Trial Code
With Start and End Date

Proposed Trial
Include LAUNCH, if appropriate
## Summary of Key Support - Schizophrenia

<table>
<thead>
<tr>
<th>Year</th>
<th>Indications/Formulations</th>
<th>Key Data Available</th>
<th>Key Publications Available</th>
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<tbody>
<tr>
<td>2003</td>
<td>RAIM Global Launch</td>
<td>HGGF - Prodrome HGDH - First Episode LOBU - High Dose pk/tol SOHO 6 month HGHJ - Zyp v Zip EU SOHO 1 year</td>
<td>Pri efficacy/safety (HJ) Relapse Prevention (GI) First Episode MRI (DH) MRS, lactate metabolism &amp; attention correlate (DH)</td>
</tr>
<tr>
<td>2004</td>
<td>EU SOHO 2 year</td>
<td></td>
<td>Clin &amp; soc outcomes (SOHO - 6 month &amp; 1 year)</td>
</tr>
<tr>
<td>2005</td>
<td>Zydus submission (Japan)</td>
<td>EU SOHO 3 year HGLB - Zyp v Arip</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>RAIM submission (Japan)</td>
<td>HGIN - Adolescent Schiz S014 - Insulin Zyp v Risp Depot Registration</td>
<td></td>
</tr>
</tbody>
</table>
Key Takeaways

- Schizophrenia is core global business with lots of up-side
- Achieving $6B by ’06 can only come from delivery on schizophrenia and bipolar objectives
- Phased approach is critical to achieve goals
- Significant HO data available
- Exciting new imaging and outcomes data becoming available, gray matter and cognition
- Focus on enabling an effective therapeutic alliance to help move lives forward is next step in Brand evolution
# Schizophrenia Gap Analysis

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<td>Programs</td>
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</tr>
</tbody>
</table>
Schizophrenia Gap Analysis Debrief

- Synergies
- Discrepancies/Reconciliation
- Priorities
- Action Plans
  - What
  - By who
  - By when
Zyplexa Global Bipolar Strategy

This document is for strategy and evaluation purposes only and does not represent definitive plans for implementation.

Lilly
Answers That Matter.
Strategic Overview

- Key Takeaways
- Strategic Direction
- Market Opportunity
- Data and Indications for Message
- Phased Approach for Strategic Evolution
- PLC Exploration Priorities
- Bipolar Summary
- What’s Missing?
Key Takeaways

- Bipolar opportunity is tremendous, and the market dynamics are shifting

- Customer Target: Patient (symptoms) + Brand promise

- Phased approach is critical to achieve goals, with established triggers and metrics for moving on to next phase

- Significant data is available, with exciting new indication for maintenance expected early 2004

- We have an opportunity to establish and differentiate before new competition enters the market (Lamictal, Seroquel BP, Risperdal BP)
Zy prexa Strategy in Bipolar Disorder

Internal Goal: Establish Zy prexa as #1 foundational therapy for mood stabilization

Reason to believe:
- Brand Promise: Dependable Control, Therapeutic Alliance, Helping Move Lives Forward to realize individual potential
- Indications in mania and maintenance
- Data in bipolar depression

What we want our customers to remember:
- Target patient (symptoms) + brand promise
  - Focus on what Zy prexa does (benefit) vs. what Zy prexa is (label)
  - Avoid referring to Zy prexa as a mood stabilizer... remember whatever equity we create for bipolar carries over to schizophrenia.

Where the Business Comes from ’03-’05:
- Accelerate conversion from bipolar competitors
- Begin market creation in EU, more advanced in US
Zyprexa DOTs... Big Opportunity!!!
Bipolar/Mood Regulatory Priorities – ’03-’06

- US Zyprexa Bipolar Maintenance
- EU Zyprexa Bipolar Maintenance
- US Zyprexa Bipolar Mania Combination

Redacted
- Canada Zyprexa Bipolar Mania
- AU Zyprexa Bipolar Maintenance
- EU Zyprexa Bipolar Mania Commitment Trials

