

Lilly

Answers That Matter.



Agenda

- **Meeting Objectives (5 minutes)** Torres
- **US Focus (30 minutes)** Bandick
 - Takeaways from APA
 - Typical vs Atypical Debate
 - NY Times Article and Marketplace Response
 - Media strategy Newton
 - Review of Diabetes Verbatims Bandick
 - Update on May 9 Action Plan List Torres/Group
- **Discussion (15 minutes)** Group
- **Resource Request – Global Marketing Team (10 minutes)** Torres
 - Pilot programs for diabetes management
 - Increase in customer programs focusing on Europe/ICR
 - PLC resource

Objectives of Meeting

- Provide an update on APA takeaways relative to competition and diabetes
- Provide an update on the f/up plan in response to the NY Times article (prelude to Policy Committee meeting)
- Review of diabetes verbatims for the field
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- Request for resourcing of global initiatives around diabetes and product lifecycle planning

APA 2003: Key Takeaways

- Lilly had best data
- BMS had best “presence”
- Significant competitive focus on Zyprexa, particularly metabolic
 - AZ increasingly aggressive
 - Pfizer takes a “creative” approach with “Endocrine Matters”
- Growing concern about Zyprexa
 - Some customers willing to trade-off efficacy for greater perceived “safety”
 - Some customer “concern” is progressing to “fear”
- Significant focus on bipolar – particularly AZ
- Increased competitive emphasis on special populations (women, children)
- Limited media coverage across the board

APA 2003: Market Research

- Confusion reigns
- Lilly credibility gap: Weight gain => diabetes
- Increased competitive intensity
 - Collective negative voice is now 5:1
- Abilify arrived at the right time
 - Customers increasingly willing to compromise “some” efficacy
- Zyprexa is drug of choice in acute episode; switch to “safer” agents in stabilize / maintenance phases

Atypicals vs. Typical “Debate”

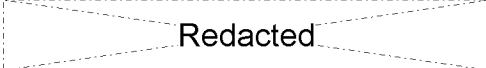
- Sequence of events: Lancet / NY Times / APA debate
- NY Times piece – provocative, but not sensational
- APA event was modestly attended; no surprises or media coverage
- Debate’s been answered in the U.S. by millions of patients and their clinicians
- May create pressure with selected payors, but overall, does not represent significant threat (relative to other issues)... impacts all major competitors

Environment: 6 months out

Marketplace

- VA study complete
- Class labeling? Selective labeling?
- Verdict in on Abilify utility
- Potential for 50 percent increase in Abilify voice
- Risperdal / Seroquel bipolar mania on market
- Lamictal approved for relapse prevention in bipolar depression

Zyprexa

- Zyprexa RAIM launched
-  Redacted
- Zyprexa bipolar maintenance
- Relaunch of Zyprexa Zydis
- SOHO data
- Increased litigation pressure

Bottom line:

Increased opportunity
Increased competition

Supporting the Defining Moment

Goal: Constant Flow of Indications and Supporting Publications

Registration Studies

(initiate '03/'04):

- /OFC relapse prevention
- Bipolar II
- Borderline
- Schizoaffective
- Bipolar Depot (2005) Long-term

Dependable Control (initiate '03/'04)

(affiliate studies; global coordination):

Thought

- Zyprexa v. Abilify

Mood

- Zyprexa v. Seroquel in BP
- Zyprexa v. Abilify in BP
- v. Depakote

Depot

(initiate '05/'06):

- Schizo switching study
- Schizo comparator trial
- BP switching study
- BP comparator trial

Require R&D Funding

Therapeutic Alliance / Helps Move Lives Forward

(initiate '03/'04):

- Zyprexa and functional outcomes – cognition and supportive employment (funded - contingency)
- and functional outcomes
- Zyprexa v. Risperdal (affiliate studies; global coordination)
- Bipolar combo (funded)

