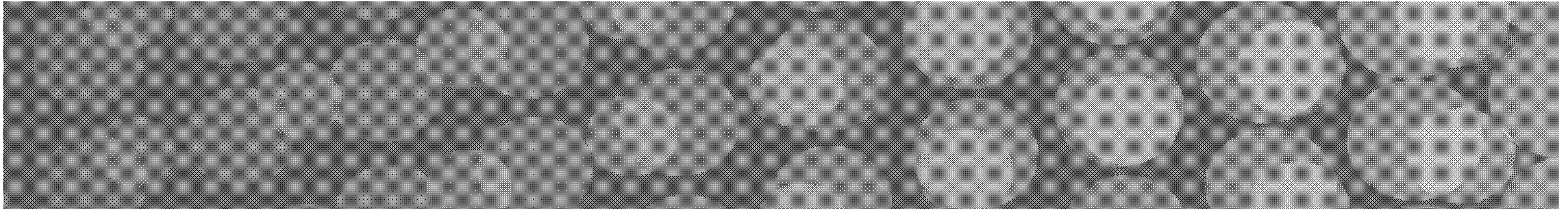


Brand Council I - 2003

ZYPREXA®
Olanzapine

Lilly

Answers That Matter.



WELCOME!

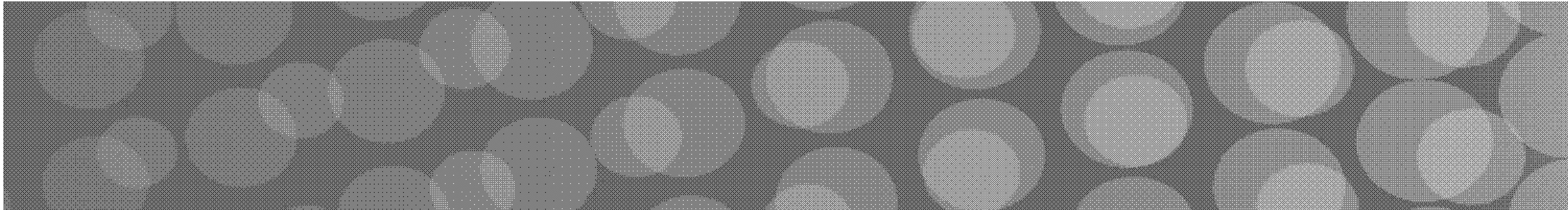


Introductions

- Name
- Area / Role



Answers That Matter.



Agenda Review

Answers That Matter.

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, Redacted 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

Leading Products in 2002 Global Pharmaceutical Sales

“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.”

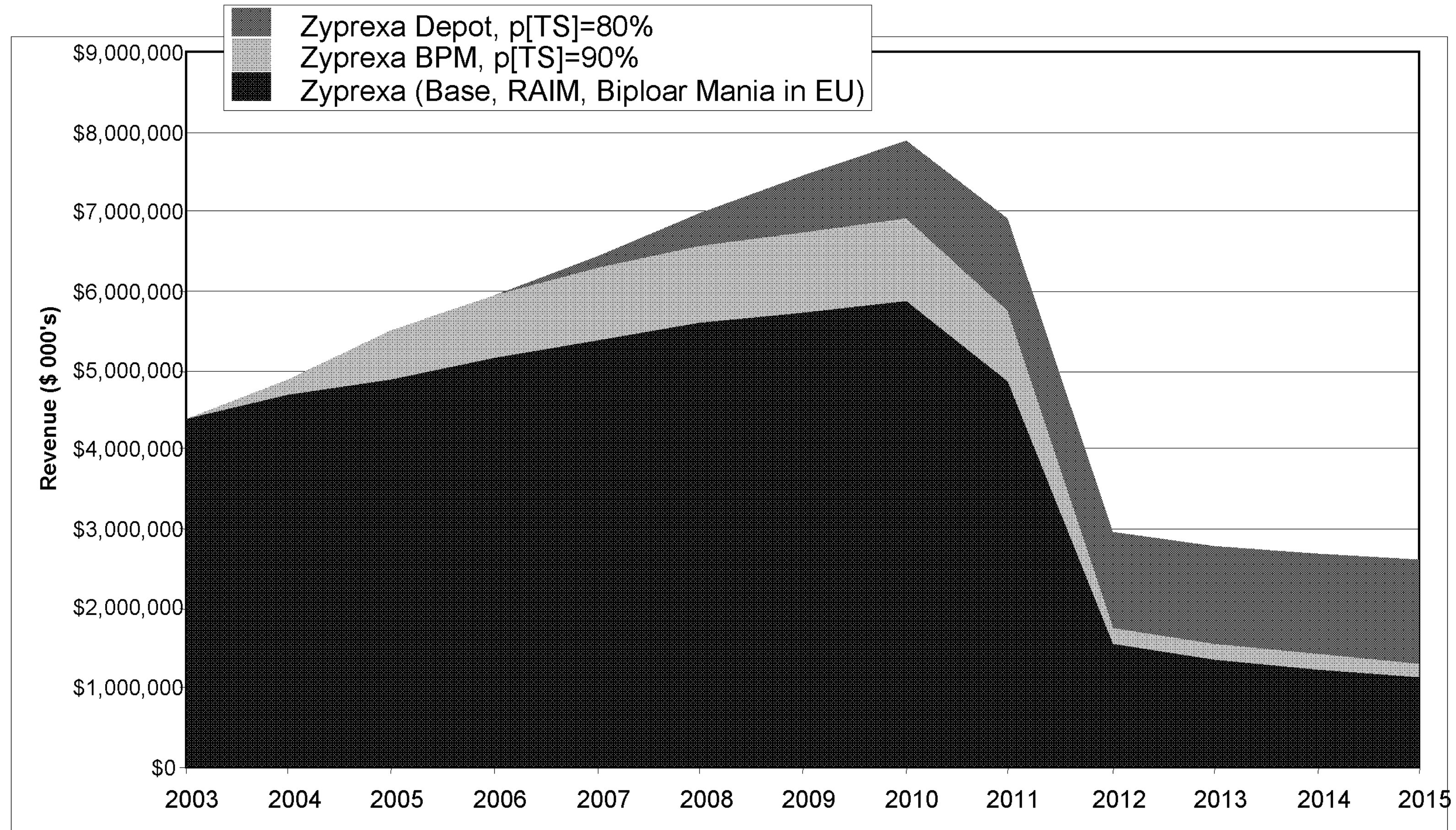
Source: IMS World Review 2003.

Leading Products in 2002 Global Pharmaceutical Sales

Audited World Product Sales	2002 Sales (US\$B)	Percentage Global Sales (US\$)	Percentage Growth Year-over-Year (Constant dollar)
1. Lipitor	\$8.6	2%	+20%
2. Zocor	\$6.2	2%	+13%
3. Losec/Prilosec	\$5.2	1%	-19%
4. Zyprexa	\$4.0	1%	+21%
5. Norvasc	\$4.0	1%	+6%
6. Erypo	\$3.8	1%	18%
7. Ogastro/Prevacid	\$3.6	1%	+3%
8. Seroxat/Paxil	\$3.3	1%	+13%
9. Celebrex	\$3.1	1%	-1%
10. Zoloft	\$2.9	1%	+12%
Total	\$44.7	11%	+11%

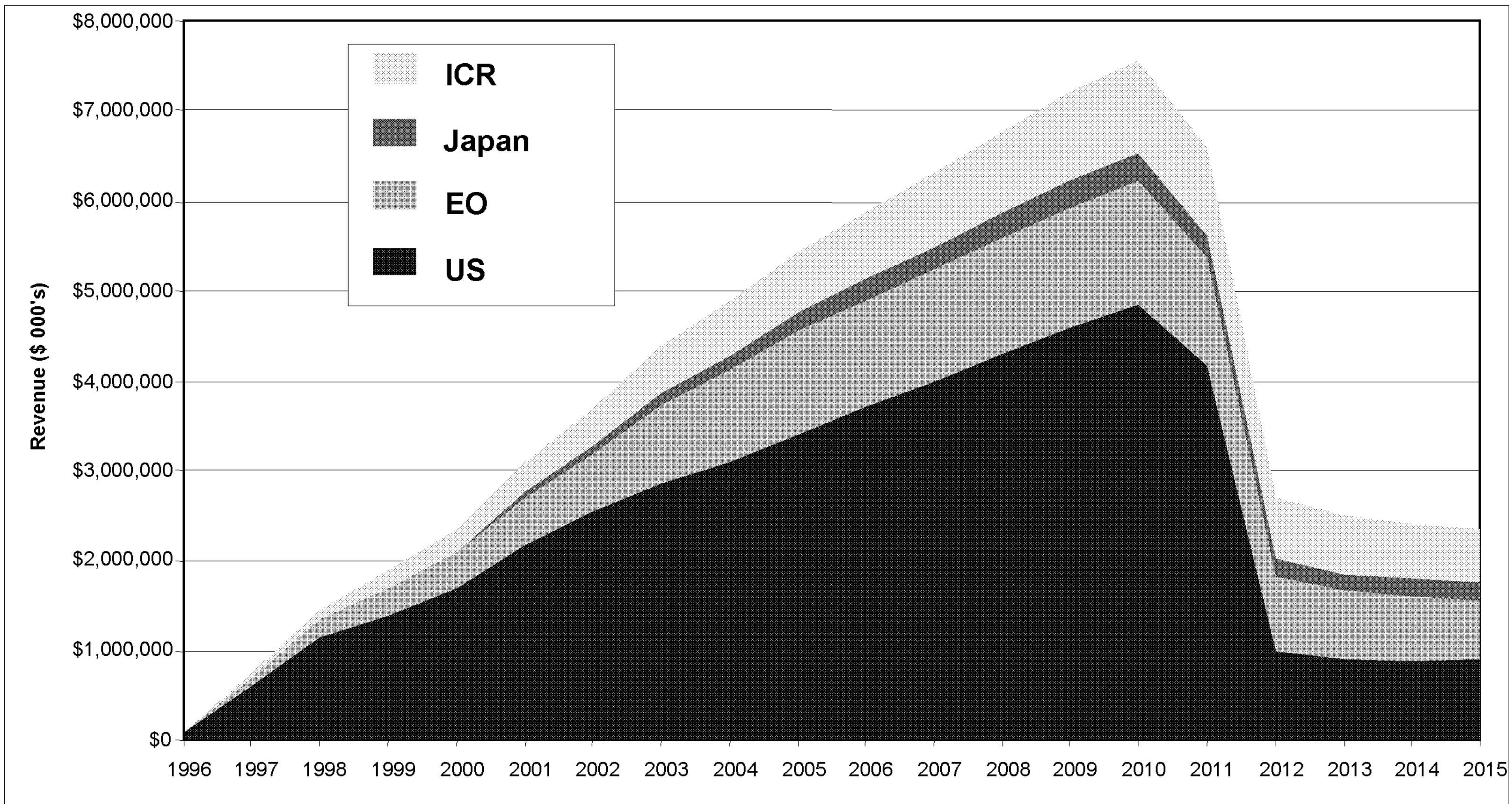
Zyprexa 2003 Long Range Plan – Based on Affiliate Forecast Roll-Up

Zyprexa 2003 Long Range Plan by Line Extension (unprobablized)

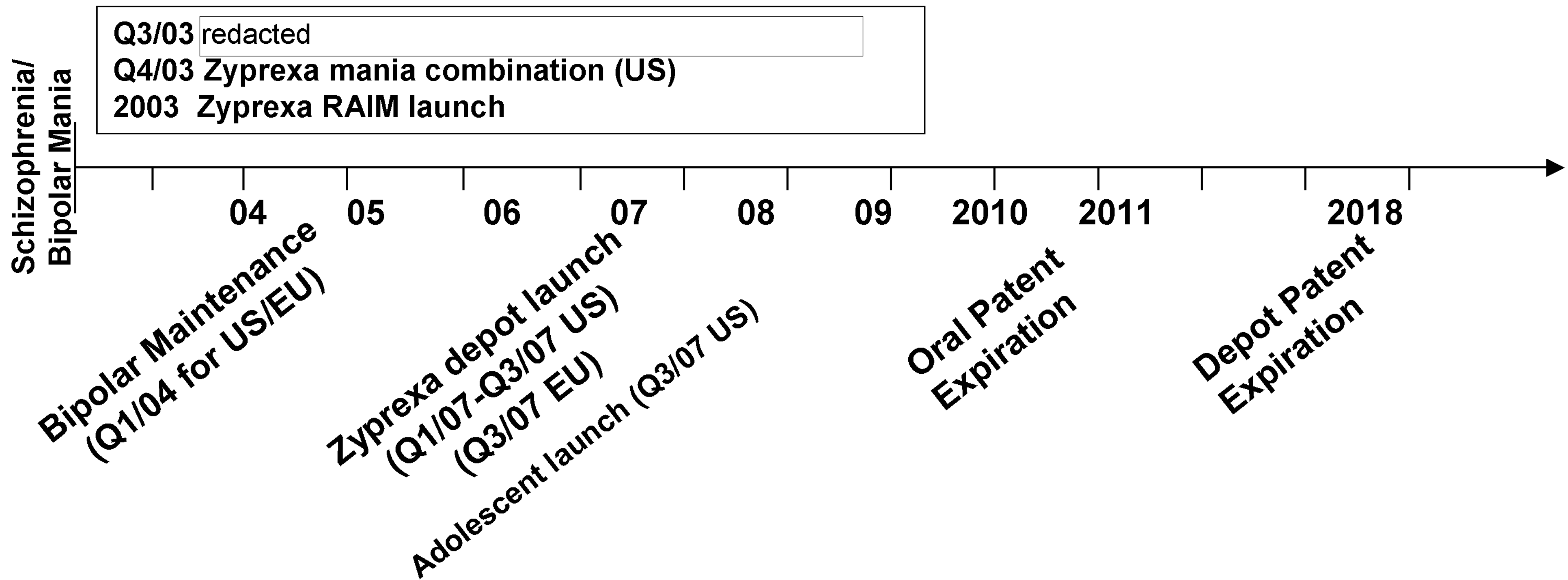


Zyprexa 2003 Long Range Plan - Global

Zyprexa 2003 Long Range Plan by Region (probablized)



Zyprexa Lifecycle Road Map



Additional considerations:

Risperdal patent expiration (2006)
Depakote patent expiration (2008)

Competitive Landscape by Indications and Formulations

	Zyprexa	Risperdal	Seroquel	Geodon	Abilify	Depakote	Lamictal	Others
Schizophrenia								
Acute	X	X	X	X	X			
Maintenance	X	X	X	X				
Adolescent	Dvlp	Dvlp						
Suicide								Cloraril
Bipolar								
Mania	X	2003	2003		2004	X		
Depression	2003						2003	
Maintenance	2004							
BP II								
Other								
Dementia					Dvlp			
Anxiety								
Borderline								
Formulations								
Oral	X	X	X	X	X	X	X	Typicals
Liquid		X						
Dissolving	X							
IM	2003			X	Dvlp			Typicals
Depot	Dvlp	X			Dvlp			Typicals
Extended Release			Dvlp			X		

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.