Zyprexa Mania
Canada Approval 2.03

Zyprexa Maintenance
US/EU Approval 2.04

Zyprexa Mania Combo
US Approval 12.03

Zyprexa Maintenance
US Submission 11.02

Zyprexa Maintenance
EU Submission 12.02

Q4’02 | Q1’03 | Q2’03 | Q3’03 | Q4’03 | Q1’04 | Q2’04 | Q3’04 | Q4’04 | Q1’05 – Q4’06
Data to Support Message Evolution – ’03-’06

Today – BP Mainia indication
- Zyprexa treats mania without inducing depression (EH/GW/HQ)
- Zyprexa quickly improves depressive symptoms in mania (EH/GW/HQ)
- Zyprexa reduces the severity of symptoms in both mania and depression (EH/GW/HQ/FU/GY)

New data w/ Maintenance Indication (Q1 2004)
- Better than Lithium for Relapse Prevention (HT) Indication
- Zyprexa prevents bipolar relapse to either mania or depression (HL) Indication
- Zyprexa cuts relapse by 50% when used as a foundation treatment with appropriate combinations (lithium/valproate) (FU) Indication

New data – BP depression (Available today)
- Zyprexa reduces severity of bipolar depression without inducing mania (GY)
- [redacted]
SDDs/Customer Relations Priorities – ’03-’06

- TL Collaborative Publications/Alignment Projects
- US Communication Partnership (SDD/PR/IR)
- Bipolar Global Medical Conference, London
- HGGY Primary Manuscripts
- HGHT Primary Manuscripts
- HGHL Primary Manuscripts

* Indicates ongoing Annual Meetings

Redacted

Zyp v. Pcb Relapse Prevention Manuscript Publication
Zyp v. Li Relapse Prevention Manuscript Publication

Q4’02 Q1’03 Q2’03 Q3’03 Q4’03 Q1’04 Q2’04 Q3’04 Q4’04 Q1’05 – Q4’06

Bipolar GMC* London
EO Tx Guidelines Group
US Academic Ad Board*
Canada Academic Ad Board*
EO Academic Ad Board*

APA* ICBD* ECNP* ACNP*
PLC Management Priorities for Exploration

Funded

- HDAO Treatment-Resistant Depression (TRD)
- HGIU Child & Adolescent Bipolar I
- 8004 PET Study (FPV 4/03)

Unfunded

- Bipolar Depression (EU)
- Bipolar II
- Schizoaffective
- Depot Bipolar
# Phased Approach for Growth in Bipolar

<table>
<thead>
<tr>
<th>Brand Equity Dependent</th>
<th>PHASE I: Introduction</th>
<th>PHASE II: Accelerate Conversion</th>
<th>PHASE III: Foundation Differentiation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT TYPE</strong></td>
<td>Acute manic patient + Rapid cycling (Stabilize, Hope)</td>
<td>Expand: + Acutely symptomatic bipolar patient with frequent relapses (Stabilize, Hope, Motivate)</td>
<td>Expand: + Symptomatic bipolar patients with a need for long-term control and mood stabilization (Stabilize, Hope, Motivate)</td>
</tr>
<tr>
<td><strong>WHERE BUSINESS COMES FROM</strong></td>
<td>Conversion Displace current market leaders in bipolar mania</td>
<td>Deeper Conversion First line mania and maintenance for many customers</td>
<td>Market Leadership + Aggressive Grow the Market</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Establish as foundational therapy for mood stabilization for most customers</td>
</tr>
</tbody>
</table>
# Phased Approach for Growth in Bipolar

<table>
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<th>PHASE I: Introduction</th>
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<tbody>
<tr>
<td><strong>FOCUS FOR FIELD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Share monotherapy data to establish the <strong>dependable control</strong> of Zyprexa in manic and mixed patients (don’t insist on monotherapy)</td>
<td>Introduce:</td>
<td></td>
</tr>
</tbody>
</table>
| - Enables a **therapeutic alliance** in non-psychotic and psychotic patients with a profile of safety, tolerability and ease of use | - Better than Lithium for Relapse Prevention  
- Zyprexa prevents bipolar relapse to either mania or depression  
- Zyprexa cuts relapse by 50% when used as a foundation treatment with appropriate combinations (lithium/valproate) |
| - Zyprexa Treats mania without inducing depression  
- Zyprexa quickly improves depressive symptoms in mania  
- Zyprexa reduces the severity of symptoms in both mania and depression | - Dependable control for spectrum of bipolar disorder  
Introduce:  
- Zyprexa reduces severity of bipolar depression without inducing mania  
- Redacted |
# Phased Approach for Growth in Bipolar