FTE Request: One G2 Position for Zyprexa/Symbyax Product Lifecycle Planning

From

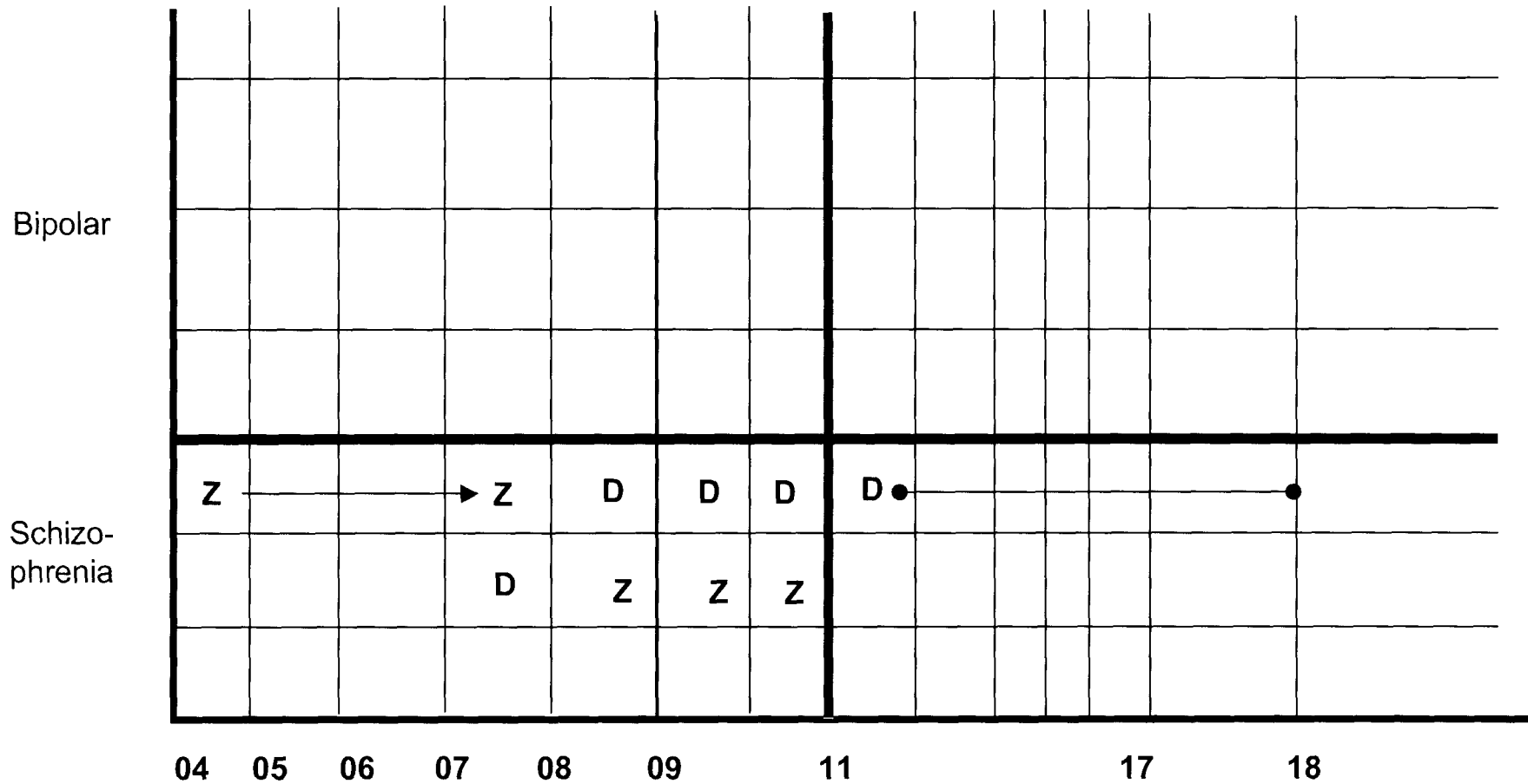
- Schizophrenia Depot
- Adolescent
- Redacted TRD