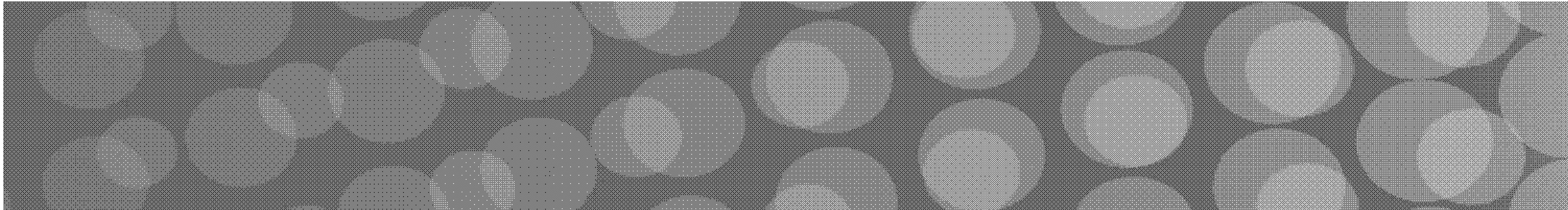
Needs to Achieve \$6B by '06

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

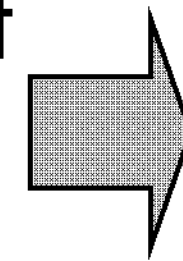
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Summary of Key Themes

CSFs

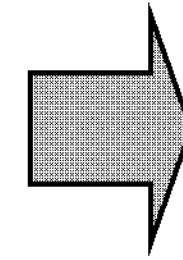
- Need greater competitive differentiation in core business of bipolar and schizophrenia. Establish mood without diluting schizophrenia. Opportunity to redefine outcomes!



Brand Promise Differentiation

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

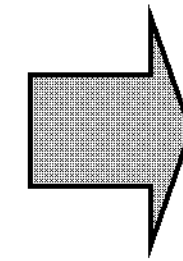
- Manage balance of side effect association / relevance



Brand Protection

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

- \$6B by '06 attainable but need more "insurance" to increase probability



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.

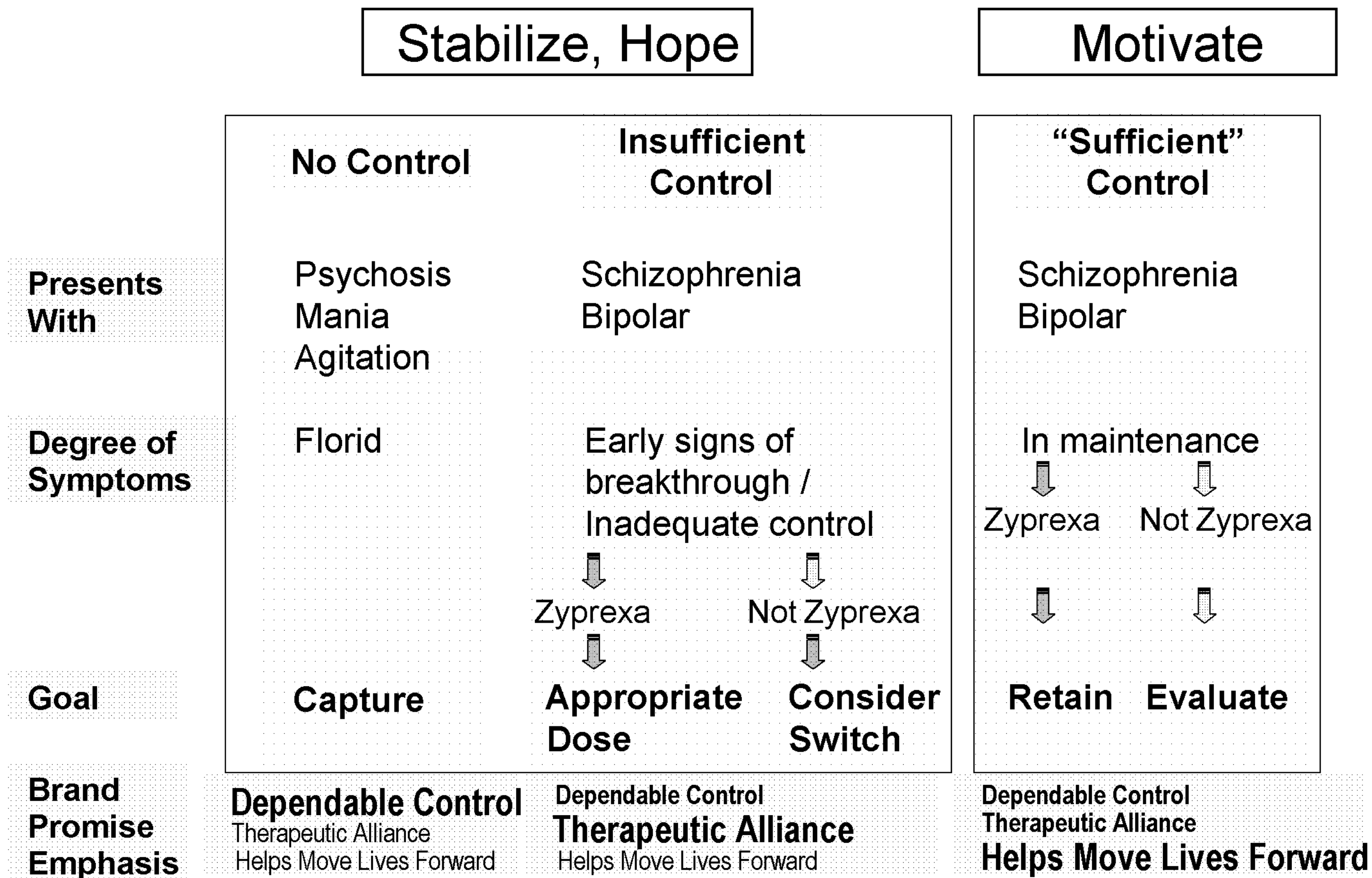
Brand Protection

- 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, redacted
Redacte 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