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<tbody>
<tr>
<td><strong>MARKET CONDITIONING (DTP)</strong></td>
<td></td>
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</tr>
<tr>
<td>One step ahead of the field</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Share data on maintenance and expanded patient types</td>
<td>• Share data on bipolar depression and expanded patient types</td>
<td>• Significant expansion of bipolar spectrum of efficacy and patient types</td>
</tr>
<tr>
<td>• Share combination data</td>
<td>• Establish spectrum of bipolar efficacy</td>
<td></td>
</tr>
<tr>
<td>• Clear competitive differentiation from other AP</td>
<td>• Clear competitive differentiation from other traditional mood stabilizers</td>
<td></td>
</tr>
</tbody>
</table>
## Summary of Key Support - Bipolar

<table>
<thead>
<tr>
<th>Year</th>
<th>Indications</th>
<th>Key Data Available</th>
<th>Key Publications Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Bipolar Mania (US/EU/CA/AU)</td>
<td>• Treats mania without inducing depression (EH/GW/HQ)</td>
<td>Mania Maintenance (Q2)</td>
</tr>
<tr>
<td></td>
<td>Redacted</td>
<td>• Quickly improves depressive symptoms in mania (EH/GW/HQ)</td>
<td>Onset of Action (Q3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reduces severity of bipolar depression without inducing mania (GY)</td>
<td>Treatment-Resistant Depression (TRD) (Q3)</td>
</tr>
<tr>
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<td></td>
<td>Bipolar Depression (Q4)</td>
</tr>
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<td></td>
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<td></td>
<td>Mania Combination (Q4)</td>
</tr>
<tr>
<td>2004</td>
<td>Bipolar Maintenance (US/EU)</td>
<td>• Better than Lithium for Relapse Prevention (HT)</td>
<td>Relapse Prevention (Q1)</td>
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<td>Bipolar Combination (US/AU)</td>
<td>• Prevents bipolar relapse to either mania/depression (HL)</td>
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<td></td>
<td>• Cuts relapse by 50% when used as a foundation treatment with appropriate combinations (FU)</td>
<td></td>
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<tr>
<td>2005</td>
<td>Bipolar Maintenance (CA)</td>
<td></td>
<td>Treatment-Resistant Depression (Q4)</td>
</tr>
<tr>
<td></td>
<td>Treatment-Resistant Depression (US/CA/AU)</td>
<td></td>
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<tr>
<td>2006</td>
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</tbody>
</table>
Takeaways

- **Bipolar opportunity is tremendous**, and the market dynamics are shifting
  
- **Customer Target**: Patient (symptoms) + Brand promise
  
- **Phased approach is critical** to achieve goals, with established triggers and metrics for moving on to next phase
  
- **Significant data is available**, with exciting new indication for maintenance expected early 2004
  
- We have an opportunity to **establish and differentiate** before new competition enters the market (Lamictal, Seroquel BP, Risperdal BP)
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Bipolar Gap Analysis Debrief

- Synergies
- Discrepancies/Reconciliation
- Priorities
- Action Plans
  - What
  - By who
  - By when
Competitive and Issues

Strategy

Answers That Matter.
Competitors, Issues

- Global Strategy
- Updates on Abilify
- Updates on label changes
- Global Marketing Team deliverables
Overarching Competitive Strategy – Where we are

- Individual positioning for individual competitors
- Varying descriptors of efficacy (e.g., “limited,” “unpredictable,” “disappointing”)
- Executed with tone & content consistent with brand character
Overarching Competitive Strategy –
Where we’re headed

- Simultaneously address competitive threats while reinforcing and differentiating on the brand promise
- Themes affect multiple competitors
- Stimulate competition among competitors for non-target patients
- “Bucket” the competitors:
  - **Capture** (Risperdal, Depakote) – Boost efficacy image by differentiating on long-term outcomes (e.g., functioning, maintaining response)
  - **Retain** (Seroquel, Geodon/Zeldox, Abilify) – establish relapse and “worsening” as side effects, and making efficacy matter in maintenance. More important to manage the potential weight gain than risk the chance of relapse.
Zyprexa is Superior in Relapse and Maintaining Response