To

- Schizophrenia Depot
- Adolescent
- Redacted TRD
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- Schizoaffective
- Cognition
- Bipolar Depot exploration

- One associate

- One experienced, top talent manager +
- One experienced associate



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File name location
5/12/2003 10

Business Case Summary

Redacted		
R&D Investment	\$47	\$162
Year of Submission	2007	2005/06
Year of Launch	2008	2007
Est. Prob (TS)	High	High

R&D Expense Summary

Description: Includes registration studies (Bipolar II, Borderline Personality disorder, Schizoaffective disorder, and Bipolar Depot) and Depot switching and comparator trials

Excludes affiliate studies

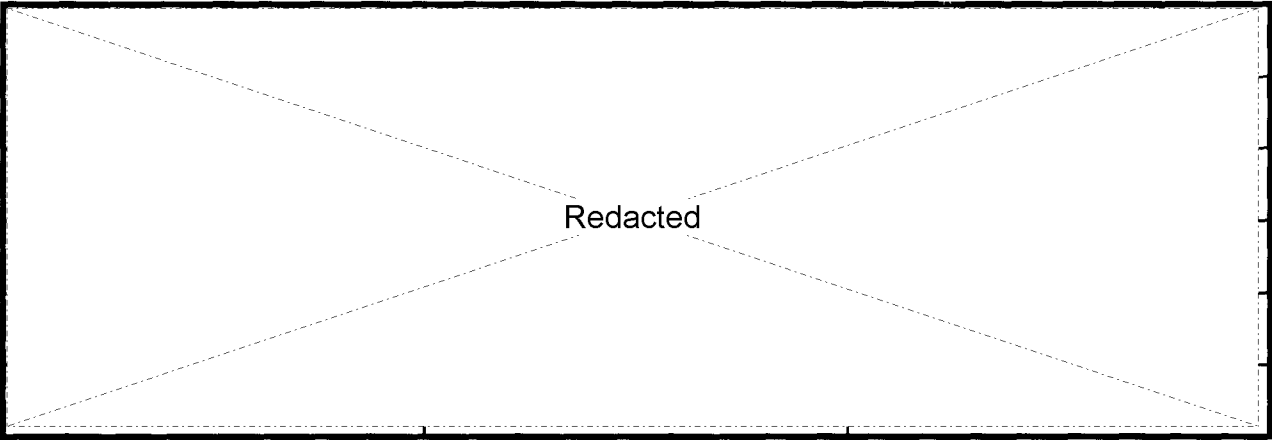
(\$M)	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>Total</u>
PT	Redacted						
Non-PT							
Total R&D							
ZPT Frcst							

Planned growth drivers 2004 v 2003:

- * New depot trials
- * Ramp up of Abilify study, insulin sensitivity study, and CPMP commitment


Short-Term Resource Needs

Headcount	<u>2003</u>	<u>2004</u>
Bipolar II	4.5	4.5
Borderline	4.5	4.5
Schizoaffective	-	4.0
Total	9.0	13.0



The Landscape

Positive

- 
- Bipolar mania approval in EU and Canada
- Extremely positive SOHO results
- Exploration of new areas for schizophrenia: cognition, gray matter, prodromal, 1st episode
- Positive Geodon head-to-head
- Bipolar Maintenance Submission in U.S., EU and ICR

Challenges

- Significant delay in RAIM
- Delay in depot
- Discontinuation of dementia
- Discontinuation of Zyprexa bipolar depression
- Discontinuation of high dose
- No longer funding borderline
- Risperdal generic in 2007
- Depakote generic in 2008
- \$ growth of 13% in '05 vs. 8% in '04 with a 0-4% growth in OPEX 2004-2006
- Seroquel increasing as a competitive threat
- Seroquel, Abilify, and Risperdal soon-to-be players in bipolar
- Increased access pressure

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