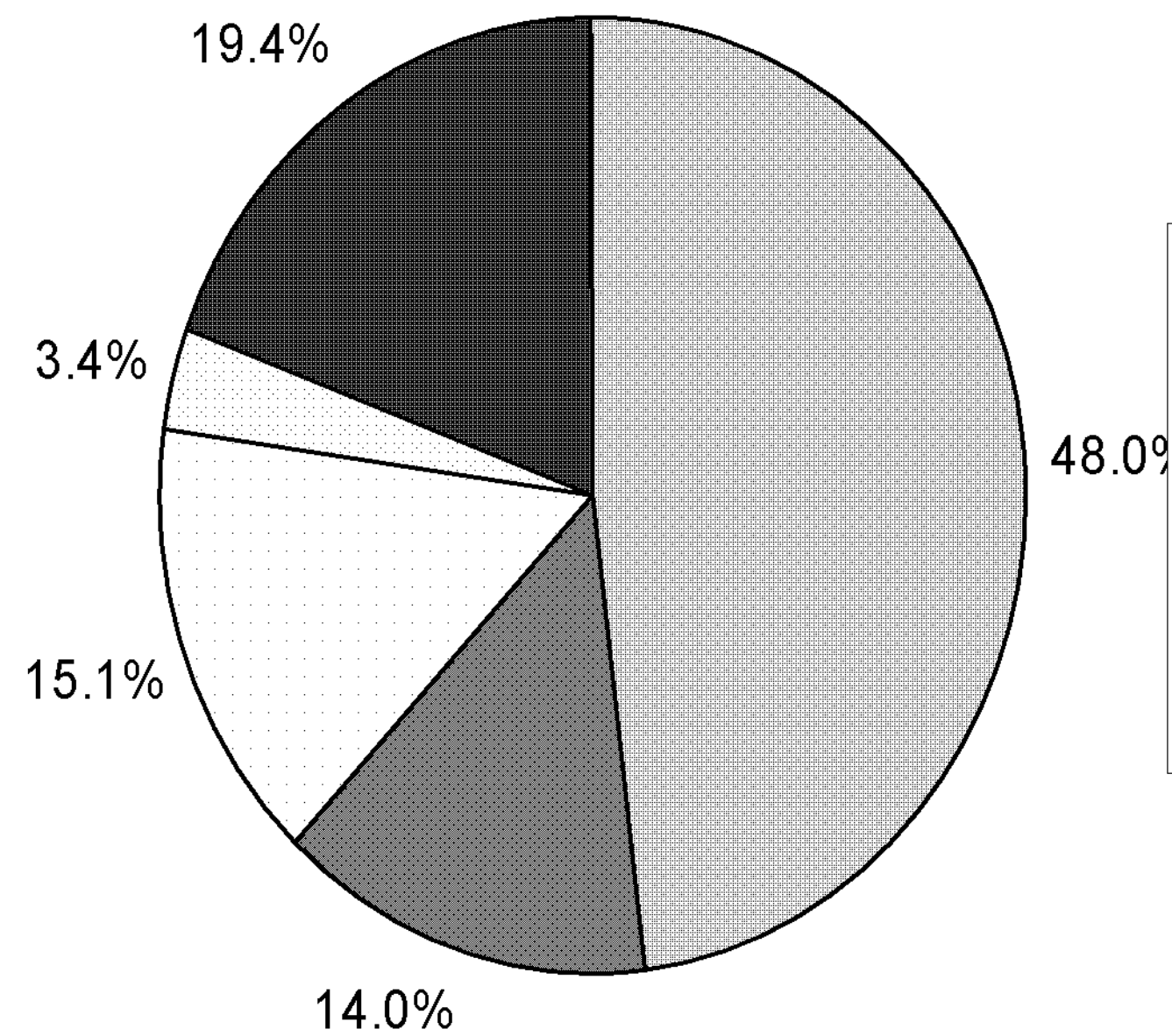


Our Business

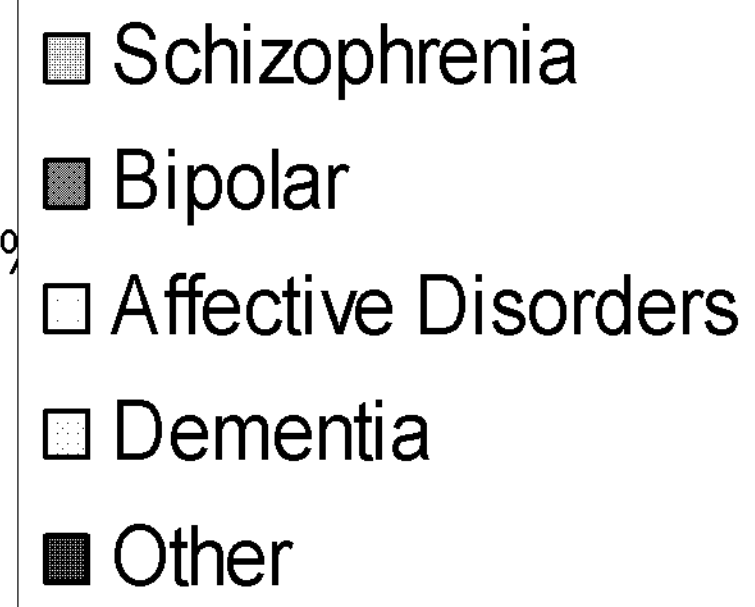
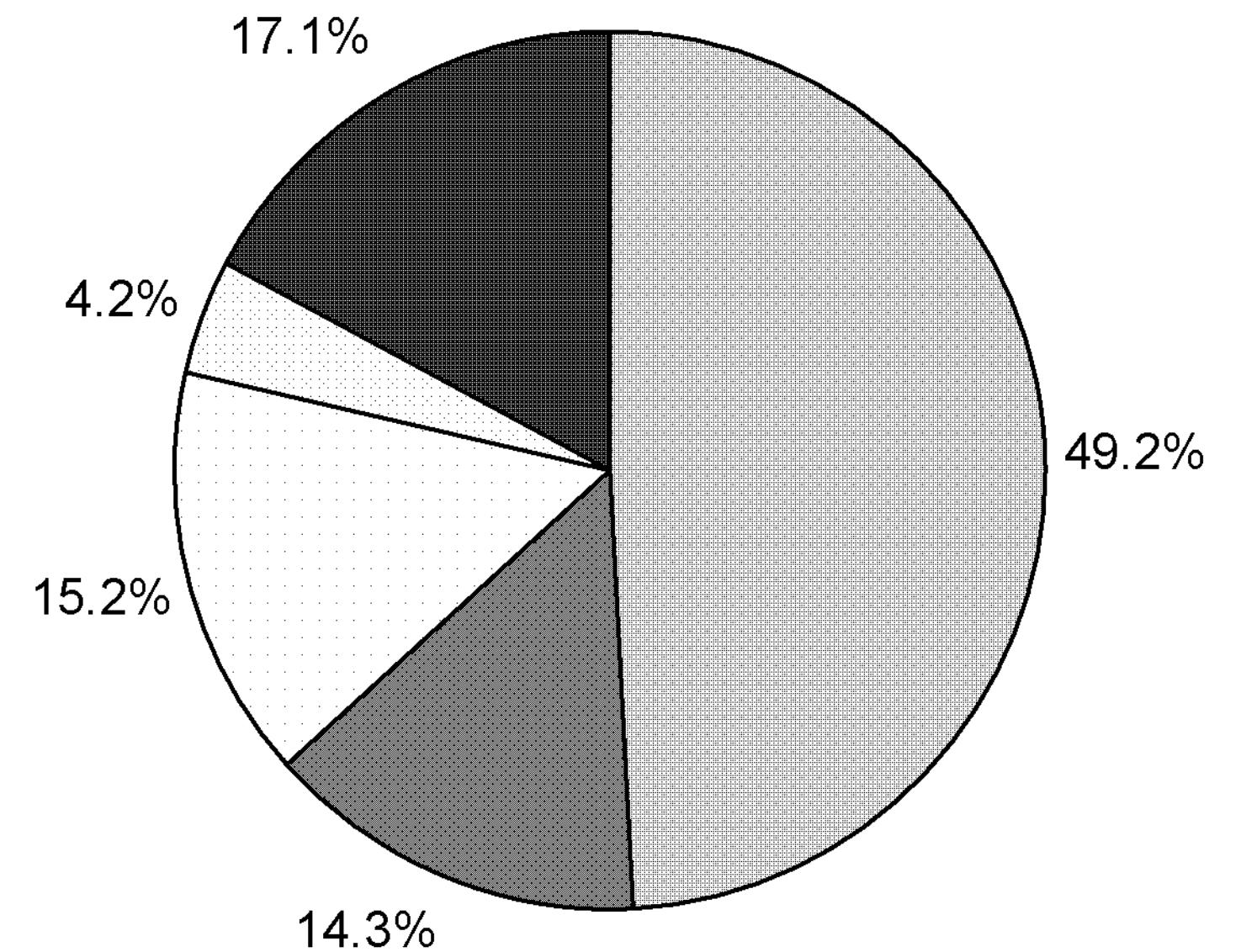
- Is comprised of four “buckets”
 - What we control:
 - Schizophrenia
 - Bipolar
 - What customers drive:
 - Other “mood” (depressive disorders)
 - Other uses (stuttering, dementia, PTSD, etc.)

Total BC* Zyprexa DOTs by Diagnosis

DOT MAT Q2 2001



DOT MAT Q2 2002



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 22

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



Answers That Matter.



Brand Equity Review: The Most Important Measurement of our Success



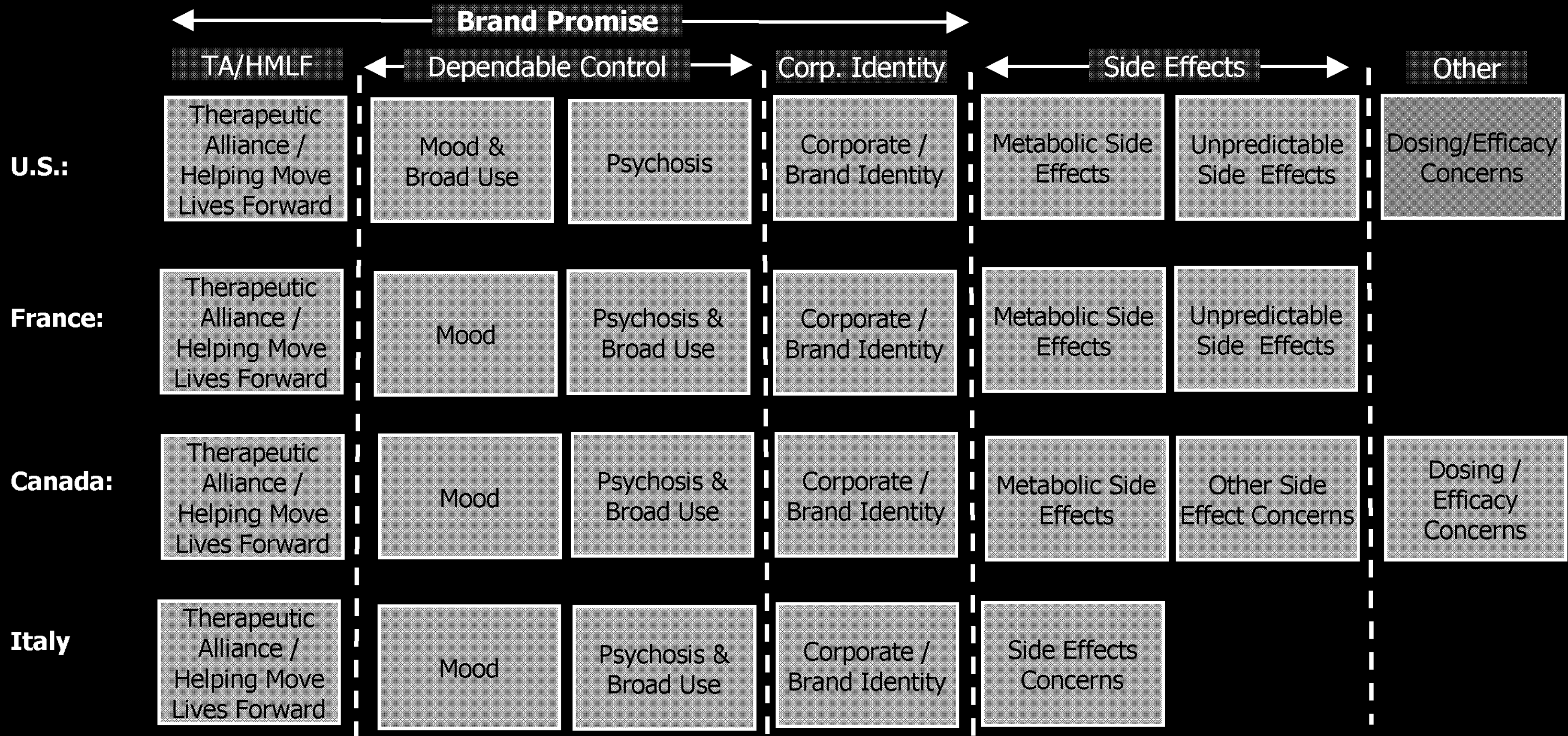
Answers That Matter.

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

Brand Equity Review – Wave 2

Across the 4 affiliates, general alignment on most relevant factors.



~~Note: Dosing concerns is a new factor for the US. France and Canada have not been "re-factored" yet. This was Italy's first~~

9/1/2004
Wave
File name/location

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Brand Equity Review

Wave 2

Wave 1

- ✓ ➤ **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.,)

December 2002-February 2003

Competitive and Issues Tracker Global Comparison

Results for US, Japan, Australia, Spain, France

The Lilly logo is written in a black, cursive script font.

Answers That Matter.

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

Prescribing Behavior for Schizophrenia

Among Psychiatrists

% of Psychs that indicated Zyprexa was the most commonly prescribed for Schizophrenia

		First Episode	Relapse	Refractory	Side Effects
		%	%	%	%
(a)	US	37	37	16	17
(b)	AUS	39	60	11	15
(c)	Japan	6	2	40	20
(d)	France	42	24	5	39
(e)	Spain	19	25	83	86

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.

Prescribing Behavior for Bipolar

Among Psychiatrists

% of Psychs that indicated Zyprexa was the most commonly prescribed for Bipolar Disorder

	Mania	Bipolar	Rapid	Side
	%	Depression	Cyclers	Effects
		%	%	%
(a) US	18	9	5	20
(b) AUS	20	1	1	7
(c) Japan	0	1	2	4
(d) France	7	7	1	15
(e) Spain	13	1	4	11

Only in the US is Zyprexa used more broadly across the range of bipolar disorder patients.

Prescribing Behavior for Bipolar

Among Psychiatrists

% of Psychiatrists that indicated that Zyprexa is used as their foundation of treatment in Bipolar

	Zyprexa %
(a) US	47
(b) AUS	25
(c) Japan	4
(d) France	12
(e) Spain	13

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

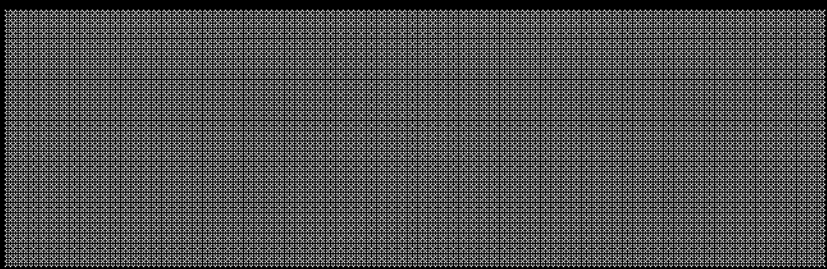
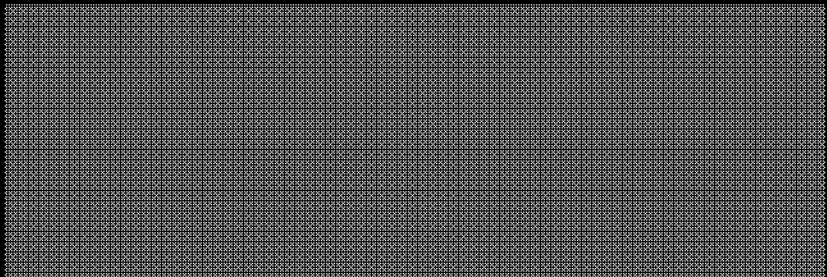
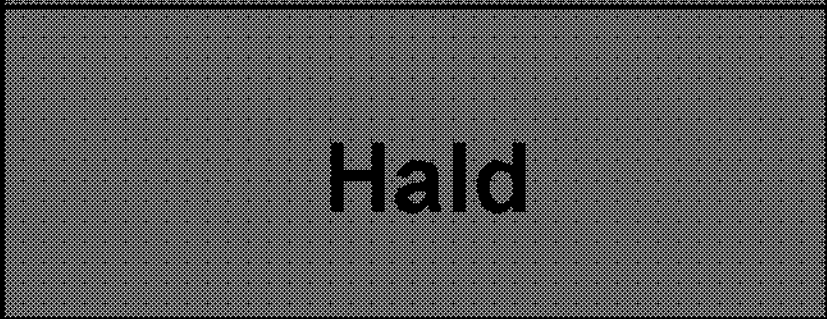
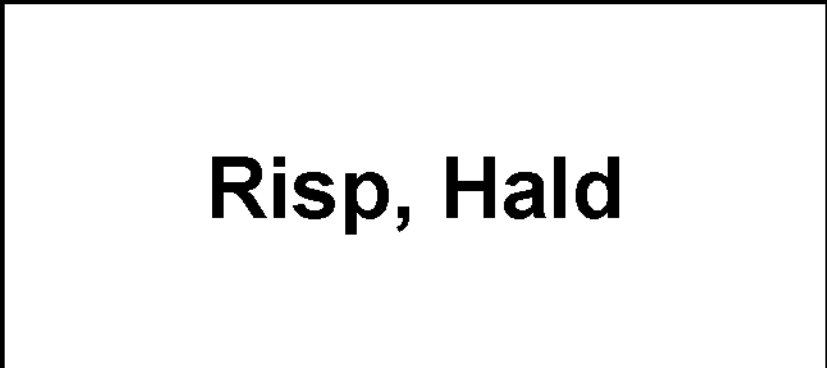

% of Psychiatrists that feel Zyprexa is effective in Schizophrenia

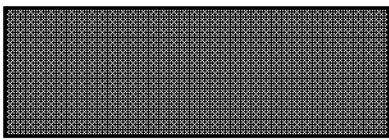

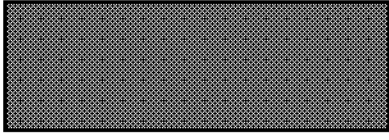
US	Risp, Hald	Zyprexa parity w/ competition
Australia	Risp	Zyprexa parity w/ competition
Japan	Risp, Hald	Zyprexa loss over competition
France	Risp, Hald	Zyprexa parity w/ competition
Spain	Risp	Zyprexa loss over competition

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

US	
Australia	
Japan	 Hald
France	 Risp, Hald
Spain	 Risp, Hald

 Zyprexa win over competition
 Zyprexa parity w/ competition
 Zyprexa loss over competition

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.