**Olanzapine vs Lithium**

**Time to Relapse into Mania or Depression Based on Hospitalization and/or Symptomatic Rating Scale Criteria**

- **Olanzapine**
- **Lithium**

Olanzapine mean dose: 11.3 mg/day
Lithium mean level: 0.77

**Olanzapine vs Quetiapine**

- **Olanzapine**
- **Quetiapine**

Olanzapine mean daily dose: 15.26 mg
Quetiapine mean daily dose: 437.28 mg

**Olanzapine vs Risperidone**

**Estimated Survival Curve at Week 28 Based on PANSS and CGI Rating Scales**

- **OLZ**
- **RIS**

**p=.001 vs RIS**

87.9% **
67.7%

**Olanzapine vs Ziprasidone**

HGHJ
Superior with \( p=0.002 \)
using the criteria selected for HGLB (Abilify study)

(Survival graph being developed)
Competitive Threats

➢ Potential to fundamentally change the market
  – Abilify
  – Risperdal - Depot

➢ Potential to fundamentally change Zyprexa’s uptake
  – Seroquel (esp. in bipolar)

➢ Potential to incrementally change the market
  – Geodon / Zedoxx
  – Lamictal (Lamotrigine)
  – Depakote
Early Customer Feedback on Abilify

- Well tolerated / low side effects – less mention of efficacy
- Broad patient use – Schizophrenia, Bipolar, Dementia, Depressive Psychosis
- Described as “activating”
  - Positively – more alert, good in the depressive patients
  - Negatively – restlessness, insomnia, akathisia, anxiety
- Nausea and vomiting – usually only short term
- Uncertainty about long term results
- Some accounts of disappointing efficacy and patients’ psychosis worsening

- Sources:
  - 2 Market Research Studies Conducted to Date
    - Online survey with physicians who participated in BMS’s physician experience clinical program
    - Telephone focus groups with physicians that have used Abilify
  - Sales Representatives and Thought Leader Feedback
Our Aripiprazole Strategy

- **Positioning Statement:** For your patients with who have not responded to currently available treatments, aripiprazole represents another option.

  - Disappointing efficacy
    - Worsening of Psychosis
  - Side effects – reports of agitation / anxiety / akathisia

- **Direct Competitors:** Seroquel & Geodon/Zelodox (weak efficacy)

Disappointing: Another example of over promising
# Competitive – Key Deliverables 2003-2005

<table>
<thead>
<tr>
<th>Category</th>
<th>2003</th>
<th>2004</th>
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<td>√ Q2, Q4</td>
<td>√ Q2, Q4</td>
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<tr>
<td>• New competitor indications, formulations and drugs; patent expirations</td>
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<tr>
<td><strong>Consolidated Competitive Strategy/Positioning</strong></td>
<td>√ BC II</td>
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<tr>
<td>• Risperdal, Seroquel, Geodon, Abilify, Depakote, Lamictal, and Lithium in schizophrenia and bipolar</td>
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<td>• Publications, posters, clinical studies, data mining</td>
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<td><strong>Updates &amp; Dissemination of Strategy and key information</strong></td>
<td>√ On-going</td>
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<td>• Virtual team, Zyprexa infonet</td>
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<tr>
<td>• Competitor tracker, brand equity</td>
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Shared Landscape Database – View of the Competition

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Shared Landscape Database Updated 2 times a Year
# Shared Landscape Database - View of Zyprexa Activities (w/ Major Competitor Implications)

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<td>Bipolar Mania</td>
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<td>Adj. use in many EU countries</td>
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<td>Bipolar Maintenance</td>
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<td>US &amp; EU Launch (Q1)</td>
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<td>New Formulations</td>
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<td>EU Launch?</td>
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<td>Zyprexa Depot</td>
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<td>Submission (Q4)</td>
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<td>Clinical Trials</td>
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<td>SOHO</td>
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<td>Completed</td>
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</table>
Competitive Management - Critical Objectives

• Deliver on the Zyprexa brand promise
  ➢ Zyprexa offers the dependable control you need to establish a more effective therapeutic alliance so you can help your patients begin to move their lives forward and realize their potential

• Proactively influence the positioning of top competitors; differentiate on Dependability, Outcomes
Issues Strategy

• Issues Management

Lilly

Answers That Matter.
Zyprexa and Issues – a brief history

- In the beginning, there was the anticholinergic hypothesis
- Weight gain – to own or not to own
- Metabolic issues, beginning with Hyperglycemia
- Which begat diabetes
- Which begat DKA
- Which will beget…? (pancreatitis, Syndrome X, or ?)

- Unpleasant, but a badge of our success
- Unacceptable when clinicians / consumers act on false information
- Burden of proof is on the accused
Issues Management 2003

- Weight gain is known, and increasingly, predictable and manageable (handle locally)

- Metabolic issues will persist (ZPT data, affiliate implementation)
  - Diabetes et al may be losing steam as a competitive weapon
  - Pancreatitis is a real and likely threat

- Lipid issues are next (ZPT owns data, framing)
  - Cholesterol
  - Triglycerides
Summary of Issues Positions

• Weight gain
  ➢ Common side effect among psychotropics
  ➢ With Zyprexa: predictable and manageable

• Diabetes/Hyperglycemia
  ➢ Comorbidity within schizophrenia and bipolar (population issue)
  ➢ Comparable treatment emergent risk among commonly prescribed antipsychotics (comparable rates)

• Lipids
  ➢ Broad public health issue
  ➢ Measurable and manageable
# Regulatory at a Glance

<table>
<thead>
<tr>
<th></th>
<th>Zyprexa</th>
<th>Risperdal</th>
<th>Geodon</th>
<th>Clozaril</th>
<th>Seroquel</th>
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<td>JP, Swe, Den</td>
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<td>JP*</td>
<td>US, AU, CA</td>
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<tr>
<td><strong>Post Introduction Reports</strong></td>
<td>US, EU</td>
<td>US</td>
<td></td>
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<td>US</td>
</tr>
</tbody>
</table>

*Hyperglycemia is listed in other adverse reactions under Precautions based on English translation of excerpts from “Notice of Revision of Precautions” issued by Janssen in Sep. 2002*
Issues Management: What Does Success Look Like?

- **Brand Equity** – Flat or decreasing relevance for targeted issues on prescribing
- **Issues Tracker** – Decreasing concern / differentiation on targeted issues (metrics set locally)
- **Regulatory** – Accelerate trend toward class labeling re: metabolic issues, especially in U.S.
- **Investor Relations** – Wall Street confirms that Zyprexa has no material liability
- **Customers** – No one suffering from schizophrenia or bipolar disorder is denied Zyprexa based on false information / perception
<table>
<thead>
<tr>
<th>Year</th>
<th>Issue</th>
<th>Study</th>
<th>Desired Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Weight</td>
<td>Management Weight (Birt J.)</td>
<td>Management of weight gain associated with atypical antipsychotics.</td>
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<tr>
<td>2003</td>
<td>Weight</td>
<td>Slim PEP</td>
<td>Amantadine therapy associated with weight loss in patients treated with Olanzapine: a case series</td>
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<tr>
<td>2004</td>
<td>Weight</td>
<td>HGJN</td>
<td>Amantadine helps patients manage olanzapine induced weight gain</td>
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<tr>
<td>2003</td>
<td>Diabetes</td>
<td>PCS</td>
<td>Comparable risk of developing diabetes among patients that take commonly prescribed antipsychotics</td>
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<tr>
<td>2003</td>
<td>Diabetes</td>
<td>TED</td>
<td>Schizophrenia patients appeared to have an increased risk for the development of diabetes; treatment-emergent weight gain or treatment assignment appeared to have a relative smaller impact on treatment emergent diabetes</td>
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<tr>
<td>2003</td>
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<td>SO13</td>
<td>Olanzapine does not have an acute direct effect that promotes insulin resistance</td>
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<td>2004</td>
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<td>GPRD</td>
<td>The risk of developing diabetes during exposure to risperidone was significantly higher than that of the GPRD general population</td>
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<td>2004</td>
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<td>Glucose Analysis</td>
<td>Antipsychotics have comparable effects with regards to glucose regulation</td>
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<td>2004</td>
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<td>Bipolar TED</td>
<td>Comparable risk of developing diabetes in patients that take commonly prescribed drugs for bipolar disorder</td>
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<td>2004</td>
<td>Lipid</td>
<td>HGJX</td>
<td>Olanzapine and Risperdal have comparable effects on triglyceride levels and other metabolic measures</td>
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<td>Updates on Strategy and Key Information (including best practice/shared learning, Virtual Team)</td>
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</table>
Existing Tools to Support Issues and Competitive Management