Competitive Tracker – Australia

Brand Association with Side Effects (Summary of Top 2 Box) Among Psychiatrists

	Zyprexa (75) % a	Risperdal (75) % b	Seroquel (74) % c	Clozaril/ Clopine (70) % d	Haldol (75) % e
Weight gain	95 ^{bcd}	9	4	79 ^{bce}	8
Activation	11	15	12	17	9
Is associated with cardiac complications	7 ^{bc}	1	--	59 ^{abce}	7 ^{bc}
Unpredictable efficacy	7	7	31 ^{abde}	3	8
Prolactin elevation	5	64 ^{acde}	3	17 ^{ac}	48 ^{abd}
Limited efficacy due to an EPS dose ceiling	3	33 ^{acd}	3	1	85 ^{abcd}
Complicated titration	3	8	27 ^{abe}	47 ^{abce}	11 ^a
Prolongation of the QTc wave	5	5	4	24 ^{abce}	13 ^{abc}
EPS (extra pyramidal side effects)	1	20 ^{acd}	--	1	97 ^{abcd}
Inferior relapse prevention	1	3	15 ^{abc}	3	19 ^{abd}
Is associated with nausea and/or vomiting	--	1	--	10 ^{abc}	5 ^{ac}
Worsening of psychosis	--	--	7 ^{abc}	--	3

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

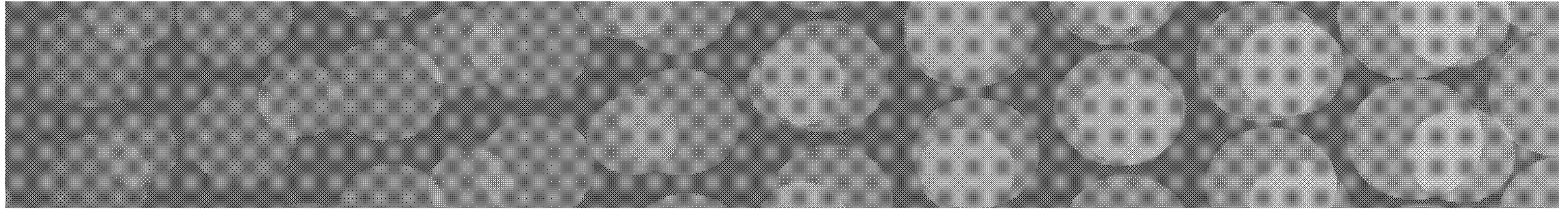
Summary of Key Themes

- 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



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Schizophrenia Strategy

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

Lilly
Answers That Matter.

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

Zyprexa Strategy in Schizophrenia

Internal Goal:

- Zyprexa is the first-choice treatment for patients with psychosis.

Reason to believe:

- Zyprexa 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.

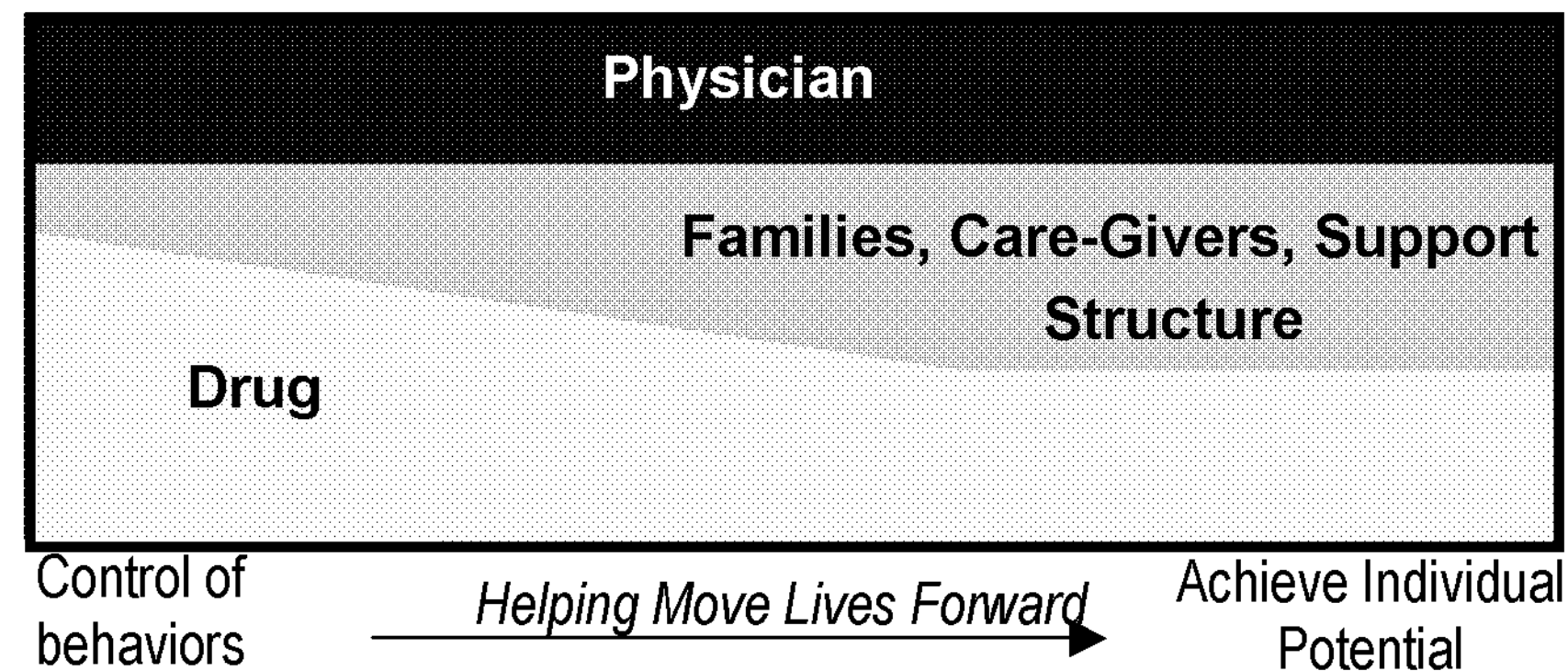
What we want our customers to remember:

- 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

How Zyprexa Helps Move Lives Forward



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

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

Phased Approach for Growth

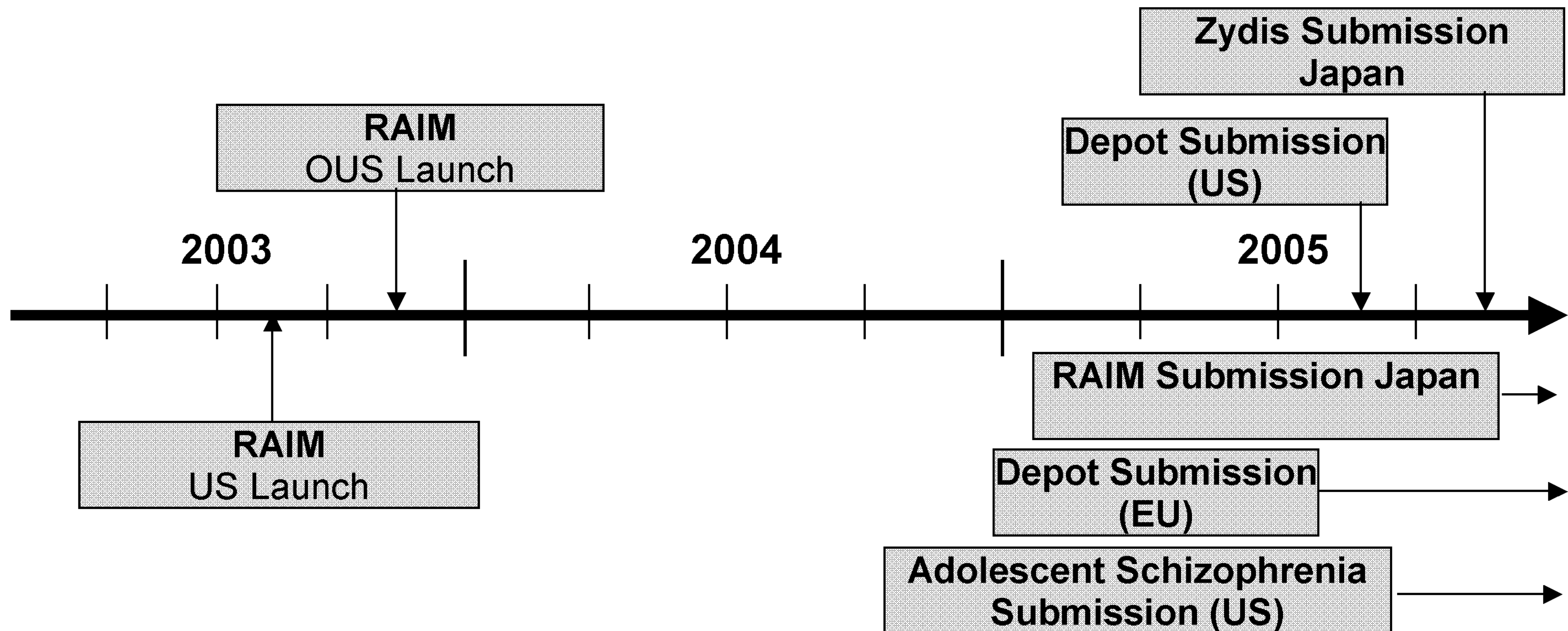
	PHASE I: <u>DC</u>-TA-HMLF	PHASE II: DC- <u>TA</u> -HMLF	PHASE III: DC-TA- <u>HMLF</u>
FOCUS FOR FIELD	<ul style="list-style-type: none"> • Effective in wide range of patients • Effective in wide range of symptoms • Breadth of Zyprexa Franchise • Rapid and Dependable control of dangerous and inappropriate behaviors • Zyprexa provides enduring efficacy and relapse prevention • Known and manageable side effect profile • Helps Move Lives Forward by addressing patient needs 	<p>Remove barriers to Therapeutic Alliance</p> <ul style="list-style-type: none"> • Mood (depressive symptoms) • Thinking more clearly • Negative symptoms • Attention • Lack of support system • Stigma • Fear of relapse • Lack of trust <p>Helps patients achieve individual potential</p>	<ul style="list-style-type: none"> • Superior functional outcomes

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



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

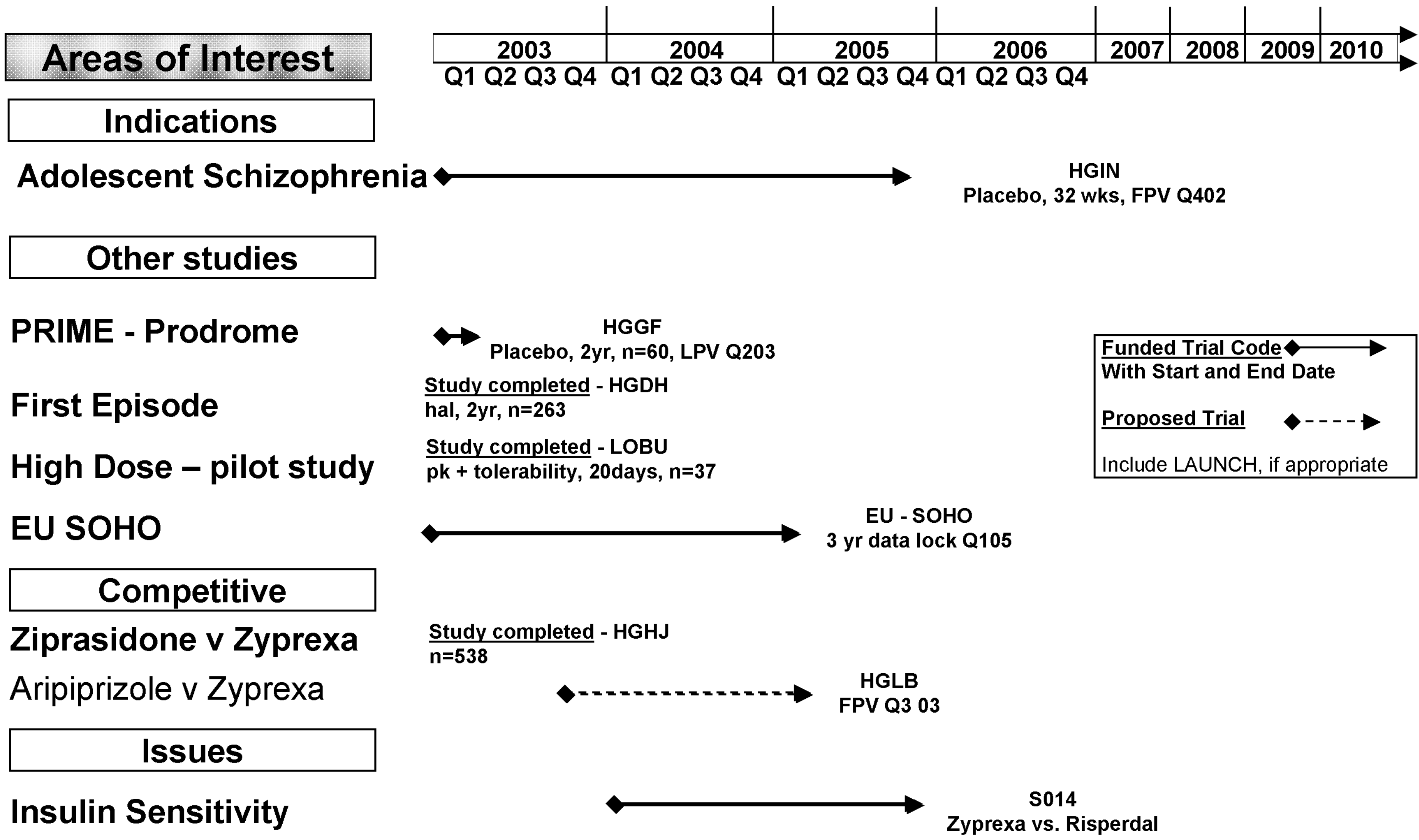
Phase II

- 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

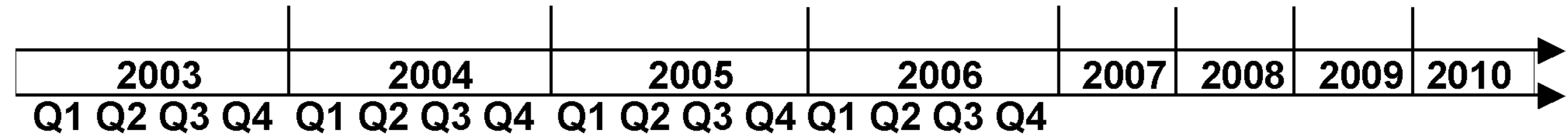
- Olz patients significantly more likely to work part or full time at 52 wks vs hal, Hamilton, 1999
- Olz patients experienced significant improvements in social outcomes at 52 wks vs hal, Hamilton, 1999