- Zyprexa InfoNet one stop site to get tools:
  - Zyprexa issue position paper
    (Weight gain; Diabetes/Hyperglycemia/DKA; Lipids)
  - Safety literature review
  - New published articles and communication guide
  - Slide sets
  - Shared learning/Best practice
  - Competitive profiles, backgrounders, strategies
  - Company overviews
  - Competitive landscape

- Issues Management resource binder (being developed to access through InfoNet)
- DVD-ROM: Considering the benefits and risks (being developed to run on LAVA accessed through InfoNet)
Key TakeAways

- Competitors will continue to focus on and exaggerate the metabolic side effect profile of Zyprexa
- Zyprexa’s benefits outweigh its liabilities
- ZPT will deliver key studies and data on targeted issues to strengthen our position
- Affiliates need to be fully prepared to manage issues at local level with tailored message / program that aligns with global position
## Competitive Landscape – Indications, Formulations and Patent Expiration

<table>
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<tr>
<th></th>
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<th>2003</th>
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<td>4wk Depot</td>
<td>Expire: US 2011</td>
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<td><strong>Risperdal</strong></td>
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<td>Bipolar Mania (US Q4); 2 wk Depot (US Q4); Dissolvable (US Q4)</td>
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<td>Expire: US Q4</td>
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<td><strong>Seroquel</strong></td>
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<td>SR Granules</td>
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<td>Schizo (EU Q3); Schizo Maint. (US Q4)</td>
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## Competitive Gap Analysis

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## Issues Management Gap Analysis

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Competitive and Issues Gap Analysis Debrief

- Synergies
- Discrepancies/Reconciliation
- Priorities
- Action Plans
  - What
  - By who
  - By when
Summary of Key Themes

CSFs

- Need greater competitive differentiation in core business of bipolar and schizophrenia. Establish mood without diluting schizophrenia. Opportunity to redefine outcomes!

Brand Promise Differentiation
- 1st choice for patients with schizophrenia and the preferred foundational therapy for mood stabilization.

Brand Protection
- Physicians prescribing decisions are driven by a brand's ability to deliver dependable control

Lifecycle Growth

$6B by '06 attainable but need more “insurance” to increase probability

Brand promise is the enabler
Wrap-up

• Next Steps
  ➢ Compile feedback, priorities and action plans (we will distribute back to BC members by April 1)
  ➢ Incorporate into product strategy document (replaced old IPP process)
  ➢ Incorporate into Column 3 of the Global Marketing Plan – you will receive in June

• Tonight
  ➢ Dinner at Alcatraz, 6 pm (or immediately following)
    – Circle Center Mall, 49 West Maryland Street
  ➢ Casual!

• Feedback!
  ➢ Please provide us your honest opinions!
Thank You!!

Lilly

Answers That Matter.
Mark, Patrizia, and Jim,

When Freda faxed the MCC comments regarding S. Africa's IM submission, she also sent me a fax of their comments to a recent oral olanzapine submission she had made based on several CDS revisions (Jamie has a copy of both of these faxes as they were sent all at once).

I have looked through the MCC's comments regarding the changes to the oral olanzapine package insert and need to have the product team and PhV provide input regarding a newly proposed glucose paragraph. The newly proposed paragraph is more closely aligned with the approved EU text, but does not match it exactly. Attached you will find a summary of the changes the MCC has recommended as well as my comments regarding CDS compliance.

Mark, could you please network this through Patrizia?

I am also providing a copy of the glucose labeling comparison between the US, EU, CDS, and Japan for your reference. Please let me know if you have any questions, thanks.

MCC response to labeling supplement JUL 2002.doc  Glucose Label Comparison by Section 09MAY02.doc

Best regards,
Lisa
3-0861