Schizophrenia- Zyprexa Lifecycle Map



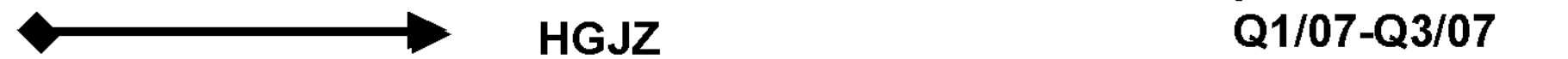
Schizophrenia- Zyprexa Lifecycle Map

Areas of Interest



Formulations

Depot US registration study



Depot EU registration study



Comparator study



Switching study



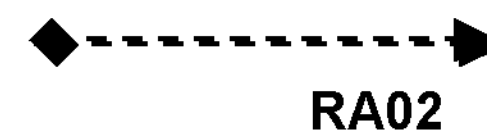
Conversion – oral to depot



RAIM pk pilot Japan submission



RAIM dose finding Japan submission



Funded Trial Code ◆————▶
 With Start and End Date

Proposed Trial ◆-----▶
 Include LAUNCH, if appropriate

Summary of Key Support - Schizophrenia

	Indications/ Formulations	Key Data Available	Key Publications Available
2003	RAIM Global Launch	HGGF - Prodrome HGDH - First Episode LOBU – High Dose pk/tol SOHO 6 month HGHJ – Zyp v Zip EU SOHO 1 year	Pri efficacy/safety (HJ) Relapse Prevention (GI) First Episode MRI (DH) MRS, lactate metabolism & attention correlate (DH)
2004		EU SOHO 2 year	Clin & soc outcomes (SOHO – 6 month & 1 year)
2005	Zydis submission (Japan)	EU SOHO 3 year HGLB – Zyp v Arip	
2006	RAIM submission (Japan) Adolescent Schiz (US Q3 07)	HGIN – Adolescent Schiz S014 – Insulin Zyp v Risp Depot Registration	

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

	2003	2004	2005	2006
Registration (label) studies				
Non-registration studies				
Data (including health outcomes)				
Publications				
Programs				

Schizophrenia Gap Analysis Debrief

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

Zyprexa Global Bipolar Strategy

ZYPREXA[®]
Olanzapine

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)

Zyprexa Strategy in Bipolar Disorder

Internal Goal: Establish Zyprexa 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 Zyprexa does (benefit) vs. what Zyprexa is (label)
 - Avoid referring to Zyprexa as a mood stabilizer... remember whatever equity we create for bipolar carries over to schizophrenia.

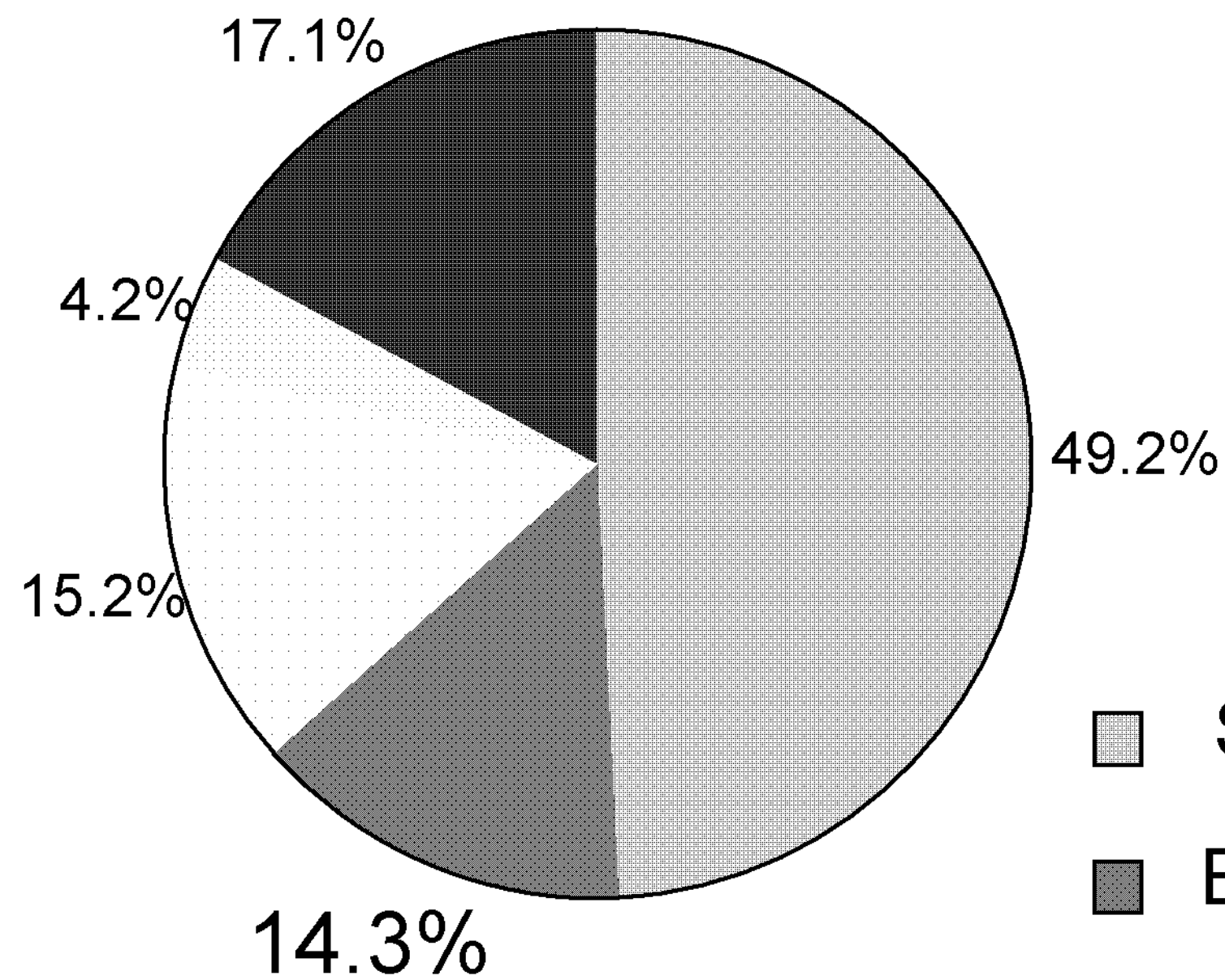
Where the Business Comes from '03-'05:

- Accelerate conversion from bipolar competitors
- Begin market creation in EU, more advanced in US

Zyprexa DOTs... Big Opportunity!!!

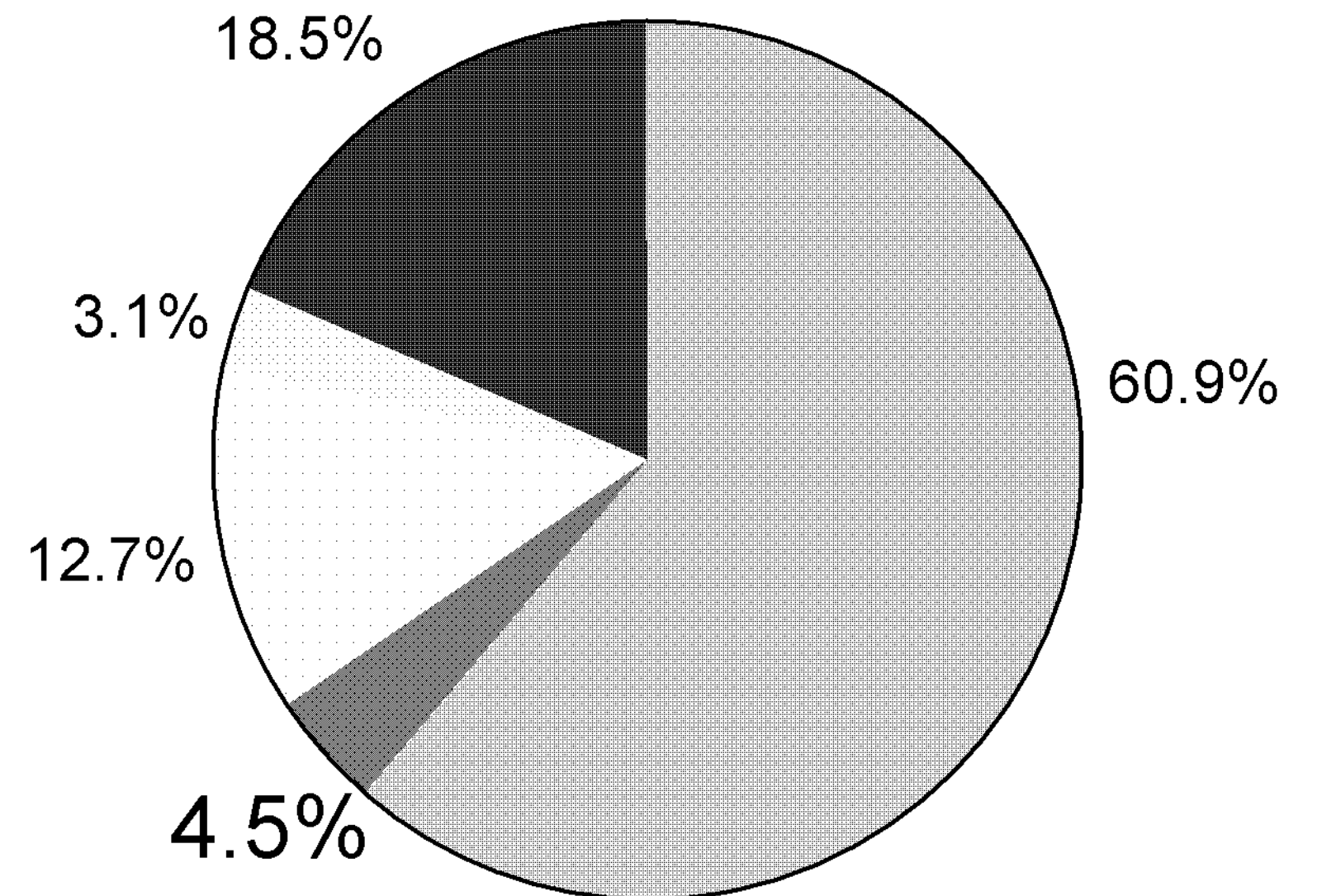
BC Affiliates*

DOT MAT Q2 2002



EU BC-5 Affiliates

DOT MAT Q2 2002



- Schizophrenia
- Bipolar
- Affective Disorders
- Dementia
- Other

* Australia not available
Source: Medical Dynamics

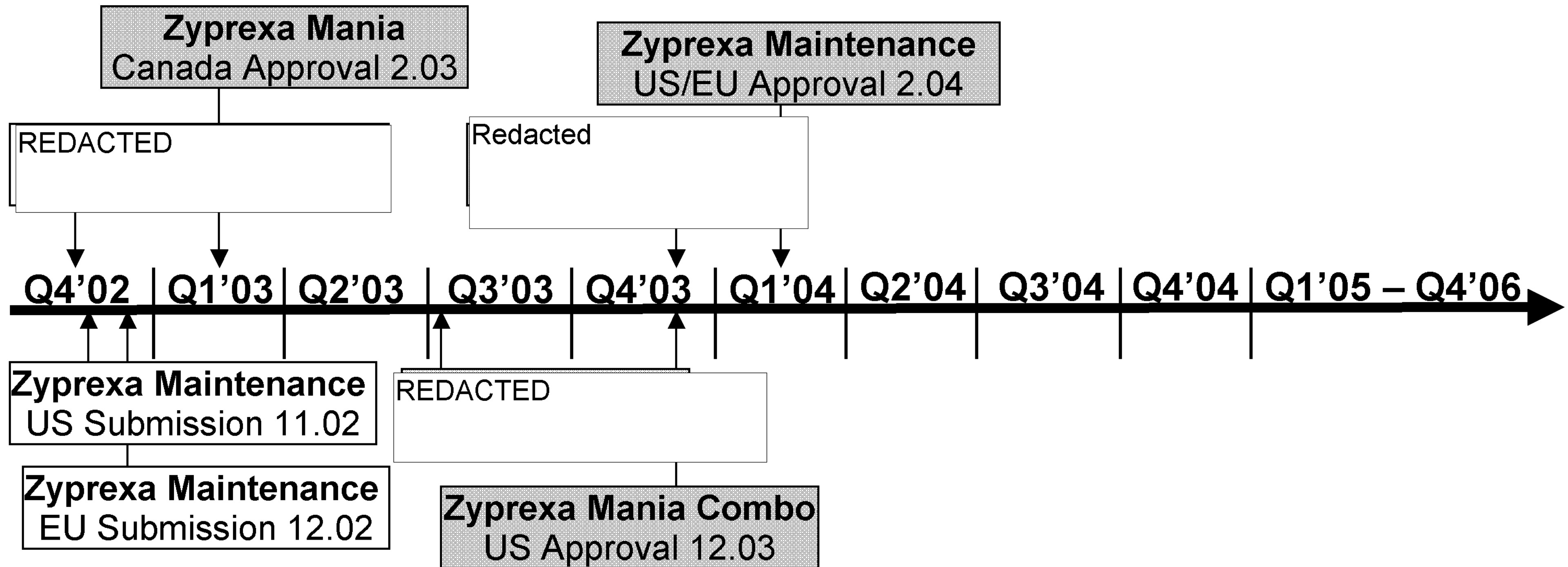
Bipolar/Mood Regulatory Priorities – '03-'06

REDACTED

- 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



Data to Support Message Evolution – '03-'06

Today – BP Mania 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)

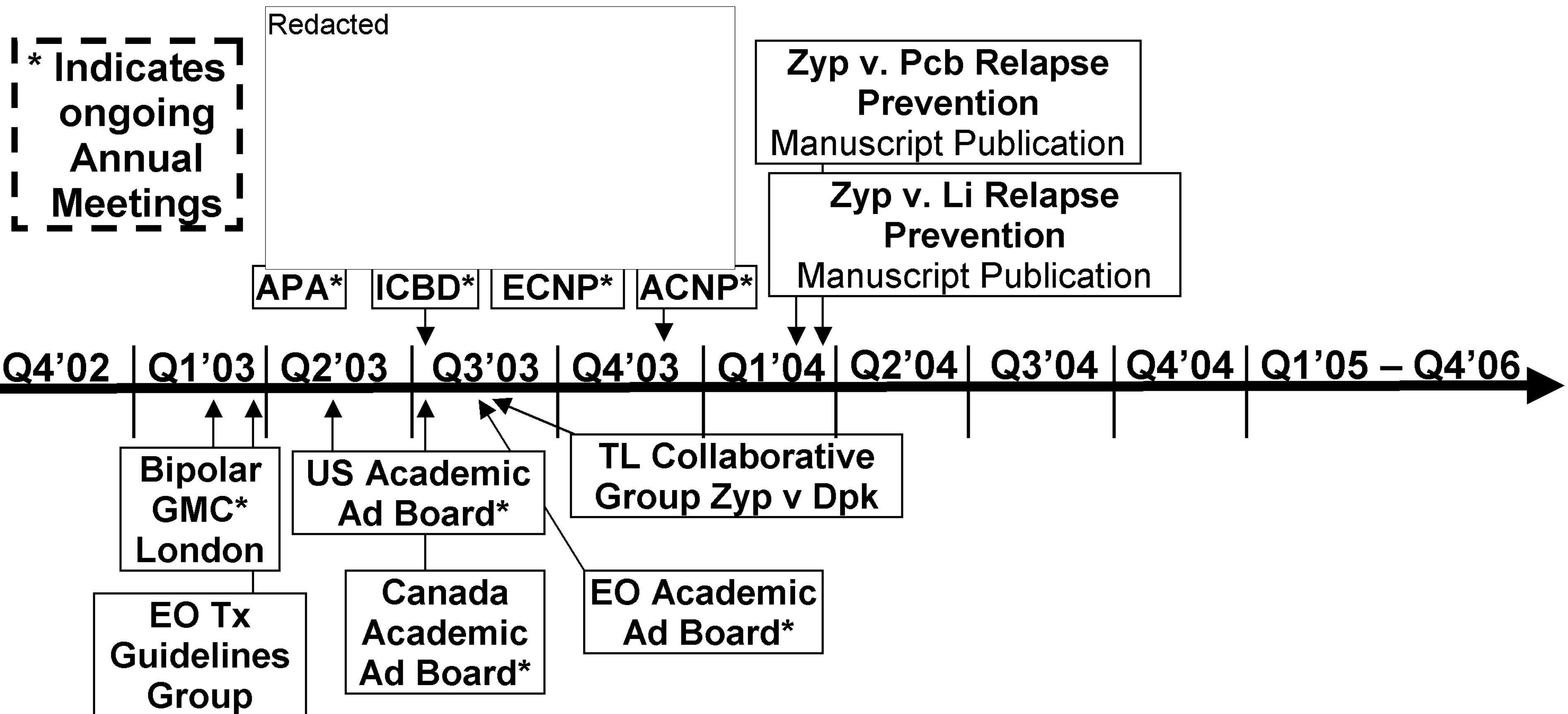
- Better than Lithium for Relapse Prevention (HT) Indication
- Zyprexa prevents bipolar relapse to either mania or depression (HL) Indication
- Zyprexa cuts relapse by 50% when used as a foundation treatment with appropriate combinations (lithium/valproate) (FU) Indication

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



PLC Management Priorities for Exploration

Funded

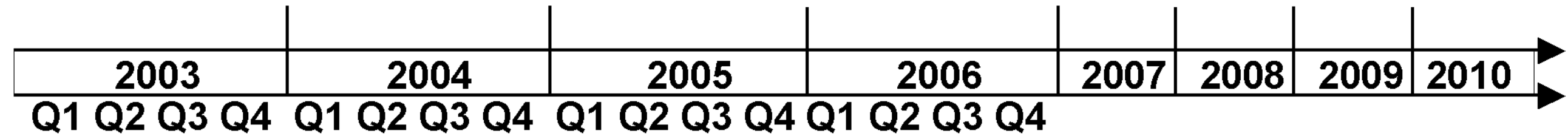
- HDAO Treatment-Resistant Depression (TRD)
- HGIU Child & Adolescent Bipolar I
- 8004 PET Study (FPV 4/03)

Unfunded

- *Bipolar Depression (EU)*
- *Bipolar II*
- *Schizoaffective*
- *Depot Bipolar*

Mood Disorders- Zyprexa Lifecycle Map

Areas of Interest



Indications

Redacted

**Mania Combination
Bipolar Maintenance**

redacted

HGFU Complete
US LAUNCH – Q4/03

HGHT & HGHL Complete
US/EU LAUNCH – Q1/04

◆—————▶ HDAO
US/ICR LAUNCH – Q1/06

Adolescent – Mania

◆—————▶ US LAUNCH Q3/07

Redacted

Bipolar II (Zyprexa & redacted)

◆-----▶ HG??/Other?
US/EU LAUNCH – Q?/0?

Bipolar depot

◆-----▶ HG??/Other?
US/EU LAUNCH – Q?/0?

Competitive

**Lamictal for Bipolar
Maintenance/Relapse**

US/EU LAUNCH – Q2/03

Lamictal for Bipolar Depression

US/EU LAUNCH – Q?/0?

Lamictal for Unipolar Depression

US/EU LAUNCH – Q?/0?

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

Phased Approach for Growth in Bipolar

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

Phased Approach for Growth in Bipolar

	PHASE I: Introduction	PHASE II: Accelerate Conversion	PHASE III: Foundation Differentiation
FOCUS FOR FIELD	<ul style="list-style-type: none"> • Share monotherapy data to establish the dependable control of Zyprexa in manic and mixed patients (don't insist on monotherapy) • Enables a therapeutic alliance in non-psychotic and psychotic patients with a profile of safety, tolerability and ease of use • Zyprexa Treats mania without inducing depression • Zyprexa quickly improves depressive symptoms in mania • Zyprexa reduces the severity of symptoms in both mania and depression 	<p>Introduce:</p> <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Dependable control for spectrum of bipolar disorder <p>Introduce:</p> <ul style="list-style-type: none"> • Zyprexa reduces severity of bipolar depression without inducing mania • redacted

Phased Approach for Growth in Bipolar

	PHASE I: Introduction	PHASE II: Accelerate Conversion	PHASE III: Foundation Differentiation
<p>MARKET CONDITIONING (DTP)</p> <p>One step ahead of the field</p>	<ul style="list-style-type: none"> • Share data on maintenance and expanded patient types • Share combination data • Clear competitive differentiation from other AP 	<ul style="list-style-type: none"> • Share data on bipolar depression and expanded patient types • Establish spectrum of bipolar efficacy • Clear competitive differentiation from other traditional mood stabilizers 	<ul style="list-style-type: none"> • Significant expansion of bipolar spectrum of efficacy and patient types

Summary of Key Support - Bipolar

	Indications	Key Data Available	Key Publications Available
2003	Bipolar Mania (US/EU/CA/AU) Redacted	<ul style="list-style-type: none"> •Treats mania without inducing depression (EH/GW/HQ) •Quickly improves depressive symptoms in mania (EH/GW/HQ) •Reduces severity of bipolar depression without inducing mania (GY) 	Mania Maintenance (Q2) Onset of Action (Q3) Treatment-Resistant Depression (TRD) (Q3) Bipolar Depression (Q4) Mania Combination (Q4)
2004	Bipolar Maintenance (US/EU) Bipolar Combination (US/AU)	<ul style="list-style-type: none"> •Better than Lithium for Relapse Prevention (HT) •Prevents bipolar relapse to either mania/depression (HL) •Cuts relapse by 50% when used as a foundation treatment with appropriate combinations (FU) 	Relapse Prevention (Q1)
2005	Bipolar Maintenance (CA) Treatment-Resistant Depression (US/CA/AU)		Treatment-Resistant Depression (Q4)
2006			

Takeaways

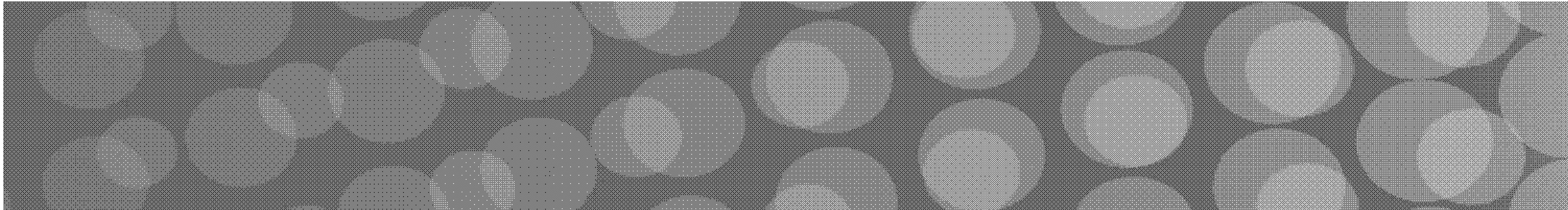
- **Bipolar opportunity is tremendous**, and the market dynamics are shifting
- Customer Target: **Patient (symptoms) + Brand promise**
- **Phased approach is critical** to achieve goals, with established triggers and metrics for moving on to next phase
- **Significant data is available**, with exciting 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)

Bipolar (mania, maintenance, depression) Gap Analysis

	2003	2004	2005	2006
Registration (label) studies				
Non-registration studies				
Data (including health outcomes)				
Publications				
Programs				

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

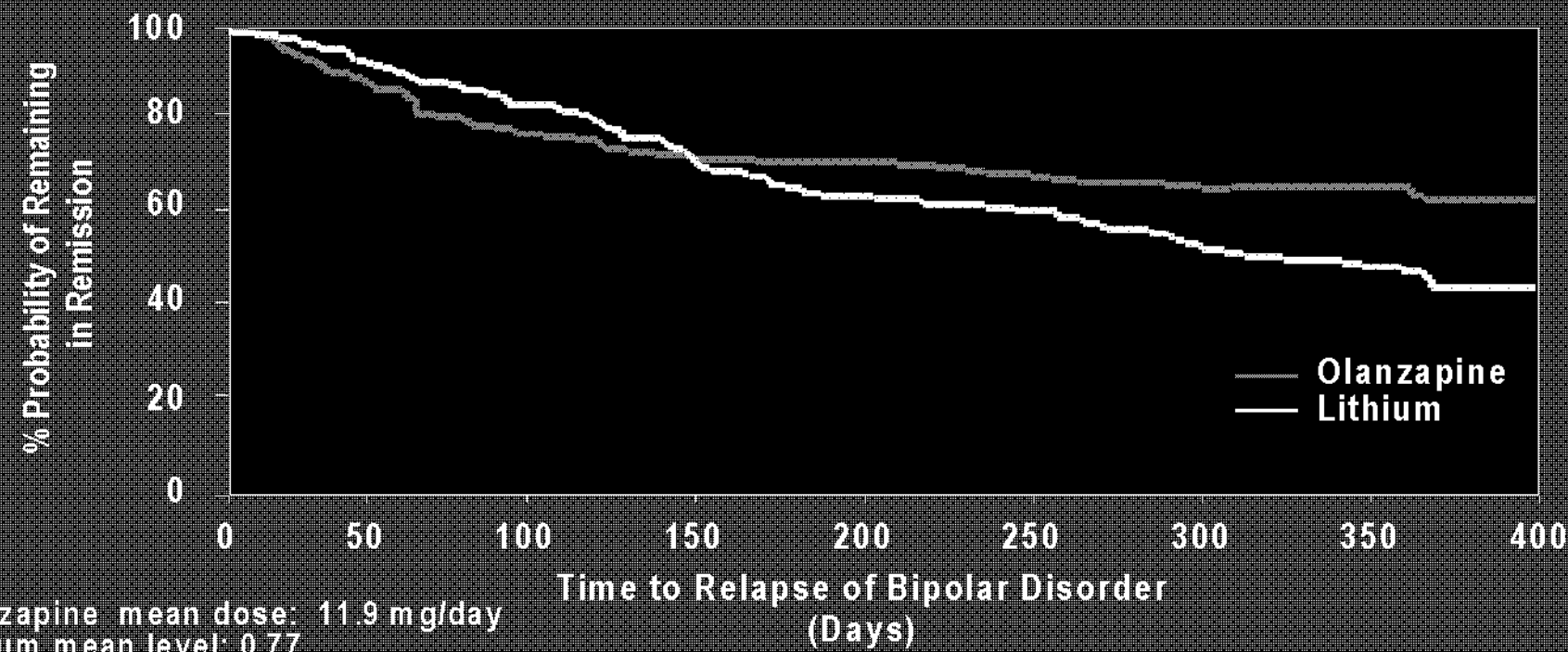
Overarching Competitive Strategy – Where we're headed

- 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

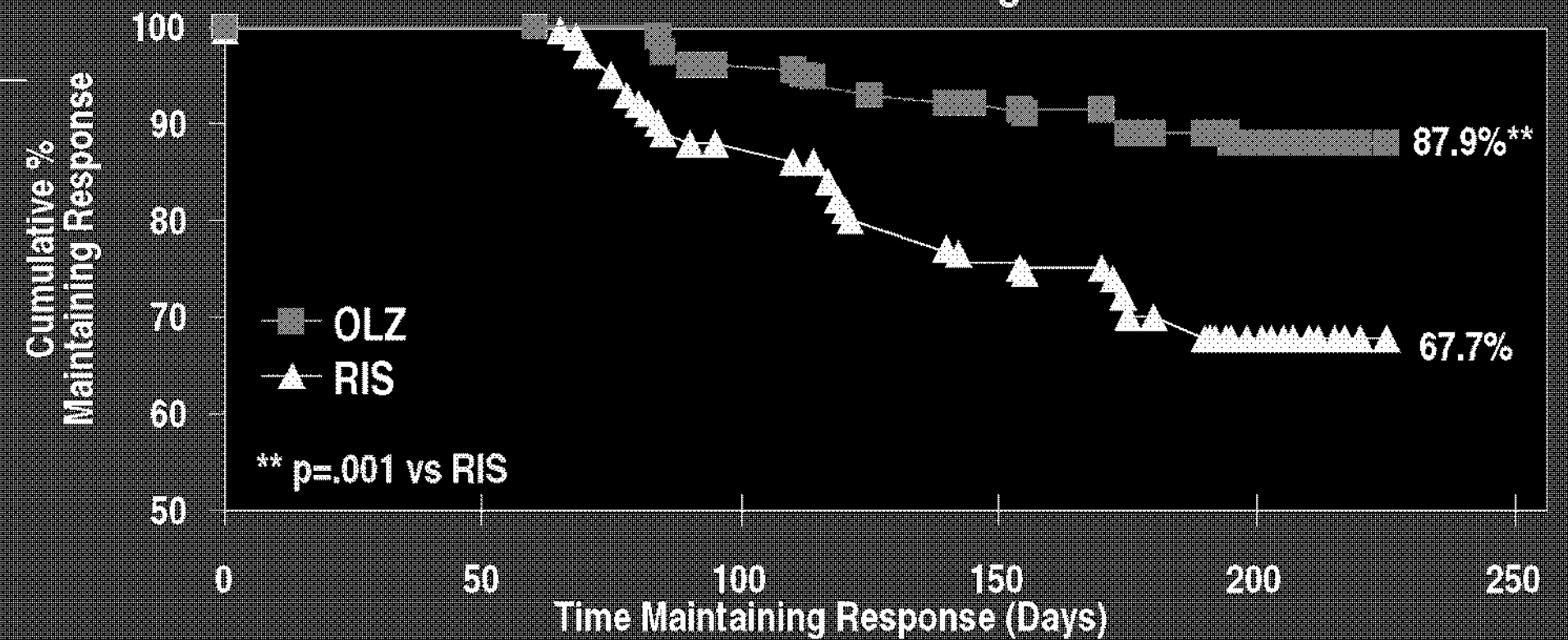
Time to Relapse Into Mania or Depression Based on Hospitalization and/or Symptomatic Rating Scale Criteria



Tohan M, et al. Presenting at Stanley Bipolar Meeting, September 11-14, 2002; Freiberg, Germany.

Olanzapine vs Risperidone

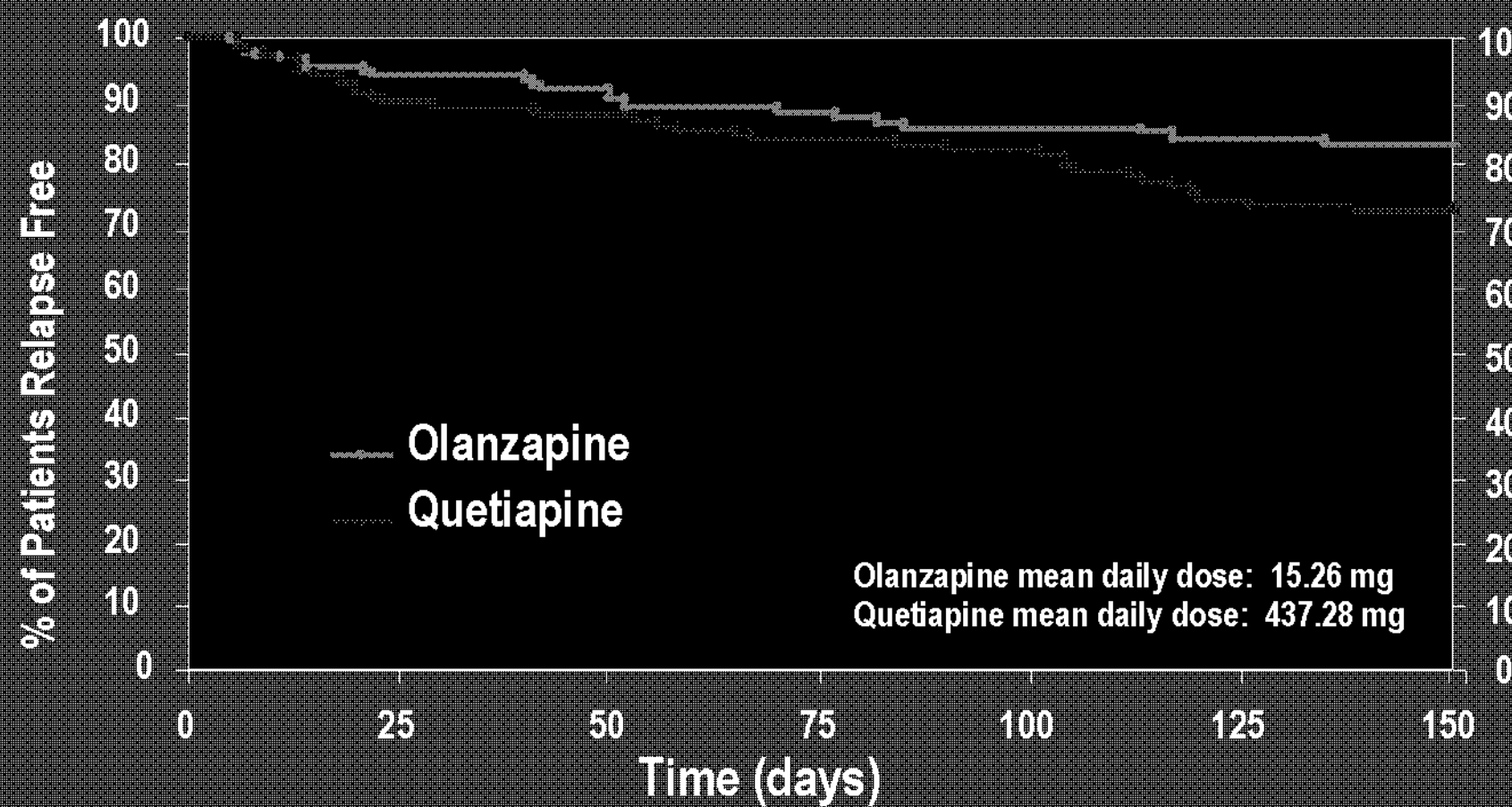
Estimated Survival Curve at Week 28 Based on PANSS and CGI Rating Scales



*Response was defined as $\geq 20\%$ improvement in PANSS Total score at Week 8 (OLZ n=105; RIS n=94).
Relapse was defined as $\geq 20\%$ worsening + CGI ≥ 3 after 8 weeks of treatment.

Tran PV, et al. *J Clin Psychopharmacol.* 1997;17(5):407-418.

Olanzapine vs Quetiapine



Data on file. Eli Lilly and Company.

Olanzapine vs Ziprasidone

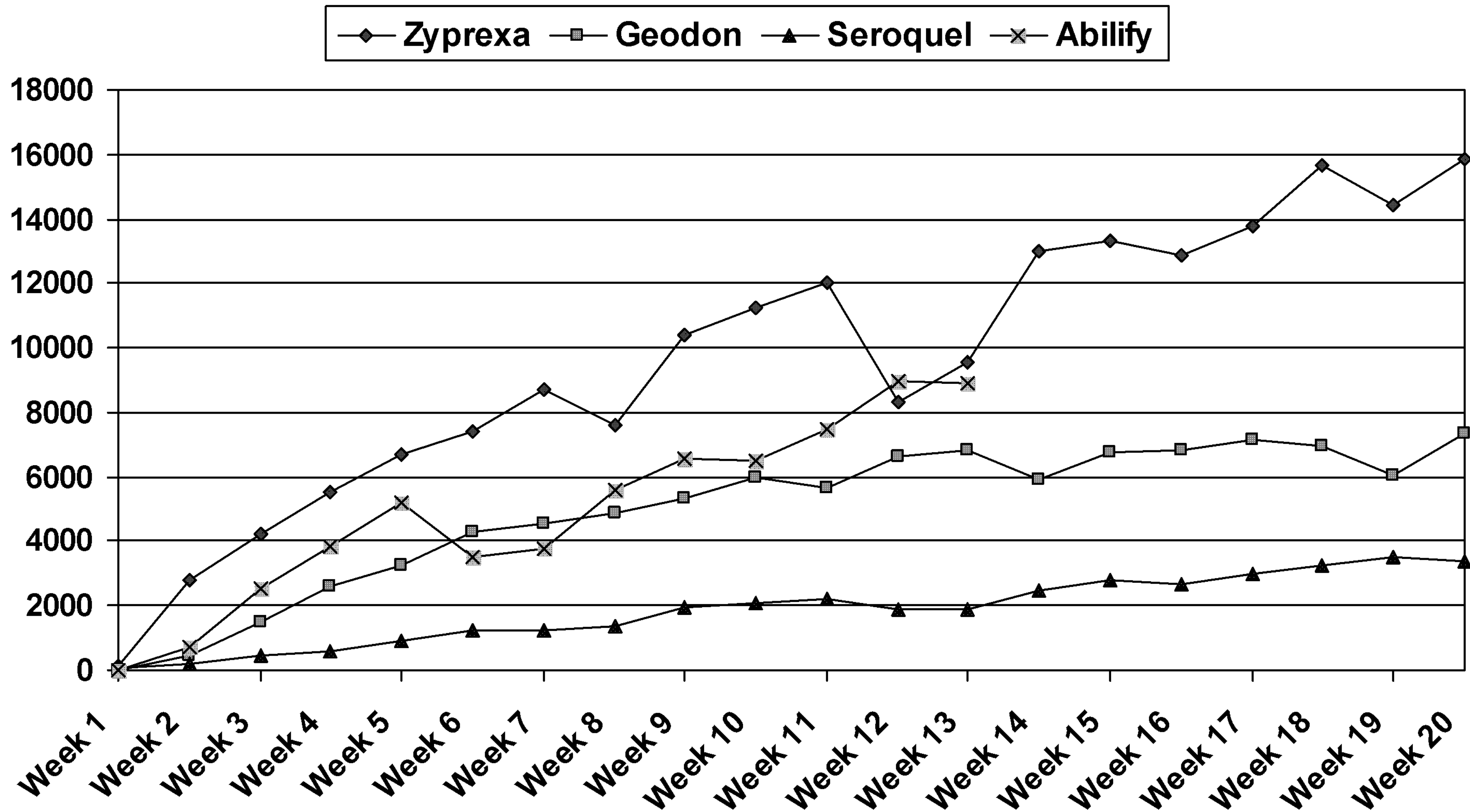
HGHJ
Superior with $p=0.002$
using the criteria
selected for HGLB (Abilify study)
(Survival graph being developed)

Global Competitive Management Priorities

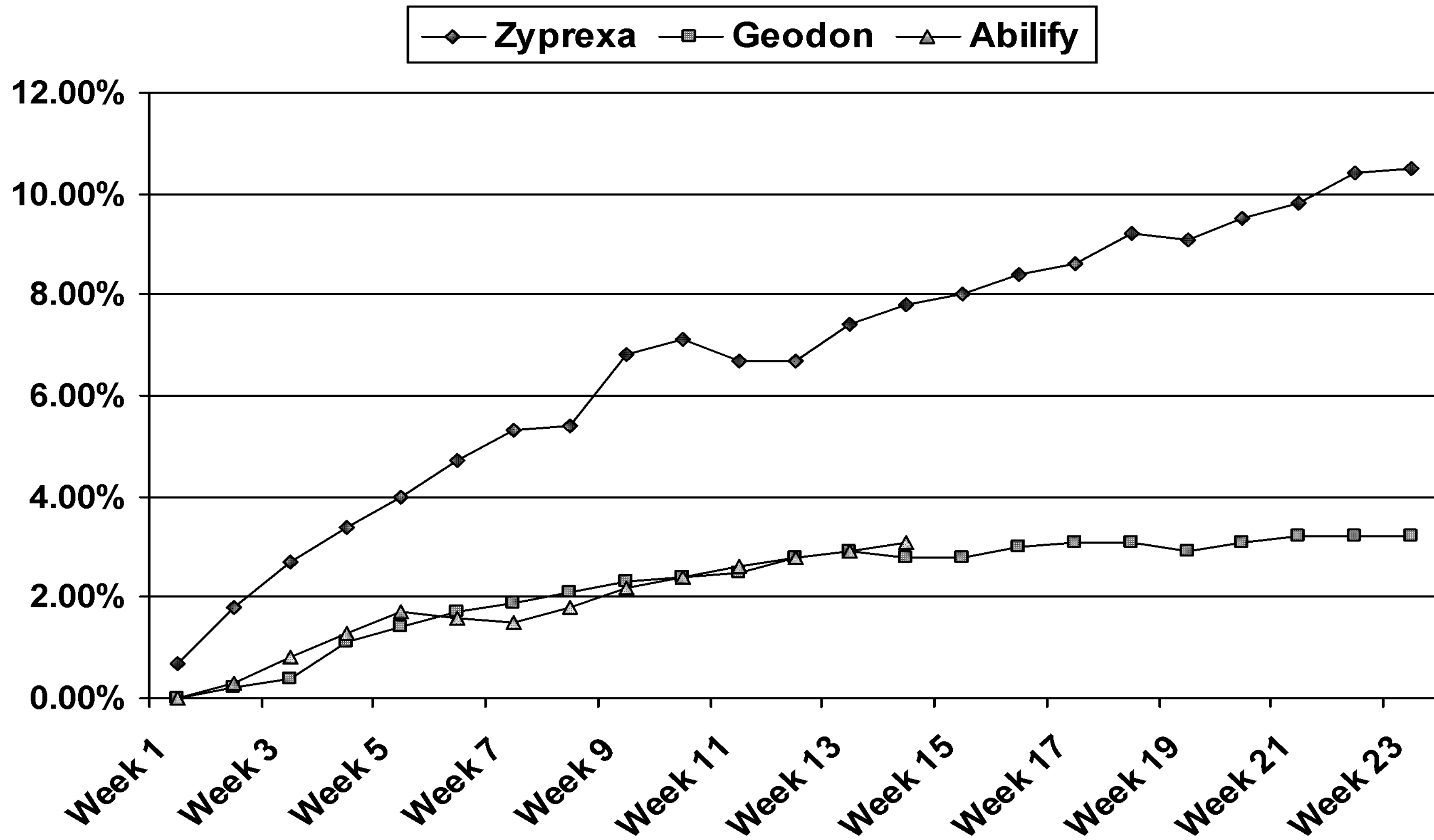
Competitive Threats

- 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 / Zeldox
 - Lamictal (Lamotrigine)
 - Depakote

U.S. Weekly NRx Launch Comparison



U.S. Weekly NRx SOM Launch Comparison



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 a 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**

← **Key Message**

- Side effects – reports of agitation / anxiety / akathisia

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

Disappointing: Another example of over promising

Competitive – Key Deliverables 2003-2005

	2003	2004	2005
Competitive Landscape <ul style="list-style-type: none"> New competitor indications, formulations and drugs; patent expirations 	√ Q2, Q4	√ Q2, Q4	√ Q2, Q4
Consolidated Competitive Strategy/Positioning <ul style="list-style-type: none"> Risperdal, Seroquel, Geodon, Abilify, Depakote, Lamictal, and Lithium in schizophrenia and bipolar 	√ BC II		
Tools to Support the Competitive Strategies <ul style="list-style-type: none"> Publications, posters, clinical studies, data mining 	√ On-going	√	√
Updates & Dissemination of Strategy and key information <ul style="list-style-type: none"> Virtual team, Zyprexa infonet 	√ On-going	√	√
Competitive Tracking and Alignment <ul style="list-style-type: none"> Competitor tracker, brand equity 	√ On-going	√	√

Shared Landscape Database – View of the Competition

Microsoft Excel - Test.xls

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C30 =

	A	B	C	D	E	F	G	H	I
1	DRAFT - Competitive Landscape - DRAFT								
2	UPDATED:								
3	OWNER:								
4									
5		Marketed (date)	Current \$ & Rx Share	2003	2004	2005	2006	2007	Source of ai
6	New Competitor Activities								
7	Risperdone								
8	Indications	Schizophrenia (94)		Bipolar Mono & Adjunctive (Q4)					
9	Formulations	Oral		Depot (Q4)					
10	Studies vs. Zyprexa								
11	Quetiapine								
12	Indications								
13	Formulations								
14	Studies vs. Zyprexa								
15	Ziprasidone								
16	Indications								
17	Formulations								
18	Studies vs. Zyprexa								
19	Aripiprazole								
20	Indications	Schizophrenia (10.02)		Schizophrenia Maint. (Q4)					
21	Formulations	Oral							
22	Studies vs. Zyprexa								
23	Clozapine								
24	Indications								
25	Formulations								
26	Studies vs. Zyprexa								
27	Lamictal								
28	Indications								
29	Formulations								
30	Studies vs. Zyprexa								
31	Donepezil								
	Global	US	EU	ICR	Affiliate 1	Affiliate 2			

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Shared Landscape Database
Updated 2 times a Year

Shared Landscape Database - View of Zyprexa Activities (w/ Major Competitor Implications)

Microsoft Excel - Test.xls

File Edit View Insert Format Tools Data Window Help

95%

Arial 10

B34 = Studies vs. Zyprexa

				2003	2004	2005	2006	2007	
35	Zyprexa Activities with Major Competitor Implications								
36				2003	2004	2005	2006	2007	
37	New Indications								
38	Bipolar Mania			Adj use in many EU countries					
39	Redacted								
40	Bipolar Maintenance				US & EU Launch (Q1)				
41	New Formulations								
42	Zydis								
43	Zyprexa IM				EU Launch?				Dependent on
44	Zyprexa Depot					Submission (Q4)			
45	Clinical Trials								
46	Abilify (HGLB)			Start		Complete			Being planned
47	Seroquel (JB)			Completed					
48	Geodon (Glb and US)								
49	SOHO			Completed					
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Global / US / EU / ICR / Affiliate 1 / Affiliate 2

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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



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

	Zyprexa	Risperdal	Geodon	Clozaril	Seroquel
Black Box					
Contraindication	JP				JP
Warning	JP, EU, Kor				JP, Swe, Den
Precaution	EU, AU, JP	JP*		US, AU, CA	JP
Adverse Reaction	US, EU, AU, JP	US, AU, UK, JP*	US	EU, AU, CA	US, JP, NZ
Post Introduction Reports	US, EU	US		US	

*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

Key Data Dissemination Plan to Strengthen Issues Position 2003-2005

Year	Issue	Study	Desired Outcome
2003	Weight	Management Weight (Birt J.)	Management of weight gain associated with atypical antipsychotics.
2003	Weight	Slim PEP	Amantadine therapy associated with weight loss in patients treated with Olanzapine: a case series
2004	Weight	HGJN	Amantadine helps patients manage olanzapine induced weight gain
2003	Diabetes	PCS	Comparable risk of developing diabetes among patients that take commonly prescribed antipsychotics
2003	Diabetes	TED	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
2003	Diabetes	SO13	Olanzapine does not have an acute direct effect that promotes insulin resistance
2004	Diabetes	GPRD	The risk of developing diabetes during exposure to risperidone was significantly higher than that of the GPRD general population
2004	Diabetes	Glucose Analysis	Antipsychotics have comparable effects with regards to glucose regulation
2004	Diabetes	Bipolar TED	Comparable risk of developing diabetes in patients that take commonly prescribed drugs for bipolar disorder
2004	Lipid	HGJX	Olanzapine and Risperdal have comparable effects on triglyceride levels and other metabolic measures

Key Deliverables to Support Issues Management 2003-2005

	2003	2004	2005
Scientific data dissemination	Ongoing	Ongoing	Ongoing
Global speaker training	Q3		
Issues Tracking study	√	√	√
Position paper evolution		Q2	Q2
Issues resource binder update	Ongoing	Ongoing	Ongoing
Slide set update	Q2	Q2	Q2
Safety literature review update	Ongoing	Ongoing	Ongoing
Updates on Strategy and Key Information (including best practice/shared learning, Virtual Team)	Ongoing	Ongoing	Ongoing

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

	Current	2003	2004	2005	2006	2007	2008-2011
Zyprexa	Schizophrenia; Bipolar Mania; Zydis	Redacted IM	Bipolar Maintenance			4wk Depot	Expire: US 2011
Risperdal	Schizophrenia; Liquid; 2 wk Depot (EU_Q3); Dissolvable (EU_Q4)	Bipolar Mania (US_Q4); 2 wk Depot (US_Q4); Dissolvable (US_Q4)				Expire: US_Q4	
Seroquel	Schizophrenia	Bipolar Mania (US & EU_Q4)	SR	Granules			Expire: US 2011
Geodon	Schizophrenia; IM (US & EU_Q3)						Expire: US 2012-18
Abilify	Schizophrenia Acute (US_Q4)	Schizo (EU_Q3); Schizo Maint. (US_Q4)	Bipolar Mania; IM Formulation				
Depakote	Bipolar Mania; Epilepsy; Migraine; ER formulation						
Lamictal	Epilepsy	Bipolar - delay the relapse of depressive episodes (US_Q2)					Expire (US Q3_08);
Others	Clozaril Suicide Indication		Iloperidone	Sertindole (EU)			Depakote Expire (US Q2_08)

Competitive Gap Analysis

	2003	2004	2005	2006
Registration (label) studies				
Non-registration studies				
Data (including health outcomes)				
Publications				
Programs				

Issues Management Gap Analysis

	2003	2004	2005	2006
Registration (label) studies				
Non-registration studies				
Data (including health outcomes)				
Publications				
Programs				

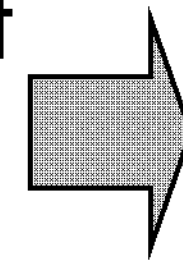
Competitive and Issues Gap Analysis Debrief

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

Summary of Key Themes

CSFs

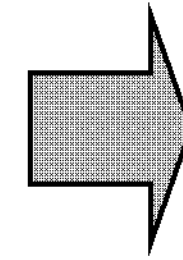
- Need greater competitive differentiation in core business of bipolar and schizophrenia. Establish mood without diluting schizophrenia. Opportunity to redefine outcomes!



Brand Promise Differentiation

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

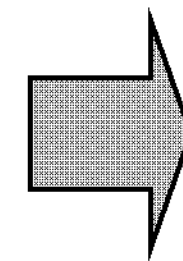
- Manage balance of side effect association / relevance



Brand Protection

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

- \$6B by '06 attainable but need more "insurance" to increase probability

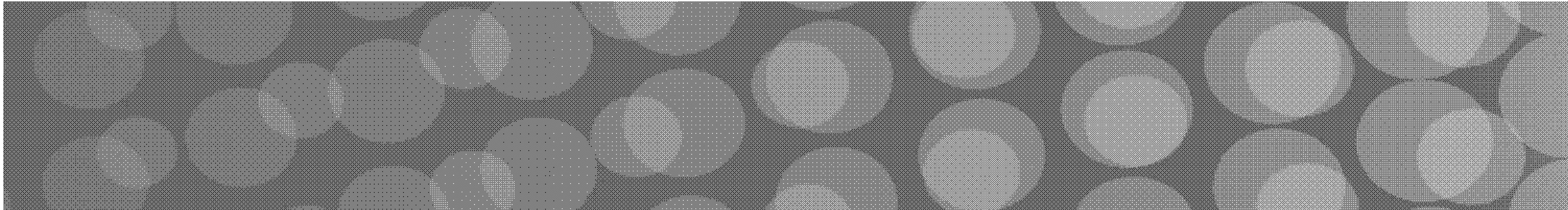


Lifecycle Growth

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.

To: CN=Patrizia Cavazzoni/OU=AM/O=LLY@Lilly; CN=James L Gahimer/OU=AM/O=LLY@Lilly;
CN=Mark D Millikan/OU=AM/O=LLY@Lilly
CC: CN=James A Edwards/OU=AM/O=LLY@Lilly
Date: 07/29/2002 12:30:04 PM
From: CN=Lisa A Vierhile/OU=AM/O=LLY
Subject: S. Africa Glucose Labeling
Attachments: Glucose Label Comparison by Section 09MAY02.doc; MCC response to labeling supplement JUL 2002.doc

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